In line with policy the HSCB will consider Individual Funding Requests for the use of this therapy for this indication on the grounds of clinical exceptionality as defined in the *HSCB/PHA Arrangements for the consideration of request for care/and or treatment on behalf of individual patients.* A copy of this is available on request from the HSCB Commissioning Directorate.

Assrance arrangements

The Board will seek direct assurances from Trusts on an ongoing basis regarding the actions outlined above.

Thank you for your attention with this matter. If you have any queries please contact Emma McKee Personal Information redacted by the USI in the HSCB Commissioning Directorate in the first instance.

Yours sincerely

Personal information redacted by USI

Paul Cavanagh
Interim Director of Planning & Commissioning

Cc Chief Medical Officer
Chief Executive Patient and Client Council
Chief Executive/Postgraduate Dean, NIMDTA
Chief Executive, NICPLD
Chief Executive, NIPEC
Chief Executive, NIBTS
Chief Executive, RQIA
Chief Executive, PHA
Senior Management Team, HSCB
Assistant Directors of Commissioning, HSCB

NICE National Institute for Health and Care Excellence

NICE guidance

Pentosan polysulfate sodium for treating bladder pain syndrome

Technology appraisal guidance
Published: 13 November 2019
www.nice.org.uk/guidance/ta610

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance are at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces ESUOM43.

1 Recommendations

1.1 Pentosan polysulfate sodium is recommended as an option for treating bladder pain syndrome with glomerulations or Hunner's lesions in adults with urinary urgency and frequency, and moderate to severe pain, only if:

- their condition has not responded to an adequate trial of standard oral treatments
- it is not offered in combination with bladder instillations
- any previous treatment with bladder instillations was not stopped because of lack of response
- it is used in secondary care and
- the company provides pentosan polysulfate sodium according to the commercial arrangement.

1.2 This recommendation is not intended to affect treatment with pentosan polysulfate sodium that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Why the committee made these recommendations

Bladder pain syndrome causes extreme pain and severely affects quality of life. It is challenging to treat and there is an unmet need for other treatments. It is currently managed with oral treatments, then bladder instillations if symptoms don't improve. Pentosan polysulfate sodium is an oral treatment.

Clinical trials suggest that pentosan polysulfate sodium may be more effective at relieving pain than placebo. A comparison of clinical trials that includes best supportive care and bladder instillations suggests that pentosan polysulfate sodium may have a modest benefit over these alternatives. But how much benefit it provides is unclear because these treatments haven't been

compared directly. Also, the available evidence is not of high quality.

Pentosan polysulfate sodium is not cost effective compared with best supportive care. But the most plausible cost-effectiveness estimates for pentosan polysulfate sodium compared with bladder instillations are likely to be a cost-effective use of NHS resources. So, it is recommended for a defined population.

2 Information about pentosan polysulfate sodium

Information about pentosan polysulfate sodium

Marketing authorisation indication	Pentosan polysulfate sodium (Elmiron, Consilient Health) has a marketing authorisation for treating 'bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition'.
Dosage in the marketing authorisation	300 mg/day taken as 1 × 100-mg capsule orally 3 times daily. Treatment is stopped if no improvement is reached 6 months after starting treatment. In people whose condition responds, treatment should be continued as long as the response is maintained. Response to treatment should be reassessed every 6 months.
Price	A pack of 90 capsules (100 mg each) costs £450. The company has a commercial arrangement. This makes pentosan polysulfate sodium available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Committee discussion

The appraisal committee (section 5) considered evidence submitted by Consilient Health, a review of this submission by the evidence review group (ERG), and the technical report developed through engagement with stakeholders. See the committee papers for full details of the evidence.

The appraisal committee was aware that several issues were resolved during the technical engagement stage, and agreed that these were acceptable:

- using a lifetime time horizon in the economic model (issue 2, see technical report page 21)
- assuming response rates to best supportive care did not recede over time in the model (issue 3, see technical report pages 7 to 10)
- using the ERG's updated survival analysis that censored those who died and used a log-normal extrapolation (issue 4, see technical report page 21)
- assuming utility scores and costs returned to baseline in the model for people whose condition did not respond to treatment who moved on to best supportive care (issue 6, see technical report pages 21 to 22).

It recognised that there were remaining areas of uncertainty associated with the analyses presented (see technical report, table 2, pages 19 to 20), and took these into account in its decision making.

The condition

Bladder pain syndrome is challenging to manage and affects quality of life

3.1 The clinical experts explained that bladder pain syndrome is a chronic bladder condition characterised by pain, urinary urgency, frequency and getting up at night to pass urine. The patient expert explained that people with bladder pain syndrome need the toilet up to 60 times a day and that some people had considered suicide because of the pain. Treatments generally aim to control the symptoms because there is no cure for the condition. The committee concluded that bladder pain syndrome is incurable, very challenging to manage and causes extreme pain, which severely affects quality of life.

Clinical management

The relevant population is people with bladder pain syndrome and either glomerulations or Hunner's lesions

3.2 The clinical experts explained that bladder pain syndrome may affect approximately 400,000 people in the UK but only around 10% of these will present for treatment. The committee acknowledged that within the broader bladder pain syndrome population are people who also have glomerulations or Hunner's lesions. The marketing authorisation for pentosan polysulfate sodium is for treating 'bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition'. The committee considered that this was the relevant population for the appraisal.

There is an unmet need for effective treatment options

3.3 Treatment options for people with bladder pain syndrome and either glomerulations or Hunner's lesions include:

- oral treatments (such as amitriptyline, gabapentin, pregabalin, paracetamol, non-steroidal anti-inflammatory drugs, hydroxyzine, cimetidine and ranitidine) and
- bladder instillations (a plastic tube inserted into the bladder to administer liquid medication).

The patient expert stated that there were few treatment options and people often need multiple treatments to manage the symptoms. The clinical experts explained that bladder instillations were invasive and can cause adverse effects. The patient and clinical experts explained that pentosan polysulfate sodium may also affect quality of life because it has to be taken 3 times a day on an empty stomach, which affects mealtimes. The committee concluded that there was an unmet need for effective treatment options that can be used instead of invasive bladder instillations.

There is substantial variability in the treatment pathway

3.4 The clinical experts explained that the treatment pathway for bladder pain syndrome can vary substantially between services across the country. They added that the condition is difficult to diagnose and the presence of

glomerulations is not specific to bladder pain syndrome. Services use international guidelines to guide clinical management and the recommendations for treating the condition vary. The company noted that bladder pain syndrome is initially treated with oral medication (see section 3.3). If glomerulations or Hunner's lesions are found, then people can continue to have oral treatments as best supportive care or be offered bladder instillations. The patient experts explained that not all treatments are available in all areas of the country. Treatments typically depend on where a person lives and what is offered at their local hospital rather than what is best for their condition. The company and clinical experts stated that pentosan polysulfate sodium would only be used in secondary care. The committee recognised that there is substantial variability in the clinical management of bladder pain syndrome and the treatment pathway is poorly defined. However, the committee agreed that pentosan polysulfate sodium would only be available as a treatment option in secondary care.

The comparison with bladder instillations is relevant for decision making

3.5 The company submitted analyses comparing pentosan polysulfate sodium with bladder instillations. At the second committee meeting, the company said that it was positioning pentosan polysulfate sodium as an alternative to bladder instillations. Bladder instillations are offered to people who can tolerate them. The clinical experts explained that other treatment options for the condition are available. They noted that laser surgery for Hunner's lesions can be considered at any point in the treatment pathway. Also, botulinum toxin type A and sacral neuromodulation are generally used in research and not routine clinical practice. The clinical experts explained that, if available, pentosan polysulfate sodium would be tried before bladder instillations. The committee recognised that pentosan polysulfate sodium could be offered at different points in the treatment pathway but would tend to be used before bladder instillations. Considering the information from the clinical experts, the committee agreed that bladder instillations were a standard clinical management option for this condition and were a relevant comparator.

The comparison with best supportive care is also relevant for decision making

3.6 The company's submission included analyses comparing pentosan polysulfate sodium with best supportive care (which is the continuation of oral medication). However, after consultation the company stated that it did not consider pentosan polysulfate sodium to be an alternative to best supportive care. At the first committee meeting, the clinical experts advised that best supportive care is offered to people who can't tolerate bladder instillations, or if bladder instillations are unsuitable for them. They highlighted that some people would choose best supportive care because bladder instillations are invasive. The clinical experts estimated that bladder instillations would not be suitable for less than 5% of patients. The committee recognised that the proportion of people who would have best supportive care instead of bladder instillations was low. However, it considered that pentosan polysulfate sodium would be an alternative treatment option for this group of people. Because of this, the committee concluded that best supportive care was still a relevant comparator for this limited population.

Clinical effectiveness

There is substantial uncertainty in the pentosan polysulfate sodium evidence

3.7 The company's clinical effectiveness evidence came from 4 randomised controlled trials comparing pentosan polysulfate sodium with placebo in people with bladder pain syndrome and either glomerulations or Hunner's lesions. The trials were published between 1987 and 2003. The ERG noted that:

- 3 of the trials were of good methodological quality but the other trial should be interpreted with caution because of uncertainty about allocation concealment and numbers of patients withdrawing from treatment
- sample sizes were not calculated for 3 of the trials and the target sample size for the other trial was not met
- the author was common to all 4 trials and there were no independent studies validating the results

- the definition of the primary outcome used in the company's model varied and
- follow-up times varied between all trials.

The committee concluded that the company's evidence for pentosan polysulfate sodium was based on the most relevant trials available but acknowledged the limitations of the trials. It considered that there was substantial uncertainty in the clinical effectiveness evidence.

There are substantial uncertainties in determining the relative treatment effect using an indirect treatment comparison

3.8 To compare pentosan polysulfate sodium with bladder instillations, the company used an indirect treatment comparison. Both the company and the ERG acknowledged that this was necessary, but agreed it was challenging because of:

- Differences in trial populations: Uracyst was the only bladder instillation suitable for indirect comparison with pentosan polysulfate sodium via placebo. The pentosan polysulfate sodium trials were in people with interstitial cystitis or bladder pain syndrome who had Hunner's lesions or glomerulations or both. But the Uracyst trials were in people with the broader bladder pain syndrome.
- Differences in placebos: Pentosan polysulfate sodium was compared with an oral placebo, whereas Uracyst was compared with a placebo instillation.
- Differences in the timings of outcome measurement.

- Differences in the definition of the main outcome (global response assessment).

The company compared meta-analysed data from 2 Uracyst trials with meta-analysed data from 4 pentosan polysulfate sodium trials using the Bucher method of indirect treatment comparison (an adjusted method that retains patients' original randomisation). Response rates to treatment were 33% for pentosan polysulfate sodium compared with 22% for bladder instillations. The ERG considered that the Bucher method did not adequately acknowledge the heterogeneity in treatment effect between the studies. Instead, it proposed using a Bayesian network meta-analysis, which provides a more flexible framework for incorporating and exploring the uncertainties in the evidence. The committee acknowledged that both the Bucher method and Bayesian approach were valid methods of analysis in this setting, but the company's application of the Bucher method did not account for heterogeneity. The committee agreed that there was significant heterogeneity in the treatment effect and therefore concluded that it would prefer a Bayesian network meta-analysis.

The ERG's Bayesian network meta-analysis is an acceptable method for an indirect treatment comparison

3.9 The ERG did a Bayesian network meta-analysis, which showed response rates of 33% for pentosan polysulfate sodium compared with 24% for bladder instillations. After the technical engagement stage, the company also did a Bayesian network meta-analysis comparing pentosan polysulfate sodium with bladder instillations as a scenario analysis. This showed response rates of 38% for pentosan polysulfate sodium compared with 28% for bladder instillations. The ERG advised that the company's network meta-analysis had methodological limitations because it did not use separate baseline and treatment effects models to estimate absolute response rates. The committee understood that although both the company's and the ERG's approaches had their limitations, the best possible methods should be used for an indirect treatment comparison. At the first meeting, the committee concluded that the ERG's Bayesian network meta-analysis was acceptable because it better characterised the uncertainty in comparing active treatments. After consultation, the company argued that neither method was ideal and so kept the Bucher method in its base-case analysis. The committee agreed that all the indirect treatment comparisons it had seen had limitations. But it considered that it had not heard anything to change its original decision that the ERG's Bayesian network meta-analysis was more acceptable than the company's Bucher method.

It is acceptable to use the 16% response rate to placebo from the pentosan polysulfate sodium trials in the cost-effectiveness analysis

3.10 The company noted that the high response rates (16%) in the placebo arms of the pentosan polysulfate sodium trials did not reflect clinical practice. It considered these high response rates would underestimate the effectiveness of pentosan polysulfate sodium. The ERG noted that the high response rates could be explained by regression to the mean, which would also be present in the intervention arms. The ERG also noted that in the company's model, the absolute difference in treatment effect becomes greater with increasing best supportive care response. This would result in the high response rate in the placebo arm favouring pentosan polysulfate sodium because the company's analysis used relative risks. The company's base-case analysis modelled a 15.8% placebo response rate. The company's Bayesian scenario analysis included the placebo arms of the bladder instillation trials, which gave an 18.9% estimated response rate. The clinical experts explained that real-world evidence may suggest even higher placebo response rates. This is expected because patients with the condition initially have benefit, but this is not sustained beyond 3 months. The committee acknowledged that the clinical experts' views and the ERG's analysis results (15.5%) were broadly in line with the placebo response rates from the pentosan polysulfate sodium trials (16%). The committee concluded that a 16% response rate to placebo was acceptable to use in the cost-effectiveness analysis, and that the company's base-case analysis was in line with this.

Utilities

Missing data on utility values are not adequately accounted for in the company's model

3.11 In its base-case model, the company applied a utility decrement associated with bladder instillations. The company mapped patient survey data collected in the Sant et al. (2003) trial to EQ-5D data. The company used responses to a question in the survey on the use of bladder instillations in the previous 6 months. The ERG noted that the wording of this survey question was vague. This could have meant that patients who had never had bladder instillations did not answer the question and this was recorded incorrectly as missing data. The

ERG's preferred method to account for the missing data was to use multiple imputation (a statistical method used to reduce bias arising from missing data). After consultation, the company outlined that multiple imputation was not appropriate because the missing data were not missing at random. The company also highlighted methodological challenges because the data predicted by the imputation would depend on the data that informed the imputation. The committee understood that there were very few responses from the patient survey about quality of life associated with pentosan polysulfate sodium treatment. The committee concluded that missing data from the patient survey was not adequately accounted for in the company's model.

There is insufficient evidence of a direct link between bladder instillations and urinary tract infections

3.12 After the technical engagement stage, the company provided clinical expert evidence and a systematic review to support its assumption that bladder instillations are associated with an increase in urinary tract infections (UTIs). The company explained that the evidence showed that people with UTIs have substantially lower quality of life than those without UTIs. It also proposed that UTIs in people with bladder pain syndrome have a bigger impact on quality of life than UTIs in the general population. The ERG noted that the company's model assumed that everyone having bladder instillations would have a UTI and that the associated decrement was modelled for a lifetime. The clinical experts explained that not all people having bladder instillations would get a UTI and although the symptoms may last longer than for the general population these would not continue indefinitely. They also noted that people would have the choice of continuing bladder instillation treatment if they did get a UTI. The company noted that UTIs are only 1 aspect of the decrement associated with bladder instillations. After consultation, the company emphasised the evidence relating to the impact of UTIs on quality of life including the quality of life data reported by Cervigni et al. (2017). The committee considered that the Cervigni study was not generalisable to the population covered by the pentosan polysulfate sodium marketing authorisation. This was because the study included a trial population who were not covered by the marketing authorisation (pentosan polysulfate sodium was used as initial treatment for some patients and for others, pentosan polysulfate sodium treatment had already failed before), which introduced some uncertainty into the analyses. The study was based on Italian EQ-5D valuation and the values in the study didn't

correspond with response to treatment. The committee considered that it had not seen any new information about the duration of UTIs or the proportion of patients who had UTIs. The committee concluded that there was insufficient evidence to assume a direct link between bladder instillations and UTIs and that any associated decrement was likely to be short-lived.

It is not appropriate to include a utility decrement for bladder instillations

3.13 The company justified modelling a utility decrement for bladder instillations because it considered them to be invasive and associated with adverse effects. The committee noted that the utility decrement was applied for all patients who had bladder instillations for the lifetime of the company's model. It also noted that the utility score for patients having subsequent bladder instillations was counterintuitive when compared with the utility score for people whose condition did not respond to treatment and who moved onto best supportive care (these results are academic in confidence and cannot be reported here). The ERG noted that the difference in utility score in the survey between people who had and people who had not recently had bladder instillations may have reflected baseline patient characteristics rather than treatment. The clinical experts also added that any decrement associated with bladder instillations was likely to be short-lived because the treatment would be stopped if there were any adverse events. The committee concluded that applying a utility decrement for bladder instillations was not appropriate.

Resource use

It is acceptable to assume 6-weekly administration of subsequent bladder instillations and first-time bladder instillations after the first year

3.14 The company modelled weekly administration of first-time bladder instillations for the first 4 weeks, and 4-weekly administration after this point. This frequency also applied to all subsequent bladder instillations. The clinical experts explained that initial treatment with bladder instillations would be weekly for 4 weeks followed by maintenance treatment once every 4 weeks for 4 to 6 months. Continuation would be based on response to treatment. They also noted that it was reasonable to administer maintenance treatment at

6-weekly intervals for subsequent bladder instillations if this achieved the same response in patients as 4-weekly administration. The patient expert explained that maintenance treatment intervals vary according to the person and can be either monthly or when symptoms return. If maintenance treatment is led by the patient based on their symptoms, this would lengthen the interval between instillations beyond 4 weeks. The ERG's model accounted for this variation. It included 6-weekly maintenance intervals for subsequent bladder instillations and for first-time bladder instillations after a year of treatment. The committee acknowledged the variation in clinical practice and recognised that administration would be different for first-time and subsequent bladder instillations. The committee considered the company's response to consultation. This outlined that 4-weekly administration is in line with the manufacturer's recommendations, treatment is tailored to individual patient needs, and variability in dosing frequency results in some intervals being shorter than 4-weekly whereas others are longer. However, based on the evidence from the ERG and clinical experts, the committee concluded that it was acceptable to assume 6-weekly administration for subsequent bladder instillations and for first-time bladder instillations after the first year (in line with the ERG's model).

Most people having bladder instillations would not stay on treatment indefinitely

3.15 Both the company's and the ERG's models assumed that bladder instillations were administered indefinitely. The clinical experts explained that bladder instillations would not continue for a lifetime and estimated that only 5% of patients would continue with them after 5 years. The committee acknowledged that in clinical practice bladder instillations would not continue indefinitely and most patients would stop within 5 years. It also recognised that best supportive care becomes a more relevant comparator if more patients stop treatment with bladder instillations.

Inpatient resource use is overestimated in the company's model

3.16 The company's model included a proportion of patients who would have inpatient care for bladder instillations. The ERG noted that the disease-related costs in the company's model had been overestimated because not all of the resource use was a result of bladder pain syndrome with glomerulations or Hunner's lesions. The clinical experts explained that most people having bladder

instillations are seen in outpatient care; the number having inpatient care is negligible. The committee considered that the company had overestimated the disease-related costs by modelling a proportion of patients to have inpatient care. The committee concluded that inpatient resource use would be minimal in a population having bladder instillations. However, it was aware that the incremental cost-effectiveness ratio (ICER) was not sensitive to this parameter in the model.

Cost-effectiveness estimates

There are uncertainties in the cost-effectiveness estimates that are unlikely to be resolved

3.17 The committee noted the substantial uncertainty in the model inputs, specifically:

- the considerable variability in the treatment pathway (see section 3.4)
- the significant uncertainty in the pentosan polysulfate sodium evidence (see section 3.7)
- the methodological limitations with all approaches to indirect treatment comparisons (see section 3.8)
- the challenges with the missing data on utility values (see section 3.11).

The committee concluded that these substantial uncertainties were unlikely to be resolved in the cost-effectiveness modelling.

Pentosan polysulfate sodium is likely to be cost effective for bladder pain syndrome compared with bladder instillations

3.18 The company's base case included the following assumptions:

- a lifetime time horizon in the model (issue 2 of the technical report)
- time to discontinuation based on the ERG's time-to-discontinuation data set and a log-normal extrapolation (issue 4 of the technical report)

- a utility decrement associated with having bladder instillations in the previous 6 months (issue 5 of the technical report)
- excluded missing data on previous bladder instillations (issue 5 of the technical report)
- a 4-weekly administration of bladder instillations for first-time and subsequent treatment (issue 7 of the technical report)
- treatment with bladder instillations continued indefinitely (issue 7 of the technical report).

When the confidential commercial arrangement was applied, the company's base-case analysis showed that pentosan polysulfate sodium cost less and had higher quality-adjusted life year (QALY) gain than bladder instillations.

The ERG's analyses included the following committee-preferred assumptions:

- a Bayesian network meta-analysis using the ERG's preferred approach (see section 3.9)
- a lifetime time horizon in the model (issue 2 of the technical report)
- time to discontinuation based on the ERG's time-to-discontinuation data set and a log-normal extrapolation (issue 4 of the technical report)
- treatment with bladder instillations continued indefinitely (see section 3.15)
- no utility decrement associated with having bladder instillations in the previous 6 months (see sections 3.11 to 3.13)
- 6-weekly administration of bladder instillations (see section 3.14).

The ERG's revised ICER using the committee's preferred assumptions and applying the confidential commercial arrangement was £14,418 per QALY gained when compared with bladder instillations. Based on the ERG's analysis, the committee concluded that the most plausible cost-effectiveness estimate for pentosan polysulfate sodium compared with bladder instillations was likely to be a cost-effective use of NHS resources (see NICE's guide to the methods of technology appraisal).

Pentosan polysulfate sodium is unlikely to be cost effective for bladder pain syndrome compared with best supportive care

3.19 The company's base case included the following assumptions:

- a lifetime time horizon in the model (issue 2 of the technical report)
- best supportive care response rates did not recede over time (issue 3 of the technical report)
- 15.8% placebo response rate estimated from the pentosan polysulfate sodium trials (issue 3 of the technical report)
- time to discontinuation based on the ERG's time-to-discontinuation data set and a log-normal extrapolation (issue 4 of the technical report)
- utility scores and costs returned to baseline for people whose condition did not respond to treatment who moved on to best supportive care (issue 6 of the technical report).

The company's base-case ICER compared with best supportive care (including the confidential commercial arrangement) was £52,264 per QALY gained.

The ERG's analyses included the following committee-preferred assumptions:

- a Bayesian network meta-analysis using the ERG's preferred approach (see section 3.9)
- a lifetime time horizon in the model (issue 2 of the technical report)
- best supportive care response rates did not recede over time (issue 3 of the technical report)
- time to discontinuation based on the ERG's time-to-discontinuation data set and a log-normal extrapolation (issue 4 of the technical report)
- utility scores and costs returned to baseline for people whose condition did not respond to treatment who moved on to best supportive care (issue 6 of the technical report)

- 16% placebo response rate from the pentosan polysulfate sodium trials (see section 3.10).

The ERG's revised ICER using the committee's preferred assumptions and applying the confidential commercial arrangement was £50,740 per QALY gained when compared with best supportive care. The committee concluded that the most plausible cost-effectiveness estimate for pentosan polysulfate sodium compared with best supportive care was higher than usually considered a cost-effective use of NHS resources (see NICE's guide to the methods of technology appraisal).

Positioning of treatment

The complex treatment pathway makes it hard to separate the comparison with bladder instillations from the comparison with best supportive care

3.20 The committee acknowledged that the treatment pathway for bladder pain syndrome was complex and varied between services. The clinical experts advised that pentosan polysulfate sodium would generally be used before bladder instillations or for people who could not have bladder instillations. However, the experts and responses to consultation indicated that pentosan polysulfate sodium may be used after bladder instillations have been tried. The committee accepted that the complex pathway made it difficult to separate populations based on comparators.

Neither the company nor the ERG's models capture the use of pentosan polysulfate sodium in combination with or after bladder instillations

3.21 In the company's and the ERG's models, patients having bladder instillations were assumed to stay on them indefinitely. The models did not capture the cost effectiveness of pentosan polysulfate sodium when it was taken after a lack of response to treatment with bladder instillations. The models also did not capture the cost effectiveness of pentosan polysulfate sodium when it was taken in combination with bladder instillations. The committee concluded that it could not assess the cost effectiveness of pentosan polysulfate sodium for these populations.

Pentosan polysulfate sodium is only for people whose condition has not responded well to other less expensive oral treatments

3.22 The clinical experts stated that there are many different types of oral treatments for bladder pain syndrome and that these have to be tried repeatedly. The committee was aware that best supportive care consisted of less expensive oral treatments than pentosan polysulfate sodium. It was also aware that some people get good disease control from standard oral treatments. The company and clinical experts agreed that pentosan polysulfate sodium would be used after inadequate response to standard oral treatments. The committee concluded that standard oral treatments should be tried first (see section 3.3) and that pentosan polysulfate sodium should only be used for people who have stopped these treatments because of a lack of response.

The proportion of people who have best supportive care because bladder instillations are unsuitable for them is low

3.23 The clinical experts explained that bladder instillations would be unsuitable for less than 5% of people. The committee acknowledged that because this is likely to be a small population, the estimated impact on NHS resources is also likely to be small (see section 6.2.14 in NICE's guide to the methods of technology appraisal).

Conclusion

Pentosan polysulfate sodium is recommended for some people

3.24 The ICER for the comparison with best supportive care was higher than what is considered to be cost effective. But the ICER for the comparison with bladder instillations was considered to be a cost-effective use of NHS resources, taking into account:

- the small proportion of people who would not tolerate bladder instillations or for whom they would not be suitable
- the unmet need for effective treatment options for this population and

- the committee's most plausible assumptions.

  Therefore, the committee concluded that pentosan polysulfate sodium is recommended as an option for treating bladder pain syndrome with glomerulations or Hunner's lesions in adults with urinary urgency and frequency and moderate to severe pain, only if:

- their condition has not responded to an adequate trial of standard oral treatments
- it is not offered in combination with bladder instillations
- any previous treatment with bladder instillations was not stopped because of lack of response
- it is used in secondary care and
- the company provides pentosan polysulfate sodium according to the commercial arrangement.

Other factors

There are no equalities issues that can be addressed in the guidance

3.25 The company and a clinical expert highlighted that bladder pain syndrome affects more women than men. However, issues related to differences in prevalence or incidence of a disease cannot be addressed in a technology appraisal.

4 Implementation

4.1 Section 7(6) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.

4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has bladder pain syndrome and the doctor responsible for their care thinks that pentosan polysulfate sodium is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee D.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Omar Moreea
Technical lead

Lucy Beggs
Technical adviser

Kate Moore
Project manager

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Accreditation

NICE National Institute for Health and Care Excellence

NICE guidance

Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea

Technology appraisal guidance
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www.nice.org.uk/guidance/ta605

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance are at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Xeomin (botulinum neurotoxin type A) is recommended, within its marketing authorisation, as an option for treating chronic sialorrhoea caused by neurological conditions in adults. It is recommended only if the company provides it according to the commercial arrangement.

Why the committee made these recommendations

Chronic sialorrhoea (excessive salivation and drooling) happens when neurological conditions cause problems with swallowing. Treatment is usually standard (non-drug) care such as using bibs, speech and language therapy, and occupational therapy. But some people may take anticholinergic drugs to reduce the amount of saliva produced.

Randomised controlled trial evidence shows that Xeomin reduces the amount of saliva produced. The evidence suggests that this does not improve quality of life. However, it seems that the benefit of Xeomin on quality of life might not have been fully captured in the trial because of the way that quality of life was assessed.

Taking into account the unmeasured benefits in the evidence means that the cost-effectiveness estimates are within the range that NICE usually considers a cost-effective use of NHS resources. Therefore, Xeomin is recommended.

2 Information about Xeomin (botulinum neurotoxin type A)

Information about Xeomin (botulinum neurotoxin type A)

Marketing authorisation indication	Xeomin (botulinum neurotoxin type A, Merz) is intended for 'chronic sialorrhoea due to neurological disorders in adults'.
Dosage in the marketing authorisation	A reconstituted solution at a concentration of 5 units/0.1 ml should be used. Xeomin is injected into the parotid and submandibular glands on both sides (4 injections per treatment in total). The dose is divided in a ratio of 3:2 between the parotid and submandibular glands as follows: • parotid glands: 30 units per side, 0.6 ml per injection • submandibular glands: 20 units per side, 0.4 ml per injection. The injection site should be close to the centre of the gland. The recommended dose per treatment session is 100 units. This maximum dose should not be exceeded. Treatment intervals should be determined based on the actual clinical need of the individual patient. Repeat treatment more frequent than every 16 weeks is not recommended. Because of unit differences in the potency assay, unit doses for Xeomin are not interchangeable with those for other preparations of botulinum toxin type A.
Price	£129.90 per 100-unit powder for solution for injection vial (excluding VAT; BNF accessed online July 2019). The company has a commercial arrangement. This makes Xeomin available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Committee discussion

The appraisal committee (section 5) considered evidence submitted by Merz Pharma UK, a review of this submission by the evidence review group (ERG), and the technical report developed through engagement with stakeholders. See the committee papers for full details of the evidence.

The appraisal committee was aware that none of the issues were fully resolved after the technical engagement stage.

It discussed the following issues: comparator and treatment choice; outcomes in the pivotal trial; health-related quality of life and utility value assumptions; ultrasound guidance prevalence; implementation and resource use within the trial (new since technical engagement; see technical report, issues 1 to 6), which were outstanding after the technical engagement stage.

Clinical need

Chronic sialorrhoea can affect the quality of life of patients and their carers

3.1 Chronic sialorrhoea and excessive saliva accumulation can occur because of dysfunction or weakness of the muscles in the mouth and face. It is a common secondary symptom of many neurological conditions such as Parkinson's disease, cerebral palsy, stroke and traumatic brain injury and is often caused by swallowing issues and poor lip seal. Complications of sialorrhoea may include poor oral hygiene, bad breath, perioral dermatitis, dehydration, eating and speaking difficulties, sleep disturbance and fatigue. Sialorrhoea may also increase the risk of aspiration pneumonia if the saliva is inhaled. This may affect mortality and is more prevalent in older people. Sialorrhoea, and the resulting excessive drooling, also has a psychosocial effect on patients including embarrassment, decreased self-esteem and the potential for social isolation. It can also increase the burden on caregivers who may already be helping the patient manage their neurological condition. For example, the patient may need more frequent changes of clothing or bibs, and this extra care can lead to depression and anxiety for the caregivers. The clinical experts stated that the burden of sialorrhoea may depend on the underlying neurological condition, the age and social activity of the person with sialorrhoea and their view of the severity of the drooling. They also said that results from a survey of people with

Parkinson's disease showed that sialorrhoea was considered the third most troublesome symptom of Parkinson's disease. The committee considered that sialorrhoea affects the quality of life of patients and their caregivers, but the extent of this is uncertain and depends on a number of factors.

People with chronic sialorrhoea would welcome better access to botulinum toxin type A as a first-line treatment

3.2 Botulinum toxin type A products are recommended (albeit outside of their marketing authorisations) as a second- or third-line treatment option for sialorrhoea in NICE's guidelines on motor neurone disease, Parkinson's disease and cerebral palsy in under 25s. However, referral for treatment does not always occur because of the variable availability of botulinum toxin clinics across England. The 3 clinical guidelines all recommend that anticholinergics are tried first, and that botulinum toxin products should be offered if the anticholinergics are not effective, not tolerated or contraindicated. The clinical experts highlighted a need for a targeted treatment such as botulinum toxin type A that avoids the side effects of anticholinergics. This is because people with chronic sialorrhoea caused by an underlying neurological condition often have other systemic treatments for the condition and may be taking other medications too. The committee agreed that people with chronic sialorrhoea would welcome earlier use of botulinum toxin type A and better access to it in the treatment pathway.

Comparators

Standard care and anticholinergics are appropriate comparators

3.3 The company positioned Xeomin (its preparation of botulinum neurotoxin type A) as both a first- and second-line treatment option. The committee therefore considered it as:

- an alternative first-line treatment to non-pharmacological management such as bibs, speech and language therapy and occupational therapy (referred to as standard care by the company) and to anticholinergics and

- as an alternative second-line treatment to standard care (in line with the 3 NICE guidelines).

  The clinical experts stated that anticholinergic treatments may be considered as a treatment option for some patients (particularly for younger people) but they are poorly tolerated. The choice of pharmacological treatment depends on comorbidities, the severity of the sialorrhoea, the efficacy of previous treatment and the patient and clinician's views. Glycopyrronium bromide is the most commonly used anticholinergic because it does not cross the blood-brain barrier. The committee noted that glycopyrronium bromide's summary of product characteristics specifies that treatment duration should be as short as possible, and it should be used on an intermittent rather than a continuous basis. Chronic use of anticholinergics can be associated with cognitive problems such as memory loss. The committee accepted that anticholinergics may be appropriate for a small number of people. However, it considered there to be unmet need (see section 3.2) for a large proportion of people with sialorrhoea who are not able to tolerate anticholinergics. Therefore, the committee concluded that standard care was the most relevant comparator, but that it was also appropriate to consider short-term anticholinergics such as glycopyrronium bromide as a comparator.

There are no standard measures for sialorrhoea severity in clinical practice

3.4 The marketing authorisation for Xeomin, unlike the marketing authorisation for glycopyrronium bromide, does not specify the severity of sialorrhoea for treatment. However, the committee was aware that severity is an important factor for both patients and clinicians when considering treatment options (see section 3.3). There are no standardised measures for sialorrhoea severity used in NHS clinical practice. Severity is typically determined by physical assessment and patient history. Also, because patients have underlying neurological conditions, sialorrhoea is often measured as part of neurological disease-specific questionnaires in NHS clinical practice in England. The company identified the drooling severity and frequency score (DSFS) to measure severity in the pivotal trial (SIAXI; see section 3.5). The inclusion criteria in SIAXI included patients with a DSFS score of 6 or more, which included people with 'moderate' sialorrhoea by the company definition. The clinical experts stated that severe sialorrhoea is not a distinct subgroup and severity can fluctuate. The committee concluded it was appropriate to consider Xeomin for people with chronic sialorrhoea, and that severity should be based on clinical judgement

rather than the DSFS score.

Clinical evidence

The SIAXI trial provides the main clinical evidence for Xeomin

3.5 The main evidence for Xeomin came from SIAXI, a randomised placebo-controlled trial. The population included 110 patients with chronic sialorrhoea who had either Xeomin (n=74) or placebo (n=36). The inclusion criteria specified a DSFS of 6 or more and the mean age of the patients was 65. The population included patients with Parkinson's related diseases (79%), stroke-related diseases (18%) and traumatic brain injury (3%). The co-primary outcomes were unstimulated salivary flow rate and global impression of change scale, 4 weeks after an injection with Xeomin. Secondary outcomes included health-related quality of life as measured by the EQ-5D questionnaire, safety data and the DSFS. The trial also included an extension period that measured these outcomes over 3 further injection cycles of 16 weeks. The results showed a statistically significant decrease in salivary flow rate and increase in global impression of change score at 4 weeks compared with placebo. The committee agreed that SIAXI was a well-designed study and appropriate for decision making. But it noted that it did not include aspiration pneumonia as an outcome measure, which it considered to be an important complication of sialorrhoea (see section 3.1).

The results from the SIAXI trial are generalisable to people seen in clinical practice with chronic sialorrhoea

3.6 The company stated that the reduction in saliva output in SIAXI was independent of the underlying neurological condition. Therefore, the results from SIAXI would be generalisable to everyone with chronic sialorrhoea caused by a neurological condition. The clinical experts agreed but noted that the trial largely included patients with Parkinson's disease who were younger than those who would be expected to be seen in routine NHS clinical practice. They were unable to comment on Xeomin's efficacy for populations not included in SIAXI. The committee recalled that anticholinergic therapy is more likely to be associated with systemic adverse effects in an older population so targeted treatment for sialorrhoea may have additional advantages in the population more often seen in routine clinical practice. The committee concluded that the

results of SIAXI were generalisable to the population with chronic sialorrhoea seen in NHS clinical practice and that Xeomin would reduce saliva output regardless of the underlying neurological condition.

The most relevant outcomes for decision making are the EQ-5D, global impression of change scale and the DSFS score

3.7 The committee was aware that there was no survival benefit associated with treating sialorrhoea so all the benefits of Xeomin must result from increased quality of life. Although the results of the trial suggested a statistically significant reduction in unstimulated salivary flow rate and an improvement in the global impression of change scale at 4 weeks for Xeomin compared with placebo, this did not translate into a statistically significant increase in quality of life as measured by the EQ-5D. The relationship between unstimulated salivary flow rate, global impression of change scale and DSFS to quality of life were uncertain. The committee considered unstimulated salivary flow rate to be unsuitable because the ability of a treatment to reduce saliva is not an entirely appropriate way of estimating clinical effectiveness. For example, dry mouth is a common adverse event of anticholinergic treatments, so it is inappropriate to assume that a reduction in salivary flow translates to improved clinical outcomes. The committee instead preferred direct quality-of-life measurements such as the EQ-5D questionnaire and the global impression of change scale. The committee noted that the DSFS is likely to correlate with the burden of the disease because drooling and its consequences form a large part of the symptom burden of sialorrhoea. The committee therefore concluded that the most relevant outcomes for its decision making were the EQ-5D questionnaire and the global impression of change scale and agreed to consider these further (see section 3.9). It also concluded that, although the DSFS score is not used in clinical practice (see section 3.4), it was appropriate for defining the severity of health states in the economic model (see section 3.11).

There are no robust sources of evidence for comparing Xeomin with anticholinergic treatments

3.8 The committee acknowledged that anticholinergic treatments for sialorrhoea are used outside their marketing authorisations. Therefore, there is a lack of data on their effectiveness and safety in the population with chronic sialorrhoea. The company assumed that all anticholinergic treatments were

75% as effective as Xeomin based on an assumption in NICE's guideline on cerebral palsy in under 25s. The committee considered that this may not be the case because a common adverse event of anticholinergics is dry mouth, so the drying effect would be dose related and would depend on whether the patient could tolerate dose escalation (see section 3.7). However, the clinical experts stated that glycopyrronium bromide is likely to be more effective than other anticholinergics. Therefore, the committee accepted that, because there was no evidence, equal efficacy in reducing saliva production should be assumed.

Quality of life as measured by the EQ-5D-3L in the SIAXI trial may not fully capture the consequences of sialorrhoea and the benefits of treatment

3.9 The company measured health-related quality of life using the EQ-5D-3L questionnaire. It considered that this questionnaire was not sensitive to measuring sialorrhoea symptoms because it was measuring health-related quality of life in a population with debilitating underlying neurological conditions. The EQ-5D-3L measures 5 domains including mobility, self-care, usual activities, pain and anxiety or depression using 3 levels ranging from extreme problems, some problems and no problems. It can only register a change in health state when a patient indicates a step change in at least 1 domain. Many patients answered with a score of 2 ('some problems') for multiple domains and would therefore need to answer 1 ('no problems') to register any improvement. The company considered this unlikely because every domain would be affected in some way by the underlying neurological condition. The clinical experts stated that none of the specific consequences of sialorrhoea would be reliably detected by a non-sialorrhoea specific questionnaire. The committee agreed that there was uncertainty about the extent to which the EQ-5D-3L fully captures the consequences of sialorrhoea and the benefits of any treatment and it would consider this in its decision making (see section 3.17).

The adverse effects of Xeomin can be managed in clinical practice

3.10 The committee acknowledged the SIAXI results showed that there may be a low risk of major clinical events including dysphagia. The clinical experts commented that Xeomin is unlikely to lead to an overly dry mouth as an adverse event of treatment because it is possible to titrate the dose and reduce the number of

injection sites. The committee concluded that the adverse effects of Xeomin can be managed in clinical practice.

The company's economic model

The model structure is appropriate for decision making

3.11 The company developed a Markov state-transition model that included 3 health states to represent different sialorrhoea severity: severe (DSFS score of 7 to 9); moderate (DSFS score of 4 to 6) and mild or resolved (DSFS score of 2 to 3). In the model, patients who stop treatment are assumed to continue having standard care alone. Any patient could independently transition to death at the rate of the general population, although a standardised mortality rate to represent increased mortality from Parkinson's disease was explored in a scenario analysis. The committee was concerned about anticholinergic use over the full-time horizon of the model given the short-term or intermittent use of anticholinergics and the high drop-out rates (see section 3.3). The committee also noted that the company had assumed no adverse events for either arm in the economic model. This was because of the lack of data available to do a comparison of the adverse events of Xeomin with those of the anticholinergics. The committee agreed with the company that the assumption of no adverse events was conservative, given the severe side effect burden of anticholinergics. However, it considered that the company should have included adverse events in its economic modelling. Nevertheless, the committee concluded that the economic model structure was acceptable for decision making.

Utility values in the economic model

Utility values derived from the population in the SIAXI trial are the most appropriate values to use in the economic modelling

3.12 Because of the problems with measuring health-related quality of life (see section 3.9), the company preferred to use utility values from NICE's guideline for cerebral palsy in under 25s, stratified into 3 severity groups (mild or resolved [0.5346], moderate [0.4283] and severe [0.3008]). The committee was aware that these utility values were from a hypothetical model in the guideline because there were no data available. The company stated that the psychosocial impact of social isolation, the impact on caregivers and the potential for

aspiration pneumonia were not captured in the model, and that the guideline-derived utility values were more plausible than those derived in SIAXI. The ERG considered this modelling inappropriate because the utility values were from a very different population to the SIAXI trial population, and from a hypothetical model. The ERG preferred to use utility values derived from SIAXI (mild or resolved [0.6227], moderate [0.5983] and severe [0.5774]). It considered that the small health-related quality-of-life gain in SIAXI may be an accurate translation of utility gain associated with Xeomin. The ERG calculated the effect associated with a neurological condition in the company's model (average utility for a person of 65 minus the mild or resolved state utility value) as a disutility of 0.28 and the effect of severe sialorrhoea (utility of the mild or resolved state minus the severe state utility value) as a disutility of 0.23. The ERG and clinical experts were not convinced that sialorrhoea would have a similar magnitude of disutility to the neurological condition. The committee agreed that SIAXI was the most appropriate data source for deriving utility values. But it acknowledged the substantial uncertainty for utility values associated with sialorrhoea because of the lack of data.

Utility values derived from the SIAXI trial are likely to underestimate utility gain

3.13 The committee agreed that SIAXI was the most appropriate data source for the utility data (see section 3.12). But it concluded that the EQ-5D-3L data and the derived utility value were unlikely to fully capture the health-related quality-of-life benefit (see section 3.9). Additionally, the EQ-5D-3L may not fully capture the psychosocial impact of sialorrhoea, including social isolation (see section 3.1). The committee also considered that the impact of carer quality of life was not captured, including workload and potential further social isolation of caregivers. It considered that, because the cost-effectiveness results were very sensitive to the utility values chosen and there was a lack of data for sialorrhoea, a qualitative assessment of the direction of uncertainty of the utility values in SIAXI was appropriate. The committee concluded that the EQ-5D-3L results from SIAXI were likely to underestimate utility gain from the treatment and that it would consider this in its decision making (see section 3.17).

Costs in the economic model

Using ultrasound imaging to guide injections is less frequent in NHS clinical practice than in the SIAXI trial

3.14 Ultrasound imaging is sometimes used to guide the needle into the correct injection site for administering Xeomin. Alternatively, anatomical landmarks are used as guides. The company assumed in its base case that the frequency of using ultrasound guidance in SIAXI (56% of injections) was equivalent to NHS clinical practice. The ERG provided a scenario analysis that assumed 100% of procedures involved ultrasound-guided injections. The committee noted that the summary of product characteristics for Xeomin states that ultrasound-guided application showed superior results to the anatomical landmarks method. However, the clinical experts stated that, although it may vary across centres, using ultrasound guidance for administering injections is infrequent in current NHS clinical practice in England. The committee agreed that ultrasound may be used less in clinical practice than in SIAXI. Therefore, the company's assumption may have overestimated the costs of ultrasound guidance, which would have reduced the cost-effectiveness estimates (see section 3.17).

Assuming more speech and language and occupational therapy consultations for severe than for moderate sialorrhoea is inappropriate

3.15 In SIAXI no data were collected on the resource use of standard care, which the committee considered to be the most relevant comparator (see section 3.3). Standard care was also used alongside all active treatments. The company assumed that speech and language consultations and occupational therapy consultations would be once every 16 weeks for the severe sialorrhoea group, once every 32 weeks for the moderate group, and there would be none for the mild or resolved group. The committee noted that the costs of these consultations were applied for the entire duration of the time horizon. The ERG provided a scenario exploring no associated costs for standard care for each treatment option. The clinical experts stated that speech, language and occupational therapy consultations would start with an initial assessment for all sialorrhoea severity groups. This would include training for head positioning, posture, swallow timers and speech assessment. The frequency of follow-up consultations would vary by underlying neurological condition, for example

people with stroke and traumatic brain injury may have more frequent assessments. However, in general, most patients would not have follow-up consultations as often as every 16 weeks; it would depend on individual patient needs and access to these services. The committee concluded that the speech and language and occupational therapy resource use in the model did not reflect clinical practice.

Cost-effectiveness estimates

The cost-effectiveness results are highly sensitive to assumptions about utility value

3.16 The committee considered whether Xeomin would be a cost-effective use of NHS resources for chronic sialorrhoea. The company provided base-case incremental cost-effectiveness ratios (ICERs) and scenario analyses based on the list price of Xeomin and based on a confidential commercial arrangement. Because the ICERs based on the commercial arrangement are confidential, only the list-price ICERs are presented here.

- The company's base-case deterministic ICER was £9,583 per quality-adjusted life year (QALY) gained for Xeomin compared with standard care. Xeomin dominated glycopyrronium bromide.
- The ERG's exploratory analyses provided both a deterministic ICER and a probabilistic ICER for Xeomin compared with standard care; £47,309 and £45,423 per QALY gained respectively. Xeomin continued to dominate glycopyrronium bromide.

  The committee noted that the main driver of the difference in ICERs was the source of the utility values, and that the ICER was very sensitive to small changes in assumptions about utility values. It recalled that the most appropriate source of data for the utility values was the EQ-5D-3L from SIAXI (see section 3.9), which was used in the ERG's analyses. The committee also agreed that standard care was the most appropriate comparator (see section 3.3). Therefore, it concluded that the most appropriate ICER for decision making was the ERG's exploratory probabilistic ICER of £45,423 per QALY gained for Xeomin compared with standard care.

Xeomin is recommended as a treatment option

3.17 Having considered that the ERG's probabilistic ICER is in line with its preferred

assumptions, the committee recalled that it would take into account these factors in its decision making:

- The EQ-5D-3L may not fully capture the health-related quality-of-life gain associated with sialorrhoea; this would increase QALY gains and lower the ICER (see section 3.9).
- The health-related quality of life of carers is not considered in SIAXI and the economic model; this would increase QALY gains and lower the ICER (see section 3.13).
- Ultrasound guidance is not as prevalent in NHS clinical practice as in SIAXI; using the percentage from the NHS in the economic model would reduce the costs and lower the ICER (see section 3.14).
- Resource use was inappropriately modelled; it is unclear how a more appropriate model would affect the ICER (see section 3.15).

The committee noted that when these factors and the commercial arrangement were taken into account, the ICER would reduce to within the range usually considered to be a cost-effective use of NHS resources. Therefore, the committee recommended Xeomin as a treatment option.

Other factors

There are no equalities considerations, but stigma associated with drooling may not be captured by routine quality assessments

3.18 The committee considered whether there were any equalities considerations for this appraisal, as suggested by Parkinson's UK. Potential equalities issues were age, physical disability, communication difficulties and mental health problems. The committee agreed that the increased prevalence of drooling in older people with neurological conditions is a feature of sialorrhoea. Any recommendation resulting from this appraisal will apply to all people, so age, as defined by the Equalities Act, is not a relevant equalities issue. Similarly, physical disability, communication difficulties and mental health problems vary by underlying neurological condition and will apply to all people so are not relevant equalities issues. The committee also considered whether there is stigma associated with drooling, as a social value judgement. It concluded that many of the issues associated with drooling should be picked up as part of measuring social isolation and other psychosocial symptoms (see section 3.1), although

these were not captured with the chosen assessment tools. However, there may be additional relief of stigma as a result of treatment that would not be captured in routine quality-of-life assessments.

The technology is not innovative

3.19 The company considers the drug to be innovative. However, when focusing specifically on relevant benefits associated with innovation, the committee considered that these were adequately captured in the model.

4 Implementation

4.1 Section 7(6) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.

4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has chronic sialorrhoea and the doctor responsible for their care thinks that Xeomin (botulinum neurotoxin type A) is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee D.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Adam Brooke
Technical lead

Nicola Hay
Technical adviser

Kate Moore
Project manager

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Accreditation

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Reference: HSC (SQSD) 4/22 **Date of Issue: 20 January 2022**

HSC REVISED 'NEVER EVENTS' LIST – UPDATED GUIDANCE IN RELATION TO NEVER EVENT NUMBER 4

For Action:

Chief Executives of HSC Trusts
Chief Executives HSCB and PHA
Chief Executive RQIA

For Information:
Distribution as listed at the end of this circular.

Related documents
https://www.england.nhs.uk/publication/never-events/

Superseded documents
HSC (SQSD) 56/16
HSC (SQSD) 36/18
HSC (SQSD) 7/21

Implementation
Immediate

DoH Safety and Quality Circulars including Patient Safety Alerts can be accessed on: https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

Dear Colleagues

SUMMARY

The purpose of this circular is to advise you of an update to relevant guidance in relation to Never Event Number 4 in the HSC List of Never Events, which addresses the mis-selection of a strong potassium containing solution. Reference to a previously issued circular **HSC (SQSD) 34/14** has been removed from the list of 'related safety, NICE and NIAIC guidance' associated with this Never Event. The updated full summary of 'HSC List of Never Events' is attached at **Annex 1**.

ACTION

Chief Executives of HSC Trusts should:

- Disseminate this circular to all relevant Trust staff for information.

- Ensure that any Never Events are reported to the HSCB/PHA in line with Serious Adverse Incident (SAI) guidance.

Chief Executives, HSCB and PHA should:

- Disseminate this circular to all relevant HSCB/PHA staff for consideration through the normal HSCB/PHA processes for assuring implementation of safety and quality alerts.
- Monitor the reporting of Never Events via the SAI process.
- Include information on Never Events (including numbers) in the six-monthly SAI Learning Reports published by HSCB/PHA.

Chief Executive, NIMDTA and NIPEC should:

- Disseminate this circular to doctors and dentists in training in all relevant specialities.

Chief Executive RQIA should:

- Disseminate this circular to all relevant independent providers.

BACKGROUND

Sir Liam Donaldson in his report "The Right Time, the Right Place" made a number of recommendations aimed at improving the safety, quality and effectiveness of the delivery of health and social care services in Northern Ireland. Recommendation 6 of the Donaldson Report advises that the system for serious adverse incident and adverse incident reporting should be retained but modified through the creation of a limited list of Never Events.

This recommendation has been implemented through the adoption of a HSC Never Events list containing all current categories listed in the NHS England & Improvement (E&I) Never Event List that applies in England.

The current list of 'Never Events for the HSC in Northern Ireland', including details of relevant guidance to prevent each Never Event, is attached at **Annex 1**.

Please note that for this circular the list of Never Events has not changed –the guidance relevant to Never Event Number 4 has been updated with removal of reference to the previously issued circular HSC (SQSD) 34/14.

It is important, in the spirit of transparency and candour, that when staff are engaging with service users, families and carers as part of the SAI process, that in addition to advising an individual that an SAI has or may have occurred, they should also be advised if the SAI is a Never Event and how this will be taken account of during the SAI review process.

Any enquiries about the content of this circular should be addressed to:

David Wilson
Safety Strategy Unit
Department of Health
Room D2.4
Castle Buildings
Stormont
BELFAST
BT4 3SQ

Personal Information redacted by the USI

Yours sincerely

DR LOURDA GEOGHEGAN
Deputy Chief Medical Officer

Distributed for Information to:
Executive Medical Director/Director of Public Health, PHA
Director of Nursing and Allied Health Professions, PHA
Director of Performance Management & Service Improvement, HSCB
Chief Executive, BSO
Safety and Quality Alerts Team, HSC Board
Prof Donna Fitzsimons, Head of Nursing & Midwifery, QUB
Prof Pascal McKeown, Head of Medical School, QUB
Dr Neil Kennedy, Acting Director of Centre for Medical Education, QUB
Prof Carmel Hughes, Head of School of Pharmacy QUB
Prof Sonja McIlfatrick, Head of School of Nursing, UU
Prof Paul McCarron, Head of Pharmacy School, UU
Chief Executive, NIPEC
Staff Tutor of Nursing, Open University
Director, Safety Forum
NI Centre for Pharmacy Learning and Development
Clinical Education Centre
NI Royal College of Nursing

Annex 1

HSC NEVER EVENTS LIST JANUARY 2022

NEVER EVENT	RELATED INFORMATION	RELATED NHS/NRLS GUIDANCE	RELATED SAFETY, NICE & NIAIC GUIDANCE
1. Wrong site surgery	An invasive procedure[1] performed on the wrong patient or at the wrong site (e.g. wrong knee, eye, and limb). The incident is detected at any time after the start of the procedure. **Includes:** Interventions that are considered to be surgical but may be done outside a surgical environment – for example, wrong site block (including blocks for pain relief), biopsy, interventional radiology procedure, cardiology procedure, drain insertion and line insertion (e.g. peripherally inserted central catheter (PICC)/ Hickman lines). **Excludes:** • removal of wrong teeth • local anaesthetic blocks for dental procedures (exclusion added May 2019	Safer Practice Notice – Standardising Wristbands improves patient safety, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824 Patient Safety Alert – WHO Surgical Safety Checklist, 2009, available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/ -Standards for providing a 24 hour interventional radiology service, 2008, The Royal College of Radiologists. Available at http://www.rcr.ac.uk/docs/radiology/pdf/Stand_24hr_IR_provision.pdf National safety standards for invasive procedures (NatSSIPs) (2015).	HSC (SQSD) 16/08 National Patient Safety Agency: Safer Practice Notice 24: Standardising Wristbands improves patient safety Learning Communication 5/09 Risk to patient safety of not using the H+C Number as the regional identifier for all patients and clients HSS (MD) 18/09 Safer Surgery Saves Lives

[1] The start of an invasive procedure is when a patient's anatomy begins to be permanently altered. For example, this is when the first incision is made that will scar the patient and take time to heal and recover from.

	• interventions where the wrong site is selected because the patient has unknown/unexpected anatomical abnormalities; these should be documented in the patient's notes • wrong level spinal surgery* • wrong site surgery due to incorrect laboratory reports/results or incorrect referral letters • Contraceptive hormone implant in the wrong arm. *Excluded from the current list while NHS Improvement works with the relevant professional organisations to ensure development of robust national barriers to prevent this incident. **Setting:** All patients receiving HSC funded care.	• Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).	
2. Wrong implant/prosthesis	Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient. **Excludes:** • placed implant/prosthesis is intentionally different from that	Safer Practice Notice – Standardising Wristbands improves patient safety, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824 Patient Safety Alert – WHO Surgical Safety Checklist, 2009, available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/	HSC (SQSD) 16/08 National Patient Safety Agency: Safer Practice Notice 24: Standardising Wristbands improves patient safety Learning Communication 5/09 Risk to patient safety of not using the H+C Number as the regional identifier for all patients and clients

	specified in the surgical plan, based on clinical judgement at the time of the procedure • specified implant/prosthesis is placed as planned but later found to be suboptimal • implant/prosthesis is different from the one specified due to incorrect preprocedural measurements or incorrect interpretation of the preprocedural data – for example, wrong intraocular lens placed due to wrong biometry or using wrong dataset from correct biometry. **Includes:** ·implantation of an intrauterine contraceptive device different from the one in the procedural plan **Setting:** All healthcare premises.	National safety standards for invasive procedures (NatSSIPs) (2015). Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).	HSS (MD) 18/09 Safer Surgery Saves Lives
3. Retained foreign object post-procedure	Retention of a foreign object in a patient after a surgical/invasive procedure. 'Surgical/invasive procedure' includes interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside of the surgical	Reducing the risk of retained swabs after vaginal birth and perineal suturing, 2010 available at http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=74113 Reducing the risk of retained throat packs after surgery, 2009, available at	HSC (SQSD) 16/08 National Patient Safety Agency: Safer Practice Notice 24: Standardising Wristbands improves patient safety Learning Communication 5/09 Risk to patient safety of not using the H+C Number as the regional

	environment e.g. central line placement in ward areas 'Foreign object' includes any items that should be subject to a formal counting /checking process at the commencement of the procedure and a counting /checking process before the procedure is completed (such as swabs, needles, instruments and guide wires) **except where:** Items are inserted any time before the procedure that are not subject to the formal counting/checking process, with the intention of removing them during the procedure Items are inserted during the procedure that are subject to the counting/ checking process, but are intentionally retained after completion of the procedure, with removal planned for a later time or date and clearly recorded in the patients notes Items are known to be missing prior to the completion of the procedure and may be within the patient (e.g. screw fragments, drill bits) but where further action to locate and/or retrieve would	http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59853 National safety standards for invasive procedures (NatSSIPs) (2015). • Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).	identifier for all patients and clients HSS (MD) 18/09 Safer Surgery Saves Lives NICE CG190: Intrapartum care http://www.nice.org.uk/guidance/cg190

	be impossible or be more damaging than retention		
4. Mis – selection of a strong potassium containing solution	Mis - selection refers to: • When a patient intravenously receives a strong potassium solution rather than an intended different medication **Setting:** All patients receiving HSC funded care.	Patient safety alert – Potassium chloride concentrate solutions, 2002 (updated 2003), available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59882	NICE CG174: Intravenous Fluid Therapy in Adults in Hospital (**NOTE NI Caveats**)http://www.nice.org.uk/guidance/cg174 NICE Quality Standard 66: IV Fluid Therapy in Adults http://www.nice.org.uk/guidance/qs66 NICE CG130: Hyperglycaemia in acute coronary syndromes https://www.nice.org.uk/guidance/cg130 NICE CG84: Diarrhoea and vomiting in children http://www.nice.org.uk/guidance/cg84 NICE CG99: Constipation in children and young people http://www.nice.org.uk/guidance/cg99

			NICE CG32: Nutritional support in adults http://www.nice.org.uk/guidance/cg32
5. Wrong route administration of medication	The patient receives one of the following: • Intravenous chemotherapy administered via the intrathecal route • Oral/enteral medication or feed/flush administered by any parenteral route • Intravenous administration of a medicine intended to be administered via the epidural route * During the transition period for the introduction of NRFit™ devices, the 'intravenous administration of a medicine intended to be administered by the epidural route' cannot be considered a Never Event. An update will be provided when this period ends. **Setting**: All patients receiving NHS funded care.	Patient Safety Alert NPSA/2007/19 - Promoting safer measurement and administration of liquid medicines via oral and other enteral routes, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59808 Patient Safety Alert NPSA/2007/21, Safer practice with epidural injections and infusions, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59807	HSC (SQSD) 61/08 Using Vinca Alkaloid Minibags HSC (SQSD) 85/09 Minimising risks of mismatching spinal, epidural and regional devices HSC (SQSD) 85/09 Addendum 1 HSC (SQSD) 6/11Minimising risks of mismatching spinal, epidural and regional devices with incompatible connectors HSC (SQSD) 50/08 Promoting safer measurement and administration of liquid medicines via oral and other enteral routes HSC (SQSD) 28/07 Safer practice with epidural injections and infusions

			HSC (SQSD)28/17 Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks NICE CG55: Intrapartum Care https://www.nice.org.uk/guidance/cg55 NICE Interventional Procedure 249: Ultrasound-guided catheterisation of the epidural space http://www.nice.org.uk/guidance/ipg249
6. Overdose of Insulin due to abbreviations or incorrect device	Overdose refers to when: • a patient is given a 10-fold or greater overdose of insulin because the words 'unit' or 'international units' are abbreviated; such an overdose was given in a care setting with an electronic prescribing system. **This definition of a Never Event has been temporarily suspended in the HSC**	Rapid response report – Safer administration of insulin, 2010, available at http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74287 Diabetes: insulin, use it safely Patient information booklet 03 January 2011 - NHS Diabetes and Kidney Care	HSC (SQSD) 12/10 Safer administration of insulin HSC (SQSD) 3/11 The adult patient's passport to safer use of insulin HSC (SQSD) 54/16 Ensuring the safe administration of insulin

	Never Event List pending implementation of electronic prescribing system barriers in HSC care settings. • a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin • A healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle. **Setting:** All patients receiving NHS funded care.	Patient Safety Alert – Risk of severe harm and death due to withdrawing insulin from pen devices (2016).	HSC (SQSD) 55/16 Minimising the risk of medication errors with high strength, fixed combination and biosimilar insulin products
7. Overdose of methotrexate for non-cancer treatment **s Never Event has been temporarily suspended in**	patient is given a dose of methotrexate, by any route, for non-cancer treatment that is more than the intended weekly dose; such an overdose was given in a care setting with an electronic prescribing system[2].	Patient safety alert - Improving compliance with oral methotrexate guidelines, 2006, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800	http://www.dhsspsni.gov.uk/hsc__sqsd__07_08__policy_guidance_oral_methotrexate_guidance_.pdf

[2] Electronic prescribing, dispensing and administration systems are an evidence-based method to reduce patient harm from medicines. All NHS organisations should introduce them as soon as possible. When the definitions for the insulin and methotrexate overdose Never Events were revised in 2015, it was agreed that those for insulin given in overdose because of the use of abbreviations for 'unit' and for all methotrexate overdose incidents would only apply to care settings with electronic prescribing systems as indicated. The systemic protective barriers for these two types of Never Event were found not to be strong enough in care settings where electronic barriers do not exist. For example, even though most acute hospitals do use a pre-printed insulin prescription to try and prevent prescribers using the abbreviations 'iu' or 'u', this is not the case in all care settings. Also, pre-printed prescriptions on its own are not a reliably strong enough barrier to prevent a potential 10-fold dosing error as prescribers can still prescribe insulin on general prescriptions.

the HSC Never Event List pending implementation of electronic prescribing system barriers in HSC care settings.	**Setting**: All patients receiving NHS funded care.		
8. Mis-selection of high strength of midazolam during conscious sedation	Mis - selection refers to • When a patient receives an overdose due to the selection of a high strength midazolam preparation (5mg/ml or 2mg/ml) rather than the 1mg/ml preparation, in a clinical area performing conscious sedation. • Excludes clinical areas where the use of high strength midazolam is appropriate. These are generally only in general anaesthesia, intensive care, palliative care, or where its use has been formally risk assessed within an organisation. **Setting**: All healthcare premises.	Rapid Response Report - Reducing risk of overdose with midazolam injection in adults, 2008, available at http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59896&p=2	Rapid Response Report - Reducing risk of overdose with midazolam injection in adults (issued via SABS)
9. Failure to install functional collapsible shower or curtain rails	Involves either; • Failure of collapsible curtain or shower rails to collapse when an inpatient suicide is attempted/ successful.	Safety Notice- archived document NHSE SN (2002) 01: Cubicle rail suspension system with load release support systems, 2002, http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lett	**EFA/2010/009 - Flush fitting anti-ligature curtain rails: ensuring correct installation.(PDF 28KB)**

	• failure to install collapsible rails and an inpatient suicide is attempted/successful using these non-collapsible rails **Setting:** All mental health inpatient premises.	ersandcirculars/Estatesalerts/DH_4122863?PageOperation=email Safety Notice – archived document NHSE (2004) 10: Bed cubicle rails, shower curtain rails and curtain rails in psychiatric in-patients settings, 2004, www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_4119476 Health building note 03-01 – Adult acute mental health units (2013). • Health building note 03-02 – Facilities for child and adolescent mental health services (CAMHS) (2017). NHS Improvement 03 – G-rail 2301, window curtain tracking system (2004). • NHS Improvement 08 – Cubicle rail tracking and PVC dustcovers (2004). • Department of Health 08 – Cubicle curtain track rail (2007).	**EFA/2010/003 - Anti-ligature curtain rails (including shower curtains): risks from incorrect installation or modification (PDF 27 KB)** MDEA(NI)2007/61 - Cubical curtain track rails (anti ligature): Installation issues with anti-ligature cubical curtain track rails (PDF 164 KB) MDEA(NI)2007/83 - Curtain tracks and other fixed fittings in Emergency Admission Units - used as points of ligature (PDF 120 KB)
10. Falls from poorly restricted windows	A patient falling from a poorly restricted window. • Applies to windows “within reach” of patients. This means windows (including the window	*Health Building Note (HBN) 00-10 Part D: Windows and associated hardware*, available via https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/273867/20131	EFA/2013/002 - Window restrictors. Window restrictors may be inadequate in preventing a determined effort to force a window open beyond

	sill) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to assist in climbing out of the window. • Includes windows located in facilities/areas where healthcare is provided and where patients can and do access. • Includes where patients deliberately or accidentally fall from a window where a restrictor has been fitted but previously damaged or disabled, but does not include events where a patient deliberately disables a restrictor or breaks the window immediately before the fall. • Includes where patients are able to deliberately overcome a window restrictor by hand or using commonly available flat bladed instruments as well as the 'key' provided. **Setting:** All patients receiving NHS funded care.	223_HBN_00-10_PartD_FINAL_published_version.pdf *DH(2014)/003 – Window restrictors of cable and socket design, 2014, available at https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102246*	the 100mm restriction. (PDF 40KB) EFA/2012/001 - restrictors incorporate a plastic spacer (PDF 94 KB) MDEA(NI)2007/100 - Window restrictors (PDF 5 KB) Health Building Note 00-10Part D: Windows and associated hardware- http://www.dhsspsni.gov.uk/hbn00-01-partd.pdf NICE PH29 – Strategies to prevent unintended injuries among the under-15s http://www.nice.org.uk/guidance/ph29

11. Chest or neck entrapment in bedrails	Entrapment of a patient's chest or neck within bedrails, or between bedrails, bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance[3] **Setting:** All settings providing NHS funded healthcare, including NHS funded patients in care home settings, and equipment provided by the NHS for use in patients' own homes.	*DB 2006(06) v 2.1 Safe use of bed rails,* Dec 2013, available at http://www.mhra.gov.uk/home/groups/dts-bs/documents/publication/con2025397.pdf	HSC (SQSD) 22/07 Using bedrails safely and effectively
12. Transfusion or transplantation of ABO-incompatible blood components or organs	Unintentional transfusion of ABO-incompatible blood components. Excludes where ABO-incompatible blood components are deliberately transfused with appropriate management. Unintentional ABO mismatched solid organ transplantation. Excluded are scenarios in which clinically appropriate ABO	Department of Health CEM/CMO/2017/005 – Safe transfusion practice: use a bedside checklist (2017). • British Society for Histocompatibility and Immunogenetics and British Transplantation Society – Guidelines for the detection and characterisation of clinically relevant antibodies in allotransplantation (2014). • British Transplantation Society – Guidelines for antibody incompatible transplant (2015).	HSC (SQSD) 30/07 Right Patient, Right Blood QIPP – Electronic Blood Transfusion – Improving safety & efficiency of transfusion systems https://www.nice.org.uk/savingsAndProductivityAndLocalPracticeResource?ci=http%3a%2f%2farms.evidence.nhs.uk%2fresources%2fQIPP%2f29453%3fniceorg%3dtrue

[3] This includes windows where the provider has not put a restrictor in place in accordance with guidance.

	incompatible solid organs are transplanted deliberately In this context, 'incompatible' antibodies must be clinically significant. If the recipient has donor specific anti-ABO antibodies and is therefore, likely to have an immune reaction to a specific ABO compatible organ then it would be a never event to transplant that organ inadvertently and without appropriate management. **Setting:** All patients receiving NHS funded care.	Safer Practice Notice – Standardising Wristbands improves patient safety, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824	NICE TA156: Routine antenatal anti-D prophylaxis is recommended as a treatment option for all pregnant women who are RhD negative https://www.nice.org.uk/guidance/ta156
13. Misplaced naso - or oro-gastric tubes	Misplacement and use of a naso- or oro-gastric tube in the pleura or respiratory tract where the misplacement of the tube is not detected prior to commencement of feeding, flush or medication administration. **Setting:** All patients receiving NHS funded care.	• Patient Safety Alert – Nasogastric tube misplacement: continuing risk of death and severe harm (2016). • NHS Improvement – Initial placement checks for nasogastric and orogastric tubes: resource set (2016).	HSC (SQSD) 02/11 Reducing the harm caused by misplaced nasogastric feeding tubes in adults, children and infants HSC (SQSD) 02/12 Harm from flushing of nasogastric tubes before confirmation of placement Learning Communication 2/09 Reducing Harm caused by the Misplacement of Nasogastric Feeding Tubes

			HSC (SQS) 47/16 Nasogastric tube misplacement: continuing risk of death and severe harm
14. Scalding of patients	Patient being scalded by water used for washing/bathing • Excludes scalds from water being used for purposes other than washing/bathing (e.g. from kettles) **Settings:** All patients receiving NHS funded care.	- Health Technical Memorandum 04-01 - The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems, 2006, available via http://www.whtlimited.com/doc/lib/98/htm-04-01-part-b-20061009113435.pdf - Scalding risks from hot water in health and social care LAC: 79/5, 2007, available at http://www.hse.gov.uk/lau/lacs/79-5.htm - Scalding and burning, available at http://www.hse.gov.uk/healthservices/scalding-burning.htm	See **Scottish Hospital Technical Note** 6The Safe Operation and Maintenance of Thermostatic Mixing Valves http://www.hfs.scot.nhs.uk/publications/SHTN%206%20The%20Safe%20Operation%20and%20Maintenance%20of%20Thermostatic%20Mixing%20Valves.pdf Health Technical Memorandum 04-01 - The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems, 2006, applicable to NI HBN 00-10 part C Sanitary Assemblies http://www.dhsspsni.gov.uk/hbn_00-10_part_c_l.pdf issued in NI
15. Unintentional connection of a patient requiring oxygen to an air flowmeter	This applies when a patient who requires oxygen is connected to an air flowmeter when the intention was to connect them to an oxygen flowmeter.	**National safety requirement:** • Patient Safety Alert – Reducing the risk of oxygen tubing being connected to air flowmeters (2016).	HSC (SQSD) 57/16 Reducing the Risk of Oxygen Tubing being connected to air flow meters

	Excludes: • Unintentional connection to an air cylinder instead of an oxygen cylinder as robust barriers to prevent this have not yet been identified. **Setting:** All settings providing HSC-funded care.		

NICE National Institute for Health and Care Excellence

Royal College of Physicians

NICE guideline

Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management

NICE guideline
Published: 29 October 2021
www.nice.org.uk/guidance/ng206

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

Overview

This guideline covers diagnosing and managing myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS) in children, young people and adults. It aims to improve awareness and understanding about ME/CFS and when to suspect it, so that people are diagnosed earlier. It includes recommendations on diagnosis, assessment and care planning, safeguarding, access to care and managing ME/CFS and its symptoms.

These recommendations were developed based on evidence reviewed before the COVID-19 pandemic. We have not reviewed evidence on the effects of COVID-19, so it should not be assumed that these recommendations apply to people diagnosed with post-COVID-19 syndrome. NICE has produced a guideline on managing the long-term effects of COVID-19.

Who is it for?

- Health and social care professionals, including those working or providing input into educational and occupational health services
- Commissioners
- People with suspected or diagnosed ME/CFS, their families and carers and the public

This guideline was commissioned by NICE and developed at the National Guideline Centre which is hosted by the Royal College of Physicians.

This guideline updates and replaces NICE guideline CG53 (published August 2007).

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

Box 1 Severity of ME/CFS

Unless stated otherwise, these recommendations apply to everyone with myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS) regardless of symptom severity. There are also additional considerations in the section on care for people with severe or very severe ME/CFS.

Definitions of severity are not clear cut because individual symptoms vary widely in severity and people may have some symptoms more severely than others. The definitions below provide a guide to the level of impact of symptoms on everyday functioning.

Mild ME/CFS

People with mild ME/CFS care for themselves and do some light domestic tasks (sometimes needing support) but may have difficulties with mobility. Most are still working or in education, but to do this they have probably stopped all leisure and social pursuits. They often have reduced hours, take days off and use the weekend to cope with the rest of the week.

Moderate ME/CFS

People with moderate ME/CFS have reduced mobility and are restricted in all activities of daily living, although they may have peaks and troughs in their level of symptoms and ability to do activities. They have usually stopped work or education, and need rest periods, often resting in the afternoon for 1 or 2 hours. Their sleep at night is generally poor quality and disturbed.

Severe ME/CFS

People with severe ME/CFS are unable to do any activity for themselves or can carry out minimal daily tasks only (such as face washing or cleaning teeth). They have severe cognitive difficulties and may depend on a wheelchair for mobility. They are often unable to leave the house or have a severe and prolonged after-effect if they do so. They may also spend most of their time in bed and are often extremely sensitive to light and sound.

Very severe ME/CFS

People with very severe ME/CFS are in bed all day and dependent on care. They need help with personal hygiene and eating, and are very sensitive to sensory stimuli. Some people may not be able to swallow and may need to be tube fed.

1.1 Principles of care for people with ME/CFS

Also see the section on care for people with severe or very severe ME/CFS.

Awareness of ME/CFS and its impact

1.1.1 Be aware that ME/CFS:

- is a complex, chronic medical condition affecting multiple body systems and its pathophysiology is still being investigated
- affects everyone differently and its impact varies widely – for some people symptoms still allow them to carry out some activities, whereas for others they cause substantial incapacity
- is a fluctuating condition in which a person's symptoms can change unpredictably in nature and severity over a day, week or longer
- can affect different aspects of the lives of both people with ME/CFS and their families and carers, including activities of daily living, family life, social life, emotional wellbeing, work and education.

1.1.2 Recognise that people with ME/CFS may have experienced prejudice and disbelief and could feel stigmatised by people (including family, friends, health and social care professionals, and teachers) who do not understand their illness. Take into account:

- the impact this may have on a child, young person or adult with ME/CFS
- that people with ME/CFS may have lost trust in health and social care services and be hesitant about involving them.

Approach to delivering care

1.1.3 Health and social care professionals should:

- take time to build supportive, trusting and empathetic relationships
- acknowledge to the person the reality of living with ME/CFS and how symptoms could affect them

- use a person-centred approach to care and assessment
- involve families and carers (as appropriate) in discussions and care planning if the person with ME/CFS chooses to include them
- be sensitive to the person's socioeconomic, cultural and ethnic background, beliefs and values, and their gender identity and sexual orientation, and think about how these might influence their experience, understanding and choice of management.

1.1.4 Recognise that people with ME/CFS need:

- timely and accurate diagnosis so they get appropriate care for their symptoms
- regular monitoring and review, particularly when their symptoms are worsening, changing or are severe (see the section on managing flare-ups in symptoms and relapse and review in primary care).

1.1.5 Explain to people with ME/CFS and their family or carers (as appropriate) that they can decline or withdraw from any part of their care and support plan and this will not affect access to any other aspects of their care. They can begin or return to this part of their plan if they wish to.

1.1.6 When working with children and young people with ME/CFS, ensure their voice is heard by:

- taking a child-centred approach, with the communication focusing on them
- discussing and regularly reviewing with them how they want to be involved in decisions about their care
- taking into account that they may find it difficult to communicate and describe their symptoms and may need their parents or carers (as appropriate) to help them
- recognising that they may need to be seen on more than 1 occasion to gain trust (with or without their parents or carers, as appropriate).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on principles of care for people with ME/CFS.

Full details of the evidence and the committee's discussion are in:

- evidence review A: information, education and support for people with ME/CFS and their families and carers
- evidence review C: accessing health and social care services
- appendix 2: involving adults with severe ME/CFS.

Other supporting evidence and discussion can be found in evidence review B: information, education and support for health and social care professionals and appendix 1: involving children and young people.

1.2 Suspecting ME/CFS

1.2.1 Explain to people presenting with possible symptoms of ME/CFS that there currently is no diagnostic test for ME/CFS and it is recognised on clinical grounds alone.

1.2.2 Suspect ME/CFS if:

- the person has had all of the persistent symptoms in box 2 for a minimum of 6 weeks in adults and 4 weeks in children and young people and
- the person's ability to engage in occupational, educational, social or personal activities is significantly reduced from pre-illness levels and
- symptoms are not explained by another condition.

Box 2 Symptoms for suspecting ME/CFS

All of these symptoms should be present:

- Debilitating fatigue that is worsened by activity, is not caused by excessive cognitive, physical, emotional or social exertion, and is not significantly relieved by rest.
- Post-exertional malaise after activity in which the worsening of symptoms:
  - is often delayed in onset by hours or days
  - is disproportionate to the activity
  - has a prolonged recovery time that may last hours, days, weeks or longer.
- Unrefreshing sleep or sleep disturbance (or both), which may include:
  - feeling exhausted, feeling flu-like and stiff on waking
  - broken or shallow sleep, altered sleep pattern or hypersomnia.
- Cognitive difficulties (sometimes described as 'brain fog'), which may include problems finding words or numbers, difficulty in speaking, slowed responsiveness, short-term memory problems, and difficulty concentrating or multitasking.

1.2.3 If ME/CFS is suspected, carry out:

- a medical assessment (including symptoms and history, comorbidities, overall physical and mental health)
- a physical examination
- an assessment of the impact of symptoms on psychological and social wellbeing

- investigations to exclude other diagnoses, for example (but not limited to):
  - urinalysis for protein, blood and glucose
  - full blood count
  - urea and electrolytes
  - liver function
  - thyroid function
  - erythrocyte sedimentation rate or plasma viscosity
  - C-reactive protein
  - calcium and phosphate
  - HbA1c
  - serum ferritin
  - coeliac screening
  - creatine kinase.

  Use clinical judgement to decide on additional investigations to exclude other diagnoses (for example, vitamin D, vitamin B12 and folate levels; serological tests if there is a history of infection; and 9am cortisol for adrenal insufficiency).

1.2.4 Be aware that the following symptoms may also be associated with, but are not exclusive to, ME/CFS:

- orthostatic intolerance and autonomic dysfunction, including dizziness, palpitations, fainting, nausea on standing or sitting upright from a reclining position
- temperature hypersensitivity resulting in profuse sweating, chills, hot flushes, or feeling very cold
- neuromuscular symptoms, including twitching and myoclonic jerks
- flu-like symptoms, including sore throat, tender glands, nausea, chills or muscle aches
- intolerance to alcohol, or to certain foods and chemicals

- heightened sensory sensitivities, including to light, sound, touch, taste and smell
- pain, including pain on touch, myalgia, headaches, eye pain, abdominal pain or joint pain without acute redness, swelling or effusion.

1.2.5 Primary healthcare professionals should consider seeking advice from an appropriate specialist if there is uncertainty about interpreting signs and symptoms and whether an early referral is needed. For children and young people, consider seeking advice from a paediatrician.

1.2.6 When ME/CFS is suspected:

- continue with any assessments needed to exclude or identify other conditions
- give the person advice on managing their symptoms in line with the section on advice for people with suspected ME/CFS.

Referring children and young people with suspected ME/CFS

1.2.7 When ME/CFS is suspected in a child or young person based on the criteria in recommendation 1.2.2 and the assessment in recommendation 1.2.3:

- refer them to a paediatrician for further assessment and investigation for ME/CFS and other conditions
- start to work with the child or young person's place of education or training to support flexible adjustments or adaptations.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on suspecting ME/CFS.

Full details of the evidence and the committee's discussion are in evidence review D: identifying and diagnosing ME/CFS.

1.3 Advice for people with suspected ME/CFS

1.3.1 When ME/CFS is suspected, give people personalised advice about managing their symptoms. Also advise them:

- not to use more energy than they perceive they have – they should manage their daily activity and not 'push through' their symptoms
- to rest and convalesce as needed (this might mean making changes to their daily routine, including work, school and other activities)
- to maintain a healthy balanced diet, with adequate fluid intake.

1.3.2 Explain to people with suspected ME/CFS that their diagnosis can only be confirmed after 3 months of persistent symptoms. Reassure them that they can return for a review before that if they develop new or worsened symptoms, and ensure that they know who to contact for advice.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on advice for people with suspected ME/CFS.

Full details of the evidence and the committee's discussion are in evidence review E: management strategies before diagnosis.

1.4 Diagnosis

1.4.1 Diagnose ME/CFS in a child, young person or adult who has the symptoms in recommendation 1.2.2 that have persisted for 3 months and are not explained by another condition.

1.4.2 Primary healthcare professionals should consider seeking advice from an appropriate specialist if there is uncertainty about interpreting signs and symptoms at 3 months and whether further investigations are needed.

1.4.3 Refer adults directly to an ME/CFS specialist team (see box 3) to confirm their diagnosis and develop a care and support plan.

1.4.4 Refer children and young people who have been diagnosed with ME/CFS after assessment by a paediatrician (based on the criteria in recommendation 1.2.2) directly to a paediatric ME/CFS specialist team (see box 3) to confirm their diagnosis and develop a care and support plan.

Box 3 ME/CFS specialist team

Specialist teams consist of a range of healthcare professionals with training and experience in assessing, diagnosing, treating and managing ME/CFS. They commonly have medically trained clinicians from a variety of specialisms (including rheumatology, rehabilitation medicine, endocrinology, infectious diseases, neurology, immunology, general practice and paediatrics) as well as access to other healthcare professionals specialising in ME/CFS. These may include physiotherapists, exercise physiologists, occupational therapists, dietitians, and clinical or counselling psychologists.

Children and young people are likely to be cared for under local or regional paediatric teams that have experience of working with children and young people with ME/CFS in collaboration with ME/CFS specialist centres.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on diagnosis.

Full details of the evidence and the committee's discussion are in evidence review D: identifying and diagnosing ME/CFS.

1.5 Assessment and care and support planning by an ME/CFS specialist team

Also see the section on care for people with severe or very severe ME/CFS.

1.5.1 Carry out and record a holistic assessment to confirm the person's diagnosis of ME/CFS and inform their care and support plan. This should include:

- a medical assessment (including relevant symptoms and history, comorbidities, overall physical and mental health, anything that is known to exacerbate or alleviate symptoms, and sleep quality)
- physical functioning
- the impact of symptoms on psychological, emotional and social wellbeing

- current and past experiences of medicines (including tolerance and sensitivities), vitamins and mineral supplements
- dietary assessment (including weight history before and after their diagnosis of ME/CFS, use of restrictive and alternative diets, and access to shopping and cooking).

1.5.2 Develop and agree a personalised care and support plan with the person with ME/CFS and their family or carers (as appropriate) informed by their holistic assessment. Include the following, depending on the person's needs:

- information and support needs (see the section on information and support)
- support for activities of daily living (see the section on access to care and support and recommendation 1.6.8 on accessing social care)
- mobility and daily living aids and adaptations to increase or maintain independence (see the recommendations on aids and adaptations)
- education, training or employment support needs (see the section on supporting people with ME/CFS in work, education and training)
- self-management strategies, including energy management (see the recommendations on energy management)
- physical functioning and mobility (see the recommendations on physical functioning and mobility)
- managing ME/CFS and symptom management, including medicines management (see recommendations 1.12.1 to 1.12.26 on managing symptoms)
- guidance on managing flare-ups and relapses (see the section on managing flare-ups in symptoms and relapses)
- details of the health and social care professionals involved in the person's care, and who to contact (see recommendation 1.10.3).

1.5.3 Recognise that the person with ME/CFS is in charge of the aims of their care and support plan.

1.5.4 Give the person and their family or carers (as appropriate) a copy of their care and support plan and share a copy with their GP.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on assessment and care and support planning by an ME/CFS specialist team.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS and evidence review A: information, education and support for people with ME/CFS and their families and carers.

1.6 Information and support

Communication

1.6.1 Ensure information is provided to people with ME/CFS and their family or carers (as appropriate):

- in a variety of formats, such as written materials, electronic and audio, and suitable for their needs (for example, in their preferred language or an accessible version)
- both in person in clinical settings and for them to use at home.

  Follow the principles on communication, information giving and shared decision making in the NICE guidelines on patient experience in adult NHS services, people's experience in adult social care services and shared decision making.

1.6.2 When providing information for children and young people with ME/CFS, take into account their age and level of understanding, symptoms and any disabilities or communication needs. Use interactive formats such as:

- one-to-one or group discussion
- written materials and pictures
- play, art and music activities
- digital media, for example video or interactive apps.

Information about ME/CFS

1.6.3 Give people with ME/CFS and their family or carers (as appropriate) up-to-date

information about ME/CFS as soon as it is suspected. Tailor information to people's circumstances, including their symptoms, the severity of their condition and how long they have had ME/CFS. Ask people regularly if they would like more information or to revisit discussions.

1.6.4 Explain that ME/CFS:

- is a fluctuating medical condition that affects everyone differently, in which symptoms and their severity can change over a day, week or longer
- varies in long-term outlook from person to person – although a proportion of people recover or have a long period of remission, many will need to adapt to living with ME/CFS
- varies widely in its impact on people's lives, and can affect their daily activities, family and social life, and work or education (these impacts may be severe)
- can be worsened by particular triggers – these can be known or new triggers or in some cases there is no clear trigger
- can be self-managed with support and advice (see the section on energy management)
- can involve flare-ups and relapses even if symptoms are well managed, so planning for these should be part of the energy management plan.

1.6.5 Explain to children and young people with ME/CFS and their parents or carers (as appropriate) that the outlook is better in children and young people than in adults.

1.6.6 Give people with ME/CFS and their family or carers (as appropriate) information about:

- self-help groups, support groups and other local and national resources for people with ME/CFS
- where to access advice about financial support, including applying for benefits.

Social care

1.6.7 Discuss sensitively with the person and their family or carers (as appropriate) how social care may benefit them. Explain that it can help the person living with

ME/CFS as well as provide a route to support for families and carers through a formal carer's assessment. Also see recommendations 1.8.5 and 1.8.6 on maintaining independence.

1.6.8 Explain to people with ME/CFS and their family or carers (as appropriate) how to self-refer for a social care needs assessment from their local authority. Offer to make the referral for them if they prefer.

1.6.9 Advise children and young people with moderate ME/CFS or severe or very severe ME/CFS and their parents or carers (as appropriate) that they may be entitled to support from children's social care as children in need because of their disability.

Supporting families and carers of people with ME/CFS

1.6.10 Follow recommendations in the NICE guideline on supporting adult carers on identifying, assessing and meeting the caring, physical and mental health needs of families and carers.

1.6.11 Advise families and carers about the right to assessment and support for their own needs, as follows:

- parents and carers of children and young people under 16 with ME/CFS, according to the Children and Families Act 2014
- young carers, according to the Young Carers (Needs Assessment) Regulations 2015.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on information and support.

Full details of the evidence and the committee's discussion are in evidence review A: information, education and support for people with ME/CFS and their families and carers.

Other supporting evidence and discussion can be found in:

- evidence review B: information, education and support for health and social care professionals
- evidence review C: accessing health and social care services
- appendix 1: involving children and young people.

1.7 Safeguarding

1.7.1 Recognise that people with ME/CFS, particularly those with severe or very severe ME/CFS, are at risk of their symptoms being confused with signs of abuse or neglect.

1.7.2 If a person with confirmed or suspected ME/CFS needs a safeguarding assessment, directly involve health and social care professionals who have training and experience in ME/CFS as soon as possible.

1.7.3 If a person with confirmed or suspected ME/CFS needs to be assessed under the Mental Health Act 1983 or the Mental Capacity Act 2005, directly involve health and social care professionals who have training and experience in ME/CFS as soon as possible.

1.7.4 Recognise that the following are not necessarily signs of abuse or neglect in children and young people with confirmed or suspected ME/CFS:

- physical symptoms that do not fit a commonly recognised illness pattern
- more than 1 child or family member having ME/CFS

- disagreeing with, declining or withdrawing from any part of their care and support plan, either by them or by their parents or carers on their behalf
- parents or carers acting as advocates and communicating on their behalf
- reduced or non-attendance at school.

1.7.5 Be aware that recognising and responding to possible child abuse and neglect (maltreatment) is complex and should be considered in the same way for children and young people with confirmed or suspected ME/CFS as with any child with a chronic illness or disability. Follow the NICE guidelines on child maltreatment and child abuse and neglect.

1.7.6 Offer children and young people with ME/CFS a review of their care and support plan at least every 6 months, and more frequently if needed, depending on the severity and complexity of their symptoms.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on safeguarding.

Full details of the evidence and the committee's discussion are in evidence review B: information, education and support for health and social care professionals.

Other supporting evidence and discussion can be found in evidence review A: information, education and support for people with ME/CFS and their families and carers and appendix 1: involving children and young people.

1.8 Access to care and support

Also see the section on care for people with severe or very severe ME/CFS.

1.8.1 Health and social care organisations should ensure that people with ME/CFS can use their services by:

- adapting the timing, length and frequency of all appointments to the person's needs

- taking into account physical accessibility, such as how far the person has to travel, whether there is suitable transport and parking, and where rooms are for appointments
- taking into account sensitivities to light, sound, touch, pain, temperature extremes or smells
- providing care flexibly to the person's needs, such as by online or phone consultations or making home visits.

1.8.2 If a person with ME/CFS misses an appointment:

- do not discharge them for not attending because it could be due to their symptoms worsening
- discuss why they could not attend and how the multidisciplinary team can support them.

1.8.3 Be aware that people with ME/CFS are unlikely to be seen at their worst because:

- debilitating symptoms or the risk that their symptoms will worsen may prevent people from leaving their home
- cognitive difficulties may often mean people wait until they feel they can speak and explain clearly before contacting services.

Hospital care

For improving access to hospital inpatient and outpatient care for people with ME/CFS, see recommendation 1.8.1.

1.8.4 Discuss with people who need inpatient care whether any aspects of where their care will be provided could cause problems for them, including:

- where a bed is situated on a ward (if possible, aim to provide a single room)
- the accessibility of toilets and washrooms
- environmental factors such as lighting, sound, heating and smells.

Maintaining independence

Also see the recommendations on social care and supporting families and carers of people with ME/CFS.

1.8.5 If a person with ME/CFS needs support at home, carry out a social care needs assessment. As a minimum, record and provide information and support on:

- activities of daily living
- mobility, including transferring from bed to chair, access to and use of toilet and washing facilities, use of stairs, and access to outside space
- dexterity and balance, including avoiding falls
- their home, including environmental controls to reduce light levels, sound levels and temperature fluctuations
- the feasibility of equipment and adaptations
- access to technology, including internet access
- where to get financial support and advice, for example signposting to advice on money management and making personalised arrangements with banks or the Post Office to access personal finances, and how to claim carers' and disability benefits and grants.

1.8.6 Give families and carers information on how to access training and resources about caring for the person with ME/CFS (see the NICE guideline on supporting adult carers).

Aids and adaptations

1.8.7 Enable prompt assessment for funding for home adaptation. If the person is not eligible for funding, continue to offer information and support in arranging home adaptations.

1.8.8 For people with moderate ME/CFS or severe or very severe ME/CFS, consider providing or recommending aids and adaptations (such as a wheelchair, blue badge or stairlift) that could help them maintain their independence and improve their quality of life, taking into account the risks and benefits. Include these in the person's care and support plan.

1.8.9 Provide aids and adaptations identified in the person's social care needs assessment without delay, so that people with ME/CFS can carry out activities of daily living and maintain their quality of life as much as possible.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on access to care and support.

Full details of the evidence and the committee's discussion are in evidence review C: accessing health and social care services.

Other supporting evidence and discussion can be found in evidence review A: information, education and support for people with ME/CFS and their families and carers and appendix 2: involving adults with severe ME/CFS.

1.9 Supporting people with ME/CFS in work, education and training

1.9.1 Offer to liaise on the person's behalf (with their informed consent) with employers, education providers and support services. Give them information about ME/CFS and discuss the person's care and support plan and any adjustments needed.

1.9.2 Advise and discuss with people with ME/CFS that:

- they may be able to access reasonable adjustments or adaptations (in line with the Equality Act 2010) to help them continue or return to work or education
- there may be times when they are unable to continue with work or education
- some people find that going back to work, school or college worsens their symptoms.

1.9.3 Health and social care professionals should follow the Department for Education's guidance on supporting pupils at school with medical conditions or equivalent statutory guidance.

1.9.4 Health and social care professionals should work with training and education services to:

- provide information about ME/CFS and the needs and impairments of children and young people with ME/CFS, including the need for a balance of activities in their life
- discuss the child or young person's care and support plan so that everyone has a common understanding of their priorities, hopes and plans
- discuss a flexible approach to training and education – this could include adjustments to the school day, online learning or education at home and using assistive equipment.

1.9.5 Give parents and carers information about education, health and care (EHC) plans and how to request one from their local authority.

1.9.6 Advise children and young people with ME/CFS and their parents or carers (as appropriate) that:

- training or education should not be the only activity they undertake
- they should aim to find a balance between the time they spend on education or training, home and family life, and social activities.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on supporting people with ME/CFS in work, education and training.

Full details of the evidence and the committee's discussion are in evidence review A: information, education and support for people with ME/CFS and their families and carers and appendix 1: involving children and young people.

1.10 Multidisciplinary care

1.10.1 Provide care for people with ME/CFS using a coordinated multidisciplinary approach. Based on the person's needs, include access to health and social care professionals with expertise in the following as a minimum, with additional expertise depending on symptoms:

- medical assessment and diagnosis
- developing personalised care and support plans

- self-management strategies, including energy management
- symptom management, including prescribing and medicines management
- managing flare-ups and relapses
- activities of daily living, including dental health
- psychological, emotional and social wellbeing, including family and sexual relationships
- diet and nutrition
- mobility, avoiding falls and problems from loss of dexterity, including access to aids and rehabilitation services
- social care and support
- support to engage in work, education, social activities and hobbies.

1.10.2 Care for people whose ME/CFS is managed in primary care should be supported by advice and direct clinical consultation from an ME/CFS specialist team.

1.10.3 Give adults, children and young people with ME/CFS and their family or carers (as appropriate) a named contact in their primary care and/or ME/CFS specialist team to coordinate their care and support plan, help them access services and support them during periods of relapse.

1.10.4 Provide children and young people with ME/CFS and their family or carers (as appropriate) with details of a named professional in the ME/CFS specialist team who they can contact with any concerns about the child or young person's health, education or social life.

Moving into adults' services

1.10.5 For young adults with ME/CFS moving from children's to adults' services, manage transitions in line with the NICE guideline on transition from children's to adults' services for young people using health or social care services.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on multidisciplinary care.

Full details of the evidence and the committee's discussion are in evidence review I: multidisciplinary care and evidence review C: accessing health and social care services.

Other supporting evidence and discussion can be found in evidence review A: information, education and support for people with ME/CFS and their families and carers and appendix 1: involving children and young people.

1.11 Managing ME/CFS

1.11.1 Be aware that ME/CFS symptoms can be managed but there is currently no cure (non-pharmacological or pharmacological) for ME/CFS.

For a short explanation of why the committee made this recommendation and how it might affect practice, see the rationale and impact section on managing ME/CFS.

Full details of the evidence and the committee's discussion are in evidence review F: pharmacological interventions and evidence review G: non- pharmacological management of ME/CFS.

Energy management

Also see the section on care for people with severe or very severe ME/CFS.

1.11.2 Discuss with people with ME/CFS the principles of energy management, the potential benefits and risks and what they should expect. Explain that it:

- is not curative
- is a self-management strategy led by the person themselves with support from a healthcare professional in an ME/CFS specialist team
- includes all types of activity (cognitive, physical, emotional and social) and takes into account overall level of activity

- helps people learn to use the amount of energy they have while reducing their risk of post-exertional malaise or worsening their symptoms by exceeding their limits
- recognises that each person has a different and fluctuating energy limit and they are experts in judging their own limits
- can include help from a healthcare professional to recognise when they are approaching their limit (children and young people in particular may find it harder to judge their limits and can overreach them)
- uses a flexible, tailored approach so that activity is never automatically increased but is maintained or adjusted (upwards after a period of stability or downwards when symptoms are worse)
- is a long-term approach – it can take weeks, months or sometimes even years to reach stabilisation or to increase tolerance or activity.

1.11.3 Help people with ME/CFS develop a plan for energy management as part of their care and support plan. Support them to establish realistic expectations and develop goals that are meaningful to them. Discuss and record the following in the plan along with anything else that is important to the person:

- cognitive activity
- mobility and other physical activity
- ability to undertake activities of daily living
- psychological, emotional and social demands, including family and sexual relationships
- rest and relaxation (both quality and duration)
- sleep quality and duration
- effect of environmental factors, including sensory stimulation.

1.11.4 Work with the person to establish an individual activity pattern within their current energy limits that minimises their symptoms. For example:

- agree a sustainable level of activity as the first step, which may mean reducing activity
- plan periods of rest and activity, and incorporate the need for pre-emptive rest

- alternate and vary between different types of activity and break activities into small chunks.

1.11.5 Agree how often to review the person's energy management plan with them and revise it if needed.

1.11.6 Advise people with ME/CFS how to manage flare-ups and relapses (see the section on managing flare-ups in symptoms and relapse).

1.11.7 Make self-monitoring of activity as easy as possible by taking advantage of any tools the person already uses, such as an activity tracker, phone heart-rate monitor or diary.

1.11.8 Refer people with ME/CFS to a physiotherapist or occupational therapist working in an ME/CFS specialist team if they:

- have difficulties caused by reduced physical activity or mobility (also see the sections on physical functioning and mobility and care for people with severe or very severe ME/CFS) or
- feel ready to progress their physical activity beyond their current activities of daily living (see the section on physical activity and exercise) or
- would like to incorporate a physical activity or exercise programme into managing their ME/CFS (see the section on incorporating physical activity and exercise).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on energy management.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Other supporting evidence and discussion can be found in evidence review A: information, education and support for people with ME/CFS and their families and carers and appendix 2: involving adults with severe ME/CFS.

Incorporating physical activity and exercise

1.11.9 Do not advise people with ME/CFS to undertake exercise that is not part of a

programme overseen by an ME/CFS specialist team, such as telling them to go to the gym or exercise more, because this may worsen their symptoms.

1.11.10 Only consider a personalised physical activity or exercise programme for people with ME/CFS who:

- feel ready to progress their physical activity beyond their current activities of daily living or
- would like to incorporate physical activity or exercise into managing their ME/CFS.

1.11.11 Tell people about the risks and benefits of physical activity and exercise programmes. Explain that some people with ME/CFS have found that they can make their symptoms worse, for some people it makes no difference and others find them helpful.

1.11.12 If a physical activity or exercise programme is offered, it should be overseen by a physiotherapist in an ME/CFS specialist team.

1.11.13 If a person with ME/CFS takes up the offer of a personalised physical activity or exercise programme, agree a programme with them that involves the following and review it regularly:

- establishing their physical activity baseline at a level that does not worsen their symptoms
- initially reducing physical activity to be below their baseline level
- maintaining this successfully for a period of time before attempting to increase it
- making flexible adjustments to their physical activity (up or down as needed) to help them gradually improve their physical abilities while staying within their energy limits
- recognising a flare-up or relapse early and outlining how to manage it.

1.11.14 Do not offer people with ME/CFS:

- any therapy based on physical activity or exercise as a cure for ME/CFS
- generalised physical activity or exercise programmes – this includes programmes developed for healthy people or people with other illnesses

- any programme that does not follow the approach in recommendation 1.11.13 or that uses fixed incremental increases in physical activity or exercise, for example, graded exercise therapy (see box 4)
- physical activity or exercise programmes that are based on deconditioning and exercise avoidance theories as perpetuating ME/CFS.

Box 4 Graded exercise therapy definition

Graded exercise therapy is a term used in varying ways by different services supporting people with ME/CFS.

In this guideline, graded exercise therapy is defined as first establishing an individual's baseline of achievable exercise or physical activity, then making fixed incremental increases in the time spent being physically active. This definition of graded exercise therapy reflects the descriptions given in the evidence that was reviewed, and it is this approach that the guideline says should not be undertaken.

An individualised approach that should be taken for people with ME/CFS who choose to undertake a physical activity or exercise programme is described in recommendations 1.11.10 to 1.11.13.

Flare-ups and relapse

1.11.15 Agree with the person how to adjust their physical activity during a flare-up or relapse. This should include:

- providing access to review and support from a physiotherapist in an ME/CFS specialist team
- stabilising their symptoms by reducing physical activity to within their current energy limits
- only once symptoms stabilise and the person feels able to resume physical activity, establishing a new physical activity baseline.

1.11.16 Advise people with ME/CFS after a flare-up that the time it takes to return to the level of physical activity they had before varies from person to person.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on incorporating physical activity and exercise.

Full details of the evidence and the committee's discussion are in:

- evidence review G: non-pharmacological management of ME/CFS
- evidence review A: information, education and support for people with ME/CFS and their families and carers
- appendix 1: involving children and young people.

1.12 Symptom management for people with ME/CFS

Refer to relevant NICE guidance for managing symptoms that are not covered in this section, taking into account the recommendations in the sections on principles of care for people with ME/CFS, access to care and support and energy management.

Rest and sleep

1.12.1 Advise people with ME/CFS:

- about the role of rest in ME/CFS
- that rest periods are part of all management strategies for ME/CFS
- how to introduce rest periods into their daily routine, including how often and for how long, as appropriate for each person
- that relaxation techniques at the beginning of each rest period could be helpful.

1.12.2 Give people with ME/CFS personalised sleep management advice that includes:

- explaining the role and effect of sleep disturbance in ME/CFS
- identifying the common changes in sleep patterns seen in ME/CFS (such as broken or shallow sleep, altered sleep pattern or hypersomnia)

- developing good sleep habits
- taking into account the need for rest in the day, and balancing this against how the person is sleeping at night
- introducing changes to sleep patterns gradually.

1.12.3 If sleep management strategies do not improve the person's sleep and rest, think about the possibility of an underlying sleep disorder or dysfunction and whether to refer to an appropriate specialist.

1.12.4 Review the use of rest periods and sleep management strategies regularly as part of the person's care and support plan.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rest and sleep.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Physical functioning and mobility

1.12.5 Include strategies to maintain and prevent deterioration of physical functioning and mobility in the care and support plans of people with ME/CFS. These strategies may need to be carried out in small amounts and spread out throughout the day. Think about including the following:

- joint mobility
- muscle flexibility
- balance
- postural and positional support
- muscle function
- bone health
- cardiovascular health.

1.12.6 Assess at every contact people with severe or very severe ME/CFS or those with prolonged periods of immobility for:

- areas at risk of pressure ulcers (see the NICE guideline on pressure ulcers)
- deep vein thrombosis (see the NICE guideline on venous thromboembolic diseases)
- risk of contractures.

1.12.7 Give people with ME/CFS and their family or carers (as appropriate) information, advice and support on how to recognise and prevent possible complications of long-term immobility.

1.12.8 Give families and carers information, advice and support on how to help people with ME/CFS follow their care and support plan in relation to physical functioning and mobility. This may include:

- bed mobility
- moving from lying to sitting to standing
- transferring from bed to chair
- using mobility aids
- walking
- joint mobility
- muscle stretching
- muscle strength
- balance
- going up and down stairs.

For training to provide care and support, see NICE's guideline on supporting adult carers.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on physical functioning and mobility.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Orthostatic intolerance

1.12.9 Be aware that people with ME/CFS may experience orthostatic intolerance, including postural orthostatic tachycardia syndrome (POTS).

1.12.10 Medicine for orthostatic intolerance in people with ME/CFS should only be prescribed or overseen by a healthcare professional with expertise in orthostatic intolerance.

1.12.11 Refer people with orthostatic intolerance to secondary care if their symptoms are severe or worsening, or there are concerns that another condition may be the cause.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on orthostatic intolerance.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Pain

1.12.12 Be aware that pain is a symptom commonly associated with ME/CFS.

1.12.13 Investigate and manage the person's pain according to best practice, referring to specialist pain services if appropriate.

1.12.14 Refer to the following for advice on treating neuropathic pain or headaches:

- NICE's guideline on neuropathic pain in adults

- NICE's guideline on headaches in over 12s.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on pain.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Medicines

1.12.15 Do not offer any medicines or supplements to cure ME/CFS.

Medicines for symptom management

1.12.16 Offer people with ME/CFS a medication review in line with the NICE guidelines on medicines adherence and medicines optimisation.

1.12.17 Take into account when prescribing that people with ME/CFS may be more intolerant of drug treatment. Consider:

- starting medicines at a lower dose than in usual clinical practice
- gradually increasing the dose if the medicine is tolerated.

1.12.18 Drug treatment for the symptoms associated with ME/CFS for children and young people should only be started under guidance or supervision from a medical professional trained and experienced in paediatric prescribing.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on medicines.

Full details of the evidence and the committee's discussion are in evidence review F: pharmacological interventions.

Dietary management and strategies

Also see the section on care for people with severe or very severe ME/CFS.

1.12.19 Emphasise to people with ME/CFS the importance of adequate fluid intake and a well-balanced diet according to the NHS eat well guide.

1.12.20 Work with the person and their family or carers (as appropriate) to find ways of minimising complications caused by gastrointestinal symptoms (such as nausea), changes to appetite, swallowing difficulties, sore throat or difficulties with buying, preparing and eating food.

1.12.21 Encourage people with ME/CFS who have nausea to keep up adequate fluid intake and advise them to try to eat regularly, taking small amounts often. Explain that not eating or drinking may increase their nausea.

1.12.22 Refer people with ME/CFS for a dietetic assessment by a dietitian with a special interest in ME/CFS if they are:

- losing weight and at risk of malnutrition
- gaining weight
- following a restrictive diet.

1.12.23 Be aware that people with ME/CFS may be at risk of vitamin D deficiency, especially those who are housebound or bedbound. For advice on vitamin D supplementation, see the NICE guideline on vitamin D.

1.12.24 Explain to people with ME/CFS that there is not enough evidence to support routinely taking vitamin and mineral supplements as a cure for ME/CFS or for managing symptoms. If they choose to take a vitamin or supplement, explain the potential side effects of taking doses of vitamins and minerals above the recommended daily amount.

1.12.25 Refer children and young people with ME/CFS who are losing weight or have faltering growth or dietary restrictions to a paediatric dietitian with a special interest in ME/CFS.

1.12.26 For advice on food allergies in children, see the NICE guideline on food allergy in under 19s.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on dietary management and strategies.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Lightning Process

1.12.27 Do not offer the Lightning Process, or therapies based on it, to people with ME/CFS.

For a short explanation of why the committee made this recommendation and how it might affect practice, see the rationale and impact section on the Lightning Process.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Cognitive behavioural therapy

Also see the section on care for people with severe or very severe ME/CFS.

1.12.28 Discuss cognitive behavioural therapy (CBT) with adults, children and young people with ME/CFS (and their parents or carers, as appropriate). Explain:

- its principles, including that it may help them manage their symptoms but it is not curative (see box 5) and
- any potential benefits and risks.

Box 5 Cognitive behavioural therapy

The committee wanted to highlight that cognitive behavioural therapy (CBT) has sometimes been assumed to be a cure for ME/CFS. However, it should only be offered to support people who live with ME/CFS to manage their symptoms, improve their functioning and reduce the distress associated with having a chronic illness.

1.12.29 Only offer CBT to adults, children and young people with ME/CFS if, after discussing it (see recommendation 1.12.28), they would like to use it to support them in managing their symptoms.

1.12.30 For children and young people with ME/CFS who would like to use CBT:

- involve parents or carers (as appropriate) in the therapy wherever possible
- adapt the therapy to the child or young person's cognitive and emotional stage of development.

  Also see the section on principles of care for people with ME/CFS (including the additional principles of care for children and young people with ME/CFS).

1.12.31 CBT should only be delivered by a healthcare professional with appropriate training and experience in CBT for ME/CFS, and under the clinical supervision of someone with expertise in CBT for ME/CFS.

1.12.32 Explain that CBT for people with ME/CFS:

- aims to improve their quality of life, including functioning, and reduce the distress associated with having a chronic illness
- does not assume people have 'abnormal' illness beliefs and behaviours as an underlying cause of their ME/CFS, but recognises that thoughts, feelings, behaviours and physiology interact with each other.

1.12.33 Explain what CBT involves so people know what to expect. Tell them that it:

- takes a non-judgemental, supportive approach to the person's experience of their symptoms and the challenges these present
- is a collaborative, structured, time-limited intervention that focuses on the difficulties people are having at that time
- involves working closely with their therapist to establish strategies to work towards goals and priorities that they have chosen themselves
- takes into account how symptoms are individual to each person, can fluctuate in severity and may change over time.

1.12.34 CBT for people with ME/CFS should include the following components:

- developing a shared understanding with the person about the main difficulties and challenges they face
- exploring the personal meaning of their symptoms and illness, and how this might relate to how they manage their symptoms
- developing a self-management plan
- working together to adapt and refine self-management strategies to improve the person's functioning and quality of life, for example their sleep, activity and rest
- reviewing their plan regularly to see if their self-management strategies need to be adapted, for example if their symptoms or functioning change
- developing a therapy blueprint collaboratively with their therapist at the end of therapy.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on cognitive behavioural therapy.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS and appendix 2: involving adults with severe ME/CFS.

1.13 Managing coexisting conditions

1.13.1 Be aware that other conditions may coexist with ME/CFS and should be investigated and managed according to best practice.

1.13.2 When managing coexisting conditions in people with ME/CFS, take into account the recommendations in the sections on principles of care for people with ME/CFS, access to care and support and energy management.

1.13.3 For recommendations on multimorbidity, thyroid disease and irritable bowel syndrome in adults, refer to the:

- NICE guideline on multimorbidity

- NICE guideline on thyroid disease
- NICE guideline on irritable bowel syndrome in adults.

1.13.4 For recommendations on identifying and treating associated or comorbid anxiety, depression or mood disorders, see the:

- NICE guideline on depression in adults
- NICE guideline on depression in adults with a chronic physical health problem
- NICE guideline on depression in children and young people
- NICE guideline on generalised anxiety disorder and panic disorder in adults
- NICE guideline on common mental health problems.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on managing coexisting conditions.

Full details of the evidence and the committee's discussion are in evidence review D: identifying and diagnosing ME/CFS.

1.14 Managing flare-ups in symptoms and relapse

1.14.1 Explain that flare-ups and relapses can happen in ME/CFS even if the person's symptoms are well managed.

1.14.2 Tell people with ME/CFS that:

- they are likely to be having a flare-up if they experience a worsening of their symptoms beyond their normal day-to-day variation, which lasts a few days
- a relapse is when there is a sustained and marked exacerbation of ME/CFS symptoms lasting longer than a flare-up and needing substantial and sustained adjustment of energy management.

1.14.3 Include guidance on managing flare-ups and relapses in the person's care and support plan.

1.14.4 Evaluate and investigate any new symptoms or a change in symptoms and do not assume they are caused by the person's ME/CFS.

1.14.5 Discuss and agree self-management strategies with the person with ME/CFS to help them respond promptly if they have a flare-up or relapse, and record these in their care and support plan. This should include:

- For a flare-up:
  - identifying possible triggers, such as acute illness or overexertion (in some cases, there may be no clear trigger)
  - temporarily reducing their activity levels
  - monitoring symptoms, recognising that although flare-ups are transient, some will develop into a relapse
  - not returning to usual activity levels until the flare-up has resolved.
- For a relapse:
  - reducing, or even stopping, some activities
  - increasing the frequency or duration of rest periods
  - reassessing energy limits to stabilise symptoms.

1.14.6 If a flare-up or relapse cannot be managed using the person's self-management strategies outlined in their care and support plan or they are worried about new symptoms or a change in symptoms, advise the person to contact their named contact in primary care or the ME/CFS specialist team.

1.14.7 When a person with ME/CFS has a relapse, review their care and support plan with them (if needed), and discuss and agree a course of action, taking into account:

- possible causes of the relapse, if known
- the nature of the symptoms
- the severity and duration of the relapse (bearing in mind this can be years).

After a flare-up or relapse

1.14.8 Once a flare-up or relapse has resolved or stabilised, discuss with the person:

- whether their care and support plan needs to be reviewed and adjusted to reflect their current symptoms and energy limit if this is different from before the flare-up or relapse (for people participating in physical activity or exercise programmes, see recommendations 1.11.15 and 1.11.16)
- their experience of the flare-up or relapse to determine whether strategies can be put in place to manage potential triggers in the future.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on managing flare-ups in symptoms and relapse.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

1.15 Review in primary care

1.15.1 Offer adults with ME/CFS a review of their care and support plan in primary care at least once a year.

1.15.2 Offer children and young people with ME/CFS a review of their care and support plan at least every 6 months.

1.15.3 Arrange more frequent primary care reviews for children, young people and adults with ME/CFS as needed, depending on the severity and complexity of their symptoms, and the effectiveness of any symptom management.

1.15.4 When carrying out a review in primary care, ensure you have access to the person's care and support plan and any clinical communications from the ME/CFS specialist team (including their discharge letter, if relevant).

1.15.5 As part of the review, discuss with the person with ME/CFS (and their family or carers, as appropriate) and record as a minimum:

- their condition, including any changes in their illness and the impact of this
- symptoms, including whether they have experienced new symptoms
- self-management – ask about their energy management plan and (if relevant) their physical activity or exercise programme
- who is helping them and how they provide support
- psychological, emotional and social wellbeing
- any future plans – ask if the person is considering any changes or if they have any challenges ahead.

1.15.6 Refer the person with ME/CFS to their named contact in the ME/CFS specialist team if there are any new or deteriorating aspects of their condition.

1.15.7 Consider seeking advice from an appropriate specialist if there is uncertainty about interpreting signs and symptoms and whether a referral is needed.

1.15.8 Evaluate and investigate whether new symptoms, or a change in symptoms, are due to the person's ME/CFS or whether they are due to another condition.

Additional principles for children and young people

1.15.9 Ensure reviews are carried out or overseen by a paediatrician with expertise in ME/CFS. Involve other appropriate specialists as needed.

1.15.10 When deciding how often reviews or reassessment might be needed for children and young people with ME/CFS, take into account:

- their developmental stage
- transitions, such as changing schools or exams
- the severity and complexity of symptoms
- the effectiveness of any symptom management.

Also see recommendation 1.1.6 on ensuring the child's voice is heard and on involving their parents or carers.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on review in primary care.

Full details of the evidence and the committee's discussion are in evidence review J: monitoring and reviewing people with ME/CFS.

1.16 Training for health and social care professionals

1.16.1 Health and social care providers should ensure that all staff delivering care to people with ME/CFS receive training relevant to their role so they can provide care in line with this guideline. Training should include:

- helping them to understand what ME/CFS is and its diagnosis and management
- the experiences of people with ME/CFS.

For a short explanation of why the committee made this recommendation and how it might affect practice, see the rationale and impact section on training for health and social care professionals.

Full details of the evidence and the committee's discussion are in evidence review B: information, education and support for health and social care professionals.

Other supporting evidence and discussion can be found in evidence review A: information, education and support for people with ME/CFS and their families and carers and appendix 2: involving adults with severe ME/CFS.

1.17 Care for people with severe or very severe ME/CFS

This section supplements the rest of the guideline with additional considerations for people with severe or very severe ME/CFS.

Awareness of severe and very severe ME/CFS and its impact

Also see the main section on principles of care for people with ME/CFS.

1.17.1 Be aware that people with severe or very severe ME/CFS may experience the

following symptoms that significantly affect their lives, including their mobility, emotional wellbeing and ability to interact with others and care for themselves:

- severe and constant pain, which can have muscular, arthralgic or neuropathic features
- hypersensitivity to light, sound, touch, movement, temperature extremes and smells
- extreme weakness, with severely reduced movement
- reduced ability or inability to speak or swallow
- cognitive difficulties that limit the person's ability to communicate and take in written or verbal communication
- sleep disturbance such as unrefreshing sleep, hypersomnia and altered sleep pattern
- gastrointestinal difficulties such as nausea, incontinence, constipation and bloating
- neurological symptoms such as double vision and other visual disorders, dizziness
- orthostatic intolerance and autonomic dysfunction, such as postural orthostatic tachycardia syndrome (POTS) and postural hypotension.

1.17.2 Recognise that symptoms of severe or very severe ME/CFS may mean that people:

- need a low-stimulus environment, for example a dark quiet room with interaction at a level of their choice (this may be little or no social interaction)
- are housebound or bedbound and may need support with all activities of daily living, including aids and adaptations to assist mobility and independence in activities of daily living (for example, a wheelchair)
- need careful physical contact when supported with activities of daily living, taking into account possible sensitivity to touch
- cannot communicate without support and may need to choose someone to be their advocate and communicate for them
- are unable to eat and digest food easily and may need support with hydration and nutrition (see the recommendations on dietary management and strategies)

- have problems accessing information, for example because of difficulty with screens, sound and light sensitivity, headaches affecting their ability to read, or brain fog affecting their concentration.

1.17.3 Personal care and support for people with severe or very severe ME/CFS should be carried out by health and social care practitioners who are:

- known to the person and their family or carers wherever possible
- aware of the person's needs.

1.17.4 Risk assess each interaction with a person with severe or very severe ME/CFS in advance to ensure its benefits will outweigh the risks (for example, worsening their symptoms) to the person. For people with very severe ME/CFS, think about discussing this with the person's family or carers on their behalf (if appropriate), while keeping the focus of the engagement on the person with ME/CFS.

Assessment and care and support planning by an ME/CFS specialist team

Also see the main section on assessment and care and support planning by an ME/CFS specialist team.

1.17.5 Offer home visits to people with severe or very severe ME/CFS to carry out their holistic assessment and develop their care and support plan.

Access to care and support

Also see the main section on access to care and support.

1.17.6 Service providers should be proactive and flexible in delivering services to people with severe or very severe ME/CFS, who may have particular difficulty accessing services and articulating their needs. This could include home visits, online or phone consultations, supplying written communication, and supporting their applications for aids and appliances.

Hospital care

1.17.7 When planning hospital care for people with severe or very severe ME/CFS:

- discuss with the person (and their family or carers, as appropriate) what to expect when they come into hospital
- aim to minimise discomfort and post-exertional malaise during transfer to hospital, for example by planning the route in advance, avoiding noisy areas and admitting them straight to the ward on arrival
- discuss the person's care and support plan with them, including information on comorbidities, intolerances and sensitivities, to plan any reasonable adjustments that are needed
- aim to provide a single room if possible
- keep stimuli to a minimum, for example by:
  - seeing them one-to-one
  - using calm movements and gestures
  - not duplicating assessments
  - being cautious about the pressure of touch
  - keeping lights dimmed
  - reducing sound
  - keeping a stable temperature
  - minimising smells.

Managing ME/CFS

Also see the main section on managing ME/CFS.

Energy management

Also see the main section on energy management.

1.17.8 Refer people with severe or very severe ME/CFS to a physiotherapist or occupational therapist working in an ME/CFS specialist team for support on developing energy management plans.

1.17.9 When agreeing energy management plans with people with severe or very severe ME/CFS (and their family or carers, as appropriate), take into account the need to make any changes in activity smaller and any increases (if possible) much slower.

Symptom management

Also see the main section on symptom management for people with ME/CFS.

Dietary management and strategies

1.17.10 Refer people with severe or very severe ME/CFS for a dietetic assessment by a dietitian with a special interest in ME/CFS.

1.17.11 Monitor people with severe or very severe ME/CFS who are at risk of malnutrition or unintentional weight loss because of:

- restrictive diets
- poor appetite, for example linked with altered taste, smell and texture
- food intolerances
- nausea
- difficulty swallowing and chewing.

Follow the recommendations on screening for malnutrition and indications for nutrition support, in the NICE guideline on nutrition support for adults.

1.17.12 Give advice to support people with severe or very severe ME/CFS, which could include:

- eating little and often
- having nourishing drinks and snacks, including food fortification
- finding easier ways of eating to conserve energy, such as food with softer textures
- using modified eating aids, particularly if someone has difficulty chewing or swallowing
- oral nutrition support and enteral feeding.

Cognitive behavioural therapy

1.17.13 Healthcare professionals delivering CBT to people with severe or very severe ME/CFS should adjust the process and pace of CBT to meet the person's needs. This might include shorter, less frequent sessions and longer-term goals.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on care for people with severe or very severe ME/CFS.

Full details of the evidence and the committee's discussion are in:

- evidence review A: information, education and support for people with ME/CFS and their families and carers
- appendix 1: involving children and young people
- evidence review B: information, education and support for health and social care professionals
- evidence review C: accessing health and social care services
- evidence review G: non-pharmacological management of ME/CFS
- evidence review I: multidisciplinary care
- evidence review J: monitoring and reviewing people with ME/CFS.

Other supporting evidence and discussion can be found in evidence review A: information, education and support for people with ME/CFS and their families and carers and appendix 2: involving adults with severe ME/CFS.

Terms used in this guideline

For other definitions, see the NICE glossary and the Think Local, Act Personal Care and Support Jargon Buster.

Activity

Any effort that uses energy, which includes cognitive, emotional and social activity as well as

physical activity. Different activities combine and interact to cause a cumulative impact for the person.

Advocate

In this guideline, the role of an advocate is to support a vulnerable or disadvantaged person with ME/CFS and ensure that their rights are being upheld in a health and social care context. They are chosen by the person with ME/CFS and could be a family member, carer, friend or an independent advocate. They make sure that the person is heard.

Care and support plan

The personalised collaborative care and support plan is developed by the ME/CFS specialist team based on a holistic assessment. It is the basis for other assessments and plans in areas such as social care, energy management, physical activity, physical functioning and mobility, cognitive behavioural therapy and dietary management.

Carers

In this guideline, a carer refers to someone who provides unpaid care and support to a family member, partner or friend with ME/CFS. This is distinct from care workers who are employed to provide support.

Children and young people

In this guideline, children and young people are aged under 18 (adults are 18 and above).

Energy limit

The amount of energy a person has to do all activities without triggering an increase or worsening of their symptoms.

Energy management

A self-management strategy that involves a person with ME/CFS managing their activities to stay within their energy limit, with support from a healthcare professional.

Exercise

Exercise is planned, structured, repetitive and purposeful activity focused on improvement or maintenance of 1 or more components of physical fitness. Exercise is a subcategory of physical activity.

Fatigue

Fatigue in ME/CFS typically has the following components:

- feeling flu-like, especially in the early days of the illness
- restlessness or feeling 'wired but tired'
- low energy or a lack of physical energy to start or finish activities of daily living and the sensation of being 'physically drained'
- cognitive fatigue that worsens existing difficulties
- rapid loss of muscle strength or stamina after starting an activity, causing for example, sudden weakness, clumsiness, lack of coordination, and being unable to repeat physical effort consistently.

Flare-up

A worsening of symptoms, more than would be accounted for by normal day-to-day variation, that affects the person's ability to perform their usual activities. Flare-ups may occur spontaneously or be triggered by another illness, overexertion or other triggers. Flare-ups usually occur as part of post-exertional malaise but it is possible for other symptoms, such as pain, to flare-up without post-exertional malaise. The worsening of symptoms is transient and flare-ups typically resolve after a few days, either spontaneously or in response to temporary changes in energy management or a change in treatment. A relapse lasts longer than a flare-up.

Graded exercise therapy

In this guideline, graded exercise therapy is defined as establishing a baseline of achievable exercise or physical activity and then making fixed incremental increases in the time spent being physically active. It is a therapy based on the deconditioning and exercise avoidance theories of ME/CFS. These theories assume that ME/CFS is perpetuated by reversible physiological changes of deconditioning and avoidance of activity. These changes result in the deconditioning being maintained and an increased perception of effort, leading to further inactivity. This definition of

graded exercise therapy reflects the descriptions of it included in evidence review G: non-pharmacological management of ME/CFS.

ME/CFS specialist team

These teams consist of a range of healthcare professionals with expertise in assessing, diagnosing, treating and managing ME/CFS. They commonly have medically trained clinicians from a variety of specialisms (including rheumatology, rehabilitation medicine, endocrinology, infectious diseases, neurology, immunology, general practice and paediatrics) as well as access to other healthcare professionals specialising in ME/CFS. These may include physiotherapists, exercise physiologists, occupational therapists, dietitians, and clinical or counselling psychologists. Children and young people are likely to be cared for under local or regional paediatric teams that have experience working with children and young people with ME/CFS in collaboration with ME/CFS specialist centres.

Orthostatic intolerance

A clinical condition in which symptoms such as light-headedness, near-fainting or fainting, impaired concentration, headaches, dimming or blurring of vision, forceful beating of the heart, palpitations, tremulousness and chest pain occur or worsen on standing up and are improved (although not necessarily resolved) by sitting or lying down. Orthostatic intolerance may include postural orthostatic tachycardia syndrome (POTS), which is a significant rise in pulse rate when moving from lying to standing, and postural hypotension, which is a significant fall in blood pressure when moving from lying to standing. People with severe orthostatic intolerance may find they are unable to sit up for any length of time.

Physical activity

Any bodily movement produced by skeletal muscles that results in energy expenditure. It should not be confused with exercise. Physical activity in daily life can be categorised into occupational, sports, conditioning, household or other activities, and can be done during leisure time, to get around or as part of a person's work. See World Health Organization advice on physical activity. Physical activity has a health benefit for most people and many conditions, but in people with ME/CFS, physical activity may make their symptoms worsen.

Physical functioning and mobility

The process of incorporating into daily activities a level of movement that helps to maintain joint and muscle flexibility without worsening symptoms of ME/CFS. This aims to support people to have

as much independence as possible in their activities, ranging from personal hygiene to activities of daily living, working and social interaction. Such movement is undertaken within the person's energy limits and avoids pushing through their boundaries of tolerance.

Post-exertional malaise

The worsening of symptoms that can follow minimal cognitive, physical, emotional or social activity, or activity that could previously be tolerated. Symptoms can typically worsen 12 to 48 hours after activity and last for days or even weeks, sometimes leading to a relapse. Post-exertional malaise may also be referred to as post-exertional symptom exacerbation.

Relapse

A sustained and marked exacerbation of symptoms lasting longer than a flare-up and needing a substantial and sustained adjustment to the person's energy management. It may not be clear in the early stages of a symptom exacerbation whether it is a flare-up or a relapse. Relapses can lead to a long-term reduction in the person's energy limits.

Special interest in ME/CFS

A special interest in ME/CFS refers to a healthcare professional who is not working in an ME/CFS specialist team service but has knowledge and experience in this area.

Therapy blueprint

This summarises the therapy and provides a basis for future independent self-management. The blueprint may include the therapy formulation, strategies that have been helpful, 'warning signs' and triggers of flare-ups and how to manage them, and goals for the future. It is important that the therapy blueprint is led by the person themselves and is in their own words, supported by guidance from the therapist.

Unrefreshing sleep

Unrefreshing sleep means sleep that is non-restorative. Even after a full night's sleep, people do not feel refreshed. People with ME/CFS often report waking up exhausted and feeling as if they have not slept at all, no matter how long they were asleep.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Diagnostic tests

What diagnostic tests are clinically and cost effective in people with suspected myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS)?

For a short explanation of why the committee made this recommendation, see the rationale section on suspecting ME/CFS.

Full details of the evidence and the committee's discussion are in evidence review D: identifying and diagnosing ME/CFS.

2 A core outcome set

What core set of relevant health outcome measures should be used for trials of treatments for ME/CFS and managing symptoms of ME/CFS?

For a short explanation of why the committee made this recommendation, see the rationale section on managing ME/CFS.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

3 Diagnostic criteria

In people with suspected ME/CFS, how effective is the NICE 2021 consensus-based diagnostic criteria in identifying people with ME/CFS?

For a short explanation of why the committee made this recommendation, see the rationale section on suspecting ME/CFS.

Full details of the evidence and the committee's discussion are in evidence review D: identifying and diagnosing ME/CFS.

Other recommendations for research

Self-monitoring management strategies

What is the clinical and cost effectiveness of self-monitoring strategies and techniques in guiding energy management?

For a short explanation of why the committee made this recommendation, see the rationale section on energy management.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Sleep management strategies

What is the clinical and cost effectiveness of sleep management strategies in managing ME/CFS?

For a short explanation of why the committee made this recommendation, see the rationale section on rest and sleep.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Dietary strategies

What is the clinical and cost effectiveness of dietary strategies in managing ME/CFS?

For a short explanation of why the committee made this recommendation, see the rationale section on dietary management and strategies.

Full details of the evidence and the committee's discussion are in evidence review G: non-pharmacological management of ME/CFS.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice.

Principles of care for people with ME/CFS

Recommendations 1.1.1 to 1.1.6

Why the committee made the recommendations

Common themes across the qualitative evidence showed a lack of belief about myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS) as a real condition by health and social care professionals, and a lack of understanding about what it is and the impact it has. The committee used this evidence to make recommendations to raise awareness about ME/CFS. One strong theme showed how experiencing a lack of understanding and prejudice can lead to people losing trust in health and social care services. The committee agreed that health and social care professionals need to take into account the impact of not being believed when building relationships with people with ME/CFS and their families. The committee considered this particularly relevant to children and young people and made separate recommendations highlighting communication with children.

The evidence showed this loss of trust can be compounded when people with ME/CFS have negative experiences of healthcare services if they decline treatments that have been offered to them. This was a strong theme in the evidence for children and young people. The committee agreed that declining a specific treatment should not affect other areas of the person's care.

The qualitative evidence also showed that one of the barriers to good ME/CFS management was a late diagnosis and a lack of monitoring, and this reflected the committee's experience.

How the recommendations might affect practice

These overarching principles will improve consistency of best practice and do not need any additional resources to deliver.

Return to recommendations

Suspecting ME/CFS

Recommendations 1.2.1 to 1.2.7

Why the committee made the recommendations

The committee took into account both the lack of evidence on diagnostic tests and the evidence that people value realistic advice about ME/CFS (particularly around diagnosis) when making the recommendation to explain how the condition is recognised.

Criteria

The committee acknowledged there is ongoing discussion in the ME/CFS community about which diagnostic criteria should be used to identify and diagnose ME/CFS. The committee made a recommendation for key symptoms based on the evidence review of the current diagnostic criteria, but no 1 set of criteria was agreed to be better overall. The factors influencing these discussions are the broadness of the inclusion criteria, the definition of some of the symptoms, and the usability of the criteria as a clinical tool. There are concerns that many of the existing criteria do not accurately identify people with or without ME/CFS. Based on both the evidence and their experience, the committee agreed that the Institute of Medicine's 2015 criteria had the best balance of inclusion and exclusion of all the reviewed criteria, but it needed to be adapted for optimal use. In particular, the committee felt that the 6-month delay should be reduced so that management could start earlier, and that fatigue and post-exertional malaise should be defined clearly to make it easier to interpret the revised criteria.

Based on their experience, the committee decided that a diagnosis of ME/CFS should be suspected if people have all 4 key symptoms (debilitating fatigue, post-exertional malaise, unrefreshing sleep or sleep disturbance [or both], and cognitive difficulties) for a minimum of 6 weeks in adults and 4 weeks in children and young people. The committee agreed it would be unusual for an acute illness, including a viral illness, to persist longer than this in someone who has all 4 key symptoms. They emphasised it is the combination and interaction of the symptoms that is critical in distinguishing ME/CFS from other conditions and illness.

Currently, because there are no validated diagnostic criteria for ME/CFS, this leads to confusion about which criteria to use. The committee agreed to make a recommendation for research on diagnostic criteria to inform future guidance.

In addition to the 4 key symptoms, the committee noted that many of the criteria used to define ME/CFS also include other symptoms that are commonly experienced by people with ME/CFS.

They agreed that although these symptoms are not crucial to a diagnosis, they are important for understanding ME/CFS and helping to manage symptoms, so they made a recommendation to raise awareness of them.

Diagnostic tests

No evidence was identified for any tests or specific signs and symptoms as predictors of a later diagnosis of ME/CFS. Accurate diagnostic tests that correctly identify ME/CFS will support healthcare professionals to identify people who have ME/CFS and rule out those who do not. The committee made a recommendation for research on diagnostic tests to help identify effective diagnostic tests for ME/CFS that will facilitate early diagnosis and potentially lead to better outcomes for people with ME/CFS. They hoped this research would inform future guidance.

In outlining key areas for assessment, the committee agreed that although they could not give a list of standard tests, it was important to carry out investigations to exclude other potential diagnoses. They listed some examples of tests that could be done to exclude reversible conditions with similar symptoms to ME/CFS and that are often missed.

The committee discussed the non-specific nature and common presentation of some ME/CFS symptoms (for example, cognitive difficulties such as brain fog), which make it difficult to diagnose and distinguish from other conditions. This has led to misdiagnosis, missed diagnosis, and delays in the diagnosis of ME/CFS and of other conditions. Because of this, the committee agreed it is important that when a healthcare professional suspects ME/CFS, they should also consider alternative explanatory diagnoses or coexisting conditions. They should investigate these and refer to an appropriate specialist if they are unsure. The committee also agreed that diagnosis can be reviewed if symptoms change or new symptoms emerge.

The evidence and the committee's experience suggested that managing symptoms early may prevent them getting worse and the person's health deteriorating. To reflect this, the committee recommended advice on symptom management for people as soon as ME/CFS is suspected.

The committee agreed that to avoid any disruption to education, once ME/CFS is suspected in a child or young person, their place of education should be contacted to advise about flexible adjustments or adaptations.

How the recommendations might affect practice

There is variation in practice and no single set of criteria is used clinically, with a 'mix and match' approach used alongside clinical experience. These recommendations will standardise practice and

it is not believed they will have any impact on resource use or training.

There will be no change to the current practice of diagnosing ME/CFS based on clinical assessment and history and performing tests for differential diagnoses as appropriate.

The recommendations aim to raise awareness of symptoms and associated conditions that should raise suspicion of ME/CFS, particularly among healthcare professionals with limited knowledge about ME/CFS. This could increase the number of people with suspected ME/CFS who are then referred to an ME/CFS specialist team, but it will help to ensure they get appropriate care and better outcomes.

The recommendation that children and young people with suspected ME/CFS should be referred to a paediatrician after 4 weeks is earlier than in current practice. However, referring earlier for further assessment will help children and young people to get appropriate care sooner by identifying and excluding other conditions as well as ME/CFS, improving their outcomes.

Return to recommendations

Advice for people with suspected ME/CFS

Recommendations 1.3.1 and 1.3.2

Why the committee made the recommendations

There was limited clinical evidence on management strategies for people with suspected ME/CFS. The qualitative evidence and the committee's experience suggested that managing symptoms early may prevent them from getting worse and the person's health deteriorating. To reflect this, the committee made a recommendation to give people advice on symptom management drawn from their own knowledge and experience.

The qualitative evidence suggested this can be an anxious time for people with suspected ME/CFS and the committee agreed it was important for people to know who to contact if their symptoms change.

How the recommendations might affect practice

Providing the advice in these recommendations would not impose a significant cost on the NHS. If this advice leads to fewer people with deteriorating symptoms, the recommendations would be highly cost effective.

Return to recommendations

Diagnosis

Recommendations 1.4.1 to 1.4.4

Why the committee made the recommendations

The committee agreed that although a 6-month delay before diagnosis is built into the Institute of Medicine criteria, the criteria could be safely amended by reducing this period to 3 months. The committee saw removing this delay as useful because it might enable earlier management and could potentially improve longer-term outcomes.

Reflecting the common theme across the evidence about a lack of knowledge of ME/CFS and evidence that non-specialists in ME/CFS are not confident about diagnosing and managing ME/CFS, the committee recommended referring people with ME/CFS to an ME/CFS specialist team at 3 months to confirm their diagnosis and develop a care and support plan.

How the recommendations might affect practice

The duration of symptoms before diagnosis can take place has been reduced but the criteria are now stricter, requiring that 4 different sets of symptoms are all present in order to suspect ME/CFS. The impact therefore will not necessarily be an increase in referrals but for people to receive their diagnosis earlier, which will bring forward their assessment and care plan. Earlier access to appropriate advice and care could prevent disease progression and therefore might lead to some resource savings in the longer term.

Return to recommendations

Assessment and care and support planning by an ME/CFS specialist team

Recommendations 1.5.1 to 1.5.4

Why the committee made the recommendations

The committee agreed that the key to managing ME/CFS symptoms successfully is having a collaborative personalised care and support plan. This should be developed based on a holistic

assessment as soon as the person's diagnosis is confirmed. The committee agreed that a medical assessment should be part of this assessment, typically requiring access to a medically trained clinician. A copy of the care and support plan can be shared with primary care and a copy held by the person themselves, and it can be referred to in situations such as planning an admission to hospital. In the committee's experience, this approach to assessment and planning is common in ME/CFS specialist teams.

The committee outlined key areas to assess what support might be needed, based on their experience. The committee noted that the key areas to assess and the support needed will depend on the person's severity of ME/CFS, the impact of their symptoms and their needs. Once the care and support plan is agreed, it then provides a basis for the more detailed assessments and plans outlined in specific interventions in the guideline, such as social care needs assessments, energy management, physical functioning and mobility, cognitive behavioural therapy (CBT) and dietary management.

How the recommendations might affect practice

Carrying out a holistic assessment and developing a care and support plan is already current practice in ME/CFS specialist services, although there may be more referrals to the specialist service resulting from these recommendations. However, having a care and support plan will facilitate people's care and may lead to better outcomes. If assessment is carried out early and a care plan is implemented, it could reduce resource use in the longer term by preventing progression of disease.

Return to recommendations

Information and support

Recommendations 1.6.1 to 1.6.11

Why the committee made the recommendations

Qualitative evidence showed that people with ME/CFS valued information from health and social care practitioners in formats that took into account the way symptoms such as 'brain fog' affected their capacity to take in and remember information. The committee highlighted formats that were reported as useful.

The evidence showed people with ME/CFS and their families and carers valued general information about ME/CFS that they could use themselves and share with others (families, friends, employers

and practitioners), particularly around the time of diagnosis and the early stages of ME/CFS. This enabled them to develop accurate expectations about the future, relieve distress caused by the general lack of information and educate others. The evidence suggested people with ME/CFS wanted realistic information about what ME/CFS is and how it might affect them in the future, and this formed the basis of the recommendations outlining the key characteristics of ME/CFS.

The recommendation noting that the long-term outlook can be better in children and young people was based on the committee's experience.

The evidence supported the committee's view that information about ME/CFS and advice about other support is not easily available from health and social care services, and they agreed that people would benefit from information from local and national support groups.

Evidence suggested that people with ME/CFS needed practical support, both for themselves and their carers. The committee considered that some people may have reservations about engaging with social care, after experiencing disbelief about their illness and the impact it has on their day-to-day functioning. For this reason, the committee emphasised the need for sensitivity when talking to people and their families about social care support.

The committee made recommendations signposting to different assessments and support that could be helpful. In their experience, health and social care professionals did not always know what support is available to families and carers of people with ME/CFS, so the committee also referred to the NICE guideline on supporting adult carers.

How the recommendations might affect practice

The recommendations are in line with the general principles for providing information already established in the existing NICE guideline on patient experience in the NHS and so were not considered likely to have any additional impact on practice.

Return to recommendations

Safeguarding

Recommendations 1.7.1 to 1.7.6

Why the committee made the recommendations

The committee recognised that safeguarding is a particular issue in ME/CFS in a way that is

different from other chronic illnesses and disabilities because people with ME/CFS commonly report that they are not believed. No evidence was identified on safeguarding in ME/CFS, but the committee agreed it was very important to make recommendations based on consensus. The recommendations address some of the misconceptions on this topic and highlight the need for expertise in ME/CFS when carrying out safeguarding assessments.

The committee emphasised the need for frequent review of children and young people with ME/CFS (in line with recommendations 1.15.2 and 1.15.3). The importance of appropriate review is also highlighted in the NICE guidelines on child maltreatment and child abuse and neglect.

The committee noted that although safeguarding is not solely about children and young people, most of the concerns they were aware of related to children and young people with ME/CFS so they made separate recommendations for this group.

How the recommendations might affect practice

The recommendations will improve consistency of best practice and do not need any additional resources to deliver.

Return to recommendations

Access to care and support

Recommendations 1.8.1 to 1.8.9

Why the committee made the recommendations

The evidence showed that people with ME/CFS can have difficulty using healthcare services, particularly because of physical accessibility and the time constraints of appointments. This can make it more difficult to get the support and treatment they need. The committee were also aware that common sensitivities in ME/CFS, such as to light and sound, can make it challenging to travel to and attend appointments and to receive inpatient care. The committee made recommendations to improve access to care based on these potential barriers.

The committee discussed the unpredictable and fluctuating nature of ME/CFS and the risk that people will be discharged from a service if they miss appointments when their symptoms worsen. They made a recommendation based on consensus to address the lack of awareness about this in health and social care services.

Maintaining independence

There was limited evidence directly addressing the barriers and facilitators to accessing social care. However, the committee agreed this was an important area of care and they could draw conclusions from the evidence on healthcare and use their own experience to make recommendations.

ME/CFS can affect a person's ability to carry out activities of daily living and maintain their independence and quality of life. The committee agreed that everyone with ME/CFS should be asked how their symptoms affect their independence and then a social care needs assessment carried out if necessary. Using their experience, the committee outlined the topics for assessment and discussion.

The committee also made further recommendations based on their own knowledge and experience, including that:

- many families and carers do not know the most appropriate ways to support someone with ME/CFS and need advice on this
- people with ME/CFS often have difficulty getting the equipment they need to support their activities of daily living and maintain their quality of life.

How the recommendations might affect practice

Some of these recommendations might need extra staff time or other healthcare resource use, for example to offer flexible appointments and home visits, make adjustments during inpatient stays and provide access to aids and adaptations. However, for equity reasons, people with ME/CFS need the same access to healthcare and support as other NHS patients that is commensurate with the severity of their illness.

Return to recommendations

Supporting people with ME/CFS in work, education and training

Recommendations 1.9.1 to 1.9.6

Why the committee made the recommendations

The evidence showed a lack of support with education and training for children and young people with ME/CFS and their families and carers, and this can result in some children or young people leaving education. This reflected the committee's experience and they agreed that many of the themes in the evidence could also be applied to people in work.

The common theme of lack of knowledge and understanding about ME/CFS was echoed in this evidence with a lack of awareness about the impact that a high-stimulus environment (such as a school) can have on someone with ME/CFS. There was a lack of understanding about the need for a flexible approach to education with possible adjustments. The committee agreed that better communication between health and social care professionals and training and education services is key to develop a shared understanding of the needs and impairments of people with ME/CFS and how to provide them with appropriate educational support.

How the recommendations might affect practice

The recommendations will improve consistency of best practice and do not need any additional resources to deliver.

Return to recommendations

Multidisciplinary care

Recommendations 1.10.1 to 1.10.5

Why the committee made the recommendations

There was limited evidence on the composition of a multidisciplinary team, but based on their experience, the committee agreed that good care for people with ME/CFS results from access to an integrated team of health and social care professionals who are trained and experienced in diagnosing and managing ME/CFS.

The fluctuating nature of ME/CFS means that people's support needs can change, so access to different expertise is needed at different times. The committee agreed that medical assessment and diagnosis would typically require access to an ME/CFS specialist physician or a GP with a special interest in ME/CFS. The committee agreed to make recommendations on providing a coordinated multidisciplinary approach and to identify the expertise that should be available.

In the committee's experience, care for most people with ME/CFS can be managed in primary care after their diagnosis is confirmed and they have a care and support plan agreed. However, the committee acknowledged the lack of confidence that non-specialists can have in managing ME/CFS and they recommended support from an ME/CFS specialist team.

The qualitative evidence showed that people with ME/CFS valued continuity of care and the committee agreed that having a single point of contact in their care team would avoid needing to have contact and appointments with multiple professionals which, for some people, could worsen their health.

How the recommendations might affect practice

The recommendations on the ME/CFS specialist multidisciplinary team, providing a named contact and giving support to primary care services may need resources. Current provision of ME/CFS specialist teams is very uneven across the country and increased staffing may be needed in some areas if there are more referrals. The specialist team will need to cover different areas of expertise, but most people will only need access to some elements and only at specific times. However, faster access to diagnosis and appropriate care should lead to better symptom management and to substantially better outcomes for people with ME/CFS and so might reduce health and care costs in the longer term.

Allocating a single point of contact to people with ME/CFS is not routine practice across the NHS. This could be implemented differently in different regions according to local service structures and may not necessarily need the addition of new staff. It could improve the efficiency of care for people with ME/CFS by reducing the burden of repeated appointments.

Return to recommendations

Managing ME/CFS

Recommendation 1.11.1

Why the committee made the recommendation

Overall, the evidence for non-pharmacological and pharmacological interventions for ME/CFS was heterogenous and inconclusive, with limited evidence for any single intervention, and this supported the committee's experience. The committee were aware of claims that have been made about cures for ME/CFS and that there is often a financial cost to people with ME/CFS when they pursue these. To address this, the committee agreed to raise awareness in the recommendations of

the current lack of a cure for ME/CFS.

Core outcomes in ME/CFS

There is considerable controversy over the outcome measures used in trials of treatments for ME/CFS and managing symptoms. Inconsistency in outcomes used and concerns over the validity of some outcome measures in an ME/CFS population makes it difficult to combine and compare results from different trials, limiting the ability to draw conclusions on the clinical and cost effectiveness of interventions. The committee made a recommendation for research on core outcome sets to enable the direct comparison of treatments for ME/CFS and symptom management and to shape and optimise ME/CFS trial design.

How the recommendation might affect practice

The recommendations reflect current practice so no effect on resources is anticipated.

Return to recommendation

Energy management

Recommendations 1.11.2 to 1.11.8

Why the committee made the recommendations

The committee discussed how the controversy over graded exercise therapy had resulted in confusion over what support should be available to people with ME/CFS to safely manage their level of activity, including physical activity or exercise. They agreed it was important to provide clarity of information and clear guidance around energy management, physical activity and exercise to people with ME/CFS. The committee also agreed people need clear information about services available to them to support the development of energy management plans.

Based on their experience, the committee agreed that energy management is one of the most important tools that people with ME/CFS have to support them in living with the symptoms of ME/CFS. They agreed that people with ME/CFS should have access to support from an ME/CFS specialist team to develop a plan for energy management.

The committee listed the components of energy management and what an assessment and plan would include, noting that the key component is understanding the principle of using energy in a way to minimise post-exertional malaise. They recommended a detailed assessment that takes into

account all areas of current activity and evaluation of rest and sleep, to establish an individual activity pattern within the person's current energy limit. The committee noted that energy management is not a physical activity or exercise programme, although the principles of energy management do apply to physical activity and exercise programmes.

To avoid potential harms by energy management being wrongly applied to people with ME/CFS without adequate support and expertise, the committee recommended that in specific circumstances, people with ME/CFS should be referred to a physiotherapist or occupational therapist in an ME/CFS specialist team.

Self-monitoring strategies and techniques

There was a lack of effectiveness evidence on strategies and tools to support people to self-monitor activity management. The committee considered the qualitative evidence and their own experience of the benefits of using strategies and tools to monitor activity alongside the potential harms of increasing the burden on the person and causing them additional anxiety about their activity levels. The committee decided to recommend that activity recording should be as easy as possible, and people should take advantage of tools they are already using. The committee also decided to make a recommendation for research on self-monitoring management strategies to help determine which strategies and techniques are effective.

How the recommendations might affect practice

The energy management plan forms part of the care and support plan and is part of ME/CFS specialist care. Appropriate energy management supports people to stay within their energy limits and aims to prevent their symptoms from worsening. It also supports them to increase their activity if possible. If this helps people maintain or improve their health this will be highly cost effective.

Return to recommendations

Incorporating physical activity and exercise

Recommendations 1.11.9 to 1.11.16

Why the committee made the recommendations

The committee agreed that clarity of information and clear guidance on energy management in relation to all activity should be available to people with ME/CFS. The committee also agreed that people need clear information about services available to them, and particularly the specific

circumstances in which a personalised physical activity or exercise programme could be considered by a person with ME/CFS.

In the committee's experience, people with ME/CFS have had varying results from physical activity and exercise programmes. The committee agreed it was important to discuss this with people with ME/CFS and to explain to them the possible risks and benefits.

Because of the harms reported by people with ME/CFS in the qualitative evidence, as well as the committee's experience of the effects when people exceed their energy limits, the committee recommended that people with ME/CFS should not undertake a physical activity or exercise programme unless it is overseen by a physiotherapist who has training and expertise in ME/CFS.

The committee outlined what a personalised physical activity or exercise programme should, and should not, include. In developing recommendations on the content, approach and delivery of physical activity and exercise programmes, the committee considered the benefits and harms associated with graded exercise therapy that had been reported with ME/CFS across the quantitative and qualitative evidence, alongside their own experiences. They recognised that different definitions of the term 'graded exercise therapy' are used, and as a result the content and application of graded exercise therapy programmes differ. This has resulted in confusion. Taking into account descriptions of graded exercise therapy in the evidence they reviewed, the committee included a definition in this guideline to clarify what graded exercise therapy is intended to mean in the recommendation.

The committee concluded any programme using fixed incremental increases in physical activity or exercise (for example, graded exercise therapy), or physical activity or exercise programmes that are based on deconditioning and exercise avoidance theories, should not be offered to people with ME/CFS. The committee also wanted to reinforce that there is no therapy based on physical activity or exercise that is effective as a cure for ME/CFS.

For people with ME/CFS who do choose to take part in a physical activity or exercise programme, this should follow the principles set out in this section and the energy management section.

How the recommendations might affect practice

These recommendations should prevent inappropriate or unstructured physical activity or exercise programmes from worsening people's symptoms. The referral to a physiotherapist or occupational therapist in an ME/CFS specialist team may need increased resources. However, this should not impose a significant cost on the NHS and if it leads to fewer people with deteriorating symptoms, it

will be highly cost effective.

Return to recommendations

Rest and sleep

Recommendations 1.12.1 to 1.12.4

Why the committee made the recommendations

The committee considered that giving advice on planning rest and activity was a fundamental part of any management strategy. In their experience, understanding the role of rest and how to introduce rest periods was important in successful energy management.

There was a lack of evidence for sleep management, but the committee recognised that difficulty with sleep was an area of concern for many people with ME/CFS. The committee discussed making recommendations based on consensus for providing advice for people with ME/CFS and agreed they could recommend general advice for sleep management. They noted that there are common sleep patterns in people with ME/CFS that need to be considered when giving advice about sleep management. In addition, they made a recommendation for research on sleep management strategies.

How the recommendations might affect practice

The recommendations should not impose a significant cost on the NHS and if they lead to fewer people with deteriorating symptoms, they will be highly cost effective.

Return to recommendations

Physical functioning and mobility

Recommendations 1.12.5 to 1.12.8

Why the committee made the recommendations

The committee discussed that people with ME/CFS can have reduced or limited mobility and, in their experience, this can lead to health problems. Physical functioning and mobility should therefore be assessed and included in the person's care and support plan.

The committee agreed that people with ME/CFS who are immobile need information to help them recognise and prevent the possible complications of long-term immobility, for example in relation to bone health and skin problems. In the committee's experience, families and carers are given only limited information about these areas of care (for example, how to transfer someone from a bed to a chair) and it would have helped them.

How the recommendations might affect practice

The recommendations are already established in other NICE guidance and should not impose a significant cost on the NHS. If they lead to fewer people with deteriorating symptoms, they will be highly cost effective.

Return to recommendations

Orthostatic intolerance

Recommendations 1.12.9 to 1.12.11

Why the committee made the recommendations

Orthostatic intolerance is identified as one of the symptoms commonly associated with, but not exclusive to, ME/CFS (see the section on suspecting ME/CFS). In the committee's experience, although not everyone with ME/CFS experiences orthostatic intolerance, it is very common and the symptoms can be hard to differentiate from other ME/CFS symptoms.

Based on consensus, the committee made recommendations to raise awareness that people with ME/CFS may experience orthostatic intolerance, and to clarify when people with orthostatic intolerance should be referred to secondary care.

The committee did not make any recommendations on managing orthostatic intolerance because this can involve advice on diet, daily activities and activity support and needs to be tailored to each person, taking into account their other ME/CFS symptoms.

The committee recommended that medicines should only be prescribed or overseen by a clinician with expertise in orthostatic intolerance because the medicines that are usually prescribed can worsen other symptoms in people with ME/CFS.

How the recommendations might affect practice

The recommendations should not impose a significant cost on the NHS and if they lead to fewer people with deteriorating symptoms, they will be highly cost effective.

Return to recommendations

Pain

Recommendations 1.12.12 to 1.12.14

Why the committee made the recommendations

Pain is identified as one of the symptoms commonly associated with, but not exclusive to, ME/CFS (see the section on suspecting ME/CFS). The committee agreed that pain is a common symptom in people with ME/CFS and is particularly intense in people with severe or very severe ME/CFS. The lack of evidence meant they could not recommend any interventions, but they did refer to the NICE guidelines on neuropathic pain and headaches. The committee also made consensus-based recommendations to raise awareness about pain in ME/CFS and what action to take.

How the recommendations might affect practice

The recommendation referring to other NICE guidance should not have a resource impact as those recommendations are already established. The other recommendations should not impose a significant cost on the NHS and if they lead to fewer people deteriorating then they would be highly cost effective.

Return to recommendations

Medicines

Recommendations 1.12.15 to 1.12.18

Why the committee made the recommendations

The evidence for any pharmacological interventions for ME/CFS was inconclusive, with limited evidence for any one medicine, and this supported the committee's experience. The committee were aware of claims that have been made about cures for ME/CFS and there is often a financial cost to people with ME/CFS when these are pursued. The committee considered it was important

to highlight that medicines or supplements should not be offered as a cure for ME/CFS.

Medicines for symptom management

The committee recognised that medicines can be useful for people with ME/CFS to manage their symptoms. The committee agreed that people with ME/CFS may be more intolerant of drug treatment, so they decided to raise awareness of this. To reduce the risk of harm, the committee discussed using a cautious approach to medicines prescribing, which includes starting the medicine at a lower dose than in usual clinical practice and monitoring how the person's symptoms respond before adjusting the dose.

The committee discussed medicines management for children and young people, noting the potential for harm, which led them to recommend that prescribing should be initiated under the supervision of a paediatrician with expertise in ME/CFS.

How the recommendations might affect practice

The recommendations should not impose a significant cost on the NHS and if they lead to fewer people with deteriorating symptoms, they will be highly cost effective.

Return to recommendations

Dietary management and strategies

Recommendations 1.12.19 to 1.12.26

Why the committee made the recommendations

There was not enough evidence to make a recommendation for a particular dietary strategy for ME/CFS. However, the committee agreed some general recommendations to ensure that people with ME/CFS get appropriate support related to diet. This included guidance on when to refer someone to a dietitian with a special interest in ME/CFS. The committee also referred to other relevant NICE guidance.

The committee recognised that difficulties with diet and nutrition was an area of concern for many people with ME/CFS. They discussed making consensus-based recommendations for providing dietary strategies for people with ME/CFS, but they agreed it was hard to be confident in making recommendations when there was no evidence and a lack of consensus in the area, so they made a recommendation for research on dietary strategies.

How the recommendations might affect practice

The recommendations should not impose a significant cost on the NHS and if they lead to fewer people with deteriorating symptoms, they will be highly cost effective.

Return to recommendations

Lightning Process

Recommendation 1.12.27

Why the committee made the recommendation

The committee discussed the limited evidence on the Lightning Process. They acknowledged that although some benefit was demonstrated and aspects of it, such as goal setting, practical examples and applications and peer support, were found to be helpful, the qualitative evidence on people's experiences of the therapy varied and raised some concerns. In the qualitative evidence, some people reported negative experiences to do with the confusing nature of the educational component, the intensity of the sessions, and the secrecy surrounding the therapy. While in the SMILE trial children under 16 were accompanied by parents, the committee were particularly concerned about the reported secrecy of the Lightning Process in the qualitative evidence and the lack of public information on the implementation of the process in practice. The committee agreed the transparency of any intervention is important and noted that in the qualitative evidence it was reported that people had been specifically encouraged not to talk about the therapy. The committee agreed this was an inappropriate and unusual message to give, particularly to children and young people.

The committee discussed concerns that the Lightning Process encourages people with ME/CFS to ignore and 'push through' their symptoms and this could potentially cause harm. In the qualitative evidence, some participants reported they had received advice they could do what they wanted. The committee noted they had made clear recommendations on the principles of energy management and this advice appears at odds with these principles.

Overall, the committee considered there was a lack of clarity around the implementation of the Lightning Process in practice and some concerning issues raised in the qualitative evidence. As a result, the committee agreed the Lightning Process should not be offered to people with ME/CFS.

How the recommendation might affect practice

The Lightning Process is not offered as part of current practice so this recommendation will maintain current practice.

Return to recommendation

Cognitive behavioural therapy

Recommendations 1.12.28 to 1.12.34

Why the committee made the recommendations

The quantitative and qualitative evidence was mixed for adults, children and young people, and this reflected the committee's experience. Based on criticisms in the qualitative evidence of cognitive behavioural therapy (CBT) being described as a 'treatment' (cure) for ME/CFS, the committee considered it was important to highlight that CBT is not a cure for ME/CFS and should not be offered as such. Instead, it aims to improve wellbeing and quality of life, and may be useful in supporting people who live with ME/CFS to manage their symptoms and reduce the distress associated with having a chronic illness. It should therefore only be offered in this context, and after people have been fully informed about its principles and aims. The committee agreed if a child or young person would like to use CBT, it was important to adapt the therapy taking into account their cognitive and emotional maturity.

The qualitative evidence showed that people with ME/CFS have found CBT useful when delivered by a therapist who understands ME/CFS, but also that there is the potential for harm when it is inappropriately delivered. To avoid this, the committee made the recommendation about who should deliver CBT and the clinical supervision they should have.

The committee also made recommendations based on their experience to explain the principles of CBT for people with ME/CFS and what people should expect if they decide to consider CBT.

How the recommendations might affect practice

CBT is currently provided for people with ME/CFS in specialist ME/CFS services. The recommendations clarify when CBT should be offered to people with ME/CFS. They should not have an impact on NHS resource and costs.

Return to recommendations

Managing coexisting conditions

Recommendations 1.13.1 to 1.13.4

Why the committee made the recommendations

The evidence on the diagnostic criteria identified that some conditions are common in people with ME/CFS and this reflected the committee's experience. The committee made recommendations to highlight this and referred to relevant NICE guidance.

How the recommendations might affect practice

The recommendations should not impose a significant cost on the NHS.

Return to recommendations

Managing flare-ups in symptoms and relapse

Recommendations 1.14.1 to 1.14.8

Why the committee made the recommendations

In the committee's experience, flare-ups and relapse are a common part of ME/CFS. The committee considered it important to give people information about what a flare-up is, how to recognise one and how they can lead to a relapse if activity is not monitored and adjusted.

The committee discussed the importance of recognising when a flare-up has moved to a relapse and that it needs to prompt a review of their care and support plan. It is also possible that a relapse may lead to someone moving to a more severe form of ME/CFS. Part of the review of the care and support plan is to consider what the causes of relapse might have been and to consider this when revising the plan.

How the recommendations might affect practice

The recommendations should not impose a significant cost on the NHS and if they lead to fewer people with deteriorating symptoms, they will be highly cost effective.

Return to recommendations

Review in primary care

Recommendations 1.15.1 to 1.15.10

Why the committee made the recommendations

The evidence showed that people with ME/CFS did not always receive follow-up or review of their care, but those who did valued this. This reflected the committee's experience, so they recommended at least annual reviews for adults.

The committee agreed that children and young people need more frequent review to take into account changes in their ME/CFS as they develop. They also wanted to highlight the importance of involving a paediatrician.

The committee outlined areas for discussion during the review, including asking people how much support they had to carry out their activities of daily living. This was because, in the committee's experience, this is an area often overlooked and the input of family and carers is often not acknowledged. The committee noted that if any problems are identified, advice should be sought from an appropriate specialist.

How the recommendations might affect practice

There is variation in practice and some people with ME/CFS, including those with severe or very severe ME/CFS, do not get a clinical review routinely, so for some this will be a change in practice. These recommendations are in line with other long-term conditions and support equity of access to care for people with ME/CFS. Routine follow-up might not be present everywhere but most people with ME/CFS already have regular contact with their primary care teams, so there is not expected to be a large resource impact.

Return to recommendations

Training for health and social care professionals

Recommendation 1.16.1

Why the committee made the recommendation

A strong theme in the evidence was the lack of knowledge, understanding and up-to-date training that health and social care professionals have about ME/CFS. This was reflected in the committee's

experience, so they recommended that all health and social care staff who deliver care to people with ME/CFS should be trained so they are able to provide the care in this guideline.

How the recommendation might affect practice

Training and education in ME/CFS are not widespread and this will be a change in practice, so there will be a resource impact from the cost of providing this training. Improving knowledge and awareness about ME/CFS will support identifying ME/CFS earlier, which should improve people's care and lead to better outcomes.

Return to recommendation

Care for people with severe or very severe ME/CFS

Recommendations 1.17.1 to 1.17.13

Awareness of severe and very severe ME/CFS and its impact

People with severe or very severe ME/CFS were named as a group for special consideration in the guideline scope. Evidence relating to people with severe ME/CFS reinforced the committee's experience that this group of people are often neglected, and the severity of their symptoms misunderstood, and with every recommendation the committee considered whether different or additional recommendations were needed for this group. The rationale and impact sections for these recommendations are below. These additional considerations for people with severe or very severe ME/CFS were placed in a separate section to make sure they could be easily found within the guideline.

Return to recommendations

Assessment and care and support planning by an ME/CFS specialist team

Why the committee made the recommendation

Based on the evidence about problems with accessing services, the committee made a recommendation for a home visit to people with severe or very severe ME/CFS to carry out the assessment.

How the recommendation might affect practice

There may be an increased number of home visits for people with severe or very severe ME/CFS. However, this will provide equity of access to care for this group who are usually housebound.

Return to recommendation

Access to care and support

Why the committee made the recommendations

The committee were aware that difficulties accessing care are intensified in people with severe or very severe ME/CFS, particularly when they need hospital care. The evidence showed that as a result of this, some people with severe or very severe ME/CFS have little contact and support from health and social care services. To address this, the committee highlighted the flexibility and specific support needed by people with severe or very severe ME/CFS.

How the recommendations might affect practice

There may be an increased number of home visits for people with severe or very severe ME/CFS. However, this will provide equity of access to care for this group who are usually housebound. Some of these costs may be offset by the ability to provide online consultations when appropriate. The emphasis in this guideline on timely diagnosis and referral to an ME/CFS specialist team for a personalised care and support plan aims to minimise the number of people who may progress to severe ME/CFS.

Return to recommendations

Energy management

Why the committee made the recommendations

The committee agreed that if energy management strategies are inappropriately applied in people with severe or very severe ME/CFS, this will increase the potential for harm. To reflect this, they recommended specialist physiotherapy advice and additional care for people with severe or very severe ME/CFS who have chosen to develop an energy management plan.

How the recommendations might affect practice

The energy management plan forms part of the care and support plan and is a usual part of ME/CFS

specialist care. Appropriate energy management supports people to stay within their energy limits and aims to prevent their symptoms from worsening. It also supports them to increase their activity if possible. If this helps people maintain or improve their health, this will be highly cost effective.

Return to recommendations

Dietary management and strategies

Why the committee made the recommendations

The committee considered that people with severe or very severe ME/CFS are particularly at risk of problems associated with eating and are likely to need additional support and referral to a dietitian who has a special interest in ME/CFS. The committee also used their own experience to recommend some general dietary advice that could be helpful for people with severe or very severe ME/CFS.

How the recommendations might affect practice

The recommendations should not impose a significant cost on the NHS and if they lead to fewer people with deteriorating symptoms, they will be highly cost effective.

Return to recommendations

Cognitive behavioural therapy

Why the committee made the recommendation

None of the clinical evidence included or reflected the needs of people with severe or very severe ME/CFS, and the qualitative evidence was mixed, with some people reporting benefit and others harm. The committee recognised that CBT could be supportive for people with severe or very severe ME/CFS in some circumstances, but because of the severity of their symptoms, it is important to be more flexible and adapt the delivery of CBT to accommodate people's limitations.

How the recommendation might affect practice

CBT is currently provided for people with ME/CFS in specialist ME/CFS services. The recommendations clarify when CBT should be offered to people with ME/CFS. They should not have an impact on NHS resource and costs.

Return to recommendation

Context

The terms myalgic encephalomyelitis (ME; or encephalopathy), chronic fatigue syndrome (CFS), CFS/ME and ME/CFS have all been used for this condition and are not clearly defined. There is little pathological evidence of brain inflammation, which makes the term 'myalgic encephalomyelitis' problematic. Myalgic encephalomyelitis is classified under diseases of the nervous system in the SNOMED CT and ICD10 (G93.3). Many people with ME/CFS consider the name 'chronic fatigue syndrome' too broad, simplistic and judgemental. For consistency, the abbreviation ME/CFS is used in this guideline.

Recent data from the UK Biobank suggest that there are over 250,000 people in England and Wales with ME/CFS, with about 2.4 times as many women affected as men. ME/CFS can affect people of all ages. It is a complex, multi-system, chronic medical condition that has considerable personal, social and economic consequences and a significant impact on a person's quality of life, including their psychological, emotional and social wellbeing.

Everyday life for people with ME/CFS, their family and carers is disrupted and unpredictable. Many people with the condition are unemployed, and less than a fifth work full-time. Approximately 25% have severe disease and are housebound or bedbound. The quality of life of people with ME/CFS is lower than that of many people with other severe chronic conditions, including multiple sclerosis and some forms of cancer.

It is not clear what causes ME/CFS. In many cases, symptoms are thought to have been triggered by an infection but it is not simple post-illness fatigue. It lasts longer and even minimal mental or physical activity can make symptoms worse.

There is no diagnostic test or universally accepted definition for ME/CFS. People with the condition report delays in diagnosis, and many healthcare professionals lack the confidence and knowledge to recognise, diagnose and manage it. Fatigue associated with another chronic disease may be confused with ME/CFS and some practitioners are reluctant to positively diagnose ME/CFS when no other causes are found.

People with ME/CFS report a lack of belief and acknowledgement from health and social care professionals about their condition and related problems, which may lead them to be dissatisfied with care and to disengage from services. There are added issues for children and young people if illness makes school attendance difficult, bringing families to the attention of educational and social care services.

NICE produced a guideline on CFS/ME in 2007. That guideline made recommendations on cognitive behavioural therapy and graded exercise therapy. Both treatments are controversial for this condition, and there are disagreements and uncertainty about their effectiveness among both people with ME/CFS and health providers. The evidence for the effects of other commonly prescribed therapies has also been questioned.

There is unequal access to ME/CFS specialist services across England and Wales with some areas reporting very limited access. It is important this inequity of access is addressed.

Finding more information and committee details

You can see everything NICE says on this topic in the NICE Pathway on ME (chronic fatigue syndrome).

To find NICE guidance on related topics, including guidance in development, see the NICE webpage on ME/CFS.

For full details of the evidence and the guideline committee's discussions, see the evidence reviews. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

Update information

This guideline updates and replaces NICE's guideline on chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management, published in August 2007.

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Accreditation

Maternal, Newborn and Infant Clinical Outcome Review Programme

MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

MBRRACE-UK
Perinatal Mortality Surveillance Report

UK Perinatal Deaths for Births from January to December 2019

October 2021

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UK Perinatal Deaths for Births from

January to December 2019

Elizabeth S Draper, Ian D Gallimore, Lucy K Smith, Alan C Fenton,
Jennifer J Kurinczuk, Peter W Smith, Thomas Boby, Bradley N Manktelow

on behalf of the MBRRACE-UK collaboration

October 2021

Department of Health Sciences
University of Leicester
George Davies Centre
University Road
Leicester LE1 7RH

Funding

The Maternal, Newborn and Infant Clinical Outcome Review Programme, delivered by MBRRACE-UK, is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing, and National Voices. Its aim is to promote quality improvement in patient outcomes. The Clinical Outcome Review Programmes, which encompass confidential enquiries, are designed to help assess the quality of healthcare, and stimulate improvement in safety and effectiveness by systematically enabling clinicians, managers, and policy makers to learn from adverse events and other relevant data. HQIP holds the contract to commission, manage, and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The Maternal, Newborn and Infant Clinical Outcome Review Programme is funded by NHS England, NHS Wales, the Health and Social Care division of the Scottish Government, the Northern Ireland Department of Health, and the States of Jersey, Guernsey, and the Isle of Man.

More details can be found at: www.hqip.org.uk/national-programmes.

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Executive Summary

Introduction

MBRRACE-UK is commissioned by the Healthcare Quality Improvement Partnership (HQIP) to undertake the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP). The aims of the MNI-CORP are to collect, analyse and report national surveillance data and conduct national confidential enquiries in order to stimulate and evaluate improvements in health care for mothers and babies (Box 1). This report focuses on **the surveillance of perinatal deaths from 22^{+0} weeks gestational age (including late fetal losses, stillbirths, and neonatal deaths) of babies born between 1st January and 31st December 2019**.

Box 1: Scope of the Maternal, Newborn and Infant Clinical Outcome Review Programme

- Surveillance and confidential enquiries of all maternal deaths – that is, deaths of women who are pregnant or who die up to 1 year after their pregnancy ends.
- Confidential enquiries of an annual rolling programme of topic-specific, serious maternal morbidity.
- Surveillance of all late fetal losses (22^{+0} to 23^{+6} weeks gestational age), stillbirths, and neonatal deaths (from 20^{+0} weeks gestational age).
- A biennial programme of topic-specific confidential enquiries into aspects of stillbirth and infant death or serious infant morbidity.

Perinatal mortality surveillance involves the identification and notification of all eligible deaths and the timely collection of a limited and tightly defined demographic and clinical dataset. The goal is to receive notification of every death and to collect high-quality data about each one. This information allows the calculation of 'stabilised & adjusted' mortality rates which take into account the effects of chance variation and also allow for key factors known to increase the risk of perinatal mortality. The information is presented in order to assist clinicians, commissioners, managers, parents, and the public in raising standards of maternity and neonatal care in order to reduce perinatal mortality across the UK.

Mortality rates for individual organisations, including Trusts and Health Boards, can be found online at: http://www.npeu.ox.ac.uk/mbrrace-uk/reports. Additional tables and figures can be found in the accompanying Tables and Figures document. This report should be read in conjunction with the accompanying Technical Document which contains full details of the MBRRACE-UK methodology, including case ascertainment and statistical methods. All these documents are available for download from the MBRRACE-UK website: http://www.npeu.ox.ac.uk/mbrrace-uk/reports.

Key findings

Perinatal mortality rates in the UK: 2019

1. Extended perinatal mortality has reduced by 18% over six years, from 6.04 per 1,000 total births in 2013 to 4.96 per 1,000 total births in 2019, equivalent to approximately 770 fewer deaths in 2019.
2. Over two-fifths of this reduction has occurred since 2017: this increased trajectory is likely to have resulted from various national initiatives to reduce perinatal mortality across the UK.
3. Stillbirth rates have reduced by just over 20% from 4.20 per 1,000 total births in 2013 to 3.35 per 1,000 total births in 2019, representing approximately 610 fewer stillbirths in 2019.

4. Neonatal mortality has reduced by 12% from 1.84 per 1,000 live births in 2013 to 1.62 deaths per 1,000 live births in 2019, representing approximately 160 fewer neonatal deaths in 2019.

Mortality rates by gestational age

5. The overall reduction in the stillbirth rate is mainly due to a reduction in the rate of term stillbirths of one-fifth (19%), from 1.45 per 1,000 total births in 2015 to 1.17 in 2019.

6. The largest reduction in the neonatal mortality rate was for very preterm births (28^{+0} to 31^{+6} weeks gestational age) of one-seventh (14%) from 33.8 per 1,000 live births in 2015 to 28.9 in 2019.

7. Almost three-quarters of both stillbirths and neonatal deaths (including babies born at 22-23 weeks gestational age) were for preterm births (<37 weeks gestational age): 75% and 73% respectively.

8. In 2019, 38% of stillbirths and 46% of neonatal deaths occurred in babies who were born extremely preterm (22^{+0} to 27^{+6} weeks gestational age).

Effect of deprivation on perinatal mortality

9. Despite rates of stillbirth and neonatal mortality reducing over time, babies born to women living in the most deprived areas are twice as likely to be stillborn and at a 73% excess risk of neonatal death compared to babies born to women living in the least deprived areas; this excess risk has increased over the period from 2015 to 2019.

Effect of ethnicity on perinatal mortality

10. Mortality rates remain exceptionally high for babies of Black and Black British ethnicity: stillbirth rates are over twice those for babies of White ethnicity and neonatal mortality rates are 43% higher.

11. Similarly, mortality rates remain high for babies of Asian and Asian British ethnicity: stillbirth and neonatal mortality rates are both around 60% higher than for babies of White ethnicity.

Effect of mother's age on perinatal mortality

12. The lowest stillbirth and neonatal mortality rates are for mothers aged 30 to 34 years: stillbirths, 3.15 per 1,000 total births and neonatal deaths, 1.50 per 1,000 live births.

13. The largest reductions in both stillbirth and neonatal mortality rates were for babies born to the oldest mothers.

14. Mothers aged under 20 are at a 33% increased risk of stillbirth and a 75% increased risk of neonatal death compared to mothers aged 30-34.

15. Mothers aged 40 and above are at a 41% increased risk of stillbirth and a 37% increased risk of neonatal death compared with mothers aged 30-34.

Multidimensional effects of ethnicity, deprivation and mother's age on perinatal mortality

16. Stillbirth and neonatal mortality rates increased with deprivation and were higher for mothers under 25 years and over 35 years across all ethnic groups.

17. Stillbirth rates and neonatal mortality rates were lowest for babies of White ethnicity born to mothers aged 25 to 34 living in the least deprived areas (2.61 to 2.76 stillbirths per 1,000 total births and 1.24 to 1.26 neonatal deaths per 1,000 live births).

18. The multiple impact of ethnicity, mother's age and deprivation is highlighted by a stillbirth rate of 10.54 and 6.91 per 1,000 total births for babies of Black and Black British ethnicity and Asian and Asian British ethnicity respectively born to mothers aged over 35 years living in the most deprived areas.

19. Neonatal mortality rates were over 3 per 1,000 live births for babies of Black and Black British ethnicity and Asian and Asian British ethnicity born to mothers under 25 years and over 35 years living in the most deprived areas.

20. Due to high proportions of babies of Black and Black British ethnicity being born to mothers living in deprived areas, they are disproportionately affected by the higher rates of stillbirth associated with deprivation.

Perinatal mortality rates for Trusts and Health Boards

21. After adjustment for risk factors and unit size, stillbirth rates show little variation between Trusts and Health Boards with stabilised & adjusted rates for almost all (97%) organisations falling within 5% of their comparator group average.

22. Stabilised & adjusted neonatal mortality rates for organisations which care for the most complex pregnancies and births show wide variation: only 13% of Trusts and Health Boards with a Level 3 Neonatal Intensive Care Unit (NICU) and neonatal surgical provision had a stabilised and adjusted neonatal mortality rate within 5% of their comparator group average.

23. Exclusion of deaths due to congenital anomalies removes variation in stabilised & adjusted stillbirth rates almost entirely, resulting in all Trusts and Health Boards falling within 5% of their comparator group average.

24. Exclusion of deaths due to congenital anomalies has little effect on the variation in stabilised & adjusted neonatal mortality rates, with only 12% of Trusts and Health Boards with a Level 3 Neonatal Intensive Care Unit (NICU) and neonatal surgical provision having a stabilised and adjusted neonatal mortality rate within 5% of their comparator group average.

Causes of perinatal death

25. Rates of stillbirth classified as of unknown cause have fallen by 8% between 2015 and 2019, much of which may be ascribed to the increasing proportions of stillbirths from placental causes.

26. Of the two-fifths of neonatal deaths attributed to neonatal causes, mortality rates have fallen over the 5 year period for extreme prematurity as well as the neurological and cardio-respiratory categories.

27. Congenital anomalies continue to contribute significantly to mortality rates, comprising around one-third of neonatal deaths and just under one-tenth of stillbirths.

28. Whilst almost all parents were offered a post-mortem for their stillborn baby (97%), only 85% of parents received an offer of a post-mortem following a neonatal death in 2019.

29. Where a post-mortem was offered following a stillbirth or neonatal death, half of parents gave consent for full or limited post-mortem.

30. In 2019, 78% of neonatal deaths occurring on day one after birth or which were classified as intrapartum-related deaths had placental histology investigations carried out.

Timeliness of notification of perinatal deaths

31. Timeliness of notification of deaths is improving. Approximately four-fifths of deaths were notified within the MBRRACE-UK benchmark time of 30 days: 80% of stillbirths and 76% of neonatal deaths (an increase from 69% of stillbirths and 64% of neonatal deaths in 2018).

32. There was no correlation between the total number of deaths per Trust or Health Board and the percentage of deaths notified within 30 days.

33. Variation between UK countries in the percentage of deaths notified within 30 days has reduced, from 35% variation between countries in 2017 (36% to 71% notified within 30 days) to 19% variation between countries in 2019 (63% to 82% notified within 30 days).

New recommendations

1. Enhance current programmes in order to accelerate the reduction of stillbirths and neonatal deaths to meet national targets, with an emphasis on reducing rates of preterm birth, particularly the most extreme preterm group. **ACTION: Policy Makers, UK Public Health Services.**

2. Continue to develop innovative new programmes of research into reducing preterm birth. **ACTION: Policy Makers, UK Public Health Services, Research Funders.**

3. Use the MBRRACE-UK guidance for the assessment of signs of life in births before 24^{+0} weeks gestational age. **ACTION: Trust and Health Board Directors, Clinical Directors, Heads of Midwifery, Health Professionals.**

4. Ensure the continuation of targeted initiatives with health education organisations not only aimed at reducing teenage pregnancy but also providing pre-conception advice. **ACTION: UK Government Education Departments, UK Public Health and Health Education Services, Primary Care Providers, Health Professionals**.

5. Provide pre- and post-conception information for women aged 35 and over, clarifying the risk of stillbirth and neonatal death associated with increased maternal age to empower their decision making throughout the care pathway. **ACTION: UK Health Education Services, Primary Care Providers, Trust and Health Board Directors, Clinical Directors, Heads of Midwifery, Health Professionals**.

6. Initiate a research programme to inform the development of effective interventions to address health inequalities and reduce stillbirth and neonatal mortality rates. **ACTION: Policy Makers, UK Public Health Services, Research Funders.**

7. Develop focused initiatives to reduce stillbirths and neonatal deaths among groups of mothers at the highest risk, informed by the multidimensional effects of ethnicity, deprivation and mother's age. **ACTION: Policy Makers, UK Public Health Services.**

8. Use the newly-developed MBRRACE-UK interactive maps and tables to compare stabilised and adjusted stillbirth, neonatal mortality and extended perinatal mortality rates between organisations. **ACTION: Service Commissioners, Trust and Health Board Directors, Clinical Directors, Heads of Midwifery, Health Professionals.**

9. Emphasise the importance of pre-conception health as a routine part of every health professional's interaction with women who have risk factors for congenital anomaly. **ACTION: UK Public Health Services, Primary Care Providers, Royal Colleges, Trust and Health Board Directors, Clinical Directors, Heads of Midwifery, Health Professionals**.

10. Notify all deaths via the MBRRACE-UK system within 2 working days of the death occurring. Incorporate mechanisms for timely notification into local processes. **ACTION: Trust and Health Board Directors, Clinical Directors, Heads of Midwifery, Health Professionals.**

Previous recommendations requiring improved implementation

- Develop public health initiatives to address issues linked to high risk populations. **ACTION: Policy Makers, UK Public Health Services.**
- Ensure that healthcare providers have implemented national initiatives to reduce stillbirth and neonatal deaths and are monitoring their impact on reducing preterm birth. **ACTION: Service Commissioners, Trust and Health Board Directors, Clinical Directors.**
- Ensure that there is a multi-agency targeted approach affecting women living in areas of high socio-economic deprivation across all points of the reproductive, pregnancy and neonatal healthcare pathway. **ACTION: Policy Makers, UK Public Health Services, Service Planners and Commissioners at local and national level.**
- Identify the specific needs of Black and Asian populations and ensure that these are addressed as part of their reproductive and pregnancy healthcare provision. **ACTION: Service Planners, Service Commissioners, Health Professionals.**
- Use the MBRRACE-UK real-time data monitoring tool as part of regular mortality meetings to help identify why an organisation's stabilised & adjusted stillbirth, neonatal mortality or extended perinatal mortality rate falls into the red or amber band. **ACTION: Trust and Health Board Directors, Clinical Directors, Heads Of Midwifery, Health Professionals.**
- Investigate potential modifiable factors in the treatment of neonates when an organisation's stabilised and adjusted neonatal mortality rate falls into the red or amber bands after exclusion of deaths due to congenital anomalies. Ensure that this encompasses both local population characteristics and quality of care provision. **ACTION: Trust and Health Board Directors, Clinical Directors, Heads Of Midwifery.**
- Explore local variation in post mortem uptake by different population groups, particularly by ethnicity and deprivation, and tailor training for consent takers based on the local population. **ACTION: Trust and Health Board Directors, Clinical Directors, Heads Of Midwifery, Health Professionals.**
- Undertake placental histology for all babies admitted to a neonatal unit, preferably by a specialist perinatal pathologist. **ACTION: Trust And Health Board Directors, Clinical Directors, Heads Of Midwifery, Health Professionals**.

Contents

Introduction

Deaths reported to MBRRACE-UK

Deaths reported to MBRRACE-UK since 1 January 2013 are:

- *late fetal losses*: a baby born between 22^{+0} and 23^{+6} weeks gestational age showing no signs of life, irrespective of when the death occurred;
- *stillbirths*: a baby born at or after 24^{+0} weeks gestational age showing no signs of life, irrespective of when the death occurred;
- *neonatal deaths*: a liveborn baby (born at 20^{+0} weeks gestational age or later) who died before 28 completed days after birth.

These definitions also include any late fetal loss, stillbirth, or neonatal death resulting from a termination of pregnancy.

The 2019 birth cohort

In this report rates of stillbirth, neonatal death and extended perinatal death are presented for births from 1 January 2019 to 31 December 2019; thus, neonatal deaths of babies born in December 2019 which occurred in January 2020 are included. The reporting of mortality for a birth cohort is in contrast to statutory publications, which are based on deaths in a calendar year. This method of reporting allows more accurate estimates of mortality rates to be produced as appropriate denominators are available.

Data sources

The data presented in this report is derived from a number of sources in addition to the information submitted via the MBRRACE-UK web-based reporting system: ONS, PDS, NRS, PHS, NISRA, Health and Social Services Department (Bailiwick of Guernsey), and the Health Intelligence Unit (Bailiwick of Jersey). Full details of all data sources and the case ascertainment procedure can be found in the accompanying Technical Document.

The UK total births is based on all births for the UK (irrespective of country of residence) whereas the number of births for each individual UK country and the Crown Dependencies is based on those births for which the country of residence of the mother was known.

Deaths included in reported mortality rates

This report focuses on **births from 24^{+0} weeks gestational age,** with the exception of the chapter on mortality rates by gestational age, which includes information on births at 22^{+0} to 23^{+6} weeks gestational age. **All terminations of pregnancy have been excluded from the mortality rates reported**. This avoids the influence of the wide disparity in the classification of babies born before 24^{+0} weeks gestational age as a neonatal death or a fetal loss, as well as the known variation in the rate of termination of pregnancy for congenital anomaly across the UK.

Report overview

This is the seventh MBRRACE-UK Perinatal Mortality Surveillance Report. The main report is divided into nine sections: perinatal mortality rates in the UK; mortality rates by gestational age; the effect of deprivation on perinatal mortality; the effect of ethnicity on perinatal mortality; the effect of maternal age on perinatal mortality; multidimensional effects of ethnicity, deprivation and maternal age on perinatal mortality; variation in mortality rates for Trusts and Health Board comparator groups; causes of death; and the timeliness of notification of death.

Mortality rates for individual organisations, including Trusts and Health Boards, together with interactive maps, can be found online at: www.npeu.ox.ac.uk/mbrrace-uk/reports. Additional tables and figures can be found in the accompanying Tables and Figures document. This report should be read in conjunction with the accompanying Technical Document which contains full details of the MBRRACE-UK methodology, including case ascertainment and statistical methods. All these documents are available for download from the MBRRACE-UK website: www.npeu.ox.ac.uk/mbrrace-uk/reports.

Key to colour coding

Recommendations arising from existing national guidelines, initiatives or previous reports and the source of these recommendations are cited within green boxes. Example:

Recommendation A

Existing guidance requiring improved implementation is presented in green boxes.

NICE 2345

New recommendations which are not based on current national guidance and which have not been noted in previous reports or initiatives are shown in purple boxes. Example:

Recommendation B **N**

New recommendations are presented in purple boxes with the character N in the corner.

Perinatal mortality rates in the UK: 2019

Key findings

- Extended perinatal mortality has reduced by 18% over six years, from 6.04 per 1,000 total births in 2013 to 4.96 per 1,000 total births in 2019, equivalent to approximately 770 fewer deaths in 2019.
- Over two-fifths of this reduction has occurred since 2017: this increased trajectory is likely to have resulted from various national initiatives to reduce perinatal mortality across the UK.
- Stillbirth rates have reduced by just over 20% from 4.20 per 1,000 total births in 2013 to 3.35 per 1,000 total births in 2019, representing approximately 610 fewer stillbirths in 2019.
- Neonatal mortality has reduced by 12% from 1.84 per 1,000 live births in 2013 to 1.62 deaths per 1,000 live births in 2019, representing approximately 160 fewer neonatal deaths in 2019.

Data presented

1. **Rates of stillbirth, neonatal death, and extended perinatal death (stillbirth and neonatal deaths combined) for births that occurred in 2019 at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the UK and the devolved nations based on the mother's country of residence.**

2. **Trends in stillbirth, neonatal mortality and extended perinatal mortality rates for the UK and the devolved nations over the seven years of the MBRRACE-UK programme, 2013 to 2019.**

Results

Since 2015 there has been a steady reduction in the total number of births at 24^{+0} weeks or greater gestational age (excluding terminations of pregnancy) for the UK from 783,144 to 716,825 in 2019: an overall reduction of 66,319 (8.5%) births. Following the first report from MBRRACE-UK (2013) there has been a year on year reduction in both the total number of stillbirths and the total number of neonatal deaths, and this trend has continued in 2019: 2,399 stillbirths in 2019 compared with 2,579 in 2018 and 2,840 in 2017 and 1,158 neonatal deaths in 2019 compared with 1,199 in 2018 and 1,267 in 2017. The extended perinatal mortality rate for 2019 across the UK as a whole was 4.96 per 1,000 total births (5.13 in 2018), comprising 3.35 stillbirths per 1,000 total births (3.51 in 2018) and 1.62 neonatal deaths per 1,000 live births (1.64 in 2018).

Across the four UK, nations the lowest rate of both stillbirth and neonatal mortality in 2019 was in Scotland, although there was no overall change in the Scottish stillbirth rate which has remained at 3.22 per 1,000 total births since 2018 and the Scottish neonatal mortality rate has increased from 1.36 per 1,000 live births in 2018 to 1.49. For stillbirths the highest rate in 2019 was in Wales (4.02 per 1,000 total births, an increase from 3.76 in 2018) whilst the highest neonatal mortality rate was in Northern Ireland (2.85 per 1,000 live births, an increase from 2.05 in 2018). However, it is important to note that during this period stillbirth and, in particular neonatal mortality rates in Northern Ireland were influenced by differences in the law relating to termination of pregnancy, with more babies affected by major congenital anomalies being carried into the later stages of pregnancy and resulting in early neonatal deaths. The law in Northern Ireland was changed on 21st October 2019, decriminalising abortion in defined circumstances: this does not affect the data in this report as legislation governing the provision of abortion services did not come into force until 31st March 2020. As in previous years the number of babies born in the Crown Dependencies is too few to permit reliable comparison with the four countries of the UK.

Table 1: Number of births, stillbirths, neonatal deaths, and extended perinatal deaths by country of residence: United Kingdom and Crown Dependencies, for births in 2019

Number§	UK^	England	Scotland	Wales	Northern Ireland°	Crown Dep.
Total births	**716,825**	**612,522**	**49,737**	**29,815**	**22,548**	**2,122**
Live births	**714,426**	**610,482**	**49,577**	**29,695**	**22,475**	**2,118**
Stillbirths	**2,399**	**2,040**	**160**	**120**	**73**	**4**
Antepartum	2,121	1,804	139	107	65	4
Intrapartum	183	160	10	7	6	0
Unknown timing	95	76	11	6	2	0
Neonatal deaths	**1,158**	**948**	**74**	**69**	**64**	**3**
Early neonatal deaths	769	615	53	50	50	1
Late neonatal deaths	389	333	21	19	14	2
Perinatal deaths	**3,168**	**2,655**	**213**	**170**	**123**	**5**
Extended perinatal deaths	**3,557**	**2,988**	**234**	**189**	**137**	**7**

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
^ including the Crown Dependencies and mothers with unknown residency
° during the period reported different laws existed in Northern Ireland for the termination of pregnancy
Data sources: MBRRACE-UK, ONS, PDS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 2: Stillbirth, neonatal, and extended perinatal mortality rates (95% confidence intervals (CIs)) by country of residence: United Kingdom and Crown Dependencies, for births in 2019

Rate per 1,000 births§	UK^	England	Scotland	Wales	Northern Ireland°	Crown Dep.
Stillbirths†	**3.35**	**3.33**	**3.22**	**4.02**	**3.24**	**1.89**
	(3.21 to 3.48)	**(3.19 to 3.47)**	**(2.72 to 3.71)**	**(3.31 to 4.74)**	**(2.5 to 3.98)**	**(0.04 to 3.73)**
Antepartum†	2.96	2.95	2.79	3.59	2.88	1.89
	(2.83 to 3.08)	(2.81 to 3.08)	(2.33 to 3.26)	(2.91 to 4.27)	(2.18 to 3.58)	(0.04 to 3.73)
Intrapartum†	0.26	0.26	0.20	0.23	0.27	0.00
	(0.22 to 0.29)	(0.22 to 0.3)	(0.08 to 0.33)	(0.06 to 0.41)	(0.05 to 0.48)	(0.00 to 1.41)
Unknown timing†	0.13	0.12	0.22	0.20	0.09	0.00
	(0.11 to 0.16)	(0.10 to 0.15)	(0.09 to 0.35)	(0.04 to 0.36)	(0.00 to 0.21)	(0.00 to 1.41)
Neonatal deaths‡	**1.62**	**1.55**	**1.49**	**2.32**	**2.85**	**1.42**
	(1.53 to 1.71)	**(1.45 to 1.65)**	**(1.15 to 1.83)**	**(1.78 to 2.87)**	**(2.15 to 3.54)**	**(0 to 3.02)**
Early neonatal deaths‡	1.08	1.01	1.07	1.68	2.22	0.47
	(1 to 1.15)	(0.93 to 1.09)	(0.78 to 1.36)	(1.22 to 2.15)	(1.61 to 2.84)	(0.00 to 1.4)
Late neonatal deaths‡	0.54	0.55	0.42	0.64	0.62	0.94
	(0.49 to 0.6)	(0.49 to 0.6)	(0.24 to 0.6)	(0.35 to 0.93)	(0.3 to 0.95)	(0.00 to 2.25)
Perinatal deaths†	**4.42**	**4.33**	**4.28**	**5.70**	**5.46**	**2.36**
	(4.27 to 4.57)	**(4.17 to 4.5)**	**(3.71 to 4.86)**	**(4.85 to 6.56)**	**(4.49 to 6.42)**	**(0.29 to 4.42)**
Extended perinatal deaths†	**4.96**	**4.88**	**4.70**	**6.34**	**6.08**	**3.30**
	(4.8 to 5.12)	**(4.7 to 5.05)**	**(4.1 to 5.31)**	**(5.44 to 7.24)**	**(5.06 to 7.09)**	**(0.86 to 5.74)**

† per 1,000 total births
‡ per 1,000 live births
§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
° during the period reported different laws existed in Northern Ireland for the termination of pregnancy
^ including the Crown Dependencies and mothers with unknown residency
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

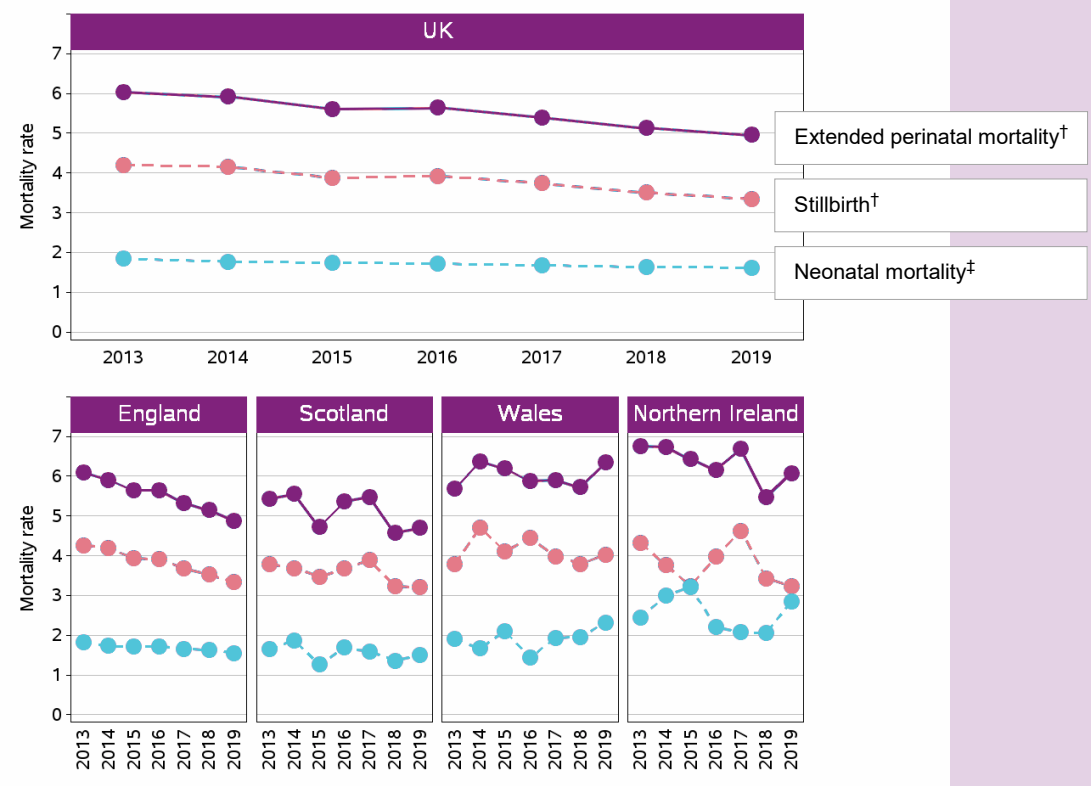
The overall reduction in stillbirth, neonatal and extended perinatal mortality the UK since 2013 is presented in Table 3 and Figure 1. This shows a fall of 20% in the stillbirth rate, 12% in the neonatal mortality rate and 18% in the extended perinatal mortality rate, across the seven years of the MBRRACE-UK programme. As over 85% of UK births occur in England this overall pattern reflects a decline over the seven year period in England but less evidence of change over time in the remaining devolved nations where rates show more year on year variation due to their smaller population size.

Table 3: Stillbirth, neonatal, and extended perinatal mortality rates (95% confidence intervals (CIs)): United Kingdom and Crown Dependencies, for births from 2013 to 2019

Stillbirths†	4.20	4.12	3.87	3.93	3.74	3.51	3.35
	(4.06 to 4.35)	(3.98 to 4.33	(3.73 to 4.01)	(3.79 to 4.07)	(3.60 to 3.87)	(3.37 to 3.64)	(3.21 to 3.48)
Extended perinatal deaths†	6.04	5.88	5.61	5.64	5.40	5.13	4.96
	(5.87 to 6.21)	(5.71 to 6.04)	(5.44 to 5.77)	(5.48 to 5.28)	(5.24 to 5.57)	(4.97 to 5.30)	(4.8 to 5.12)

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
◦ during the period reported different laws existed in Northern Ireland for the termination of pregnancy
† per 1,000 total births
‡ per 1,000 live births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Stillbirth, neonatal, and extended perinatal mortality rates for the UK and by country of residence: United Kingdom, for births from 2013 to 2019



† per 1,000 total births
‡ per 1,000 live births
Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
During the period reported different laws existed in Northern Ireland for the termination of pregnancy
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Implications

All four UK nations have initiatives in place to reduce perinatal mortality rates [1-4]. Although the initial target in England to reduce mortality rates by 20% by 2020 [2] has been met for stillbirths, the smaller reduction in neonatal mortality rates suggests that this target will not be met for neonatal deaths. Nevertheless even for stillbirths there is still much work to be done to achieve the English Department of Health's revised target of a 50% reduction in mortality rates by 2025 which would result in more favourable comparisons with other similar high income countries. This will not only entail the provision of the highest quality of health service delivery, ensuring relevant current standards and guidance are followed throughout the care pathway, but also initiatives addressing population socio-demographic and behavioural factors including:

- reduction of the wide inequalities in social deprivation;
- investigation of the causes of the excess perinatal mortality for Black, Asian and other ethnic minority populations;
- improved strategies to reduce obesity and smoking during pregnancy [5-8].

Given the slower progress towards the reduction in neonatal mortality rates emphasis should be placed on reducing rates of preterm birth, particularly the most extreme preterm group. Whilst there is evidence that outcomes from very preterm births (<32 weeks gestational age) in the UK are similar to other European and high income countries [9, 10] the higher rate (and consequent numbers) of very preterm birth in the UK results in high neonatal mortality rates. The prediction and prevention of preterm birth element of the Saving Babies' Lives Care Bundle [11], The Scottish Government's Best Start initiative [12], and other similar initiatives across the UK is therefore of major importance in the reduction of neonatal mortality rates.

Recommendation 1 **N**

Enhance current programmes in order to accelerate the reduction of stillbirths and neonatal deaths to meet national targets, with an emphasis on reducing rates of preterm birth, particularly the most extreme preterm group.

Recommendation requiring improved implementation

Develop public health initiatives to address issues linked to high risk populations.

MBRRACE-UK 2020 [13]

Mortality rates by gestational age

Key findings

- The overall reduction in the stillbirth rate is mainly due to a reduction in the rate of term stillbirths of one-fifth (19%), from 1.45 per 1,000 total births in 2015 to 1.17 in 2019.
- The largest reduction in the neonatal mortality rate was for very preterm births (28^{+0} to 31^{+6} weeks gestational age) of one-seventh (14%) from 33.8 per 1,000 live births in 2015 to 28.9 in 2019.
- Almost three-quarters of both stillbirths and neonatal deaths (including babies born at 22-23 weeks gestational age) were for preterm births (<37 weeks gestational age): 75% and 73% respectively.
- In 2019, 38% of stillbirths and 46% of neonatal deaths occurred in babies who were born extremely preterm (22^{+0} to 27^{+6} weeks gestational age).

Data presented

1. **Rates of stillbirth (including late fetal losses), neonatal death, and extended perinatal death (stillbirth and neonatal deaths combined) for births that occurred from 2015 to 2019 at 22^{+0} weeks gestational age or later (excluding terminations of pregnancy) in the UK, by gestational age.**
2. **Trends in rates of stillbirth (including late fetal losses), neonatal death, and extended perinatal death (stillbirth and neonatal deaths combined) for births that occurred from 2015 to 2019 at 22^{+0} weeks gestational age or later (excluding terminations of pregnancy) in the UK, by gestational age.**

Births with missing gestational age information were excluded (n=22,918 in 2019; 3% of births).

Results

The data shows the marked impact of preterm birth in relation to both stillbirth and neonatal death rates in the UK, with data for 2019 showing that almost three-quarters of stillbirths (including late fetal losses) and neonatal deaths were for births before 37 weeks gestational age (75% and 73% respectively). Including babies born at 22 to 23 weeks gestational age, almost two-fifths of stillbirths and just under half of neonatal deaths in 2019 were extremely preterm (<28 weeks gestational age): 38% and 46% respectively, once again emphasising the impact of preterm birth in the UK.

There have been reductions in extended perinatal mortality rates across all gestational age groups (Table 6), with the largest reduction in babies born at 37^{+0} to 41^{+6} weeks (16%). Excluding babies born at 42^{+0} weeks and over, who are most affected by short term variations because the number of deaths is extremely small, the largest reduction in deaths is seen for stillbirths at 37^{+0} to 41^{+6} weeks, with a fall in mortality rates of one-fifth (19%) over the most recent five year period. This is likely to reflect initiatives in place across the UK focusing on the reduction of term stillbirths. However, preterm stillbirth rates have also reduced over this five year period by 10% at 32^{+0} to 36^{+6} weeks, by 7% at 28^{+0} to 31^{+6} weeks and by 10% at 24^{+0} to 27^{+6} weeks. For neonatal deaths the largest reduction of one-eighth (12%) was seen at 28^{+0} to 32^{+6} weeks.

Table 4: Number and percentage of stillbirths and late fetal losses by gestational age at birth: United Kingdom and Crown Dependencies, for births from 2015 to 2019

Gestational age at birth (weeks)		2015	2016	2017	2018	2019
22^{+0}-23^{+6}	Births§	1,001	1,040	1,078	1,022	1,039
	Late fetal losses N (%)	524 (14.7)	529 (14.7)	530 (15.7)	508 (16.5)	514 (17.7)
	Rates per 1,000 births†	523.5	508.7	491.7	497.1	494.7
24^{+0}-27^{+6}	Births§	3,221	3,269	3,227	3,064	2,943
	Stillbirths N (%)	733 (20.6)	717 (19.9)	710 (21.1)	665 (21.6)	604 (20.7)
	Rates per 1,000 births†	227.6	219.3	220.0	217.0	205.2
28^{+0}-31^{+6}	Births§	6,558	6,620	6,540	6,083	5,958
	Stillbirths N (%)	495 (13.9)	512 (14.2)	482 (14.3)	467 (15.1)	417 (14.3)
	Rates per 1,000 births†	75.5	77.3	73.7	76.8	70.0
32^{+0}-36^{+6}	Births§	49,652	50,371	50,296	48,189	46,518
	Stillbirths N (%)	762 (21.4)	786 (21.9)	730 (21.7)	658 (21.3)	635 (21.8)
	Rates per 1,000 births†	15.3	15.6	14.5	13.7	13.7
37^{+0}-41^{+6}	Births§	704,733	678,093	660,980	637,280	625,274
	Stillbirths N (%)	1025 (28.8)	1031 (28.7)	894 (26.5)	772 (25.0)	733 (25.2)
	Rates per 1,000 births†	1.45	1.52	1.35	1.21	1.17
≥42	Births§	18,980	18,277	16,212	14,307	13,214
	Stillbirths N (%)	15 (0.4)	19 (0.5)	22 (0.7)	15 (0.5)	8 (0.3)
	Rates per 1,000 births†	0.79	1.04	1.36	1.05	0.61
	Total births	**784,145**	**757,670**	**738,333**	**709,945**	**694,946**

§ excluding terminations of pregnancy and births with missing gestational age
† per 1,000 total births
‡ per 1,000 live births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 5: Number and percentage of neonatal deaths by gestational age at birth: United Kingdom and Crown Dependencies, for births from 2015 to 2019

Gestational age at birth (weeks)		2015	2016	2017	2018	2019
22^{+0}-23^{+6}	Live births§	477	511	548	514	525
	Neonatal deaths N (%)	342 (20.1)	360 (21.3)	386 (23.4)	356 (22.9)	337 (22.6)
	Rates per 1,000 births‡	717.0	704.5	704.4	692.6	641.9
24^{+0}-27^{+6}	Live births§	2,488	2,552	2,517	2,399	2,339
	Neonatal deaths N (%)	383 (22.5)	404 (23.9)	365 (22.2)	342 (22.0)	349 (23.4)
	Rates per 1,000 births‡	153.9	158.3	145.0	142.6	149.2
28^{+0}-31^{+6}	Live births§	6,063	6,108	6,058	5,616	5,541
	Neonatal deaths N (%)	205 (12)	177 (10.5)	187 (11.4)	167 (10.8)	160 (10.7)
	Rates per 1,000 births‡	33.8	29.0	30.9	29.7	28.9
32^{+0}-36^{+6}	Live births§	48,890	49,585	49,566	47,531	45,883
	Neonatal deaths N (%)	271 (15.9)	275 (16.2)	270 (16.4)	244 (15.7)	241 (16.2)
	Rates per 1,000 births‡	5.54	5.55	5.45	5.13	5.25
37^{+0}-41^{+6}	Live births§	703,708	677,062	660,086	636,508	624,541
	Neonatal deaths N (%)	495 (29.1)	468 (27.6)	428 (26)	431 (27.8)	398 (26.7)
	Rates per 1,000 births‡	0.70	0.69	0.65	0.68	0.64
≥42	Births§	18,965	18,258	16,190	14,292	13,206
	Neonatal deaths N (%)	7 (0.4)	9 (0.5)	11 (0.7)	13 (0.8)	6 (0.4)
	Rates per 1,000 births‡	0.37	0.49	0.68	0.91	0.45
	Total live births	**780,591**	**754,076**	**734,965**	**706,860**	**692,035**

§ excluding terminations of pregnancy and births with missing gestational age
† per 1,000 total births
‡ per 1,000 live births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 6: Number and percentage of extended perinatal deaths by gestational age at birth: United Kingdom and Crown Dependencies, for births from 2015 to 2019

Gestational age at birth (weeks)		2015	2016	2017	2018	2019
22^{+0}-23^{+6}	Births§	1,001	1,040	1,078	1,022	1,039
	Extended perinatal deaths N (%)	866 (16.5)	889 (16.8)	916 (18.3)	864 (18.6)	851 (19.3)
	Rates per 1,000 births†	865.1	854.8	849.7	845.4	819.1
24^{+0}-27^{+6}	Births§	3,221	3,269	3,227	3,064	2,943
	Extended perinatal deaths N (%)	1116 (21.2)	1121 (21.2)	1075 (21.4)	1007 (21.7)	953 (21.6)
	Rates per 1,000 births†	346.5	342.9	333.1	328.7	323.8
28^{+0}-31^{+6}	Births§	6,558	6,620	6,540	6,083	5,958
	Extended perinatal deaths N (%)	700 (13.3)	689 (13)	669 (13.3)	634 (13.7)	577 (13.1)
	Rates per 1,000 births†	106.7	104.1	102.3	104.2	96.8
32^{+0}-36^{+6}	Births§	49,652	50,371	50,296	48,189	46,518
	Extended perinatal deaths N (%)	1033 (19.6)	1061 (20.1)	1000 (19.9)	902 (19.4)	876 (19.9)
	Rates per 1,000 births†	20.8	21.1	19.9	18.7	18.8
37^{+0}-41^{+6}	Births§	704,733	678,093	660,980	637,280	625,274
	Extended perinatal deaths N (%)	1520 (28.9)	1499 (28.4)	1322 (26.4)	1203 (25.9)	1131 (25.7)
	Rates per 1,000 births†	2.16	2.21	2.00	1.89	1.81
≥42	Births§	18,980	18,277	16,212	14,307	13,214
	Extended perinatal deaths N (%)	22 (0.4)	28 (0.5)	33 (0.7)	28 (0.6)	14 (0.3)
	Rates per 1,000 births†	1.16	1.53	2.04	1.96	1.06
	Total births	**784,145**	**757,670**	**738,333**	**709,945**	**694,946**

§ excluding terminations of pregnancy and births with missing gestational age
† per 1,000 total births
‡ per 1,000 live births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Implications

As noted in our last report, the large reduction in stillbirth rates for term births provides evidence of the successful implementation of targeted initiatives across the four nations of the UK. Most of this work was initially focused on reducing term stillbirths and the impact of this work is reflected in the largest rate of reduction of stillbirths being in this group. Newer initiatives, e.g. version 2 of the Saving Babies' Lives Care Bundle which was launched in March 2019, were only in place for part of the year for the data presented in this report. Such initiatives have expanded their focus to include the prevention of neonatal deaths and preterm births. It is too early to assess the impact of these initiatives, although it is pleasing to note that preterm stillbirth rates are showing a small reduction. However, there is little evidence of a similar trend in neonatal mortality rates.

The high rates of preterm in birth in the UK compared to other European countries [14] highlights the importance of intervention programmes to reduce preterm births and the need to use gestation specific mortality rates for international and between organisation comparisons. Furthermore, in order to ensure the standardised reporting of deaths before 24^{+0} weeks gestational age we would encourage healthcare professionals to use the MBRRACE-UK guidance for the assessment of signs of life in births before 24^{+0} weeks gestational age [15].

Recommendation 2 **N**

Continue to develop innovative new programmes of research into reducing preterm birth.

Recommendation 3 **N**

Use the MBRRACE-UK guidance for the assessment of signs of life in births before 24^{+0} weeks gestational age.

Recommendation requiring improved implementation

Ensure that healthcare providers have implemented national initiatives to reduce stillbirth and neonatal deaths and are monitoring their impact on reducing preterm birth.

MBRRACE-UK 2020 [13]

Effect of deprivation on perinatal mortality

Key findings

- Despite rates of stillbirth and neonatal mortality reducing over time, babies born to women living in the most deprived areas are twice as likely to be stillborn and at a 73% excess risk of neonatal death compared to babies born to women living in the least deprived areas; this excess risk has increased over the period from 2015 to 2019.

Data presented

1. **Rates of stillbirth and neonatal death for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by socio-economic deprivation quintile of mothers' residence.**

2. **Mortality rate ratios for stillbirths and neonatal deaths for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by socio-economic deprivation quintile of mothers' residence, relative to the least deprived group.**

Socio-economic deprivation is measured using the Children in Low-Income Families Local Measure [16] based on the mother's postcode of residence at the time of birth.

Results

The direct relationship between increasing levels of socio-economic deprivation and increasing stillbirth and neonatal mortality rates can be seen for all years (Table 7 and Table 8). While there is a decline in overall stillbirth rates over time, relative reductions have been least among babies born to women living in more deprived areas, with an 8% reduction in stillbirth rates from 5.05 to 4.67 per 1000 births between 2015 and 2019 for those living in the most deprived areas compared to a 22% reduction from 3.00 to 2.33 per 1000 births over the same period for those living in the least deprived areas. Similarly for neonatal mortality rates there was 9% reduction among babies born to women living in the most deprived areas between 2015 and 2019; from 2.28 to 2.07 per 1000 live births. This is compared to a 15% reduction in neonatal mortality over the same period among babies born to women living in the least deprived areas; from 1.41 to 1.20 per 1000 live births.

Relative to the least deprived group, mortality rate ratios for the other four quintiles of socio-economic deprivation show an increased risk with increasing levels of deprivation throughout the period 2015 to 2019. The increasing deprivation gap between the most affluent and most deprived women is particularly clear. The excess risk for babies born to women living in the most deprived quintile, compared to those living in the least deprived quintile, has increased from 68% to 100% for stillbirth (Table 9) and from 61% to 73% for neonatal death (Table 10).

Table 7: Stillbirth rates by socio-economic deprivation quintile of residence by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Socio economic deprivation quintile*		2015	2016	2017	2018	2019
1 - Least deprived	Stillbirths N (%)	464 (15.3)	456 (14.9)	424 (14.9)	387 (15.0)	330 (13.8)
	Rates per 1,000 births†	3.00	2.96	2.81	2.61	2.33
2	Stillbirths N (%)	513 (16.9)	546 (17.8)	471 (16.6)	400 (15.5)	387 (16.1)
	Rates per 1,000 births†	3.25	3.48	3.12	2.77	2.69
3	Stillbirths N (%)	570 (18.8)	608 (19.8)	545 (19.2)	504 (19.5)	478 (19.9)
	Rates per 1,000 births†	3.68	3.95	3.58	3.41	3.32
4	Stillbirths N (%)	690 (22.7)	671 (21.9)	660 (23.2)	596 (23.1)	528 (22.0)
	Rates per 1,000 births†	4.44	4.33	4.34	4.09	3.73
5 - Most deprived	Stillbirths N (%)	787 (25.9)	764 (24.9)	733 (25.8)	686 (26.6)	670 (27.9)
	Rates per 1,000 births†	5.05	4.91	4.84	4.68	4.67
Not known	Stillbirths N (%)	10 (0.3)	20 (0.7)	7 (0.2)	6 (0.2)	6 (0.25)
	Rates per 1,000 births†	2.09	4.33	2.74	2.40	2.43

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
† per 1,000 total births
• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 8: Neonatal mortality rates by mothers' socio-economic deprivation quintile of residence by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Socio economic deprivation quintile*		2015	2016	2017	2018	2019
1 - Least deprived	Neonatal deaths N (%)	218 (15.9)	186 (13.9)	199 (15.7)	182 (15.2)	169 (14.6)
	Rates per 1,000 births‡	1.41	1.21	1.32	1.23	1.20
2	Neonatal deaths N (%)	237 (17.3)	234 (17.5)	212 (16.7)	202 (16.8)	192 (16.6)
	Rates per 1,000 births‡	1.51	1.50	1.41	1.40	1.34
3	Neonatal deaths N (%)	247 (18.0)	257 (19.2)	230 (18.2)	235 (19.6)	230 (19.9)
	Rates per 1,000 births‡	1.60	1.68	1.52	1.59	1.60
4	Stillbirths N (%)	310 (22.6)	303 (22.7)	310 (24.5)	259 (21.6)	269 (23.2)
	Rates per 1,000 births‡	2.00	1.96	2.05	1.78	1.91
5 - Most deprived	Neonatal deaths N (%)	353 (25.7)	351 (26.3)	312 (24.6)	320 (26.7)	295 (25.5)
	Rates per 1,000 births‡	2.28	2.27	2.07	2.20	2.07
Not known	Neonatal deaths N (%)	8 (0.6)	6 (0.4)	4 (0.3)	1 (0.1)	3 (0.3)
	Rates per 1,000 births‡	1.68	1.31	1.57	0.40	1.22

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
‡ per 1,000 live births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 9: Ratios of mortality rates for stillbirth by mothers' socio-economic deprivation quintile of residence by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Socio economic deprivation quintile*	Ratio of mortality rates (95% confidence intervals)§				
	Stillbirths				
	2015	2016	2017	2018	2019
1 - Least deprived	Reference	Reference	Reference	Reference	Reference
2	1.08 (0.96 to 1.23)	1.18 (1.08 to 1.28)	1.11 (1.01 to 1.22)	1.06 (0.96 to 1.17)	1.15 (1.04 to 1.28)
3	1.23 (1.09 to 1.39)	1.33 (1.23 to 1.45)	1.27 (1.17 to 1.39)	1.31 (1.19 to 1.43)	1.42 (1.30 to 1.56)
4	1.48 (1.31 to 1.66)	1.46 (1.35 to 1.58)	1.54 (1.43 to 1.67)	1.57 (1.44 to 1.7)	1.60 (1.47 to 1.75)
5 - Most deprived	1.68 (1.50 to 1.89)	1.66 (1.54 to 1.78)	1.72 (1.60 to 1.86)	1.79 (1.66 to 1.94)	2.00 (1.85 to 2.17)

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 10: Ratios of mortality rates for neonatal death by mothers' socio-economic deprivation quintile of residence by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Socio economic deprivation quintile*	Ratio of mortality rates (95% confidence intervals)§				
	Neonatal deaths				
	2015	2016	2017	2018	2019
1 - Least deprived	Reference	Reference	Reference	Reference	Reference
2	1.07 (0.89 to 1.28)	1.24 (1.08 to 1.42)	1.07 (0.93 to 1.23)	1.14 (0.99 to 1.31)	1.12 (0.96 to 1.29)
3	1.13 (0.94 to 1.36)	1.39 (1.22 to 1.58)	1.15 (1.01 to 1.32)	1.29 (1.13 to 1.48)	1.33 (1.16 to 1.53)
4	1.42 (1.19 to 1.68)	1.62 (1.44 to 1.82)	1.55 (1.38 to 1.74)	1.45 (1.27 to 1.64)	1.59 (1.40 to 1.80)
5 - Most deprived	1.61 (1.36 to 1.91)	1.88 (1.68 to 2.09)	1.57 (1.40 to 1.76)	1.79 (1.59 to 2.01)	1.73 (1.53 to 1.94)

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Implications

Whilst there has been a reduction in the stillbirth and neonatal mortality rates across all levels of deprivation over the past five years, initiatives to reduce perinatal mortality do not appear to have been equally effective across those same groups, leading to a widening of the deprivation gap. This means that women living in the most deprived areas are now twice as likely to suffer a stillbirth as women living in the least deprived areas, and at over 70% excess risk of their baby dying during the neonatal period.

In order to have a major impact on these rates, public health, commissioning bodies and healthcare providers should co-ordinate intervention programmes to ensure maternity services are easily accessible by all women and to target interventions to try and reduce the impact of high socio-economic deprivation on women's health. A PhD studentship is currently underway at the University of Leicester to explore inequalities in adverse pregnancy outcome aiming to identify sub groups of women with multiple risk factors and their geographical distribution, to facilitate the development of focused intervention programmes.

Recommendation requiring improved implementation

Ensure that there is a multi-agency targeted approach affecting women living in areas of high socio-economic deprivation across all points of the reproductive, pregnancy and neonatal healthcare pathway.

MBRRACE-UK 2020 [13]

Effect of ethnicity on perinatal mortality

Key findings

- Mortality rates remain exceptionally high for babies of Black and Black British ethnicity: stillbirth rates are over twice those for babies of White ethnicity and neonatal mortality rates are 43% higher.
- Similarly, mortality rates remain high for babies of Asian and Asian British ethnicity: stillbirth and neonatal mortality rates are both around 60% higher than for babies of White ethnicity.

Data presented

1. **Rates of stillbirth and neonatal death for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by babies' ethnicity.**
2. **Mortality rate ratios for stillbirths and neonatal deaths for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by babies' ethnicity, relative to White ethnicity.**

Results

A reduction in stillbirth rates over time can be seen for all ethnic groups (Table 11). There has been an overall decrease in the rate of stillbirth for babies of Black or Black British ethnicity of 11.5% over the five years shown, although the rate of decrease has slowed substantially with only a 3% decrease between 2017 and 2019 (from 7.46 in 2017 to 7.23 per 1,000 total births in 2019). However a much larger 14% decrease in the rate of stillbirth can be seen for babies of Asian or Asian British ethnicity, reducing from 5.88 to 5.05 per 1,000 total births over the 2015 to 2019 period. This is greater than the 9% decrease seen in the rate of stillbirth for babies of White ethnicity (3.55 to 3.22 per 1,000 total births).

Whilst there was a small 5% reduction in neonatal mortality rates, between 2015 and 2019, in babies of White ethnicity (from 1.71 to 1.62 per 1,000 live births) and babies of Black or Black British ethnicity (from 2.45 to 2.32 per 1,000 live births) there was an overall 3% increase in neonatal mortality rates for babies of Asian and Asian British ethnicity over the same period (Table 12). This is mainly due to the higher neonatal mortality rates seen in 2016 and 2017 following the lowest reported rate for this group over this period in 2015. Consequently there is little change in neonatal mortality rates for babies of Asian and Asian British ethnicity for 2015 and 2019.

Despite the reduction in both stillbirth and neonatal mortality rates over time across most groups, these reductions have not been the same across all ethnicities. As a result there has been a small increase in the ratio of stillbirth rates for babies of Black or Black British ethnicity compared to babies of White ethnicity (Tables 13 and 14). Compared to babies of White ethnicity, babies of Black or Black British ethnicity remain at over twice the risk of stillbirth (124% increased risk). Babies of Black or Black British ethnicity remain at 43% increased risk of neonatal mortality compared to babies of White ethnicity. Babies of Asian or Asian British ethnicity are at 57% increased risk of stillbirth and 59% increased risk of neonatal mortality compared to babies of White ethnicity. These marked differences in risk, particularly the risk of stillbirth, suggest that current interventions continue to have more impact on babies of White ethnicity.

Table 11: Stillbirth rates by babies' ethnicity by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Baby s ethnicity		2015	2016	2017	2018	2019
White	Stillbirths N (%)	1,987 (65.5)	2,067 (67.4)	1,911 (67.3)	1,738 (67.4)	1,606 (66.9)
	Rates per 1,000 births†	3.55	3.74	3.59	3.39	3.22
Mixed	Stillbirths N (%)	162 (5.3)	164 (5.4)	184 (6.5)	170 (6.6)	146 (6.1)
	Rates per 1,000 births†	4.11	4.01	4.56	4.25	3.58
Asian, Asian British	Stillbirths N (%)	433 (14.3)	457 (14.9)	415 (14.6)	370 (14.3)	359 (15.0)
	Rates per 1,000 births†	5.88	6.09	5.70	5.31	5.05
Black, Black British	Stillbirths N (%)	269 (8.9)	275 (9.0)	239 (8.4)	226 (8.8)	220 (9.2)
	Rates per 1,000 births†	8.17	8.29	7.46	7.35	7.23
Other	Stillbirths N (%)	71 (2.3)	87 (2.8)	73 (2.6)	64 (2.5)	56 (2.3)
	Rates per 1,000 births†	3.56	4.14	3.68	3.29	2.95
Refused/Not Known	Stillbirths N (%)	112 (3.7)	15 (0.5)	18 (0.6)	11 (0.4)	12 (0.5)
	Rates per 1,000 births†					

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
† per 1,000 total births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 12: Neonatal mortality rates by babies' ethnicity by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Socio economic deprivation quintile*		2015	2016	2017	2018	2019
White	Neonatal deaths N (%)	953 (69.4)	937 (70.1)	878 (69.3)	843 (70.3)	802 (69.3)
	Rates per 1,000 births‡	1.71	1.70	1.66	1.65	1.62
Mixed	Neonatal deaths N (%)	65 (4.7)	71 (5.3)	54 (4.3)	62 (5.2)	51 (4.4)
	Rates per 1,000 births‡	1.66	1.74	1.34	1.56	1.25
Asian, Asian British	Neonatal deaths N (%)	183 (13.3)	211 (15.8)	207 (16.3)	182 (15.2)	182 (15.7)
	Rates per 1,000 births‡	2.50	2.83	2.86	2.63	2.57
Black, Black British	Stillbirths N (%)	80 (5.8)	84 (6.3)	88 (6.9)	73 (6.1)	70 (6.0)
	Rates per 1,000 births‡	2.45	2.55	2.77	2.39	2.32
Other	Neonatal deaths N (%)	32 (2.3)	29 (2.2)	32 (2.5)	26 (2.2)	37 (3.2)
	Rates per 1,000 births‡	1.61	1.38	1.62	1.34	1.95
Refused/Not Known	Neonatal deaths N (%)	60 (4.4)	5 (0.4)	8 (0.6)	13 (1.1)	16 (1.4)
	Rates per 1,000 births‡					

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
‡ per 1,000 live births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 13: Ratios of mortality rates for stillbirth by babies' ethnicity by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Socio economic deprivation quintile*	Ratio of mortality rates (95% confidence intervals)§				
	Stillbirths				
	2015	2016	2017	2018	2019
White	Reference	Reference	Reference	Reference	Reference
Mixed	1.16 (0.99 to 1.36)	1.07 (0.92 to 1.25)	1.27 (1.10 to 1.47)	1.25 (1.08 to 1.46)	1.11 (0.94 to 1.31)
Asian, Asian British	1.66 (1.49 to 1.84)	1.63 (1.48 to 1.78)	1.59 (1.44 to 1.75)	1.57 (1.41 to 1.73)	1.57 (1.41 to 1.74)
Black, Black British	2.30 (2.03 to 2.61)	2.21 (1.97 to 2.49)	2.08 (1.83 to 2.36)	2.17 (1.90 to 2.47)	2.24 (1.96 to 2.56)
Other	1.00 (0.79 to 1.27)	1.10 (0.89 to 1.36)	1.02 (0.81 to 1.29)	0.97 (0.76 to 1.24)	0.91 (0.70 to 1.19)

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 14: Ratios of mortality rates for neonatal death by babies' ethnicity by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Socio economic deprivation quintile*	Ratio of mortality rates (95% confidence intervals)§				
	Neonatal deaths				
	2015	2016	2017	2018	2019
White	Reference	Reference	Reference	Reference	Reference
Mixed	0.97 (0.75 to 1.25)	1.02 (0.81 to 1.29)	0.81 (0.62 to 1.06)	0.94 (0.73 to 1.21)	0.78 (0.59 to 1.02)
Asian, Asian British	1.46 (1.25 to 1.71)	1.66 (1.45 to 1.90)	1.73 (1.50 to 1.98)	1.59 (1.37 to 1.84)	1.59 (1.38 to 1.84)
Black, Black British	1.43 (1.14 to 1.80)	1.50 (1.21 to 1.86)	1.67 (1.35 to 2.06)	1.45 (1.15 to 1.82)	1.43 (1.13 to 1.81)
Other	0.94 (0.66 to 1.34)	0.81 (0.56 to 1.17)	0.98 (0.69 to 1.38)	0.81 (0.55 to 1.19)	1.21 (0.88 to 1.67)

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Implications

Interventions to reduce stillbirth and neonatal mortality rates are leading to reductions in these rates across all ethnicities. Nevertheless the small upturn in the ratio of mortality rates for babies of Black and Black British ethnicity compared to babies of White ethnicity suggests that current interventions are having a larger impact on outcomes of babies of White ethnicity which needs to be addressed. As such a more targeted approach is required for the Black and Black British population. Further work is required to investigate the high rates of stillbirth and neonatal death for both the Black and Asian communities to facilitate the development of new intervention programmes for these populations. The current MBRRACE-UK confidential enquiry, which will report in 2022, is reviewing the quality of care provision provided for mothers and babies of Black and Black British ethnicity to identify areas where care could be improved and to assess whether the care provided for these communities is equitable. In the development of this enquiry we included key stakeholder groups to ensure that we considered those issues pertinent to Black and Black British women.

Recommendation requiring improved implementation

Identify the specific needs of Black and Asian populations and ensure that these are addressed as part of their reproductive and pregnancy healthcare provision.

MBRRACE-UK 2020 [13]

Effect of mother's age on perinatal mortality

Key findings

- The lowest stillbirth and neonatal mortality rates are for mothers aged 30 to 34 years: stillbirths, 3.15 per 1,000 total births and neonatal deaths, 1.50 per 1,000 live births.
- The largest reductions in both stillbirth and neonatal mortality rates were for babies born to the oldest mothers.
- Mothers aged under 20 are at a 33% increased risk of stillbirth and a 75% increased risk of neonatal death compared to mothers aged 30-34.
- Mothers aged 40 and above are at a 41% increased risk of stillbirth and a 37% increased risk of neonatal death compared with mothers aged 30-34.

Data presented

1. **Rates of stillbirth and neonatal death for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by mother's age.**
2. **Mortality rate ratios for stillbirths and neonatal deaths for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by mother's age, relative to age 30-34.**

Results

A reduction in stillbirth rates over time can be seen for all age groups (Table 15), with the largest reductions seen in the oldest mothers. For mothers aged 35-39 there has been a 17% reduction in the stillbirth rate over the five year period (down from 4.36 to 3.61 per 1,000 total births), with a 21% reduction in the stillbirth rate for mothers aged 40 and over (down from 5.62 to 4.45 per 1,000 total births).

For neonatal mortality the picture is less clear, with more fluctuation in rates over time (Table 16). The largest reductions in mortality over the five years are again seen in babies born to the oldest mothers. For mothers aged 35-39 there has been a 15% reduction in the neonatal mortality rate over the five year period (down from 1.85 to 1.57 per 1,000 total births), with an 18% reduction in the neonatal mortality rate for mothers aged 40 and over (down from 2.52 to 2.06 per 1,000 total births).

Stillbirth and neonatal mortality rate ratios show some fluctuation over time across almost all age groups (Tables 17 and 18). The youngest and oldest groups of mothers remain at the highest risk of stillbirth and neonatal death compared to mothers aged 30-34. Mothers aged under 20 are at a 33% increased risk of stillbirth and a 75% increased risk of neonatal death compared to mothers aged 30-34. Mothers aged over 40 are at a 41% increased risk of stillbirth and a 37% increased risk of neonatal death compared with mothers aged 30-34.

Table 15: Stillbirth rates by mother's age by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Mother s age		2015	2016	2017	2018	2019
<20	Stillbirths N (%)	122 (4.0)	125 (4.1)	120 (4.2)	109 (4.2)	82 (3.4)
	Rates per 1,000 births†	4.65	5.05	5.31	5.25	4.20
20-24	Stillbirths N (%)	500 (16.5)	539 (17.6)	464 (16.3)	420 (16.3)	362 (15.1)
	Rates per 1,000 births†	4.22	4.77	4.34	4.24	3.82
25-29	Stillbirths N (%)	804 (26.5)	799 (26.1)	762 (26.8)	631 (24.5)	618 (25.8)
	Rates per 1,000 births†	3.73	3.74	3.68	3.22	3.26
30-34	Stillbirths N (%)	858 (28.3)	832 (27.1)	788 (27.7)	735 (28.5)	719 (30.0)
	Rates per 1,000 births†	3.62	3.47	3.34	3.19	3.15
35-39	Stillbirths N (%)	573 (18.9)	560 (18.3)	541 (19.0)	520 (20.2)	476 (19.8)
	Rates per 1,000 births†	4.36	4.12	3.98	3.88	3.61
≥40	Stillbirths N (%)	175 (5.8)	210 (6.9)	165 (5.8)	163 (6.3)	141 (5.9)
	Rates per 1,000 births†	5.62	6.61	5.27	5.30	4.45
Not known	Stillbirths N (%)	2 (0.1)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)
	Rates per 1,000 births†	0.08	0.00	0.00	0.04	0.05

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
† per 1,000 total births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 16: Neonatal mortality rates by mother's age by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Mother s age		2015	2016	2017	2018	2019
<20	Neonatal deaths N (%)	77 (5.6)	80 (6.0)	67 (5.3)	51 (4.3)	51 (4.4)
	Rates per 1,000 births‡	2.95	3.25	2.98	2.47	2.62
20-24	Neonatal deaths N (%)	239 (17.4)	226 (16.9)	200 (15.8)	204 (17.0)	177 (15.3)
	Rates per 1,000 births‡	2.03	2.01	1.88	2.07	1.88
25-29	Neonatal deaths N (%)	360 (26.2)	340 (25.4)	329 (26.0)	315 (26.3)	317 (27.4)
	Rates per 1,000 births‡	1.68	1.60	1.59	1.61	1.68
30-34	Stillbirths N (%)	377 (27.5)	380 (28.4)	365 (28.8)	336 (28.0)	342 (29.5)
	Rates per 1,000 births‡	1.60	1.59	1.55	1.46	1.50
35-39	Neonatal deaths N (%)	242 (17.6)	226 (16.9)	231 (18.2)	222 (18.5)	206 (17.8)
	Rates per 1,000 births‡	1.85	1.67	1.71	1.66	1.57
≥40	Neonatal deaths N (%)	78 (5.7)	85 (6.4)	75 (5.9)	71 (5.9)	65 (5.6)
	Rates per 1,000 births‡	2.52	2.69	2.41	2.32	2.06
Not known	Neonatal deaths N (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Rates per 1,000 births‡	0.00	0.00	0.00	0.00	0.00

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
‡ per 1,000 live births
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 17: Ratios of mortality rates for stillbirth by mother's age by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Mother s age	Ratio of mortality rates (95% confidence intervals)§				
	Stillbirths				
	2015	2016	2017	2018	2019
<20	1.28 (1.06 to 1.55)	1.46 (1.22 to 1.74)	1.59 (1.33 to 1.90)	1.65 (1.36 to 1.99)	1.33 (1.07 to 1.66)
20-24	1.17 (1.04 to 1.30)	1.37 (1.26 to 1.5)	1.30 (1.19 to 1.42)	1.33 (1.21 to 1.46)	1.21 (1.09 to 1.35)
25-29	1.03 (0.94 to 1.13)	1.08 (1.00 to 1.16)	1.10 (1.03 to 1.18)	1.01 (0.93 to 1.09)	1.03 (0.96 to 1.12)
30-34	Reference	Reference	Reference	Reference	Reference
35-39	1.20 (1.08 to 1.34)	1.19 (1.09 to 1.29)	1.19 (1.09 to 1.30)	1.22 (1.11 to 1.33)	1.15 (1.05 to 1.26)
≥40	1.55 (1.32 to 1.82)	1.90 (1.66 to 2.18)	1.58 (1.35 to 1.84)	1.66 (1.42 to 1.94)	1.41 (1.20 to 1.67)

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 18: Ratios of mortality rates for neonatal death by mother's age by year: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Mother s age	Ratio of mortality rates (95% confidence intervals)§				
	Neonatal deaths				
	2015	2016	2017	2018	2019
<20	1.85 (1.44 to 2.36)	2.04 (1.64 to 2.55)	1.92 (1.51 to 2.45)	1.69 (1.28 to 2.23)	1.75 (1.32 to 2.30)
20-24	1.27 (1.08 to 1.49)	1.26 (1.11 to 1.44)	1.21 (1.05 to 1.40)	1.42 (1.23 to 1.63)	1.25 (1.08 to 1.46)
25-29	1.05 (0.91 to 1.21)	1.08 (1.00 to 1.16)	1.10 (1.03 to 1.18)	1.01 (0.93 to 1.09)	1.03 (0.96 to 1.12)
30-34	Reference	Reference	Reference	Reference	Reference
35-39	1.16 (0.99 to 1.36)	1.05 (0.92 to 1.2)	1.10 (0.97 to 1.26)	1.14 (0.99 to 1.30)	1.05 (0.91 to 1.20)
≥40	1.58 (1.24 to 2.01)	1.69 (1.36 to 2.1)	1.55 (1.24 to 1.95)	1.59 (1.26 to 2.01)	1.37 (1.07 to 1.76)

§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Implications

The excess stillbirth and neonatal mortality rates associated with teenage pregnancy and older mothers (>40 years) has been known for many years [17-19]. Successful public health strategies to reduce the rate of conceptions for women aged <18 years are in place in all UK nations [20-24]. Recent data from the Office for National Statistic for England and Wales has shown that both the teenage conception and birth rates have declined year on year since 2007 [25]. However, despite this reduction, in 2018 over half of conceptions for women aged <18 years resulted in abortion suggesting that more work is needed to prevent unwanted pregnancies. Continuing efforts to reduce teenage pregnancy by improving sex education and access to sexual and reproductive health services, including health education, may also help reduce stillbirth and neonatal mortality rates for these women.

Numbers of births to older mothers aged 40 years or more increased steadily in the 1990s and 2000s up until 2012 and have remained fairly constant since then, despite the overall average age of mothers increasing to 30.7 years over the past decade [26]. Older women are more likely have one or more complication of pregnancy

such as hypertension, diabetes and placental problems as well as being at increased risk of their baby having a chromosomal anomaly. Adherence to standards and guidance developed by the RCOG and NICE [27, 28] with respect to screening and monitoring for these women is therefore important and should be regularly audited in an effort to reduce adverse outcomes such as preterm births and associated neonatal deaths as well as stillbirths. One particular area of concern is the increased risk of stillbirth at around term with advancing maternal age [29]. Older women in particular should therefore be counselled in order to inform decision making around birth.

Younger and older mothers require detailed information about the increased risks associated with their pregnancy to empower them to make informed decisions about their care.

Recommendation 4 **N**

Ensure the continuation of targeted initiatives with health education organisations not only aimed at reducing teenage pregnancy but also providing pre-conception advice.

Recommendation 5 **N**

Provide pre- and post-conception information for women aged 35 and over, clarifying the risk of stillbirth and neonatal death associated with increased maternal age to empower their decision making throughout the care pathway.

Multidimensional effects of ethnicity, deprivation and mother's age on perinatal mortality

Key findings

- Stillbirth and neonatal mortality rates increased with deprivation and were higher for mothers under 25 years and over 35 years across all ethnic groups.
- Stillbirth rates and neonatal mortality rates were lowest for babies of White ethnicity born to mothers aged 25 to 34 living in the least deprived areas (2.61 to 2.76 stillbirths per 1,000 total births and 1.24 to 1.26 neonatal deaths per 1,000 live births).
- The multiple impact of ethnicity, mother's age and deprivation is highlighted by a stillbirth rate of 10.54 and 6.91 per 1,000 total births for babies of Black and Black British ethnicity and Asian and Asian British ethnicity respectively born to mothers aged over 35 years living in the most deprived areas.
- Neonatal mortality rates were over 3 per 1,000 live births for babies of Black and Black British ethnicity and Asian and Asian British ethnicity born to mothers under 25 years and over 35 years living in the most deprived areas.
- Due to high proportions of babies of Black and Black British ethnicity being born to mothers living in deprived areas, they are disproportionately affected by the higher rates of stillbirth associated with deprivation.

Data presented

Rates of stillbirth and neonatal death for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by baby's ethnicity, mother's age and mother's socio-economic deprivation quintile of residence.

This chapter focuses on four main categories of ethnicity: Black, Asian, White and Mixed; Other and Unknown categories have been excluded. Due to small numbers issues maternal age has been categorised into four groups for this chapter: <25 years, 25-29 years, 30 to 34 years and 35+ years. Socio-economic deprivation is measured using the Children in Low-Income Families Local Measure [16] based on the mother's postcode of residence at the time of birth.

Results

Rates should be considered in combination with the accompanying birth numbers (Tables 21 and 22). Rates for some combinations of age, ethnicity and deprivation **must be treated with extreme caution** due to small numbers. More detailed population characteristics information is available in the accompanying Tables and Figures document (available at: https://www.npeu.ox.ac.uk/mbrrace-uk/reports).

Exploring stillbirth rates in a multidimensional way shows wide inequalities by baby's ethnicity, deprivation and mother's age, with rates for the five year period 2015 to 2019 varying between 1.55 and 10.78 stillbirths per 1,000 total births. For all ethnicities, rates of stillbirth generally increased with increasing deprivation and were higher for mothers aged under 25 and over 35.

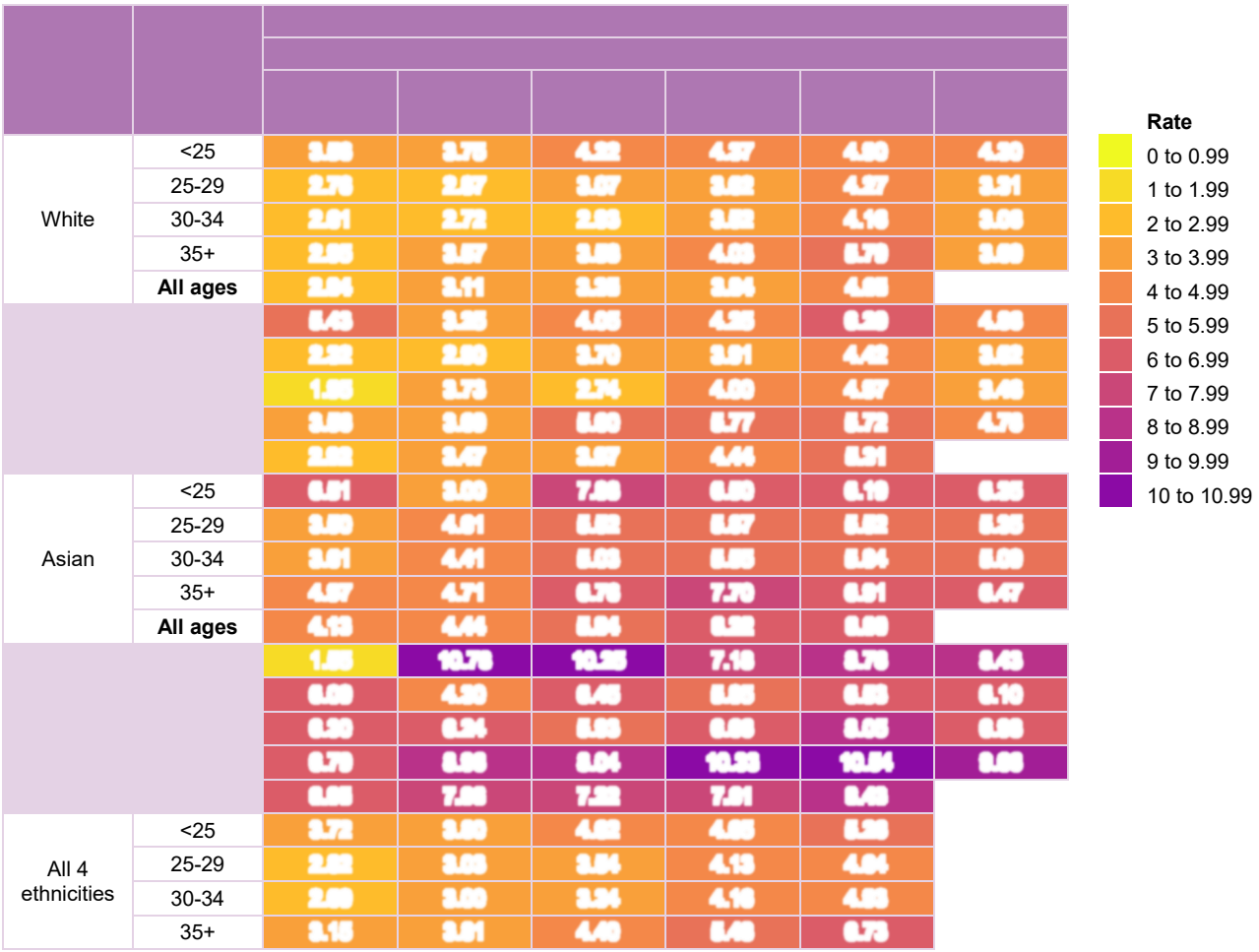
For babies of White ethnicity stillbirth rates varied from 2.61 per 1,000 total births for babies born to mothers aged 30 to 34 living in the least deprived quintile, to 5.79 per 1,000 total births for mothers over 35 in the most

deprived quintile. Rates of stillbirth for babies of mixed or multiple ethnicity were extremely similar to those of White ethnicity ranging between 1.95 and 6.29 per 1,000 total births.

For babies of Asian and Asian British ethnicity, rates of stillbirth ranged between 3.00 and 7.88 per 1,000 total births. Based on the comparison outlined for babies of White ethnicity, rates were 3.61 per 1,000 total births for babies born to mothers aged 25 to 29 and living in the least deprived areas compared to 6.91 per 1,000 total births for babies born to mothers aged over 35 living in the most deprived areas.

Rates were highest for babies of Black and Black British ethnicity with the majority of stillbirth rates by deprivation quintile and mother's age exceeding the highest stillbirth rate of 5.79 per 1,000 total births seen for babies of White ethnicity. As a comparison, rates were 6.30 per 1,000 total births for Black and Black British babies born to mothers aged 30 to 34 and living in the least deprived areas compared to 10.54 per 1,000 total births for babies born to mothers aged over 35 living in the most deprived areas.

Table 19: Stillbirths rates by baby's ethnicity, mother's age and mother's socio-economic deprivation quintile of residence: United Kingdom and Crown Dependencies, for births in 2015 to 2019



§ excluding terminations of pregnancy and births <24+0 weeks gestational age
• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

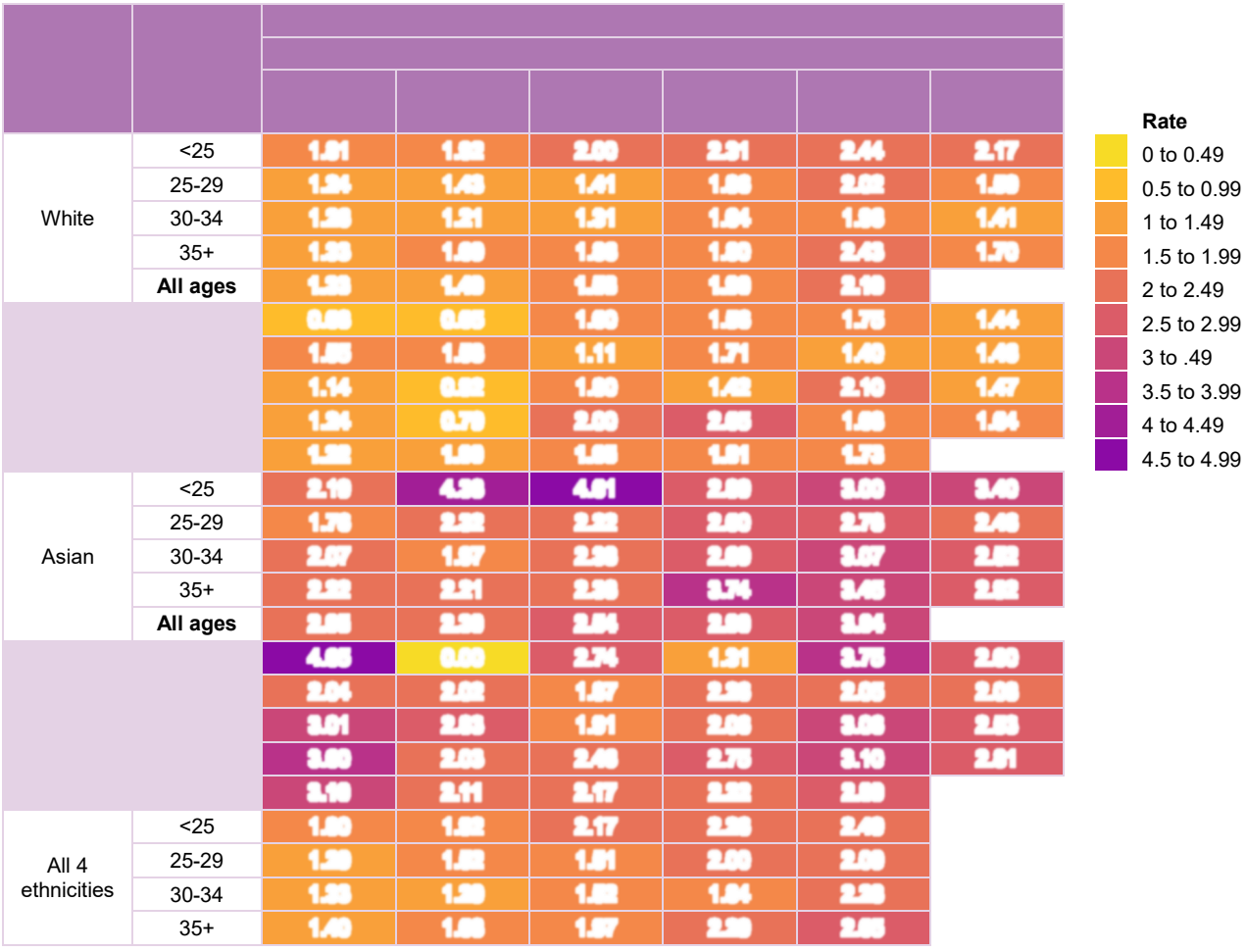
For neonatal mortality the picture is similar with, for all ethnic groups, a general trend of increasing rates of neonatal mortality with increasing deprivation and for babies born to mothers aged under 25 and over 35.

For babies of White ethnicity the lowest neonatal mortality rates were for babies born to mothers aged 25 to 29 living in the least deprived quintile (1.24 per 1,000 live births) and aged 30 to 34 living in the second least deprived quintile (1.21 per 1,000 live births. The highest rates of neonatal mortality for this group of babies were for those born to mothers over 35 and under 25 in the most deprived quintile (2.43 and 2.44 per 1,000 live births

respectively). Again, rates of neonatal death for babies of Mixed or multiple ethnicity were extremely similar to those of White ethnicity ranging between 0.65 and 2.65 per 1,000 live births.

For babies of Asian and Asian British ethnicity, rates of neonatal death ranged between 1.76 per 1,000 live births for babies born to mothers aged 25 to 29 living in the least deprived areas to 3.74 and 3.45 per 1,000 live births for babies born to mothers over 35 living in the second most and most deprived quintiles respectively. Rates of neonatal mortality were similarly high for babies of Black and Black British ethnicity, with rates over 3 per 1,000 live births for babies born to mothers of all ages except those aged 25 to 29 living in the most deprived quintile.

Table 20: Neonatal mortality rates by baby's ethnicity, mother's age and mother's socio-economic deprivation quintile of residence: United Kingdom and Crown Dependencies, for births in 2015 to 2019



§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 21: Total births by baby's ethnicity, mother's age and mother's socio-economic deprivation quintile of residence: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Baby's ethnicity	Mother's age	Total births					
		Socio economic deprivation quintile*					
		1 Least deprived	2	3	4	5 Most deprived	All quintiles
White	<25	55,348	82,142	101,146	116,597	147,572	502,805
	25-29	135,302	157,577	154,639	145,676	145,960	739,154
	30-34	222,352	198,773	163,535	133,653	112,383	830,696
	35+	179,390	139,576	106,575	82,134	63,851	571,526
	All ages	**592,392**	**578,068**	**525,895**	**478,060**	**469,766**	**2,644,181**
Mixed	<25	2,948	4,620	6,911	9,648	12,090	36,217
	25-29	6,476	8,264	9,990	11,767	12,888	49,385
	30-34	12,286	12,060	12,792	12,744	11,469	61,351
	35+	12,932	11,393	11,081	10,231	8,392	54,029
	All ages	**34,642**	**36,337**	**40,774**	**44,390**	**44,839**	**200,982**
Asian	<25	1,842	3,664	7,873	11,839	12,114	37,332
	25-29	8,562	13,885	25,354	32,540	29,694	110,035
	30-34	15,496	20,428	31,192	35,145	29,812	132,073
	35+	10,869	13,175	18,652	21,032	18,663	82,391
	All ages	**36,769**	**51,152**	**83,071**	**100,556**	**90,283**	**361,831**
Black	<25	646	1,392	3,316	6,131	8,332	19,817
	25-29	1,969	3,485	6,980	12,489	16,685	41,608
	30-34	3,014	4,970	8,935	15,172	18,758	50,849
	35+	2,799	4,465	8,208	14,327	16,975	46,774
	All ages	**8,428**	**14,312**	**27,439**	**48,119**	**60,750**	**159,048**
All 4 ethnicities	<25	60,784	91,818	119,246	144,215	180,108	596,171
	25-29	152,309	183,211	196,963	202,472	205,227	940,182
	30-34	253,148	236,231	216,454	196,714	172,422	1,074,969
	35+	205,990	168,609	144,516	127,724	107,881	754,720

• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 22: Live births by baby's ethnicity, mother's age and mother's socio-economic deprivation quintile of residence: United Kingdom and Crown Dependencies, for births in 2015 to 2019

Baby's ethnicity	Mother's age	Total live births					
		Socio economic deprivation quintile*					
		1 Least deprived	2	3	4	5 Most deprived	All quintiles
White	<25	55,151	81,834	100,719	116,088	146,849	500,641
	25-29	134,929	157,125	154,164	145,149	145,337	736,704
	30-34	221,771	198,232	163,056	133,182	111,915	828,156
	35+	178,860	139,078	106,193	81,803	63,481	569,415
	All ages	**590,711**	**576,269**	**524,132**	**476,222**	**467,582**	**2,634,916**
Mixed	<25	2,932	4,605	6,883	9,607	12,014	36,041
	25-29	6,461	8,240	9,953	11,721	12,831	49,206
	30-34	12,262	12,015	12,757	12,693	11,412	61,139
	35+	12,886	11,351	11,019	10,172	8,344	53,772
	All ages	**34,541**	**36,211**	**40,612**	**44,193**	**44,601**	**200,158**
Asian	<25	1,830	3,653	7,811	11,762	12,039	37,095
	25-29	8,532	13,821	25,214	32,349	29,530	109,446
	30-34	15,440	20,338	31,035	34,950	29,638	131,401
	35+	10,815	13,113	18,526	20,870	18,534	81,858
	All ages	**36,617**	**50,925**	**82,586**	**99,931**	**89,741**	**359,800**
Black	<25	645	1,377	3,282	6,087	8,259	19,650
	25-29	1,957	3,470	6,935	12,416	16,576	41,354
	30-34	2,995	4,939	8,882	15,071	18,607	50,494
	35+	2,780	4,425	8,142	14,179	16,796	46,322
	All ages	**8,377**	**14,211**	**27,241**	**47,753**	**60,238**	**157,820**
All 4 ethnicities	<25	60,558	91,469	118,695	143,544	179,161	593,427
	25-29	151,879	182,656	196,266	201,635	204,274	936,710
	30-34	252,468	235,524	215,730	195,896	171,572	1,071,190
	35+	205,341	167,967	143,880	127,024	107,155	751,367

• based on mothers' postcodes at time of birth, using the Children in Low-Income Families Local Measure
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Implications

This multidimensional analysis provides additional information for public health specialists, commissioners and service providers to develop initiatives targeted at those groups of mothers at the highest risk of having a baby stillborn or who dies within the neonatal period.

Due to the increased proportion of babies of Black and Black British ethnicity and to a slightly lesser extent babies of Asian and Asian British ethnicity being born to mothers living in more deprived areas they are disproportionately experiencing the higher rates observed with increasing deprivation compared to babies born to mothers of White ethnicity who were more likely to be living in less deprived areas. Only 5% of babies of Black and Black British ethnicity and 10% of babies of Asian and Asian British ethnicity were born to mothers living in the least deprived quintile compared to 22% of babies of White ethnicity. Conversely 38% of babies Black and Black British ethnicity and 25% of babies of Asian and Asian British ethnicity were born to mothers living in the most deprived quintile compared to 18% of babies of White ethnicity. This differential in the distribution of births across the quintiles of deprivation should be taken into consideration when comparing the mortality rates for babies born to Black and Black British mothers or Asian and Asian British mothers with those for babies born to White mothers.

This analysis highlights that babies of Black and Black British and Asian and Asian British mothers are not only at increased risk of being stillborn or dying in the neonatal period but they are also more likely to experience multiple other risk factors such as maternal age and deprivation. This is further confirmation that inequalities lead to an increase in the risk of stillbirth or neonatal death relating to ethnicity, deprivation and maternal age.

Further exploration of these factors to help inform effective interventions is currently being finalised to be submitted for publication.

If the English Department of Health is to achieve its target of reducing stillbirth and neonatal mortality rates by 50% by 2025 [2] then more research is needed to develop effective interventions to address these issues.

Recommendation 6 **N**

Initiate a research programme to inform the development of effective interventions to address health inequalities and reduce stillbirth and neonatal mortality rates.

Recommendation 7 **N**

Develop focused initiatives to reduce stillbirths and neonatal deaths among groups of mothers at the highest risk, informed by the multidimensional effects of ethnicity, deprivation and mother's age.

Perinatal mortality rates for Trusts and Health Boards

Key findings

- After adjustment for risk factors and unit size, stillbirth rates show little variation between Trusts and Health Boards with stabilised & adjusted rates for almost all (97%) organisations falling within 5% of their comparator group average.
- Stabilised & adjusted neonatal mortality rates for organisations which care for the most complex pregnancies and births show wide variation: only 13% of Trusts and Health Boards with a Level 3 Neonatal Intensive Care Unit (NICU) and neonatal surgical provision had a stabilised and adjusted neonatal mortality rate within 5% of their comparator group average.
- Exclusion of deaths due to congenital anomalies removes variation in stabilised & adjusted stillbirth rates almost entirely, resulting in all Trusts and Health Boards falling within 5% of their comparator group average.
- Exclusion of deaths due to congenital anomalies has little effect on the variation in stabilised & adjusted neonatal mortality rates, with only 12% of Trusts and Health Boards with a Level 3 Neonatal Intensive Care Unit (NICU) and neonatal surgical provision having a stabilised and adjusted neonatal mortality rate within 5% of their comparator group average.

Data presented

Variation in stabilised and adjusted rates of stillbirth, neonatal death, and extended perinatal death (stillbirth and neonatal deaths combined) for births that occurred in 2019 at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) by Trust and Health Board, with and without deaths due to congenital anomalies.

To account for the wide variation in case-mix, Trusts and Health Boards were classified hierarchically into five mutually exclusive comparator groups, based on their level of service provision:

1. Level 3 NICU and neonatal surgery;
2. Level 3 NICU;
3. 4,000 or more births per annum at 24 weeks or later;
4. 2,000-3,999 births per annum at 24 weeks or later;
5. Under 2,000 births per annum at 24 weeks or later.

In order to compare Trusts and Health Boards more fairly, **stabilised & adjusted mortality rates** are calculated. Where there is only a small number of births in an organisation it is difficult in any one year to be sure that any extreme value seen for the crude mortality rate is real and not just a chance finding. A ***stabilised*** rate allows for the effects of chance variation due to small numbers. The mortality rates are also ***adjusted*** to account for key factors which are known to increase the risk of perinatal mortality. The extent of the adjustment is limited to those factors that are collected for all births across the whole of the UK: mother's age; socio-economic deprivation based on the mother's residence; baby's ethnicity; baby's sex; whether they are from a multiple birth; and gestational age at birth (neonatal deaths only). A complete explanation of the MBRRACE-UK methodology, including statistical methods, can be found in the accompanying Technical Document.

Results

The extent to which the hierarchical classification of Trusts and Health Boards reflects the risk profiles of the different types of unit is presented in Figure 2. The average mortality rate for each comparator group is shown as a vertical black line, with an amber box representing up to 5% higher or up to 5% lower than the group average. In 2019 the variation in stabilised & adjusted stillbirth rates showed little variation, with 97% of Trusts and Health Boards falling within 5% of their comparator group average, increased from 85% in 2018. However, as in previous years this is not the case for the stabilised & adjusted rate of neonatal mortality where only 26% of Trusts and Health Boards fall within 5% of their comparator group average (31% in 2018). This continuing wide variation is particularly apparent between Trusts and Health Boards with a level 3 NICU and neonatal surgery, where only 15% of Trusts and Health Boards fall within 5% of their comparator group average.

Overall stabilised & adjusted stillbirth rates for Trusts and Health Boards across the UK ranged from 3.43 to 3.73 per 1,000 total births for those with a level 3 NICU and neonatal surgery and from 3.08 to 3.20 for Trusts and Health Boards with under 2,000 births per annum.

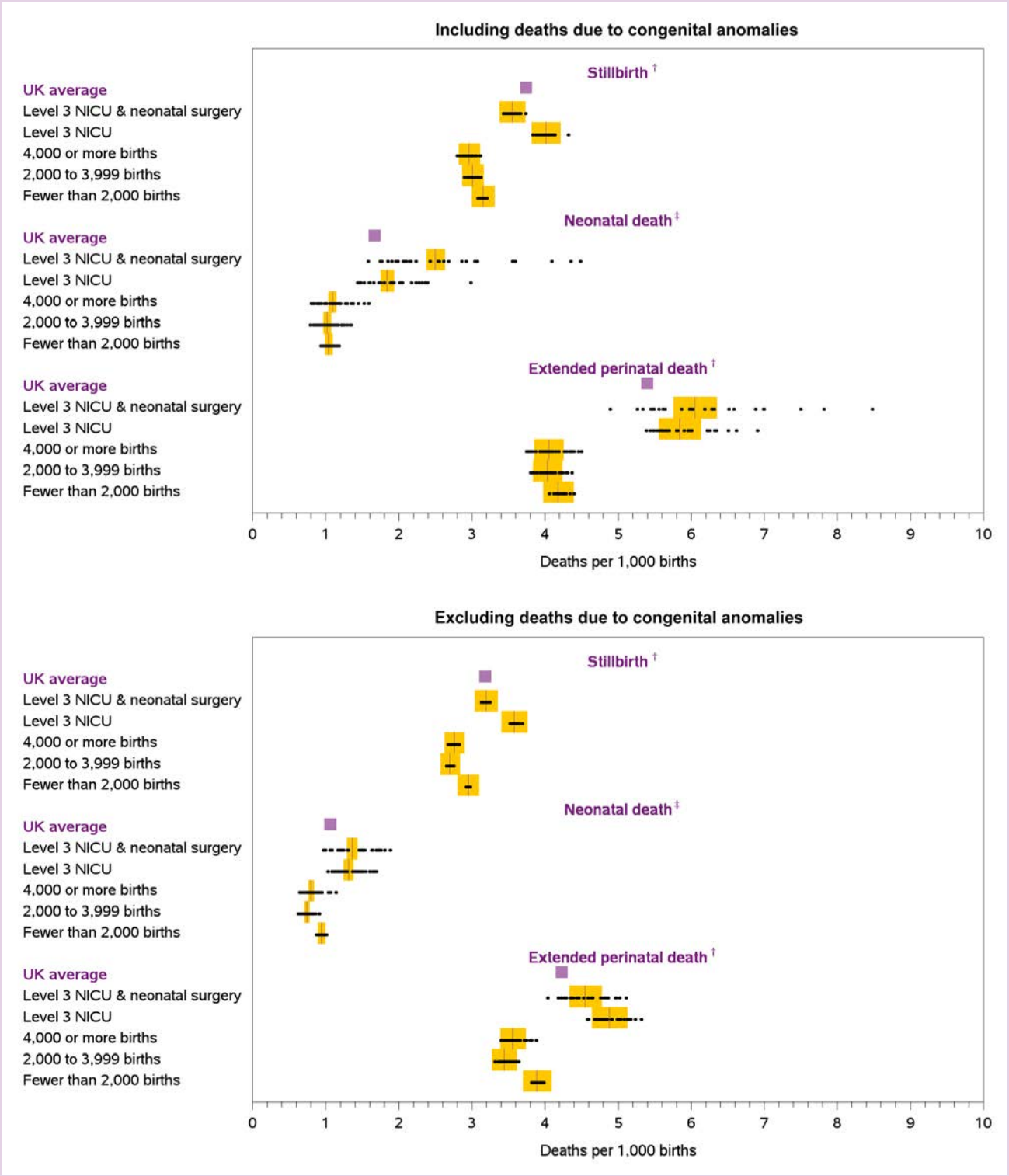
Stabilised & adjusted neonatal mortality rates for Trusts and Health Boards across the UK ranged from 1.58 to 4.49 per 1,000 live births for those with a level 3 NICU and neonatal surgery and from 0.93 to 1.18 for Trusts and Health Boards with under 2,000 births per annum.

Exclusion of deaths due to congenital anomalies has the effect of almost entirely removing variation in stabilised & adjusted stillbirth rates compared to the comparator group average, with all Trusts and Health Boards falling within 5% of the group average (range 2.66 to 3.69 per 1,000 total births across all types of unit). Overall stabilised & adjusted stillbirth rates excluding deaths due to congenital anomalies ranged from 3.52 to 3.69 per 1,000 births for those with a level 3 NICU without neonatal surgery and from 2.66 to 2.75 for Trusts and Health Boards with between 2,000 and 3,999 births per annum.

In comparison, as shown in our last report [13] exclusion of deaths due to congenital anomalies has little impact on the variation in stabilised & adjusted neonatal mortality rates, with only 30% of Trusts and Health Boards having a rate within 5% of their comparator group average (Table 15). Once deaths due to congenital anomalies are excluded only 12% of Trusts and Health Boards with a Level 3 NICU and neonatal surgery fall within 5% of their group average (range 0.97 to 1.88 per 1,000 live births). Overall, one-third of eligible Trusts and Health Boards (54 out of 155) had a neonatal mortality rate over 5% higher than the comparator average when congenital anomalies are excluded.

Crude and stabilised & adjusted rates for individual Trusts and Health Boards, with and without deaths due to congenital anomalies, can be found in the accompanying interactive maps and tables available at: www.npeu.ox.ac.uk/mbrrace-uk/reports.

Figure 2: Stabilised & adjusted mortality rates including and excluding congenital anomalies by NHS Trust (England), Health Board (Scotland and Wales), Health and Social Care Trust (Northern Ireland), and Crown Dependency based on place of birth: United Kingdom and Crown Dependencies, for births in 2019



The amber band represents up to 5% higher or up to 5% lower than the comparator group average mortality rate

† per 1,000 total births
‡ per 1,000 live births
§ excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey
Note: during the period reported different laws existed in Northern Ireland for the termination of pregnancy

Table 23: Stabilised & adjusted neonatal mortality rate colour band for Trusts and Health Boards by comparator group, including and excluding deaths due to congenital anomalies: 2019

Comparator group		Number of organisations in colour band (%)*							
		Green		Yellow		Amber		Red	
Level 3 NICU and neonatal surgery	Including congenital anomalies	9	(34.6%)	3	(11.5%)	4	(15.4%)	10	(38.5%)
	Excluding congenital anomalies	5	(19.2%)	6	(23.1%)	3	(11.5%)	12	(46.2%)
Level 3 NICU	Including congenital anomalies	6	(20.0%)	8	(26.7%)	5	(16.7%)	11	(36.7%)
	Excluding congenital anomalies	3	(10.7%)	8	(28.6%)	6	(21.4%)	11	(39.3%)
4,000 or more births	Including congenital anomalies	7	(16.7%)	8	(19.0%)	12	(28.6%)	15	(35.7%)
	Excluding congenital anomalies	4	(9.5%)	12	(28.6%)	10	(23.8%)	16	(38.1%)
2,000-3,999 births	Including congenital anomalies	6	(15.4%)	9	(23.1%)	7	(17.9%)	17	(43.6%)
	Excluding congenital anomalies	1	(2.6%)	11	(28.2%)	14	(35.9%)	13	(33.3%)
Under 2,000 births	Including congenital anomalies	0	(0.0%)	3	(15.0%)	13	(65.0%)	4	(20.0%)
	Excluding congenital anomalies	0	(0.0%)	3	(15.0%)	15	(75.0%)	2	(10.0%)
All groups	Including congenital anomalies	1	(0.8%)	31	(23.8%)	41	(31.5%)	57	(43.8%)
	Excluding congenital anomalies	13	(8.4%)	40	(25.8%)	48	(31.0%)	54	(34.8%)

* Colours represent variation from comparator group average neonatal mortality rate:

- Green: more than 15% lower than the average
- Yellow: more than 5% and up to 15% lower than the average
- Amber: up to 5% higher or up to 5% lower than the average7
- Red: more than 5% higher than the average

Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey
Note: during the period reported different laws existed in Northern Ireland for the termination of pregnancy

Implications

Stabilised and adjusted stillbirth and neonatal mortality rates for five different categories of Trusts and Health Boards have been produced to allow for a more fair comparison between similar units, both accounting for unit size and also for the case mix of the population served by each hospital. As noted in previous years, once congenital anomalies are excluded there is little variation in stillbirth rates within each of the five categories of Trusts and Health Boards, suggesting equitable healthcare provision across providers. Overall, for neonatal mortality wide variation persists despite the exclusion of congenital anomalies. This variation is mainly focused in those units with level 3 NICUs, with or without neonatal surgery, where babies at highest risk of mortality are treated. Investigations into the reasons for this wide variation should be carried out at local, organisation and population levels to determine whether this is due to local population characteristics including deprivation and ethnicity [30] or quality of care provision.

Recommendation 8 **N**

Use the newly-developed MBRRACE-UK interactive maps and tables to compare stabilised and adjusted stillbirth, neonatal mortality and extended perinatal mortality rates between organisations.

Recommendation requiring improved implementation

Use the MBRRACE-UK real-time data monitoring tool as part of regular mortality meetings to help identify why an organisation's stabilised & adjusted stillbirth, neonatal mortality or extended perinatal mortality rate falls into the red or amber band.

MBRRACE-UK 2020 [13]

Recommendation requiring improved implementation

Investigate potential modifiable factors in the treatment of neonates when an organisation's stabilised and adjusted neonatal mortality rate falls into the red or amber bands after exclusion of deaths due to congenital anomalies. Ensure that this encompasses both local population characteristics and quality of care provision.

MBRRACE-UK 2020 [13]

Causes of perinatal death

Key findings

- Rates of stillbirth classified as of unknown cause have fallen by 8% between 2015 and 2019, much of which may be ascribed to the increasing proportion of stillbirths from placental causes.
- Of the two-fifths of neonatal deaths attributed to neonatal causes, mortality rates have fallen over the 5 year period for extreme prematurity as well as the neurological and cardio-respiratory categories.
- Congenital anomalies continue to contribute significantly to mortality rates, comprising around one-third of neonatal deaths and just under one-tenth of stillbirths.
- Whilst almost all parents were offered a post-mortem for their stillborn baby (97%) only 85% of parents received an offer of a post-mortem following a neonatal death in 2019.
- Where a post-mortem was offered following a stillbirth or neonatal death, half of parents gave consent for a full or limited post-mortem.
- In 2019, 78% of neonatal deaths occurring on day one after birth or which were classified as intrapartum-related deaths had placental histology investigations carried out.

Data presented

1. **The number and proportion of stillbirth and neonatal death for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by cause of death .**
2. **Rates of stillbirth and neonatal death for births in the UK at 24^{+0} weeks gestational age or later (excluding terminations of pregnancy) for the period 2015 to 2019, by cause of death.**
3. **The number and proportion of stillbirths and neonatal deaths where there was an offer of post-mortem and whether consent was obtained, in 2019.**
4. **The number and proportion of stillbirths and neonatal deaths where a placental histology examination was carried out, in 2019.**

Causes of death are reported to MBRRACE-UK using the Cause of Death & Associated Conditions (CODAC) classification system [31]. The CODAC system has a three level hierarchical tree for the coding of both the primary cause of death and any associated conditions. The CODAC level 1 classification is presented for all stillbirths and neonatal deaths. For neonatal deaths having a CODAC level 1 “neonatal” cause the CODAC level 2 classification is also reported.

When reporting a death via the MBRRACE-UK data entry system reporters are asked to complete both a primary cause of death and up to two associated conditions. Following a detailed review of the coding of deaths reported as due to congenital anomalies in the 2015 MBRRACE-UK report, all cause of death data in this report is presented using congenital anomaly as the cause of death for all deaths where a congenital anomaly is coded as either the primary cause or an associated condition.

Results

The reported proportions and rates by CODAC level 1 cause of death for all stillbirths over the period 2015 to 2019 are presented in Tables 24 and 26 and in Figure 3. Over this period, the proportion of stillbirths classified

as unknown cause of death has fallen from 39.5% in 2015 to 31.5% in 2019. This is reflected in a reduction in the rate of stillbirth with unknown cause of death from 1.53 to 1.05 per 1,000 total births. Stillbirths ascribed to a placental cause show the opposite, with an increasing proportion over time: 27.1% in 2015 to 33.3% in 2019 mirrored by an increasing rate: 1.05 in 2015 to 1.12 in 2019. The proportion of stillbirths due to congenital anomalies has remained fairly constant over the period: 9.3% in 2019, a rate of 0.31 per 1,000 total births. Stillbirths due to intrapartum causes have shown a reduction in both the proportion and rates over the period: 2.8% to 1.3% and 0.11 to 0.04 per 1,000 total births, respectively.

For neonatal deaths the reported proportions and rates by CODAC level 1 and level 2 cause of death over the period 2015 to 2019 are presented in Tables 25 and 27 and in Figures 4 and 5. In part due to how the CODAC system is structured, once deaths due to congenital anomalies are excluded most neonatal deaths are coded within the "Neonatal" category at level 1. Around two-fifths of neonatal deaths are attributed to neonatal causes (40.3% in 2019) with decreasing rates over the five year period: 0.77 to 0.65 per 1,000 live births. Within the "Neonatal" category the majority of CODAC level 2 causes have shown little overall change. However the mortality rates for the three largest CODAC level 2 neonatal causes have all fallen over the 5 year period: extreme prematurity from 0.25 to 0.19 per 1,000 live births, neurological from 0.23 to 0.17 per 1,000 live births and cardio-respiratory 0.19 to 0.15 per 1,000 live births. Just over one third of neonatal deaths are due to congenital anomalies; 35.1% in 2019 and with rates remaining fairly static over the period: 0.57 per 1,000 live births in 2019. The rate and proportion of neonatal deaths attributed to intrapartum causes remains low at around 2.2% and 0.04 per 1,000 live births in 2019. Contrary to the findings for stillbirths the proportion and rate of neonatal deaths of unknown cause also remain low 5.1% and 0.08 per 1,000 live births in 2019.

Table 24: Stillbirths by CODAC level 1 cause of death: United Kingdom and Crown Dependencies, for births in 2015 to 2019

CODAC cause of death: level 1	2015	2016	2017	2018	2019
	N (%)	N (%)	N (%)	N (%)	N (%)
Infection	116 (3.8)	108 (3.5)	121 (4.3)	101 (3.9)	94 (3.9)
Neonatal	45 (1.5)	42 (1.4)	41 (1.4)	42 (1.6)	39 (1.6)
Intrapartum	84 (2.8)	71 (2.3)	51 (1.8)	53 (2.1)	30 (1.3)
Congenital anomaly	268 (8.8)	280 (9.1)	262 (9.2)	249 (9.7)	223 (9.3)
Fetal	150 (4.9)	149 (4.9)	113 (4.0)	109 (4.2)	93 (3.9)
Cord	140 (4.6)	130 (4.2)	148 (5.2)	127 (4.9)	128 (5.3)
Placenta	822 (27.1)	882 (28.8)	904 (31.8)	780 (30.2)	800 (33.3)
Maternal	129 (4.3)	122 (4.0)	103 (3.6)	88 (3.4)	94 (3.9)
Unknown	1197 (39.5)	1145 (37.4)	982 (34.6)	853 (35.1)	756 (31.5)
Missing	83 (2.7)	136 (4.4)	115 (4)	177 (6.9)	142 (5.9)

Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 25: Neonatal deaths by CODAC level 1 and level 2 cause of death: United Kingdom and Crown Dependencies, for births in 2015 to 2019

CODAC cause of death	2015	2016	2017	2018	2019
	N (%)	N (%)	N (%)	N (%)	N (%)
Infection	**97 (7.1)**	**101 (7.6)**	**95 (7.5)**	**84 (7.0)**	**101 (8.7)**
Neonatal	**603 (43.9)**	**586 (43.8)**	**517 (40.8)**	**491 (41)**	**467 (40.3)**
Unspecified or other	36 (2.6)	29 (2.2)	19 (1.5)	24 (2.0)	34 (2.9)
Extreme prematurity	194 (14.1)	210 (15.7)	155 (12.2)	154 (12.8)	136 (11.7)
Neurological	177 (12.9)	157 (11.7)	139 (11)	136 (11.3)	121 (10.4)
Cardio-respiratory	148 (10.8)	127 (9.5)	119 (9.4)	109 (9.1)	107 (9.2)
Gastrointestinal	62 (4.5)	43 (3.2)	57 (4.5)	31 (2.6)	41 (3.5)
Multi-organ failure	33 (2.4)	16 (1.2)	20 (1.6)	28 (2.3)	17 (1.5)
Trauma or suffocation	2 (0.1)	4 (0.3)	7 (0.6)	7 (0.6)	10 (0.9)
Inadequate care	1 (0.1)	0 (0.0)	1 (0.1)	2 (0.2)	1 (0.1)
Intrapartum	**34 (2.5)**	**27 (2.0)**	**46 (3.6)**	**25 (2.1)**	**26 (2.2)**
Congenital anomaly	**454 (33.1)**	**448 (33.5)**	**458 (36.1)**	**426 (35.5)**	**407 (35.1)**
Fetal	**35 (2.5)**	**49 (3.7)**	**40 (3.2)**	**40 (3.3)**	**36 (3.1)**
Cord	**5 (0.4)**	**2 (0.1)**	**1 (0.1)**	**3 (0.3)**	**4 (0.3)**
Placenta	**40 (2.9)**	**31 (2.3)**	**25 (2.0)**	**36 (3.0)**	**27 (2.3)**
Maternal	**2 (0.1)**	**5 (0.4)**	**4 (0.3)**	**5 (0.4)**	**8 (0.7)**
Unknown	**55 (4.0)**	**65 (4.9)**	**49 (3.9)**	**58 (4.8)**	**59 (5.1)**
Missing	**48 (3.5)**	**23 (1.7)**	**32 (2.5)**	**31 (2.6)**	**23 (2.0)**

Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 26: Stillbirth rates by CODAC level 1 cause of death: United Kingdom and Crown Dependencies, for births in 2015 to 2019

CODAC cause of death: level 1	Rate per 1,000 total births				
	2015	2016	2017	2018	2019
Infection	0.15	0.14	0.16	0.14	0.13
Neonatal	0.06	0.05	0.05	0.06	0.05
Intrapartum	0.11	0.09	0.07	0.07	0.04
Congenital anomaly	0.34	0.36	0.34	0.34	0.31
Fetal	0.19	0.19	0.15	0.15	0.13
Cord	0.18	0.17	0.19	0.17	0.18
Placenta	1.05	1.13	1.19	1.06	1.12
Maternal	0.16	0.16	0.14	0.12	0.13
Unknown	1.53	1.47	1.29	1.16	1.05
Missing	0.11	0.17	0.15	0.24	0.20

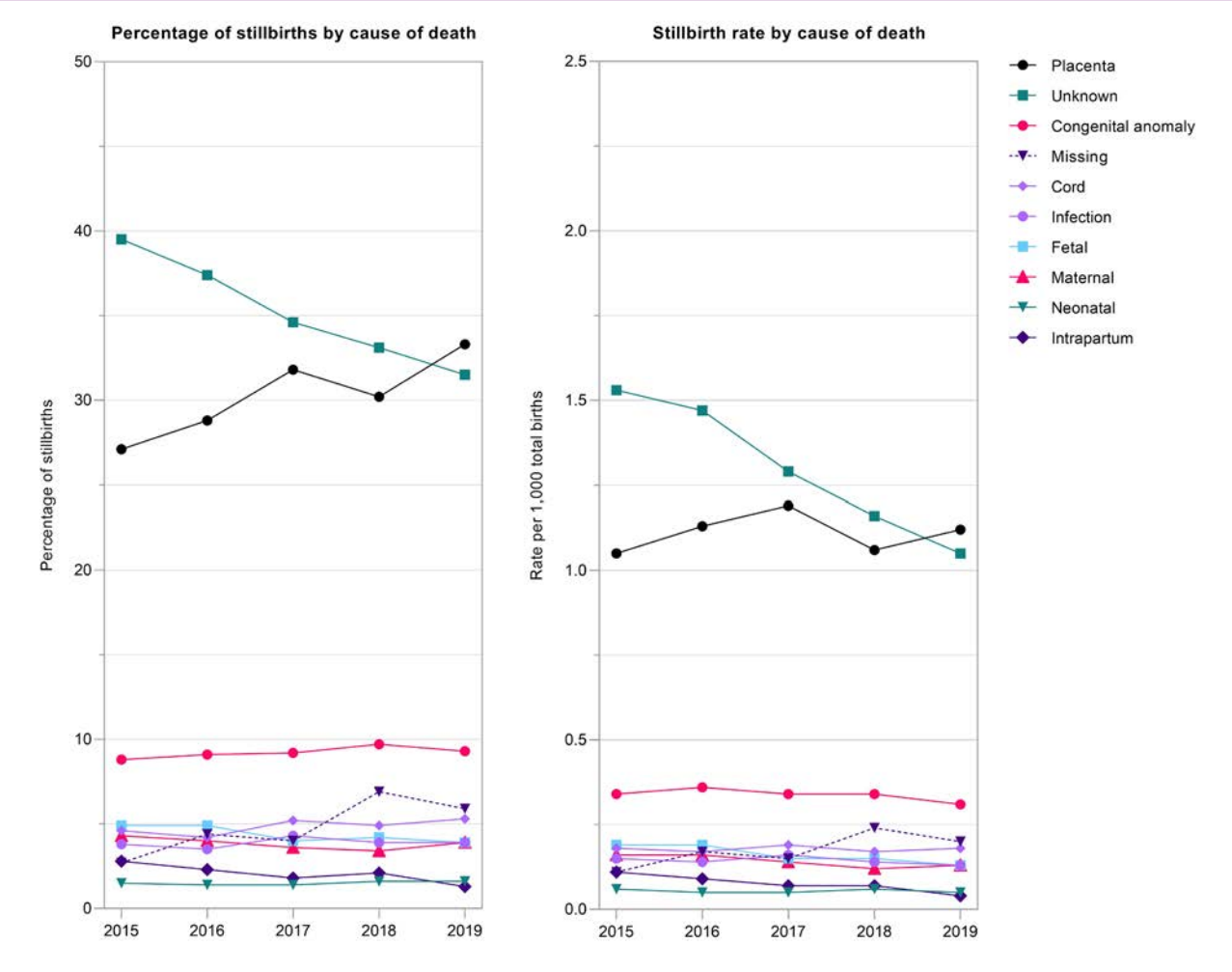
Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Table 27: Neonatal mortality rates by CODAC level 1 and level 2 cause of death: United Kingdom and Crown Dependencies, for births in 2015 to 2019

CODAC cause of death	Rate per 1,000 live births				
	2015	2015	2015	2015	2015
Infection	**0.12**	**0.13**	**0.13**	**0.11**	**0.14**
Neonatal	**0.77**	**0.75**	**0.68**	**0.67**	**0.65**
Unspecified or other	0.05	0.04	0.03	0.03	0.05
Extreme prematurity	0.25	0.27	0.20	0.21	0.19
Neurological	0.23	0.20	0.18	0.19	0.17
Cardio-respiratory	0.19	0.16	0.16	0.15	0.15
Gastrointestinal	0.08	0.06	0.08	0.04	0.06
Multi-organ failure	0.04	0.02	0.03	0.04	0.02
Trauma or suffocation	0.00	0.01	0.01	0.01	0.01
Inadequate care	0.00	0.00	0.00	0.00	0.00
Intrapartum	**0.04**	**0.03**	**0.06**	**0.03**	**0.04**
Congenital anomaly	**0.58**	**0.58**	**0.60**	**0.58**	**0.57**
Fetal	**0.04**	**0.06**	**0.05**	**0.05**	**0.05**
Cord	**0.01**	**0.00**	**0.00**	**0.00**	**0.01**
Placenta	**0.05**	**0.04**	**0.03**	**0.05**	**0.04**
Maternal	**0.00**	**0.01**	**0.01**	**0.01**	**0.01**
Unknown	**0.07**	**0.08**	**0.06**	**0.08**	**0.08**
Missing	**0.06**	**0.03**	**0.04**	**0.04**	**0.03**

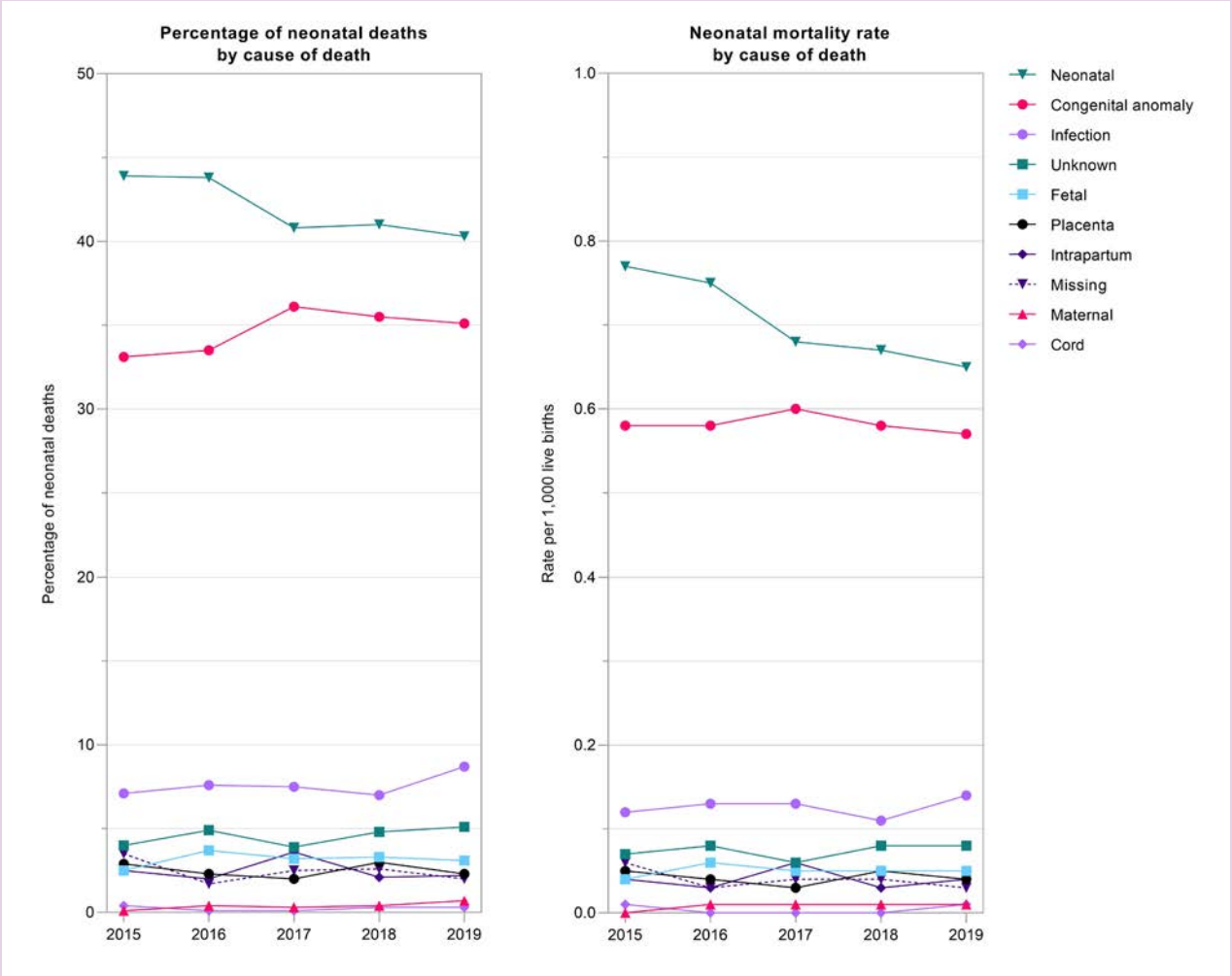
Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Figure 3: Stillbirths by CODAC level 1 cause of death: United Kingdom and Crown Dependencies, for births in 2015 to 2019



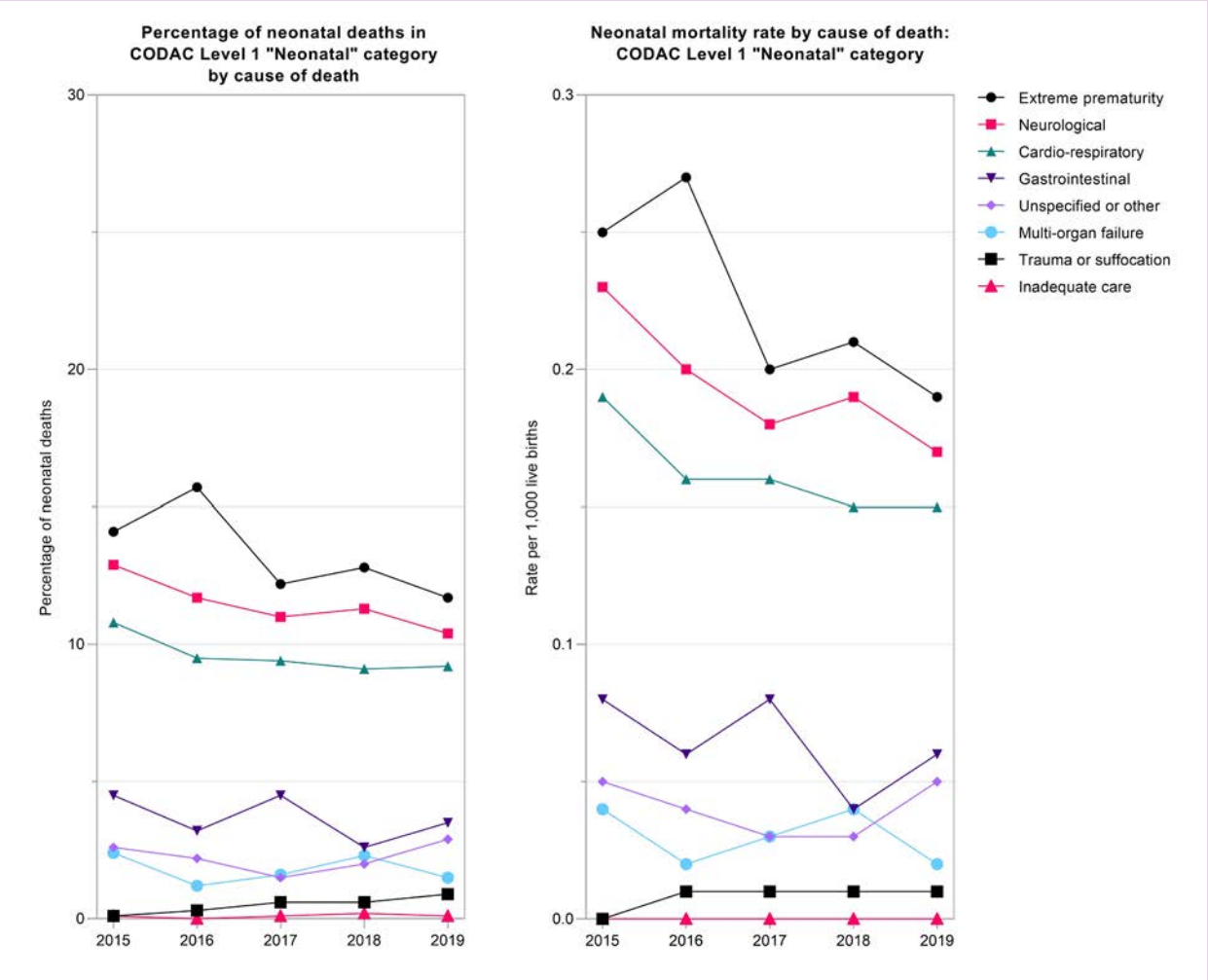
Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Figure 4: Neonatal deaths by CODAC level 1 cause of death: United Kingdom and Crown Dependencies, for births in 2015 to 2019



Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Figure 5: Neonatal deaths in CODAC level 1 "Neonatal" category by CODAC level 2 cause of death: United Kingdom and Crown Dependencies, for births in 2015 to 2019



Excluding terminations of pregnancy and births <24^{+0} weeks gestational age
Data sources: MBRRACE-UK, PDS, ONS, NRS, PHS, NIMATS, States of Guernsey, States of Jersey

Parents were offered a post-mortem for almost all stillborn babies (97%) and just over four-fifths of neonatal deaths (85%). For around half of deaths a post-mortem was declined when offered.

A higher proportion of stillbirths had placental histology examination carried out in 2019 (93%) than in 2018 (90%), continuing the steady increase observed in these procedures over recent years. A similar small increase was noted for neonatal deaths occurring on the first day of life or of an intrapartum-related cause, 78% had placental histology carried out in 2019 (74% in 2018).

Implications

The proportion of stillbirths classified as being of unknown cause continues to fall, probably reflecting the concomitant increase in identification of placental causes. Congenital anomalies continue to contribute a significant, unchanging proportion to overall stillbirth rates. The downward trends in both maternal and intrapartum causes of stillbirth are encouraging and may reflect lessons learned from both local and national mortality review processes.

The overall reduction in neonatal mortality is less than that for stillbirths. Neonatal mortality attributed to extreme prematurity has fallen, but from a clinical and family standpoint does not include post-neonatal mortality prior to discharge home in this group of infants. National guidance on the management of extreme preterm infants [32],

introduced in October 2019, has led to an increase in the numbers of infants <24^{+0} weeks gestational age offered neonatal intensive care and the contribution of these infants to overall neonatal mortality may need to be considered in future years.

Congenital anomalies contribute significantly to neonatal mortality as well as to stillbirth rates. Many of these anomalies, once established, are not amenable to intervention, which has major implications for nationally-stated targets for reductions in overall perinatal mortality rates. To realise these goals will require concerted efforts to achieve and maintain consistent improvements for all other causes of perinatal mortality, in addition to increasing focus on pre-conception care for women with risk factors for congenital anomaly. A deep-dive into the effects of different types of congenital anomaly on perinatal mortality, and possible intervention strategies, will form part of the next MBRRACE-UK Perinatal Mortality Surveillance Report.

Post-mortem examination remains an important tool in determining cause of death. We have previously discussed the difference between the offer of post-mortem and consent to undertaking the examination [13]. It is likely that wider uptake by families may provide further insight into causes of perinatal mortality with consequent impact on treatment.

Recommendation 9 **N**

Emphasise the importance of pre-conception health as a routine part of every health professional's interaction with women who have risk factors for congenital anomaly.

Recommendation requiring improved implementation

Explore local variation in post mortem uptake by different population groups, particularly by ethnicity and deprivation, and tailor training for consent takers based on the local population.

MBRRACE-UK 2020 [13]

Recommendation requiring improved implementation

Undertake placental histology for all babies admitted to a neonatal unit, preferably by a specialist perinatal pathologist.

MBRRACE-UK 2020 [13]

Timeliness of notification of perinatal deaths

Key findings

- Timeliness of notification of deaths is improving. Approximately four-fifths of deaths were notified within the MBRRACE-UK benchmark time of 30 days: 80% of stillbirths and 76% of neonatal deaths (an increase from 69% of stillbirths and 64% of neonatal deaths in 2018).
- There was no correlation between the total number of deaths per Trust or Health Board and the percentage of deaths notified within 30 days.
- Variation between UK countries in the percentage of deaths notified within 30 days has reduced, from 35% variation between countries in 2017 (36% to 71% notified within 30 days) to 19% variation between countries in 2019 (63% to 82% notified within 30 days).

Data presented

1. **Percentage of deaths of babies born from 22^{+0} weeks gestational age notified within 30 days, from 2017 to 2019.**
2. **Regional variation in the timing of the notification of perinatal deaths.**

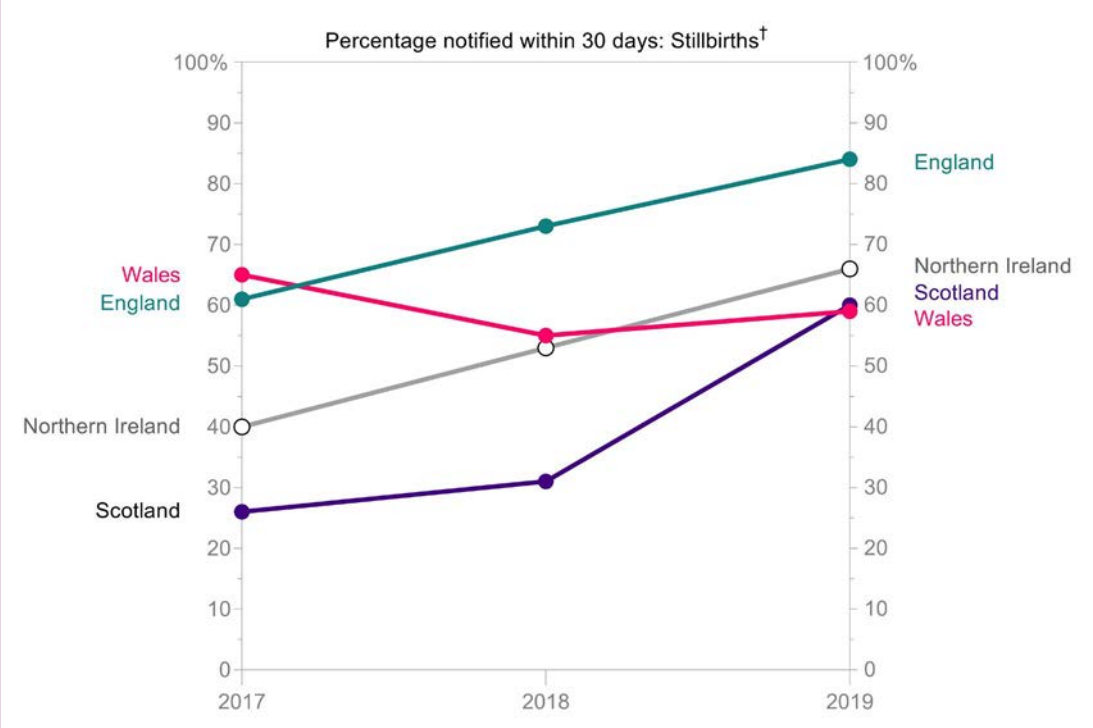
The data shown in Figures 6 and 7 below is derived from information submitted via the MBRRACE-UK web-based reporting system.

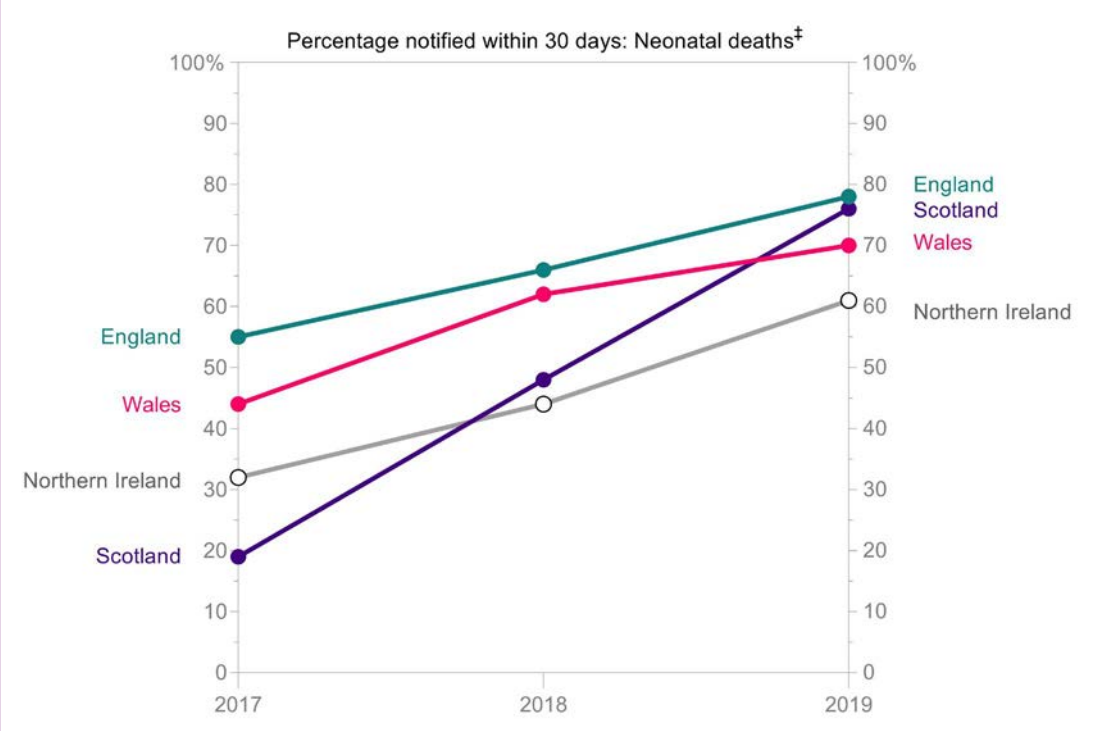
Results

The number of deaths notified within 30 days across all types of death has again shown a substantial increase across most of the countries of the UK, with variation between countries being greatly reduced (Figure 6). Whilst English Trusts continue to be the most timely notifiers of both stillbirths and neonatal deaths, the most obvious improvement is in the notification of perinatal deaths by Scottish Health Boards. Over the period 2017 to 2019 the percentage of Scottish stillbirths notified within 30 days has increased from 26% to 60%. Whilst this is a substantial improvement over previous years, it is important to note that the timeliness of notification of stillbirths by Scottish Health Boards still lags behind the 84% notified by English Trusts by some margin. However, for neonatal deaths in Scotland the improvement is even more pronounced; the percentage of neonatal deaths notified by Scottish Health Boards within 30 days has increased from 19% to 76%, meaning that Scotland was the second most timely notifier of neonatal deaths in 2019 after England (78%). This improvement is despite the continued slow reporting by one large unit. For Wales the percentage of neonatal deaths meeting the 30 day benchmark for notification increased from 62% in 2018 to 70% in 2019. However, there was only a slight increase in the percentage of notifications for stillbirths in Wales meeting the benchmark (from 55%% in 2017 to 59% in 2018), again falling well below the standard of English Trusts. Data entry is carried out centrally in Northern Ireland by the NIMACH office, which contributes to an initial delay in notification of deaths. Despite this procedural delay timeliness of notification continues to improve, and for the first time more than half of stillbirths and neonatal deaths in Northern Ireland were notified within 30 days (66% and 61% respectively).

There was no correlation between the total number of deaths per Trust or Health Board and the percentage of deaths notified within 30 days (Figure 7). Only 34 Trusts and Health Boards notified all of their deaths within 30 days.

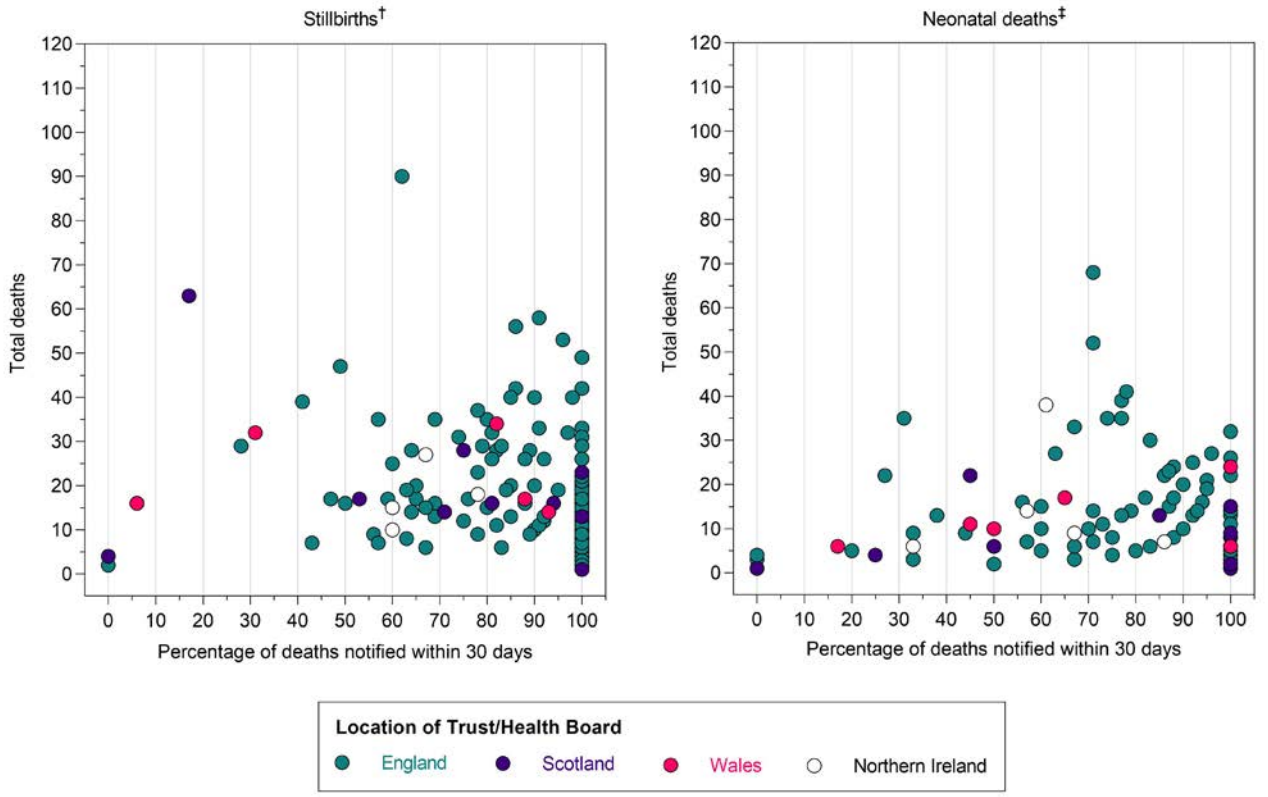
Figure 6: Percentage of deaths notified to MBRRACE-UK within 30 days, by country: 2017 to 2019





† Includes late fetal losses at 22-23 weeks gestational age
‡ From 22^{+0} weeks gestational age at birth
Excluding terminations of pregnancy
Data source: MBRRACE-UK

Figure 7: Percentage of deaths notified to MBRRACE-UK within 30 days, by Trust and Health Board: 2019



† Includes late fetal losses at 22-23 weeks gestational age
‡ From 22^{+0} weeks gestational age at birth
Excluding terminations of pregnancy
Data source: MBRRACE-UK

The number of days taken to notify deaths ranged from zero to 652 for stillbirths (UK-wide average 28 days) and zero to 630 days for neonatal deaths (UK-wide average 40 days). Most late notifications (more than six months after the death) are deaths identified by MBRRACE-UK via the case ascertainment/validation process using routine data sources, which are subsequently highlighted to Trusts and Health Boards as "missing" cases. As in previous years, a very small proportion of late notifications were due to deaths which occurred outside a clinical setting where the maternity or neonatal team were not aware of the death and which were identified later by MBRRACE-UK. However, this does not account for the 85 deaths which were notified more than a year after the death occurred (down from 143 deaths in 2018).

Implications

In the previous report MBRRACE-UK recommended that Trusts and Health Boards should notify all perinatal deaths within 7 working days, but with an aim to notify within 2 working days [13]. Whilst all of the deaths included in this year's report were notified before this particular recommendation was published it is encouraging to note that for 2019 more than half of English stillbirths and around half of English and Scottish neonatal deaths were notified within 7 days. The similar requirement for all English Trusts to notify deaths within a specific time frame as part of the Maternity Incentive Scheme (7 working days in Year 3 and 2 working days in Year 4), together with the alignment of data submission to the National Child Mortality Database (NCMD) and Perinatal Mortality Review Tool (PMRT), should ensure that in future the vast majority of perinatal deaths continue to be notified in a much more timely manner than in previous years.

However, the discrepancy between reporting requirements for stillbirths and neonatal deaths cannot go unnoticed. Notification of stillbirths within 7 working days is still a substantial delay when compared to the rapid statutory notification already required for most neonatal deaths (within 48 hours for the CDOP process in England), and the revised Maternity Incentive Scheme standards will remove that gap for most deaths. As we noted in the previous report, as a matter of good practice Trusts and Health Boards should incorporate MBRRACE-UK notification within local processes for all perinatal deaths and implement a similar standard for the notification of stillbirths as is already required for neonatal deaths.

The effects of the Perinatal Mortality Review Tool on notification time continue to be seen, particularly in England where the Maternity Incentive Scheme makes timely notification of critical importance. However, for the devolved nations, and Scotland in particular, improvements have been made without such financial incentive.

The MBRRACE-UK case ascertainment process ensures that, ultimately, all deaths are identified and included in the annual surveillance report. Deaths identified in routine data sources which have not been reported to MBRRACE-UK are flagged as “missing” cases for Trusts and Health Boards to report. However, it is important to note that the identification of missing cases is delayed by the availability of the routine data, and it may therefore be six to nine months before an unreported death is identified by MBRRACE-UK.

Regular late notification should prompt Trusts and Health Boards to consider whether there are particular local factors which may be impacting on the timely notification of deaths, such as resourcing issues, inadequate staffing or time allocation, or a more systemic problem. Delays caused by rare occurrences, such as deaths outside of the hospital setting, can be avoided in future by ensuring there are clear lines of communication between A&E, local hospices, and those responsible for notifying deaths to MBRRACE-UK

Recommendation 10 **N**

Notify all deaths via the MBRRACE-UK system within 2 working days of the death occurring. Incorporate mechanisms for timely notification into local processes.

Definitions used in this report

Late fetal loss	A baby born between 22^{+0} and 23^{+6} weeks gestational age showing no signs of life, irrespective of when the death occurred.
Stillbirth	A baby born at or after 24^{+0} weeks gestational age showing no signs of life, irrespective of when the death occurred.
Antepartum stillbirth	A baby born at or after 24^{+0} weeks gestational age showing no signs of life and known to have died before the onset of care in labour.
Intrapartum stillbirth	A baby born at or after 24^{+0} weeks gestational age showing no signs of life and known to have been alive at the onset of care in labour.
Neonatal death	A liveborn baby (born at 20^{+0} weeks gestational age or later, or with a birthweight of 400g or more where an accurate estimate of gestation is not available), who died before 28 completed days after birth.
Early neonatal death	A liveborn baby (born at 20^{+0} weeks gestational age or later, or with a birthweight of 400g or more where an accurate estimate of gestation is not available) who died before 7 completed days after birth.
Late neonatal death	A liveborn baby (born at 20^{+0} weeks gestational age or later, or with a birthweight of 400g or more where an accurate estimate of gestation is not available) who died after 7 completed days but before 28 completed days after birth.
Perinatal death	A stillbirth or early neonatal death.
Extended perinatal death	A stillbirth or neonatal death.
Termination of pregnancy	The deliberate ending of a pregnancy, normally carried out before the embryo or fetus is capable of independent life.

Abbreviations

BMI	Body Mass Index
CCG	Clinical Commissioning Group
CDOP	Child Death Overview Panel
HQIP	Healthcare Quality Improvement Partnership
LFL	Late Fetal Loss
MBRRACE-UK	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK
MNI-CORP	Maternal, Newborn and Infant Clinical Outcome Review Programme
NICU	Neonatal Intensive Care Unit
NIMACH	Northern Ireland Maternal and Child Health
NIMATS	Northern Ireland Maternity System
NISRA	Northern Ireland Statistics and Research Agency
NRS	National Records of Scotland
ONS	Office for National Statistics
PDS	Personal Demographics Service
PHS	Public Health Scotland
PMRT	Perinatal Mortality Review Tool
RCOG	Royal College of Obstetricians and Gynaecologists
STP	Sustainability and Transformation Partnership

Acknowledgements

It is with grateful thanks that the MBRRACE-UK collaboration would like to acknowledge the contribution of the many healthcare professionals and staff from the health service and other organisations who were involved in the reporting of perinatal deaths in the UK. It is only through this generous contribution of their time and expertise that it has been possible to conduct this national perinatal mortality surveillance and to continue the UK tradition of national self-audit to improve care for mothers, babies and their families. A full list can be found in the accompanying Tables and Figures document.

Members of the MBRRACE-UK collaboration

Members of the Leicester based MBRRACE-UK team

Members of the Oxford based MBRRACE-UK team

Office for National Statistics

National Records of Scotland

Public Health Scotland

Health Improvement Scotland

Northern Ireland Maternal and Child Health, HSC Public Health Agency

Health and Social Services Department, States of Guernsey

Health Intelligence Unit, Public Health Services, Jersey

Noble's Hospital, Isle of Man

NHS Digital

The Maternal, Newborn and Infant Clinical Outcome Review Independent Advisory Group

Healthcare Quality Improvement Partnership

MBRRACE-UK Third Sector Stakeholder Group Representatives

MBRRACE-UK Royal College and Professional Association Stakeholder Group Representatives

Reporters at all UK Trusts and Health Boards

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MBRRACE-UK

Department of Health Sciences
University of Leicester
George Davies Centre
University Road
Leicester
LE1 7RH

Tel: +44 (0)116 252 5425
Email: mbrrace-uk@npeu.ox.ac.uk
Web: www.npeu.ox.ac.uk/mbrrace-uk

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Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

National Perinatal Mortality Review Tool

PMRT
Supporting high quality local perinatal reviews

Learning from Standardised Reviews When Babies Die

National Perinatal Mortality Review Tool

Third Annual Report

October 2021

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National Perinatal Mortality Review Tool

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Third Annual Report

Jennifer J Kurinczuk, Peter Smith, Sarah Prince, Tracey Johnston, Miguel Neves, Charlotte Bevan, Christy Burden, Elizabeth S Draper, Alan Fenton, Ian D Gallimore, Alexander Heazell, Sara Kenyon, Marian Knight, Bradley Manktelow, Dimitros Siassakos, Lucy Smith, Claire Storey, Zeenath Uddin

October 2021

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HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales.

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Foreword

We welcome the PMRT's third annual report which shows there have been modest improvements in the way hospital reviews have been undertaken across the UK over the 12-month period spanning the pandemic. These improvements have been made against the backdrop of extreme pressures on the NHS during an unprecedented global health crisis.

The emergence of Covid-19 has compounded an already unequal picture in maternity. The evidence increasingly suggests that the virus is likely to hit those families who are also most at risk of poor outcomes in maternity hardest, yet again highlighting the UK's stark health inequalities. Stillbirth rates for Black/ Black British babies remain twice as high, and for Asian/Asian British babies 1.6 times as high, compared to White babies. For babies from the most deprived families, stillbirth rates are 1.7 times higher than from the least deprived families.

While progress has been made in reducing the number of baby deaths in the UK, 14 babies still die every day, and many of these deaths remain potentially preventable. Robust implementation of the PMRT is key in addressing this. It will answer parents' questions about why their baby died whilst also helping to identify where lessons need to be learned to save future lives.

However, this third report highlights the same issues with gaps in care that have already been raised by previous PMRT reports and by several confidential enquiries. It therefore begs question: what now needs to change?

We believe listening to parents is crucial to improving safety. Giving parents the opportunity to engage in the review of their care will not only support them in the grieving process, but evidence shows it will also improve the focus and quality of the review itself. As witnesses to their own care, parents and their narratives are an essential part of understanding the whole picture.

While this year the PMRT reports that more parents are told about review (90% compared to 84% in the previous report) and fewer raise concerns about their care, questions remain around whether the care reported by health professionals as being delivered is indeed the care experienced by parents themselves.

A recent Sands survey of bereaved parents whose baby died between 2019 and 2021, indicates that only 63% of parents were told about review, and 1 in 5 were not entirely clear what 'review' meant. Furthermore, although the majority of parents in our survey who were informed about a review were also asked if they would like the review to address any questions or concerns, 1 in 3 parents said they did not feel entirely listened to.

Another significant stumbling block to using the PMRT to improve lessons learnt is the fact that 1 in 7 reviews in this report are carried out by only one or two people. This latest annual report shows a possible correlation between the improvements in the number of external reviewers that units are using for their reviews, and an increase in the number of reviews identifying poor care. An external reviewer may, it appears, improve a hospital's ability to self-examine its care and learn lessons. Importantly, it will also improve parents' confidence in the process.

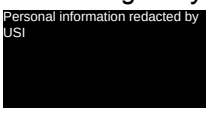
But, as this and previous reports have shown, implementing both these and other elements of the tool requires adequate resourcing, administrative support, and protected staff time. Sands believes there must be ring-fenced funding to secure staff training and time to support parents throughout the review, to release staff to participate in hospital reviews, and to resource the presence of an independent reviewer at every review meeting.

With this support in place the PMRT has the potential to prevent further harm to bereaved parents, whose search for answers about why their baby died may be life-long, and the power to make care safer for future families and reduce inequalities.

In the words of two bereaved mothers:

"It was nice to see changes that have been put in place following my son's death and how the hospitals are going to link together better. They picked this up to be a bigger issue than I did...."

"We felt we had enough time to discuss our son's death and they explained what had happened in detail while being as sympathetic as possible."



Clea Harmer

Chief Executive, Sands

Executive Summary

All the reviews reported in this, the third national PMRT annual report, were carried out from the start of the SARS-CoV-2 global pandemic and is the probable explanation as to why there have only been modest improvements in the use of the tool. Nevertheless, the value of reflecting on these findings in this report comes from identifying where things have improved and where improvements still need to be made.

Review of care when a baby dies should be a routine part of maternity and neonatal care. Importantly the process needs to be resourced adequately to ensure that high quality and cost-effective reviews are carried out. Resourcing involves including time in job plans for consultants and prioritising the time of other staff to participate. One notable improvement during this period was the increase in the proportion of reviews of neonatal deaths which involved a neonatologist and/or a neonatal nurse. The continued involvement of members of governance/risk teams and of service managers in the process of review is also a positive development. This increases the probability that the action plans developed as a consequence of review will be translated into quality improvement activities and clinical practice. More concerning is the fact that in the vast majority of instances Trusts and Health Boards do not provide appropriate administrative support to reduce the burden of routines tasks for other staff carrying out reviews.

There have only been modest shifts in the holistic grading of care suggesting that either the discipline of robust self-examination is still not wholly embedded in many units or care has already improved significantly. Evidence against the latter comes from the modest, but important, impact of the presence of a professional external to the Trust/Health Board on the grading of care, suggesting that they may strengthen the quality of critical reflections of the care during the process of review. This clearly requires the sharing of resources between Trusts and Health Boards and again needs to be appropriately resourced by the inclusion of this important work in job plans. This will ensure that more parents and families benefit from reviews conducted by groups including the fresh independent eyes provided by external members.

The quality of the action plans developed following reviews also remains of concern with a continued focus on actions in relation to individuals rather than system level changes designed to reduce the capacity for human error.

Supporting parents and families through the review process and other aspects of bereavement needs to be prioritised. Meaningful engagement with parents and families improves the quality of their review from which they will benefit directly. However, it also improves the potential for wider lessons to be learned and the prevention of deaths where service improvements are instigated as a consequence of high quality review.

Local reviews using the PMRT are particularly important for the 92% of baby deaths which will not benefit from a review by other organisations such as the Healthcare Safety Investigation Branch who investigate about 8% of the deaths in England eligible for a PMRT review. Child Death Overview Panels (CDOP) in England review all neonatal deaths and use, as the fundamental basis of their discussions, the local review conducted by the hospital team, which the CDOPs require to be carried out using the PMRT.

The issues with care identified in this report are largely focused around the same areas as in previous reports. This national report alongside the local summary reports, which can be generated from the PMRT, provide the basis for prioritisation of local service improvement activities.

It remains the case that the PMRT is only a tool, and will therefore, only be as good as the information recorded in it, and the way in which it is used. If the PMRT is to achieve the original vision set out by the Sands/Department of Health Task and Finish Group in 2012, it is the responsibility of Trusts and Health Boards to improve the way in which it is supported, resourced and implemented.

The recommendations from this reports are:

1) Provide adequate resourcing of multidisciplinary PMRT review teams, including administrative support and ensure the involvement of independent external members in the team.

   Action: Trusts and Health Boards, regional/network support systems and organisations, Service Commissioners

2) Use the PMRT parent engagement materials to support engaging parents and families in the review process, including them being made aware a review is taking place and being given flexible opportunities at different stages to discuss their views, ask questions and express any concerns. Many parents may want to give positive feedback about the care they received.

   Action: Trusts and Health Boards, staff caring for bereaved parents, Service Commissioners

3) Use the local PMRT summary reports and this national report as the basis to prioritise resources for key aspects of care and quality improvement activities identified as requiring action.

   Action: Trusts and Health Boards, Service Commissioners, regional/network support systems, Governments

4) Improve the quality of recommendations developed as a consequence of reviews by developing actions targeted at system level changes and audit their implementation and impact.

   Action: PMRT review teams, governance teams in Trusts and Health Boards, Service Commissioners

Learning from Standardised Reviews
When Babies Die – 2020 Annual Report

Key Messages – October 2021

PMRT
Supporting high quality local perinatal reviews

Multi-disciplinary group review is essential

39%	Met recommended minimum review group composition
14%	Only 1 or 2 individuals carried out the review
46%	Neonatal nurse present for the review of neonatal deaths
81%	Neonatologist present for the review of neonatal deaths
22%	Had administrative support
71%	Risk manager/governance team member present

Issue with care and areas for improvement identified at review

19 out of 20 reviews identified areas for improvement

5 out of 20 issues identified may have made a difference to the outcome

Parent engagement improves the quality of reviews

90%	Parents told about the review
40%	No concerns or questions about care raised
16%	Communication was poor
54%	Concerns/questions about management plans
16%	Concerns/questions about technical aspects of care e.g. scans

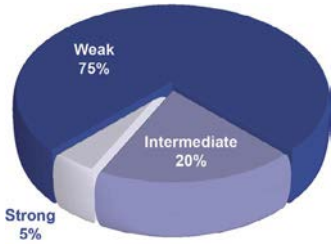
Comments, question and concerns raised by parents

Our concerns were not listened to by the midwives. Why were we discharged home when [baby's name] was blue around the lips?

I had frequent episodes of bleeding – why was I not kept in?

My concerns about my baby's movements were not taken seriously.

Action plans need to be strong[1]



1. Strong actions are system changes which remove the reliance on individuals to choose the correct action. They use standardised and permanent physical or digital designs to eliminate human error and are sometimes referred to as 'forcing actions'.
2. Artificial rupture of membranes
3. Electronic patient record

Examples of the strength[1] of actions planned

Intermediate

"Major review which led to a new staffing model and a newly appointed Lead for Triage and Induction."

A new system in place but still requires individuals to act without any controls

Contents

Glossary

ARM	Artificial Rupture of Membranes – breaking the waters
CDOP	Child Death Overview Panel (England)
CTG	Cardiotocograph
DH	Department of Health
DNA	Did not attend (appointment)
EPR	Electronic Patient Record
FIGO	International Federation of Gynecology and Obstetrics
GDM	Gestational diabetes mellitus
NCMD	National Child Mortality Database
NPSA	National Patient Safety Authority
MBRRACE-UK	The collaboration established to deliver the MNI-CORP
MNI-CORP	Maternal, Newborn and Infant Clinical Outcome Review Programme
MSU	Mid-stream sample of urine
PMRT	Perinatal Mortality Review Tool
Sands	Stillbirth and neonatal death charity

1. Background

The national Perinatal Mortality Review Tool (PMRT) was launched in January 2018. Implementation was rapid in England, Wales and Scotland during 2018 and the tool was subsequently adopted in Northern Ireland in autumn 2019.

The design of the tool places at its core the fundamental aim of supporting objective, robust and standardised review to provide answers for bereaved parents and their families about why their baby died. A second, but nonetheless important, aim is to ensure local and national learning occurs as a consequence of review findings in order to improve care and ultimately prevent future baby deaths.

Unlike other review or investigation processes, the PMRT makes it possible to review every baby death, after 22 weeks' gestation, including late miscarriages, stillbirths and neonatal deaths, and not just a particular group of deaths. For about 92% of parents the PMRT review process is likely to be the only review of their baby's death they will receive.

This third annual report builds on previous annual reports and presents an analysis of reviews carried out from March 2020 to February 2021. Of note the PMRT was adapted in mid-2020 to enable the impact of the SARS-CoV-2 global pandemic on care to be specifically reflected in reviews.

An accompanying technical paper details the process of development of the PMRT, aspects of how it is used and the relevant approvals needed in relation to the data collected.

www.npeu.ox.ac.uk/pmrt/reports

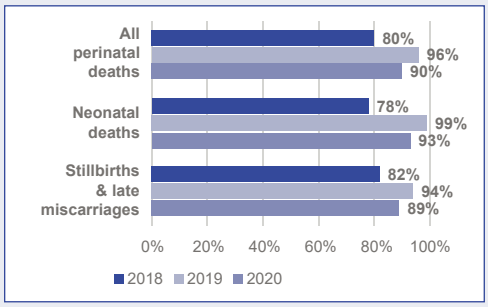
2. Findings

This report presents findings from the 3,981 reviews which were completed between March 2020 and February 2021 and follows on from the PMRT second annual report.

Tables of the findings presented here are available in a separate accompanying report.

www.npeu.ox.ac.uk/pmrt/reports

Since it was launched all Trusts and Health Boards across England, Wales, Scotland and Northern Ireland have engaged with the PMRT over 14,000 reviews had been started and/or completed using the tool. During the period March 2020 to February 2021 a review of care was started for an estimated 90% of all babies who died in the perinatal period comprising 89% of stillborn babies and those who died in the late second trimester, and 93% of babies who died in the neonatal period. The proportion of deaths reviewed has increased since the launch of the tool (Tables 1.1 to 1.4).



Proportion of deaths with review started from 2018 to 2020

2.1 Multidisciplinary review

It is essential that the review process is appropriately multidisciplinary to reflect the mix of professionals caring for mothers, babies and their families, and recommendations regarding the constitution of PMRT review groups are available on the PMRT website and in Appendix B.

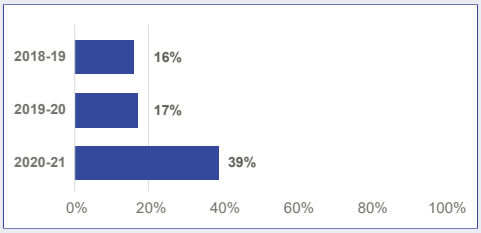
Although increased from earlier years the majority of reviews (61%) continue to be carried out by groups that do not include at least the minimum recommended number of staff fulfilling appropriate roles (Table 1.5).

Again although an improvement from the earlier one in five; nevertheless, about one in seven of the reviews were reported as being carried out by only one or two individuals. This does not constitute a robust multidisciplinary review process.

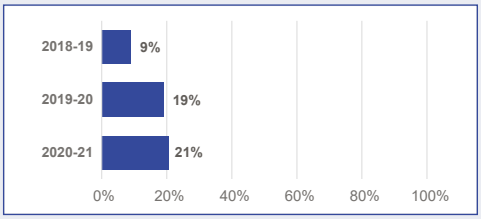
The involvement of a relevant professional, who is external to the Trust or Health Board, as part of the PMRT review team is also recommended. In this period 21% of reviews, compared with 19% previously, involved an external member (Table 1.6). This represents only a small improvement and the vast majority of reviews still did not involve someone, who can provide a 'fresh eyes' independent perspective to the review of care provided, as recommended by the Kirkup Inquiry [1].

The proportion of reviews with administrative support increased from 18% in the previous report to 22%. Just less than four in five reviews nevertheless appear to lack this type of support which is vital to ensure timely reviews with all the relevant information available are carried out in the most cost-effective way.

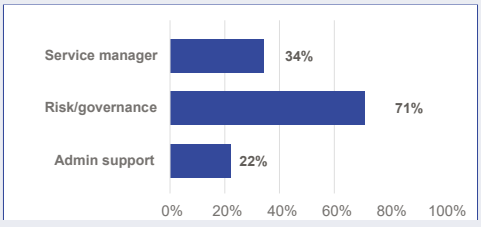
Whilst a member of the local governance/risk management team (71%) and/or a service manager (34%) was present, this represents a reduction from the previous annual report period of 92% and 40% respectively. These members of the team



Proportion of reviews with at least the minimum number of staff fulfilling appropriate roles



Proportion of reviews with an external member in the review team



Proportion of reviews with administrative support, governance/risk management team and service manager members

have the vital role of ensuring that the process of review, the findings and actions are embedded in the safety and service improvement culture of the trust/health board and should form part of the review team.

On a more positive note an increasing proportion of reviews of neonatal deaths were conducted by review groups which included a neonatologist at 59%, 71% and 81%, from the first to the third annual report periods respectively.

2.2 Parent engagement

It was reported that overall 90% of parents had been told that a review of their care and that of their baby would be carried out (Table 1.8). While this represents an improvement from 84% in the previous report and is a considerable improvement compared with MBRRACE-UK Perinatal Confidential Enquiries [2] and the Each Baby Counts project [3] it is nevertheless concerning that not all parents for whom a review was conducted were told that a review would take place and for this to be recorded in the PMRT.

Two fifths of parents were reported to have indicated they had no questions or concerns about their care they wanted their review to address. This was an increase from a quarter in the previous year.

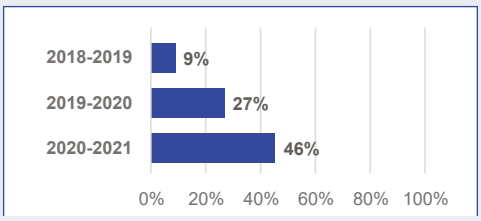
As in the previous annual reports just over half of parents comments related to management plans and the care received (Table 1.9). Poor communication was mentioned in an increasing proportion of parents' questions over the three annual reports: 5%, 9% and 16% respectively over subsequent years. Questions and concerns about technical aspects of care, for example the frequency and quality of scans, were also mentioned in an increasing proportion of comments over the three reports: 5%, 4% and 16% respectively. Around one in 10 parents said they did not feel listened to.

The PMRT 'Parent Engagement' materials [4] were available throughout the period covered by this report. However, it is not possible to assess from the information available from the PMRT reviews what impact these material have had on the quality of engagement with parents. Importantly the PARENTs study has shown that the more meaningful the engagement the more likely that important lessons for care will be identified in the review [5-7].

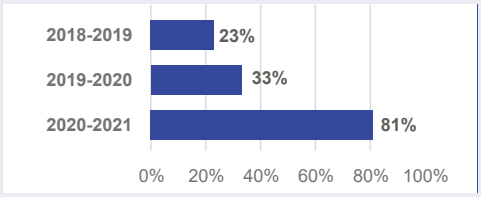
2.3 Issues with care identified

Overall 97% of reviews identified at least one issue with care, with an average of four issues per death reviewed increasing to five issues per death where the baby was born at term (Table 2.2). This represents a slight increase from 93% in the previous annual report period. Importantly, not all issues identified were deemed relevant to the outcome for that specific baby by the review team.

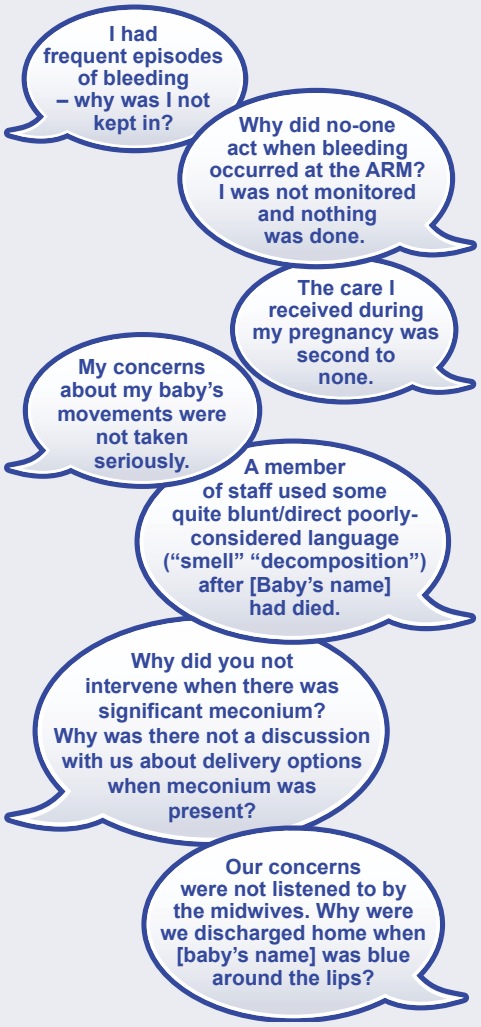
Issues with care relevant to the outcome nevertheless affected many aspects of care throughout the maternity and neonatal pathway. Issues were also identified at all stages of care regardless of the type of death, for example there were issues



Proportion of reviews of neonatal deaths with a neonatal nurse present



Proportion of reviews of neonatal deaths with a neonatologist present



Parents' comments, questions and concerns about their care and that of their baby

with care during labour and birth for both intrapartum deaths and deaths which occurred at other stages of pregnancy and postnatally.

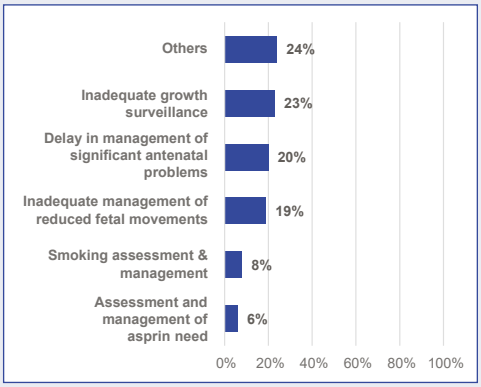
i) Antenatal care

The reviews highlighted particular issues with antenatal care (Table 2.3) with the five most commonly issues identified being:

- Inadequate fetal growth surveillance;
- Delay in management of significant antenatal problems;
- Inadequate investigation or management of reduced fetal movements.
- Lack of smoking assessment and management of exposure to tobacco smoke;
- Failure to assess the need for and management of aspirin requirements.

These remain the same five issues most commonly identified in reviews reported in the two previous annual reports with only smoking and aspirin assessment being slightly less common in this third annual report period.

Inadequate fetal growth surveillance, identified as relevant to the death in 9% of deaths reviewed, remains the most common single issue identified as relevant to the death. Inadequate investigation or management of reduced fetal movement, identified as relevant to the death in 8% of deaths, remains the second most common single issue identified as relevant to the death.



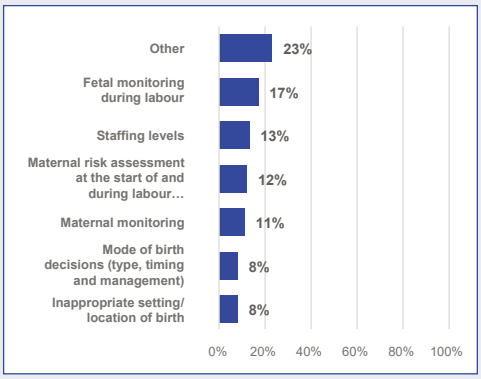
Antenatal care issues identified as relevant to the death

ii) Intrapartum care

Review of the care during labour, birth and shortly after birth (Table 2.4) identified issues with the following six main areas:

- Fetal monitoring in labour;
- Staffing levels;
- Lack of maternal risk assessment or inadequate management based on the risk assessment at the start of care or during the course of her labour;
- Monitoring of the mother in labour;
- Mode of birth decisions (type, timing and management);
- Inappropriate location of birth.

These remain the same six issues most commonly identified in reviews reported in the two previous annual reports with only maternal monitoring being identified slightly less frequently. Fetal monitoring issues, identified as relevant to the death in 4% of deaths reviewed, remains the single most common single issue identified as relevant to the death, regardless of when the baby died.

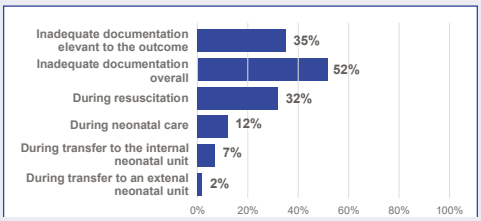


Intrapartum care issues identified as relevant to the death

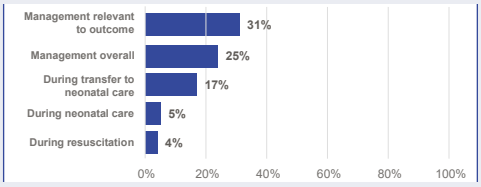
iii) Neonatal and end of life care

During neonatal care the need to improve documentation, particularly in relation to resuscitation of the baby, was once again highlighted in this report as an issue with care, with this issue identified as relevant to the death in 35% of the deaths reviewed (Table 2.5). A requirement to optimise thermal management at all stages of neonatal care, but particularly during transfer to the neonatal unit or to other locations, was also highlighted again, and was identified as relevant to the death in 31% of reviews. Issues with respiratory management during resuscitation and cardiovascular management on the neonatal unit were also highlighted although these issues were identified in the reviews as relevant to the death in less than 1% of instances.

There were few issues identified with end of life care (Tables 2.6 and 2.7). Of note the possibility of organ donation was not discussed despite there being no contraindications was identified in 16% of reviews. For the same proportion the possibility of having a post-mortem was also not discussed with the parents and family prior to the baby's death.



Issues with documentation of neonatal care



Temperature control management issues during neonatal care

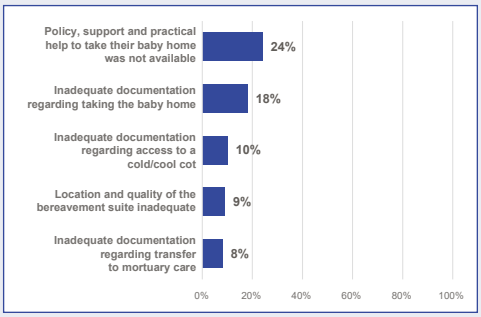
iv) Bereavement care

A specific set of questions about bereavement care were introduced into the PMRT in July 2020. This is the first annual report, therefore, to present the issues relating to the quality of bereavement care, which has the potential to impact the psychosocial wellbeing of the parents and other family members in the weeks, months and years to come.

The five main issues with bereavement care (Table 2.8) which were identified during the reviews from this period were:

- A policy, support and practical help were not available to enable parents to take their baby home for a time after the baby had died;
- There was inadequate documentation in the notes concerning discussions about taking the baby home;
- There was inadequate documentation in the notes concerning discussions about access to a cold/cool cot [i];
- The location and quality of the bereavement suite were inadequate;
- Inadequate documentation regarding transfer to mortuary care.

Embedding the National Bereavement Care Pathway [8] will support Trusts and Health Boards in these and all other aspects of good quality bereavement care for parents and families.



Bereavement care issues

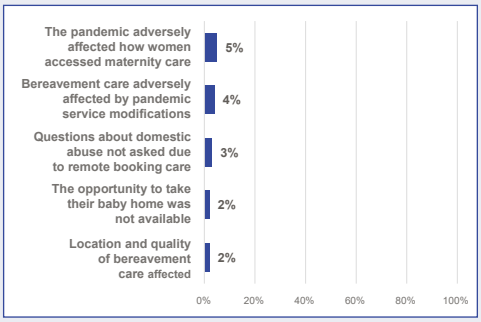
i A cold/cool cot is a cot which is kept cold or cool to preserve the baby's body, so that bereaved parents can keep their baby in their room with them or take their baby home for a while. Many parents find it comforting to be with their baby.

v) Impact of the SARS-CoV-2 global pandemic on care

A small set of new questions were added to the PMRT in July 2020 along with the addition of specific issues for existing questions to enable review teams to identify aspects of care which were impacted by the circumstances and changes to care as a result of the SARS-CoV-2 global pandemic.

Relatively few issues relating to the impact of the pandemic were identified at review (Table 2.9). The most common issue identified was that the pandemic had affected how women accessed maternity care, but this was only highlighted in 5% of the reviews carried out since these new questions and issues were added. Questions about possible domestic abuse not being asked due the remote delivery of booking care was identified in 3% of reviews.

Bereavement care was identified as having been adversely affected by the pandemic for 4% of deaths with the location and quality of bereavement care having been affected in 2% and the opportunity to take their baby home not being available also for 2% of deaths.



Impact of the SARS-CoV-2 global pandemic on care

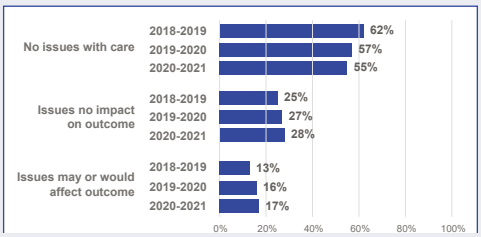
2.4 Overall grading of care

At the end of each review the review group is required to provide a holistic grading of the care provided at each stage of the care pathway. For 55% of stillbirths and late miscarriage the grading indicated that there were no issues with care during pregnancy, labour and birth (Table 2.10). For a further 28% issues were identified which would have had no effect on the outcome and in 17% of reviews there were issues identified that may or would have made a difference to the outcome. These figures were effectively unchanged from the findings in the previous annual report. The respective proportions for neonatal deaths including neonatal care were 42%, 42% and 16% (Table 2.13). These percentages represent a modest shift from the first annual report with an increase from 12% to 16% in the proportion of issues that may or would have made a difference to the outcome.

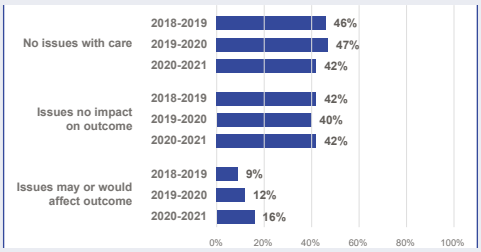
There were no issues with bereavement care identified for about 80% of late miscarriages, stillbirths and neonatal deaths (Tables 2.14 & 2.15).

This suggests that despite identifying issues with care for 97% of deaths, in the vast majority of instances the multidisciplinary review teams concluded that the majority of deaths occurred despite care that was overall deemed appropriate. There was also little shift in the proportions from the period of the last annual report. These figures contrast with those from recent MBRRACE-UK confidential enquiries and the Each Baby Counts project where a greater proportion of deaths were identified as having issues with care identified which may have a made a difference to the outcome, accepting that a specific group of deaths were reviewed in the latter two programmes using different methodologies of review.

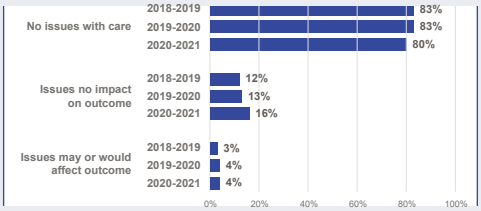
When a relevant professional external to the Trust or Health Board was present as part of the PMRT review team a greater proportion of reviews of the care during pregnancy, labour



Grading of pregnancy, labour and birth care for late miscarriages and stillbirths

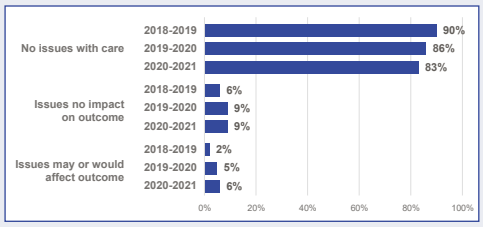


Most serious grading of pregnancy, labour, birth and neonatal care for neonatal deaths



Grading of bereavement care for late miscarriages and stillbirths

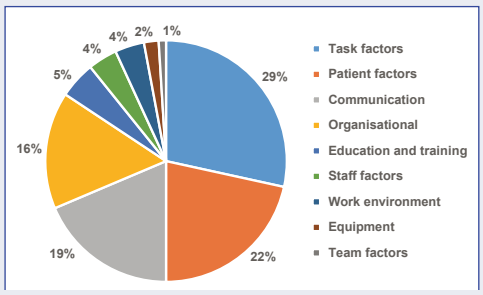
and birth were identified as having issues which may or were likely to have made a difference to the outcome: 23% with the external present versus 16% when an external member was not present for stillbirths and late miscarriages, and 17% versus 9% respectively for neonatal deaths. Whereas the presence of an external member had little impact on the grading of bereavement care. This suggests that the presence of an external professional encourages increasingly robust self-examination of the care provided. Although it may also be the case that external members are more likely to be involved where issues with care are anticipated.



Grading of bereavement care for neonatal deaths

2.5 Contributory factors

The majority of factors contributing to the issues identified with care fell into four of the National Patient Safety Agency (NPSA) level 1 contributory factors (Table 2.16). These were task factors (29%) primarily related to a failure to follow or an absence of guidelines, policies and procedures; patient factors (22%) with the clinical condition of the mother and/or baby most commonly identified; communication problems (19%); and organisational structures (16%). Communication issues in particular predominated in all categories of contributory factors for all aspects of neonatal care from resuscitation through to end of life care.



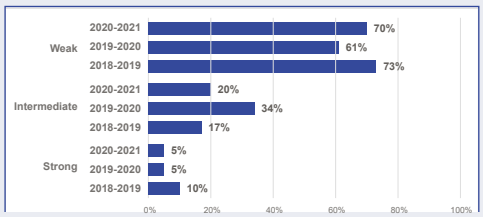
Level 1 National Patient Safety Agency contributory factors

2.6 Action plans

Across the 3,981 reviews a total of 17,429 issues were identified which represents an increase of about 20% on the number of issues identified in the previous annual report period. Overall a total of 21,069 factors contributing to the outcomes were identified (Table 2.17). Of these a total of 2,744 (13%) were indicated as factors relevant to the outcome and required action to improve future care. A further 5,805 (28%) factors were not relevant to the outcome for the baby but nevertheless required action to improve future care.

Findings from a sample of action plans were reviewed and coded according to action strength using the US Veterans Affairs definitions where the strength of an action describes how well the action would eliminate human error [9]. Strong actions are system changes which remove the reliance on individuals to choose the correct action. They use standardisation and permanent physical or digital designs to eliminate human error and are sometime referred to as 'forcing' actions.[ii]

Only 5% of the actions planned were identified as 'strong'. There remains a consistent focus on modifying the actions of individuals through training and communications to staff rather than introducing systems and processes focused on 'strong' changes with 'forcing' features which remove a reliance on individuals to choose the correct action, and places greater emphasis on system-wide improvements.



Strength[ii] of action plans

Weak

"Distribute communication to maternity staff regarding the necessity for intrapartum antibiotics in preterm labour and the importance of this."
A reminder for individual action without any controls

Intermediate

"Major review which led to a new staffing model and a newly appointed Lead for Triage and Induction."
A new system in place but may still require individuals to act without any controls

Strong

"Process for assessing need for aspirin developed and implemented via EPR"
A system level electronic design to eliminate human error

Examples of strength[ii] of actions planned

ii The strength of an action describes how well the action would eliminate human error. Strong actions are system changes which remove the reliance on individuals to choose the correct action.They use standardisation and permanent physical or digital designs to eliminate human error and are sometime referred to as 'forcing' actions [9].

3. Conclusions

All the reviews reported here were carried out during the period from the start of the SARS-CoV-2 global pandemic. The pandemic is expected to have had an impact on the delivery of care and also on the capacity of hospital staff to spend time reviewing deaths. This most likely explains why only relatively modest changes in the use of the tool are seen overall compared with the findings in the previous annual reports. Nevertheless, as efforts are made to return services back to normal it is worth reflecting on where things have improved and where improvements still need to be made.

Whilst this may not have been fully possible at the height of the pandemic, review of care when a baby dies should be universally regarded as a part of routine maternity and neonatal care, and must be resourced adequately to ensure that high quality reviews are conducted in the most cost-effective way. This means including time in job plans for consultants and prioritising the time required by other staff to participate in reviews. An indicative level of review team resourcing is given in Appendix A. There is evidence of an impact of the involvement of an appropriate professional external to the Trust/Health Board on the grading of care, suggesting that they may strengthen the quality of the critical reflections on the care provided when a death has occurred. This clearly requires the sharing of resources between Trusts and Health Boards and needs to be resourced by the inclusion of this important work in job plans. A recommended composition of the review team is given in Appendix B.

Incremental improvements are still required to ensure that more parents benefit from reviews conducted by groups including the fresh independent eyes provided by external members [1]. This is particularly important for the reviews of those 92% of deaths which will not benefit from a review by other organisations such as the Healthcare Safety Investigation Branch who investigate about 8% of the deaths in England for which a PMRT review could be undertaken. Child Death Overview Panels (CDOP) in England review all neonatal deaths and use, as the fundamental basis of their discussions, the local review conducted by the hospital team, which the CDOPs require to be carried out using the PMRT.

Resourcing is also required to support the review process and it remains disappointing that in the vast majority of instances, Trusts and Health Boards do not provide the appropriate administrative support, to reduce the burden of routine tasks for other staff carrying out reviews. One notable improvement is the increase in the proportion of neonatal deaths where a neonatologist and/or a neonatal nurse is involved in the review; this has increased from less than 25% to over 80% over the three-year period for neonatologist and from less than 10% to 46% for neonatal nurses.

There have only been modest shifts in the holistic grading of care suggesting that the discipline of robust self-examination is still not wholly embedded in many units. The continued involvement of members of governance/risk teams and of service managers in the process of review is a positive development as it is likely to increase the chances that the action plans developed by the review group will be translated into quality improvement activities and clinical practice.

Supporting parents through the review and other aspects of bereavement needs to be prioritised. There is evidence from the PARENTs [5-7] study that meaningful engagement with parents and families improves the review process and the potential for lessons to be learned. A recent Sands survey reports that parents who are given the opportunity to ask questions and express their concerns about their care, are mostly likely to express satisfaction with the review process. Meaningful engagement with parents and families not only benefits bereaved parents themselves, but may prevent future deaths where service improvements are instigated as a consequence of high quality reviews.

The issues identified in this report are largely focused around the same areas of care as in previous reports. This report alongside the local summary reports, which can be generated from the PMRT, provide the basis of prioritisation of local service improvement activities which in England should also be guided by the Saving Babies Lives Care Bundle version 2.

The strength of action plans developed follow reviews remains of concern with a continued focus on relatively weak actions focusing on the actions of individuals rather than ‘strong’, system level actions designed to reduce human error and to remove the need for individuals to remember what to do in all situations [9].

It remains the case that the PMRT is only a tool, and will therefore, only be as good as the information that is recorded in it, and the way in which it is used. If it is to achieve the original vision set out by the Sands/Department of Health Task and Finish Group in 2012, it is up to Trusts and Health Boards to improve the way the PMRT is supported, resourced and implemented.

4. Recommendations

1) Provide adequate resourcing of multidisciplinary PMRT review teams, including administrative support and ensure the involvement of independent external members in the team.

   Action: Trusts and Health Boards, regional/network support systems and organisations, Service Commissioners

2) Use the PMRT parent engagement materials to support engaging parents and families in the review process, including them being made aware a review is taking place and being given flexible opportunities at different stages to discuss their views, ask questions and express any concerns. Many parents may want to give positive feedback about the care they received.

   Action: Trusts and Health Boards, staff caring for bereaved parents, Service Commissioners

3) Use the local PMRT summary reports and this national report as the basis to prioritise resources for key aspects of care and quality improvement activities identified as requiring action.

   Action: Trusts and Health Boards, Service Commissioners, regional/network support systems, Governments

4) Improve the quality of recommendations developed as a consequence of reviews by developing actions targeted at system level changes and audit their implementation and impact.

   Action: PMRT review teams, governance teams in Trusts and Health Boards, Service Commissioners

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6. Appendices

Appendix A - Indicative level of review team resourcing

Example for 10 deaths per month

Person time required per week:

- 2PA*'s consultant obstetrician
- 12 hours midwife time
- 1PA* consultant neonatologist
- 5 hours neonatal nurse time
- 2 days of clerical support

*PA – programmed activity which is the metric used to describe consultant time

Appendix B - Recommended composition of a PMRT review team

PMRT Review Group

Core Group*

Roles within group:
- Chair and Vice-Chair
- Scribe/IT/Admin support
- PMRT Champion

Minimum of 2 of each of the following:
- Obstetrician
- Midwife
- Neonatologist and Neonatal Nurse
  - All cases where resuscitation was commenced
  - All neonatal deaths
- Risk manager/governance team member (1 acceptable) e.g. service manager
- Bereavement team (1 acceptable) **
- External panel member (1 acceptable)

* Group members can fulfil multiple roles

Additional Members

Named and invited to attend or contribute where applicable:
- Pathologist – when a PM was performed
- GP/Community Healthcare
- Anaesthetist
- Sonographer/Radiographer
- Safeguarding team
- Service manager
- Any other relevant healthcare team members pertinent to case

All opinions and views are equal, facilitate a breadth of discussion

** The role of the bereavement team member(s) is to advocate on behalf of the parents presenting their questions, concerns and comments, and not to take responsibility for the PMRT review process

7. Acknowledgements

The development of the national PMRT is as a result of a collaborative effort by a substantial number of individuals, many of whom are acknowledged below. We also owe a debt of gratitude to the many users of the PMRT who have contacted us with comments and suggestions about how we might improve the contents and operations of the PMRT.

Members of the MBRRACE-UK/PMRT Collaboration

Jenny Kurinczuk - Professor of Perinatal Epidemiology, Director of the National Perinatal Epidemiology Unit, National Programme Lead MBRRACE-UK/PMRT, Nuffield Department of Population Health, University of Oxford

Elizabeth Draper - Professor of Perinatal and Paediatric Epidemiology, Perinatal Programme Co-lead MBRRACE-UK, Department of Health Sciences, University of Leicester

Marian Knight - NIHR Professor of Maternal and Child Population Health, Maternal Programme Lead MBRRACE-UK, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford

Charlotte Bevan - Senior Research and Prevention Advisor, Sands (Stillbirth & neonatal death charity)
Christy Burden - Consultant Senior Lecturer in Obstetrics, University of Bristol

Thomas Boby - Senior Programmer, MBRRACE-UK, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford (stepped down January 2021)

Peter Brocklehurst - Professor of Women's Health, Director, Birmingham Clinic Trials Unit, Institute of Applied Health Research, University of Birmingham (stepped down November 2020)

Alan Fenton - Consultant in Neonatal Paediatrics, The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Alexander Heazell – Professor of Obstetrics and Director of the Tommy's Stillbirth Research Centre, University of Manchester

Tracey Johnston - Consultant Obstetrician, Maternal and Fetal Medicine, Birmingham Women's and Children's NHS Foundation Trust, Birmingham

Sara Kenyon - Professor in Evidence Based Maternity Care, University of Birmingham

Karen Luyt – Clinical Professor in Neonatal Medicine, Programme lead National Child Mortality Database, University of Bristol and University Hospitals of Bristol NHS Trust, University of Bristol

Bradley Manktelow – Professor of Medical Statistics, Department of Health Sciences, University of Leicester

Miguel Neves, PMRT Software Developer, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford

Sarah Prince, Consultant Obstetrician and Gynaecologist, The Princess Alexandra Hospital NHS Trust, Harlow (PMRT/RCOG Clinical Fellow July 2017–Jan2019; Collaborator February 2019 onwards)

Janet Scott - Head of Research and Prevention, Sands (Stillbirth & neonatal death charity)

Dimitrios Siassakos, Associate Professor, Maternal & Fetal Medicine, EGA Institute for Women's Health, University College London

Lucy Smith – Professor and NIHR Advanced Fellow in Perinatal, Department of Health Sciences, University of Leicester

Peter Smith – MBRRACE-UK Software Developer, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford

Claire Storey - Co-Chair, International Stillbirth Alliance and parent advocate

Derek Tuffnell - Professor and Consultant Obstetrician and Gynaecologist, Bradford Teaching Hospitals NHS Foundation Trust (Stepped down March 2021)

Zeenath Uddin, Head of Quality & Safety, Royal College of Midwives

Members of the PMRT development working groups

Julie-Clare Becher - Consultant Neonatologist, Department of Neonatology, Royal Infirmary of Edinburgh, Edinburgh

Charlotte Bevan - Senior Research and Prevention Officer, Sands (stillbirth and neonatal death charity)

Thomas Boby - MBRRACE-UK Senior Programmer, National Perinatal Epidemiology Unit, University of Oxford

Malli Chakraborty - Consultant in Neonatal Medicine, Regional Neonatal Intensive Care Unit, University Hospital of Wales, Cardiff

Katy Evans - Maternity Matron, Women and Children's Directorate Governance Lead, Taunton and Somerset NHS Foundation Trust, Taunton

Meg Evans - Consultant Perinatal Pathologist, Department of Pathology, Edinburgh Royal Infirmary, Edinburgh

David Field - Professor of Neonatal Medicine, Perinatal Programme Co-lead MBRRACE-UK Department of Health Sciences, University of Leicester, Leicester

Charlotte Gibson - Consultant Midwife, King's College Hospital NHS Foundation Trust, London

Alexander Heazell - Professor of Obstetrics and Director of the Tommy's Research Centre, University of Manchester, Manchester

Tracey Johnston - Consultant Obstetrician, Maternal and Fetal Medicine, Birmingham Women's and Children's NHS Foundation Trust, Birmingham

Sara Kenyon - Professor in Evidence Based Maternity Care, University of Birmingham, Birmingham

Jenny Kurinczuk - National Programme Lead MBRRACE-UK/PMRT, Professor of Perinatal Epidemiology, Director of the National Perinatal Epidemiology Unit, University of Oxford

Karen Luyt - Consultant Senior Lecturer in Neonatal Medicine, University of Bristol and University Hospitals of Bristol NHS Trust, Bristol

Kirsteen Mackay - Consultant Neonatologist, Jessop Wing, Sheffield Teaching Hospitals NHS Foundation Trust

Helen McElroy - Consultant Neonatologist, Medway NHS Foundation Trust, Kent David Millar - Consultant Neonatologist, Belfast Health and Social Care Trust, Belfast

Miguel Neves - MBRRACE-UK/PMRT Programmer, National Perinatal Epidemiology Unit, University of Oxford

Santosh Pattnayak - Consultant Neonatologist, Lead for Kent Neonatal Transport Service Medway NHS Foundation Trust, Kent

Sarah Prince – PMRT/RCOG Clinical Fellow Royal College of Obstetricians and Gynaecologists

Coralie Rogers - Maternity Matron, Nottingham University Hospitals NHS Foundation Trust, Nottingham

Dimitrios Siassakos - Associate Professor in Obstetrics at University College London and University College Hospital

Peter Smith - MBRRACE-UK Programmer, National Perinatal Epidemiology Unit, University of Oxford Claire Storey – Co-Chair, International Stillbirth Alliance, Parent Advocate

Melanie Sutcliffe - Consultant Neonatologist, New Cross Hospital, The Royal Wolverhampton NHS Foundation Trust, Wolverhampton

Derek Tuffnell - Professor and Consultant Obstetrician and Gynaecologist, Bradford Teaching Hospitals NHS Foundation Trust

Jonathan Wyllie - Consultant Neonatologist, South Tees Hospitals NHS Foundation Trust, South Tees, Professor of Neonatology and Paediatrics, Durham University

Members of the MBRRACE-UK/PMRT team

Caroline Ellershaw – MBRRACE-UK Administrative Support, Department of Health Sciences, University of Leicester

Ian Gallimore - MBRRACE-UK Project Team Leader, Department of Health Sciences, University of Leicester

Scott Redpath, MBRRACE-UK Data Manager, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford

MBRRACE-UK/PMRT Third Sector Stakeholder Group Representatives

Katrina Alcock, MBF

Beverly Beech, AIMS for Better Births

Charlotte Bevan, Sands

Jane Brewin, Tommy's

Ann Chalmers, CBUK

Jenny Chambers, ICP Support

Debbi Chippington Derrick, AIMS for Better Births

Jo Dagustun, AIMS for Better Births

Jane Denton, MBF

Elizabeth Duff, NCT

Ian Evans, CAPT

Jane Fisher, ARC

Jane Gorringe, Twins Trust

Marcus Green, APEC

Clea Harmer, Sands

Michelle Hemmington, Campaign for Safer Births

Caroline Lee Davey, BLISS

Nicky Lyon, Campaign for Safer Births

Therese McAlorum, CBUK

Amy McCarthy, Twins Trust

Sarah McMullen, NCT

Ashley Martin, ROSPA

Mehali Patel, Sands

Nilushka Perera, Best Beginnings

Jane Plumb, GBS Support

Keith Reed, Twins Trust

Jessica Reeves, Sands

Janet Scott, Sands

Fiona Spargo-Mabbs, DSM Foundation

Claire Storey, ISA

Liz Thomas, AvMA

Cheryl Titherly, ARC

Maureen Treadwell, BTA

Nathalie Turville, Elizabeth Bryan Multiple Births Centre

Jenny Ward, Lullaby Trust

MBRRACE-UK/PMRT Royal Colleges and Professional Association Stakeholder Group Representatives

Carmel Bagness - Royal College of Nursing

Sanjeev Deshpandi - British Association of Perinatal Medicine

Anita Dougall - Royal College of Obstetricians and Gynaecologists

Pamela Boyd - Royal College of Nursing

Denise Evans - Neonatal Nurses Association

Mervi Jokinen - Royal College of Midwives

Tamas Martan - British and Irish Paediatric Pathology Association

Surabhi Nanda - British Maternal Fetal Medicine Society

Marcia Philbin - Royal College of Paediatrics and Child Health

Felicity Plaat - Obstetric Anaesthetists Association and Royal College of Anaesthetists

Elena Pollina - British and Irish Paediatric Pathology Association

Shammi Ramlakhan - Royal College of Emergency Medicine

Rachel Scanlan - Royal College of Midwives

Trudi Seneviratne - Royal College of Psychiatrists

Clare Wade - Royal College of Physicians

Melissa Whitworth - British Maternal Fetal Medicine Society

Rachel Winch - Royal College of Paediatrics and Child Health

The Maternal, Newborn and Infant Clinical Outcome Review Independent Advisory Group

Matthew Jolly, National Clinical Director for Maternity Review and Women's Health,

NHS England (IAG Chair)

Carol Beattie, Senior Medical Officer, Department of Health, Northern Ireland

Sarah Corcoran, Team Leader, Maternal and Infant Health, Scottish Government

Jacqueline Dunkley-Bent, Chief Midwifery Officer, Nursing Directorate, NHS England and NHS Improvement

Becky Gunn, Chair of the Royal College of Obstetricians and Gynaecologists Women's Network

Karen Jewell, Nursing Officer for Maternity and Early Years, Welsh Government

Corinne Love, Senior Medical Officer, Maternity and Women's Health, Scottish Government

Eddie Morris, Consultant, Obstetrics and Gynaecology, Norfolk and Norwich University Hospital,

President, Royal College of Obstetricians and Gynaecologists

Karen Todd, Head of Maternity and Neonatal, NHS Quality and Safety Investigations, Department of Health and Social Care, England

Zeenath Uddin, Head of Quality and Standards, Royal College of Midwives

Michele Upton, Head of Maternity and Neonatal Safety, NHS England and NHS Improvement

David Williams, Consultant Obstetric Physician, University College Hospital, London

Healthcare Quality Improvement Partnership

Tina Strack, Associate Director for Quality and Development, National Clinical Audit and Clinical Outcome Review Programme

Vivien Seagrove, Project Manager, National Clinical Audit and Clinical Outcome Review Programme

MBRRACE-UK/PMRT Collaboration
National Perinatal Epidemiology Unit
Nuffield Department of Population Health
University of Oxford
Old Road Campus
Oxford OX3 7LF

Tel: +44-1865-617929
Email: pmrt@npeu.ox.ac.uk
Web: www.npeu.ox.ac.uk/pmrt

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PMRT
Supporting high quality local perinatal reviews

NICE National Institute for Health and Care Excellence

NICE guideline

Rehabilitation after traumatic injury

NICE guideline

Published: 18 January 2022
www.nice.org.uk/guidance/ng211

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

Overview

This guideline covers complex rehabilitation needs after traumatic injury, including assessment and goal setting, rehabilitation plans and programmes, physical, psychological and cognitive rehabilitation, rehabilitation for specific injuries, coordination of rehabilitation in hospital, at discharge and in the community, and commissioning and organising rehabilitation services.

Traumatic injury is any major or minor injury that requires admission to hospital at the time of injury, including musculoskeletal, visceral and nerve injuries, soft tissue damage, spinal injury, limb reconstruction and limb loss.

Who is it for?

- Healthcare professionals
- Social care practitioners
- Commissioners and providers of rehabilitation services
- Members of the public who have experienced traumatic injury, their families and carers

Context

Traumatic injury is a significant cause of early death and morbidity – particularly in the working population. Major trauma is the biggest cause of death in children and adults under the age of 40.

This guideline defines traumatic injury as any injury that requires admission to hospital at the time of injury. This could include musculoskeletal injuries, visceral injuries, nerve injuries, soft tissue damage, spinal injury, limb reconstruction and limb loss. Minor injuries can also lead to a hospital admission.

This guideline does not cover the management of traumatic brain injury, except in relation to early screening for onward referral and the coordination of services for people with multiple injuries, one of which may be traumatic brain injury. The specialist assessment and delivery of rehabilitation services for traumatic brain injury will be covered in a new NICE guideline on rehabilitation for chronic neurological disorders including traumatic brain injury.

In England, 45,000 people are affected by very severe or major trauma every year. A further 500,000 people (included in the population for this guideline) experience less severe trauma, and a proportion of those will need hospital admission because of pre-existing conditions, disability, frailty, or because the functional impact of injuries and environmental factors means that they will not be able to manage in their own home.

Trauma affects all age groups, but there are 2 peaks: younger age and older age. People may have different rehabilitation needs that reflect different functional expectations and priorities. Trauma can negatively affect quality of life, both physically and mentally. It can lead to problems with mobility, pain, breathing, swallowing, eating, drinking, toileting, cognitive function, speech, language and communication, sensory problems, and can lead to depression, anxiety and other psychological difficulties. These issues can similarly have a social and financial impact on the person, as well as on their family and carers. The impact of these problems may be influenced by pre-existing conditions.

After a traumatic injury, people need rehabilitation assessment and interventions that take account of any pre-existing conditions and focus on helping them regain optimum function and independence as quickly as possible.

This guideline focuses on people with complex rehabilitation needs after a traumatic injury. The defined population in this guideline has not been based on the severity of the injury (sometimes

measured using an injury severity score) but on the complexity of the rehabilitation need, taking into account existing conditions and circumstances that will impact rehabilitation. Complex needs cover multiple needs, and will involve coordinated multidisciplinary input from at least 2 allied health professional disciplines, which may include rehabilitation medicine, and could also include:

- vocational or educational social support for the person to return to their previous functional level, including return to work, school or college
- emotional, psychological and psychosocial support
- equipment or adaptations
- ongoing recovery from injury that may change the person's rehabilitation needs (for example, restrictions of weight-bearing, cast immobilisation in fracture clinic)
- further surgery and readmissions to hospital.

Currently, people who meet 'major trauma' criteria should have a rehabilitation assessment and prescription carried out during the hospital admission. Further assessments are performed over time to capture changing needs. For people who do not meet major trauma criteria (currently those with an injury severity score of less than 9), the pathway for rehabilitation is less clear.

There are limitations in access to the appropriate rehabilitation services for people after trauma, which may be related to geography, age, injury type or rehabilitation need. There is significant variation in practice, with no national network of services.

Improvement in survival rates resulting from the introduction of major trauma networks in 2012 has led to an increased need for rehabilitation.

Military experience has shown better outcomes with improved rehabilitation, where early and intensive rehabilitation has been shown to improve function, pain, quality of life and mental health outcomes. It can also improve outcomes for carers of those affected by traumatic injury.

Costs of treatment after a traumatic injury are high in the acute phase, and there are also long-term care costs to the NHS through ongoing treatment. Social care costs may be high for people who need ongoing care and support in the community. There are wider costs to the community if people are unable to return to work or education. Rehabilitation may be able to reduce these costs through improving overall function. Interventions may improve outcomes at a number of stages.

There are several NICE guidelines about the assessment, treatment and management of specific

injuries for adults and children. There is guidance about service delivery, assessment and management of major trauma, and rehabilitation after critical illness and stroke. There are also guidelines about the transition between hospital and home, from children's to adults' services, and about home care services.

How to use this guideline

All the recommendations apply to all people with complex rehabilitation needs after a traumatic injury, regardless of age or the nature of the injury, unless:

- the recommendation specifically states that it is for adults only, or children and young people only or
- the recommendation or section of the guideline specifically states that it is for people with a particular injury.

The following sections provide a pathway from assessment through to goal setting, agreeing and coordinating the delivery of a rehabilitation plan and programmes of therapy, and coordinating and organising rehabilitation at and following discharge:

- Initial assessment and early interventions for people with complex rehabilitation needs
- Multidisciplinary team rehabilitation needs assessment
- Setting rehabilitation goals
- Developing a rehabilitation plan and making referrals
- Rehabilitation programmes of therapies and treatments
- Principles for sharing information and involving family and carers
- Coordination of rehabilitation care in hospital:
    - From admission to hospital
    - When transferring between services and settings
- Coordination of rehabilitation care at discharge
- Supporting access and participation in education, work and community (adjustment and goal settings)
- Commissioning and organisation of rehabilitation services

The rehabilitation therapies and interventions included in the following sections apply to ALL

people with complex rehabilitation needs after a traumatic injury:

- Physical rehabilitation
- Cognitive rehabilitation
- Psychological rehabilitation

The following injury-specific sections should be read in conjunction with the sections on physical rehabilitation, cognitive rehabilitation and psychological rehabilitation:

- Rehabilitation after limb reconstruction, limb loss or amputation
- Rehabilitation after spinal cord injury
- Rehabilitation after nerve injury
- Rehabilitation after chest injury

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Initial assessment and early interventions for people with complex rehabilitation needs

1.1.1 Be aware that the severity of a person's traumatic injury does not necessarily correlate with the complexity of their rehabilitation needs, so assess the impact of the injury using a person-centred, individualised and holistic approach at all stages of their care pathway.

1.1.2 After a traumatic injury, assess the person's rehabilitation needs as an integral part of their care pathway from admission. This may include:

- discussing findings from early rehabilitation assessments with the person, and their family members or carers (as appropriate)
- helping the person, and their family members or carers (as appropriate), to think about preferred rehabilitation goals to inform shared decision making about medical or surgical options
- involving rehabilitation specialists (ideally including a consultant in rehabilitation) alongside acute care teams to discuss the implications for rehabilitation depending on different medical and surgical options.

1.1.3 All practitioners involved in the person's care should provide immediate psychological and emotional support for people who are mentally distressed and/or cognitively impaired after a traumatic injury. Request additional support and/or advice from psychology services as needed.

1.1.4 After a traumatic injury:

- Avoid delays in acute treatment so that rehabilitation can start as soon as possible, for example, to maintain movement.
- Start rehabilitation when the person is ready and able to engage and participate (see also recommendation 1.2.5). For people who lack capacity to engage in making decisions about their rehabilitation, follow the NICE guideline on decision making and mental capacity.

1.1.5 Provide access to rehabilitation therapies:

- before surgery, to maintain respiratory function and functional abilities (if surgery is delayed) and
- as soon as possible after surgery (starting ideally no later than the following day).

1.1.6 As soon as possible after the traumatic injury, assess how the person's physical impairments might affect their ability to engage in activities of daily living. Involve occupational therapy for:

- input and advice on therapies and referral for aids and
- equipment and adaptations.

1.1.7 As soon as possible after a traumatic injury, start to assess whether the person has new or existing cognitive, hearing, visual or communication impairments or emotional difficulties that might affect their ability to engage in rehabilitation and in activities of daily living. Involve occupational therapy, psychology and speech and language therapy as appropriate.

1.1.8 Use equipment as appropriate to encourage movement (for example, walking aids and transfer devices) and to protect the injury (for example, splints or orthotics).

1.1.9 Ask about the person's diet and nutrition, including their weight, eating habits and any use of health supplements such as vitamins and minerals or high-calorie drinks.

1.1.10 Ensure that the initial assessment checks to see if the person can swallow safely.

Also see recommendation 1.11.51 and the NICE guideline on nutrition support for adults.

1.1.11 Assess the person's risk of malnutrition using, for example, the Screening Tool for the Assessment of Malnutrition in Paediatrics (STAMP) score in children and young people under 16 years and, for example, the Malnutrition Universal Screening Tool (MUST) score for adults (see the section on screening for malnutrition and the risk of malnutrition in hospital and the community in the NICE guideline on nutrition support for adults).

1.1.12 Monitor the person's nutritional intake and weight throughout their hospital stay, provide nutrition support in line with the NICE guideline on nutrition support for adults, and refer for a specialist dietitian review if needed.

1.1.13 Complete a safeguarding assessment for children, young people and vulnerable adults after a traumatic injury, taking into account any known or suspected non-accidental injury. (Also see the NICE guidelines on child abuse and neglect and child maltreatment, and the Care Act 2014.)

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on initial assessment and early interventions for people with complex rehabilitation needs.

Full details of the evidence and the committee's discussion are in:

- evidence review A.1/A.2: identification and assessment of rehabilitation needs after traumatic injury
- evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury
- evidence review B.3: psychological and psychosocial interventions for people with complex rehabilitation needs after traumatic injury
- evidence review B.4: rehabilitation interventions relating to participation in society for people with complex rehabilitation needs after traumatic injury
- evidence review D.1 (service coordination): inpatient settings for people with complex rehabilitation needs after traumatic injury.

1.2 Multidisciplinary team rehabilitation needs assessment

1.2.1 The multidisciplinary team should complete a personalised and holistic rehabilitation needs assessment in partnership with the person and their family members or carers (as appropriate), which should include:

- physical functioning (see the section on assessing physical functioning)
- cognitive functioning (see the section on assessing cognitive functioning)
- psychological functioning (see the section on assessing psychological functioning).

1.2.2 In addition to the holistic rehabilitation needs assessment in recommendation 1.2.1, the multidisciplinary team should complete specialist assessments for the following injuries:

- for limb injuries, see the section on rehabilitation after limb reconstruction, limb loss or amputation
- for nerve injuries, see the section on rehabilitation after nerve injury
- for spinal injuries, see the section on rehabilitation after spinal cord injury
- for chest injuries, see the section on rehabilitation after chest injury.

1.2.3 Always think about the mechanism of injury and whether the person may have had a head injury. Be aware that the symptoms of traumatic brain injury can be subtle and regular screening may be necessary. If there are clinical symptoms, refer the person for a specialist assessment with healthcare professionals with expertise in traumatic brain injury rehabilitation. See also the NICE guideline on head injury.

1.2.4 The multidisciplinary team involved in assessing people's rehabilitation needs in hospital should consist of healthcare professionals and practitioners with expertise in rehabilitation after traumatic injury. Depending on the nature of the injury, the setting for assessment and treatment, the age of the person and other pre-existing health or care issues, the multidisciplinary team could involve:

- surgeons, rehabilitation medicine specialists, intensive care specialists, elderly care specialists and/or paediatricians (as appropriate)
- allied health professionals such as occupational therapists, physiotherapists, dietitians, orthotists and speech and language therapists
- practitioner psychologists
- specialist nurses
- play therapists
- pharmacists
- a trauma coordinator and/or rehabilitation coordinator

- when planning discharge:
  - a social worker
  - a discharge coordinator.

1.2.5 The multidisciplinary team should assess the person's rehabilitation needs as soon as possible after the traumatic injury, when measures are being taken to optimise their ability to engage in the assessment process. These measures include:

- pain management
- resolution of infections
- resolution of acute confusion or delirium
- consideration of psychological wellbeing
- making available hearing aids, glasses, dentures and other orthodontic appliances
- access to communication aids (if needed)
- access to interpreters (for example, for people who do not speak English)
- having in place drug or alcohol dependence withdrawal management
- restarting long-term medications to maintain physical and mental health; see also the NICE guideline on medicines optimisation.

1.2.6 Be aware that traumatic injury may affect sexual function. Discuss this with people at assessment and review, and seek specialist advice about sexual function, fertility issues and psychological support.

1.2.7 If a person lacks mental capacity, carry out a rehabilitation needs assessment based on the principles of best interests decision making, as set out in the NICE guideline on decision making and mental capacity.

1.2.8 As part of the rehabilitation needs assessment, the multidisciplinary team should ask about the person's pre-injury activities, for example:

- the person's background, personal history, relationships, work, education, meaningful activities, spiritual and religious practices, and hobbies and interests
- usual activities of daily living, including mobility and other physical activity
- motivational factors such as the person's lifestyle, previous ability, future aspirations, priorities and core values.

1.2.9 The multidisciplinary team should allow adequate time to:

- liaise with the clinical team managing any pre-existing, long-term conditions that may affect rehabilitation
- complete the rehabilitation needs assessment, which should include a detailed and accurate analysis of the person's injuries, impairments, goals and likely rehabilitation needs and
- discuss the findings together, to reduce the need to repeat questions and to improve the efficiency of the assessment process.

1.2.10 When discussing rehabilitation needs with people, and their family members or carers (as appropriate):

- be sensitive about the timing because pain, confusion, fatigue and trauma can make it more difficult for people to absorb and retain information
- give people sufficient time to process information about their injuries and rehabilitation options, to help them adjust after the traumatic injury and engage more readily in the rehabilitation therapy
- if people ask for information about the likely long-term prognosis, recognise that this may be difficult to predict and should only be discussed with the person after multidisciplinary team review.

1.2.11 Use validated tools (for example, the rehabilitation complexity scale [RCS], patient categorisation tool [PCAT], complex needs checklist [CNC] or post-ICU presentation screen [PICUPS]), in the rehabilitation needs assessment to determine the need for early referral to specialist rehabilitation units.

1.2.12 Regularly reassess (using clinical assessment and validated tools) whether referral for specialised rehabilitation is still needed and what other referrals

may now be needed.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on multidisciplinary team rehabilitation needs assessment.

Full details of the evidence and the committee's discussion are in:

- evidence review A.1/A.2: identification and assessment of rehabilitation needs after traumatic injury
- evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury
- evidence review B.4: rehabilitation interventions relating to participation in society for people with complex rehabilitation needs after traumatic injury
- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

Assessing physical functioning

1.2.13 As part of the rehabilitation needs assessment after a traumatic injury, the multidisciplinary team should assess the person's pre-injury and current physical functioning, which should include:

- assessing pain management to enable physical rehabilitation activities to begin
- a comprehensive neuromusculoskeletal assessment to identify physical impairments such as nerve injury, muscle imbalance and proprioception problems

- assessing upper and lower limb function and the impact of the injury on the person's ability to move and use walking aids (if needed)
- assessing and recording the range of movement for each joint affected
- asking about any problems with balance or dizziness and other vestibular symptoms (either pre-existing or new), and considering assessment for benign paroxysmal positional vertigo (BPPV) and for head injury
- if the traumatic injury has been caused by a fall, asking about previous falls and considering a falls risk assessment in line with the section on multifactorial risk assessment in the NICE guideline on falls
- assessing pre-existing or newly acquired vision or hearing problems
- assessing whether there are any new difficulties with communication, speech and language
- assessing ability to do transfers, for example, to move from lying to sitting, and sitting to standing
- assessing trunk control and core stability (if relevant)
- assessing ability to move and level of aerobic fitness and/or exercise tolerance
- assessing skin care, wound care and pressure area management
- for children and young people, asking about previous developmental attainment and functioning.

1.2.14 Refer the person for a specialist assessment if the multidisciplinary team does not have appropriate skills or expertise to perform the assessment needed. Examples are:

- to determine when and how splints and orthoses should be used, taking into account that people with complex traumatic injuries may need bespoke splints or orthoses
- if they have external fixation for lower limb fractures
- if they have sensory loss or nerve injury (see the section on rehabilitation after nerve injury).

1.2.15 Assess the person for factors that may affect their ability to engage in

rehabilitation. These may include balance and coordination issues (neurovestibular disorders), and newly acquired vision or hearing loss. Refer for specialist assessment and management as needed. Also see the section on sudden or rapid onset of hearing loss in the NICE guideline on hearing loss in adults.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on assessing physical functioning.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Assessing cognitive functioning

Please note this guideline does not cover assessment or specific rehabilitation interventions for people with traumatic brain injuries. See recommendation 1.2.3 in the section on multidisciplinary team rehabilitation needs assessment.

1.2.16 Be aware that even if there has been no brain injury, problems with cognitive functioning are common after a traumatic injury because of the psychological shock and trauma.

1.2.17 As part of the rehabilitation needs assessment after a traumatic injury, the multidisciplinary team should ask about any cognitive problems, for example:

- confusion
- disorientation
- slowed thinking and/or slowed processing of information
- withdrawal
- memory problems
- agitation
- communication, speech or language changes (for example, withdrawal or selective mutism).

1.2.18 If a person has problems with cognitive functioning after a traumatic injury, investigate for other causes such as:

- pre-existing cognitive impairment or dementia (see the NICE guideline on dementia)
- delirium (for example, alcohol or drug misuse, drug toxicity or opiate-related confusion, infection or sepsis, or hypoxia; see the NICE guideline on delirium)
- behavioural problems or learning disabilities (see the NICE guideline on challenging behaviour and learning disabilities)
- traumatic brain injury (this may not show up on scans immediately and further investigations will be needed if it is suspected; see also recommendation 1.2.3).

1.2.19 If a person has problems with cognitive functioning after a traumatic injury and the potential causes in recommendation 1.2.18 have been ruled out, assess the person's:

- orientation to time, place, person and situation
- ability to follow simple instructions
- ability to recall information and communicate it correctly after a short period of time.

1.2.20 If the assessment in recommendation 1.2.19 confirms difficulties with cognitive functioning, refer the person to an occupational therapist, practitioner psychologist (ideally a neuropsychologist) or a speech and language therapist (as appropriate) for a specialist cognitive assessment.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on assessing cognitive functioning.

Full details of the evidence and the committee's discussion are in evidence review B.2: cognitive interventions for people with complex rehabilitation needs after traumatic injury.

Assessing psychological functioning

1.2.21 As part of the rehabilitation needs assessment after a traumatic injury, the multidisciplinary team should ask about psychological and psychosocial risk factors, for example:

- past or present mental health problems, such as anxiety or depression
- past or present mental illness or psychiatric treatment
- history of traumatic brain injury
- history of self-harm or suicide attempts
- any experience of domestic violence or abuse
- any safeguarding concerns (if the person is a child or a vulnerable adult)
- excessive alcohol consumption or recreational drug use
- the circumstances of the injury, for example, self-harm or a violent crime
- social factors that mean the person may need additional support, for example, if the person is socially isolated, homeless, a refugee or recent migrant, if they have difficulty reading or speaking English, or if they have learning disabilities or other needs.

1.2.22 As part of the rehabilitation needs assessment after a traumatic injury, look for indicators of psychological problems (including lack of engagement with rehabilitation) beyond that of an acute stress response (see recommendation 1.13.1). Take into account any psychological and psychosocial risk factors (see recommendation 1.2.21) and, if needed, refer the person for a psychological assessment with a practitioner psychologist (with relevant expertise in physical trauma and rehabilitation) or a member of the liaison psychiatry team to inform their rehabilitation plan and goals.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on assessing psychological functioning.

Full details of the evidence and the committee's discussion are in evidence review B.3: psychological and psychosocial interventions for people with complex rehabilitation needs after traumatic injury.

1.3 Setting rehabilitation goals

Also see the section on supporting access and participation in education, work and community

(adjustment and goal setting).

1.3.1 Agree short-term and long-term rehabilitation goals with the person and their family members or carers (as appropriate), and review them regularly based on:

- what is most important to the person and what they most value
- activities that are meaningful for the person and relate to what is important
- a strengths-based approach, which builds on positive function and ability
- the person's home circumstances
- the person's aspirations about returning to work or education, and their preferred timeframe
- developing the knowledge, skills and confidence to manage their own health and wellbeing
- an understanding that there may be setbacks as well as gains, so goals should be flexible.

1.3.2 When setting long-term rehabilitation goals, agree small steps so that progress can be monitored in a way that is meaningful and motivational for the person.

1.3.3 Members of the multidisciplinary team involved in setting rehabilitation goals should be skilled and competent in:

- helping people identify goals that are right for them
- understanding how the psychological impact of trauma can affect goal setting and rehabilitation planning.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on setting rehabilitation goals.

Full details of the evidence and the committee's discussion are in evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

1.4 Developing a rehabilitation plan and making referrals

1.4.1 Use the rehabilitation needs assessment (see the section on multidisciplinary team rehabilitation needs assessment) and the person's rehabilitation goals (see the section on setting rehabilitation goals) to develop a rehabilitation plan for the person (this may be in the form of a rehabilitation prescription). The rehabilitation plan should include:

- information about the person's injuries
- the person's short-term and long-term rehabilitation goals (see the section on setting rehabilitation goals)
- information about the person's needs and preferences
- a suggested rehabilitation programme of therapies and treatments (see the section on rehabilitation programmes of therapies and treatments)
- how the rehabilitation programme of therapies and treatments will be delivered
- information and sources of further information about returning to vocational or leisure activities
- information about associated risks, responsibilities, and possible legal issues about returning to driving and sources of specific advice (for example, the DVLA [Driver and Vehicle Licensing Agency])
- information about referrals or sources of further information
- any follow-up arrangements (especially when transferring to home or community settings)
- who the rehabilitation plan should be shared with (with the person's consent) and details about any information that the person wants to remain confidential
- details of a rehabilitation coordinator or key worker, and the lead healthcare professional involved in the person's care.

1.4.2 The rehabilitation plan should be:

- a tailored and personalised journey towards the person's agreed goals, focusing on what is important to them
- developed with the person, and their family members or carers (as appropriate)
- based on advice and input from all members of the multidisciplinary team
- written in clear English
- a single document or file
- shared with the person, their families and carers (as appropriate), the person's GP, and healthcare professionals involved in their ongoing care
- regularly updated in partnership with the person to reflect their progress, goals, ongoing needs and key contact information, particularly at key points of transition in care.

1.4.3 Where it is not possible or appropriate for the person to have access to all of the information in a rehabilitation plan, ensure that important components of the plan are included in a summarised patient-held document that is regularly updated with progress, appointment times and contact details.

1.4.4 If there are aspects of the rehabilitation plan that the multidisciplinary team cannot implement, the rehabilitation coordinator or another senior member of the multidisciplinary team should make appropriate referrals without delay, including referrals to specialised rehabilitation services.

1.4.5 Manage the care of adults with fragility fractures of the femur within a specialist pathway involving orthogeriatricians. Also see the NICE guideline on hip fracture.

1.4.6 If an older person with a traumatic injury is on a care pathway that does not routinely involve geriatrician support, consider referral to an orthogeriatrician, a surgical liaison or a perioperative physician (as appropriate).

1.4.7 For adults with a fragility fracture, assess bone health and refer as necessary, for example, to a specialist bone health clinic or outpatient service. Also see the NICE guideline on osteoporosis.

1.4.8 If a traumatic injury has been caused by a fall, ask the person about previous

falls, and consider a falls risk assessment and a referral to a community falls service (as appropriate). Also see the section on multifactorial risk assessment in the NICE guideline on falls.

1.4.9 Assess all adults over 65 who have a traumatic injury for their risk of falls in line with the recommendations on multifactorial risk assessment in the NICE guideline on falls.

1.4.10 Provide information about, or refer people to, services that may help prevent future injury, such as falls prevention, safeguarding services, domestic abuse services, violence prevention programmes, and condition-specific support organisations.

1.4.11 For people admitted to hospital with violent injuries related to suspected criminal activity, consider a violence prevention programme and follow-up as part of their rehabilitation plans. This could include psychological support (for example, counselling), substance abuse rehabilitation, employment or education training, group sessions, family development, liaison with the police, social worker involvement, and rehousing, when needed.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on developing a rehabilitation plan and making referrals.

Full details of the evidence and the committee's discussion are in:

- evidence review A.1/A.2: identification and assessment of rehabilitation needs after traumatic injury
- evidence review B.4: rehabilitation interventions relating to participation in society for people with complex rehabilitation needs after traumatic injury
- evidence review D.1 (service coordination): inpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community.

1.5 Rehabilitation programmes of therapies and treatments

General principles for rehabilitation programmes

1.5.1 Rehabilitation programmes of therapies and treatments should:

- form part of the person's rehabilitation plan, and be tailored to their individual needs (see the section on developing a rehabilitation plan and making referrals)
- focus on outcomes (for example, return to work, school or leisure activities) and be based on the person's short-term and long-term rehabilitation goals (see the section on setting rehabilitation goals)
- include educational material to help people understand the nature of their injuries, to promote self-care and to prepare them for any long-term or intensive periods of rehabilitation (for example, sleep, pacing activities and pain management)

- include (as appropriate) physical, cognitive and psychological therapies and treatments such as physiotherapy, exercise, occupational therapy, psychology and orthotics, as well as injury-specific therapies and treatments; see the sections on:
  - physical rehabilitation
  - cognitive rehabilitation
  - psychological rehabilitation
  - rehabilitation after limb reconstruction, limb loss or amputation
  - rehabilitation after spinal cord injury
  - rehabilitation after nerve injury
  - rehabilitation after chest injury
- include access to specialist services to address complex issues such as fertility and endocrine concerns
- include (as appropriate) a combination of group and individual sessions as well as the development of a self-management rehabilitation programme (see the section on supporting access and participation in education, work and community [adjustment and goal setting])
- include and document regular progress reviews and a final assessment to review outcomes, update the rehabilitation plan and detail any ongoing rehabilitation needs for onward referrals to GP, outpatient and/or community services
- include post-programme follow-up, in person or virtually.

1.5.2 Tailor the start time, frequency, intensity and duration of the rehabilitation programme to have the most beneficial effect on the person's recovery (for example, a short period of intensive rehabilitation at an important time point might be better than weekly sessions over a long period).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on general principles for rehabilitation programmes.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Intensive rehabilitation programmes

1.5.3 In the post-acute period, consider an intensive (for example, 3 weeks) inpatient or outpatient (including residential) rehabilitation programme for adults, young people and children with complex injuries and rehabilitation needs if such an intervention is likely to have a significant impact on change in function (for example, it could result in return to work or education and living independently).

1.5.4 When providing intensive rehabilitation programmes:

- offer education and learning materials (see the section on guided self-managed rehabilitation) to prepare people for intensive rehabilitation, for example, 1 week of remote learning followed by a (for example, 3-week) residential or outpatient programme
- answer questions, such as those relating to the person's injuries and rehabilitation
- consider delivering rehabilitation therapies with regular breaks (for example, only during weekdays to allow for rest periods at weekends and time to review progress)
- communicate any changes to the rehabilitation plan with the local team following the intensive period of rehabilitation.

1.5.5 Start an intensive rehabilitation programme at the appropriate time for the person, taking into account:

- that the timing and nature of rehabilitation therapies and treatments will depend on issues such as bone and soft tissue healing, weight-bearing, and removal of weight-bearing restrictions
- the person's psychological and emotional wellbeing, levels of adjustment and engagement with the rehabilitation process.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on intensive rehabilitation programmes.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Guided self-managed rehabilitation

1.5.6 Consider guided self-managed rehabilitation to allow the person to engage in rehabilitation in their own time and by their own schedule, working with rehabilitation healthcare professionals and practitioners, with regular reviews to check on progress, provide ongoing reassurance and answer queries.

1.5.7 As part of a self-management rehabilitation programme, consider providing a tailored package of online education and learning materials for people after a traumatic injury, which could include information on:

- movement and physical activity
- energy conservation and pacing
- sleep
- activities of daily living
- work, social activities and hobbies
- nutrition and diet
- pain management and medicines
- wound healing
- mental health
- local and national sources of information

- peer support services, including local and national groups.

  For people who cannot access the internet, explore alternative ways to provide these materials.

1.5.8 If people are following a self-management rehabilitation programme, consider arranging follow-up appointments and regular reviews with rehabilitation healthcare professionals and practitioners to check on self-managed progress, provide ongoing reassurance and answer new queries.

1.5.9 For children, young people and vulnerable adults, offer additional support to develop and deliver a self-management programme that takes into account their communication needs, their own views and priorities and (for children) their developmental stage.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on guided self-managed rehabilitation.

Full details of the evidence and the committee's discussion are in:

- evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury
- evidence review B.3: psychological and psychosocial interventions for people with complex rehabilitation needs after traumatic injury
- evidence review B.4: rehabilitation interventions relating to participation in society for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

Monitoring progress against the rehabilitation plan, goals and

programme of therapies and treatments

1.5.10 Monitor the person's progress after starting rehabilitation. Use tools such as patient-reported outcome measures (PROMs) and clinician-reported outcome measures (CROMs) for adults; parent- and child-reported measures for children and young people; and consider using tools that involve family members and carers. Additional specific clinical assessments may be used as appropriate.

1.5.11 Encourage people to record information about their injuries, treatments and rehabilitation therapy options (for example, using a diary as part of their rehabilitation plan) to assist discussions and shared decision making.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on monitoring progress against the rehabilitation plan, goals and programme of therapies and treatments.

Full details of the evidence and the committee's discussion are in:

- evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community.

1.6 Principles for sharing information and involving family and carers

1.6.1 Involve people, and their families and carers (as appropriate), in assessments, in planning their coordination of care and in making decisions at all stages of the rehabilitation process. This should include discussing medical or surgical treatment options, discussing findings from assessments, setting goals, discussing potential discharge destinations and examining the different rehabilitation options after discharge.

1.6.2 Encourage and support children and young people to be actively involved in decision making about their rehabilitation to the best of their ability.

1.6.3 Be aware that encouragement from family members, carers, friends and healthcare professionals can all have a positive effect on a person's rehabilitation after a traumatic injury, so involve the person's family members, carers and friends (as appropriate) as much as possible throughout the person's rehabilitation journey.

1.6.4 In discussions and when giving information to people, and their family members or carers (as appropriate), use clear language, and tailor the timing, content and delivery of information to the needs and preferences of the person. Information should be:

- specific to the person's injuries
- offered in face-to-face (in person or remotely by video link) discussions, and in a suitable format, for example, digital, printed, braille or Easy Read
- offered throughout the person's care
- personalised and sensitive
- supportive and respectful
- evidence-based and consistent between healthcare professionals.

For more guidance on communication, providing information (including different formats and languages) and shared decision making, see the NICE guidelines on patient experience in adult NHS services, babies, children and young people's experience of healthcare, decision making and mental capacity and shared decision making.

1.6.5 Be aware that if a person has severe and complex rehabilitation needs after a traumatic injury, if they have had a brain injury or if they have problems with cognitive functioning after a traumatic injury, information giving may need to be enhanced and reinforced by:

- repeating information on several occasions
- providing information in a suitable format (for example, Easy Read)
- giving information in the presence of family members or carers (as appropriate).

1.6.6 Be aware that people who lack mental capacity may be legally entitled to professional advocacy (see the Mental Capacity Act 2005), as may people who have care and support needs (see the Care Act 2014). Also see the NICE guideline on decision making and mental capacity.

1.6.7 Advise carers about their right to a carer's assessment, an assessment for replacement care, and other support (see the NICE guideline on supporting adult carers for recommendations on identifying, assessing and meeting the caring, physical and mental health needs of families and carers).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on principles for sharing information and involving family and carers.

Full details of the evidence and the committee's discussion are:

- evidence review D.1 (service coordination): inpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

1.7 Coordination of rehabilitation care in hospital

From admission to hospital

1.7.1 Where possible, provide continuity of staff throughout the person's rehabilitation pathway.

1.7.2 Assign a named rehabilitation coordinator or key worker to oversee the person's care as soon as possible and within 72 hours of admission. Ensure that

the person knows who their rehabilitation coordinator or key worker is, how they will coordinate care, and how they can be contacted.

1.7.3 The trauma team should agree the core members of the rehabilitation multidisciplinary team who will establish an injury management plan and start developing a rehabilitation plan and goals. See recommendation 1.2.4 for details of the multidisciplinary team after hospital admission.

1.7.4 A member of the rehabilitation multidisciplinary team should discuss the person's rehabilitation at daily trauma meetings or ward rounds.

1.7.5 Where assessment identifies the need for specialist rehabilitation (see the section on multidisciplinary team rehabilitation needs assessment), complete the referral to specialist rehabilitation units as soon as possible.

1.7.6 Use a unique identifier, preferably the NHS number if this is known, when exchanging clinical information about the person's assessment, rehabilitation plan, onward referral, transition between services, discharge to community services, and all aspects of their care pathway.

When transferring between services and settings

1.7.7 Make follow-up appointments with acute teams (if needed) for people moving from an acute unit to rehabilitation services, and ensure that the person is informed before they are transferred.

1.7.8 When people transfer between service providers or settings (for example, wards, hospitals and inpatient rehabilitation facilities), share information (with the person's consent) by providing a detailed verbal and written or online handover (for example, the rehabilitation plan and the person's progress against it) and let the person know this has been done. Ensure information is promptly communicated:

- to those coordinating and delivering rehabilitation in the new setting or service
- to the person, and family members and carers (as appropriate)
- to any other service providers involved in the person's care and support.

1.7.9 The detailed handover and report should include oral and online or printed information about:

- all of the person's injuries
- different treatment options and their benefits and risks
- the person's current rehabilitation plan and goals
- the person's cultural, language and communication needs
- psychological approaches to managing pain and fatigue, if relevant
- beneficial activities, and activities to avoid
- how to manage activities of daily living, including self-care and re-engaging with everyday life
- plans for returning to work or school, housing and benefits, and driving, if relevant
- how to recognise possible problems or complications, and what to do
- local support groups, opportunities to access peer support, online forums and national charities, and how to get in touch with them
- services that provide independent legal, financial, employment and welfare advice
- advice for the family or carers about:
  - what to expect and how to support the person at home
  - the impact of the traumatic injury on family members and carers, and how they can get support.

1.7.10 When people transfer between service providers or settings, discuss with them:

- their expected recovery pathway
- what might happen if recovery is slower than expected
- the emotional impact of living with possible long-term symptoms and treatments.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on coordination of rehabilitation care in hospital.

Full details of the evidence and the committee's discussion are in:

- evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury
- evidence review D.1 (service coordination): inpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

1.8 Coordination of rehabilitation care at discharge

Discharge planning and a multidisciplinary approach

1.8.1 Consider early, multidisciplinary discharge planning to ensure appropriate and smooth discharge and transition to outpatient and community services.

1.8.2 Reassess the person's needs and review the rehabilitation plan before discharge to ensure that their needs are addressed alongside any long-term, existing health conditions or disabilities.

1.8.3 Be aware that family members and carers can play a key role in the smooth transition to outpatient and community services. If the person consents and their family members or carers agree, actively involve them in the transition process.

1.8.4 Give people information and support at the earliest opportunity if they need to apply for funded equipment for use after discharge from hospital (for example, wheelchairs) because applications can take time to process and may delay the person's discharge.

1.8.5 For children and young people, arrange a meeting between the school or education setting, 1 or more members of the multidisciplinary team, and their parents or carers, to inform the education provider about the changes to the environment and education plan that the child or young person may need to meet their education and support needs. This should take into account transport needs.

1.8.6 Advise people that further help with funding for equipment, assistive technology, environmental adaptations and other forms of support with rehabilitation might be available for their home, education and workplace settings (for example, through local authorities, the education, health and care plan, Access to Work grants, voluntary sector grants and the Department for Work and Pensions).

1.8.7 Give people, and their family members or carers (as appropriate), information about services that provide independent legal, financial, employment and welfare advice (for example, Citizens Advice).

1.8.8 If a person has significant ongoing and complex medical and therapy needs, offer a gradual and incremental return into the community, for example, transfer to a local hospital, a stepdown bed or a pre-discharge visit to home, to reduce the distress of the sudden loss of support as an inpatient.

1.8.9 Ensure that ongoing advice about pain management, including a plan to reduce analgesia, is discussed with the person and passed onto the person's GP or another lead clinician. See also the NICE guideline on medicines optimisation.

1.8.10 Where possible, arrange joint inpatient and community team home visits with the person before discharge, especially for people with significant ongoing needs.

1.8.11 If there are any concerns about how the person will manage at home after they are discharged, consider overnight or weekend visits home before discharge,

depending on their needs, preferences and home circumstances.

1.8.12 When arranging overnight or weekend visits home, involve the person in discussing the possible risks and how to manage them, especially if they live alone.

Planning for rehabilitation and other support following discharge

1.8.13 If a person is likely to have continuing health and social care needs after discharge to home:

- inform relevant healthcare professionals, social care practitioners and education practitioners (as appropriate)
- establish the person's eligibility for funded social care support, including for families and carers
- use the NHS continuing healthcare checklist, to establish the person's eligibility for a full continuing healthcare assessment before discharge
- for children and young people, establish their eligibility for emergency education funding for short-term support at school and for funded support through an education, health and social care plan (if appropriate).

  Also see the NICE guideline on transition between inpatient hospital settings and community or care home settings for adults with social care needs.

1.8.14 Offer a multidisciplinary approach to meet the person's rehabilitation and social care needs that is coordinated, consistent and as integrated as possible, to support the person, and their family or carer (as appropriate), through transfer from inpatient to outpatient rehabilitation services.

1.8.15 Document in the rehabilitation plan and handover report how rehabilitation after discharge will be delivered (see recommendations 1.7.7 to 1.7.9 for what should be included). When transferring the person to outpatient and community settings (including home), also include:

- whether ongoing support and follow-up after discharge is needed, for example, community rehabilitation, referrals and review appointments

- when community rehabilitation appointments will be likely to take place.

1.8.16 For people who will have significant ongoing needs after discharge:

- arrange a pre-discharge planning meeting with community practitioners who will be involved in the person's rehabilitation, care and support (for example, therapists, social workers and care coordinators)
- encourage pre-discharge visits by community practitioners to meet the person, and their family or carer (as appropriate)
- consider organising a joint 'handover' appointment between the inpatient multidisciplinary team and community practitioners at the point of discharge.

1.8.17 Liaise with community teams (such as community and voluntary sector providers, physiotherapists and occupational therapists, education support, and special educational needs coordinators in schools and nurseries for children and young people) to agree a staged return to the workplace or education. (See also the NICE guideline on transition between inpatient hospital settings and community or care home settings for adults with social care needs.)

1.8.18 When planning discharge, address potential barriers that may prevent the person accessing rehabilitation in the community. For example, ensure that they can travel to and access the location of treatments, and ensure that the timing and length of appointments will be manageable for them.

1.8.19 If a person cannot travel to rehabilitation appointments, offer telephone or video consultations, or rehabilitation in the person's home.

1.8.20 Consider arranging telephone or video consultations or rehabilitation in the person's home, rather than in a clinic or hospital setting (for example, if the person needs help to learn to live independently in their own home).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on coordination of rehabilitation care at discharge.

Full details of the evidence and the committee's discussion are in:

- evidence review A.1/A.2: identification and assessment of rehabilitation needs after traumatic injury
- evidence review B.4: rehabilitation interventions relating to participation in society for people with complex rehabilitation needs after traumatic injury
- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

A single point of contact, key contact and key worker after discharge

1.8.21 At discharge from hospital, provide people and their family or carers (as appropriate) with a single point of contact at the hospital for information, help and advice for a limited time period (for example, 3 months).

1.8.22 If people need ongoing rehabilitation and other health and social care support after discharge, the inpatient multidisciplinary team and community practitioners should agree who will be the key contact after discharge when contact with the hospital is no longer appropriate (see recommendation 1.8.23). This person may be a GP, rehabilitation physician, special educational needs coordinator, allied health professional, family support worker, social worker, case manager, disability paediatrician or speciality-specific coordinator, for example, a neuro navigator.

1.8.23 If people have complex or long-term conditions or social care needs, consider appointing a key worker as a direct source of advice, support and signposting. This should be a healthcare or social care professional with knowledge and expertise about inpatient or community-based rehabilitation and support, including education or training support for children and young people.

1.8.24 For young people who are transitioning between children's and adults' services, see recommendations about the role of the named worker in the NICE guideline on transition from children's to adults' services for young people using health or social care services.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on a single point of contact, key contact and key worker after discharge.

Full details of the evidence and the committee's discussion are in:

- evidence review B.4: rehabilitation interventions relating to participation in society for people with complex rehabilitation needs after traumatic injury
- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

1.9 Supporting access and participation in education, work and community (adjustment and goal setting)

Also see the section on setting rehabilitation goals.

1.9.1 Help and support the person to adjust after a traumatic injury by asking them and their family members or carers (as appropriate) about:

- their life, hobbies, occupation, usual activities, and personal and family history, and finding out what is important to them
- their views and feelings about their injuries and rehabilitation options
- the support they think they will need by asking about their views and feelings
- allowing time for adjustment and considering this before starting any new rehabilitation therapies or interventions.

1.9.2 Support the person to achieve realistic rehabilitation goals for life skills, work-related training or education (see the section on setting rehabilitation goals). Support should be tailored to the person's needs and may include:

- providing equipment and adaptations (for example, wheelchairs and seating)
- increasing independence in activities of daily living (for example, personal care, dressing and bathing, housework, shopping, food preparation, eating and drinking, managing money, how to access carers' and disability benefits and grants, driving or using public transport)
- work-related training (for example, careers advice and retraining)
- advice from job centres (for example, disability employment advisers and access to work scheme)
- access to adult education settings
- access to education for children and young people (for example, special educational needs and disabilities [SEND] adjustments in school, or new school placements).

1.9.3 Revisit rehabilitation goals with the person at regular intervals and align them with ongoing emotional and psychological adjustment.

1.9.4 Give people information about opportunities for engaging in daily meaningful activity (for example, hobbies, social activities or voluntary work) while they are in the process of a staged return to work.

1.9.5 Adapt rehabilitation activities to promote social interaction and participation in the person's normal activities of daily living consistent with the person's lifestyle and preferences.

1.9.6 Provide information for the person's employer or education provider about:

- the person's rehabilitation needs and
- how they can make adjustments to support the person's rehabilitation goals, for example, a staged or part-time return to work or education, and/or amended duties.

1.9.7 See the section on workplace culture and policies in the NICE guideline on workplace health: long-term sickness absence and capability to work for recommendations about vocational support and returning to work.

1.9.8 Provide information for early years settings or schools about the child or young person's rehabilitation needs, and the adjustments needed to enable their return to education and sports, for example, a staged return.

1.9.9 Give children and young people, and their families and carers (as appropriate), information about educational support and return to school.

1.9.10 For young people who are starting to access support from adult rehabilitation services, see the NICE guideline on transition from children's to adults' services for young people using health or social care services.

1.9.11 Community practitioners should offer emotional and psychological support to adults and their families and carers to help with lifestyle adjustments and the effects of the traumatic injury (for example, prolonged hospitalisations), and support their gradual return to work, education, social roles and leisure activities.

1.9.12 The team around the child should offer emotional and psychological support to children, young people and their families and carers to help with lifestyle adjustments and the effects of the traumatic injury (for example, prolonged hospitalisations), and support their gradual return to education, play, social and leisure activities.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on supporting access and participation in education, work and community (adjustment and goal setting).

Full details of the evidence and the committee's discussion are in:

- evidence review B.3: psychological and psychosocial interventions for people with complex rehabilitation needs after traumatic injury
- evidence review B.4: rehabilitation interventions relating to participation in society for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

1.10 Commissioning and organisation of rehabilitation services

Commissioning

1.10.1 When planning, commissioning and coordinating the delivery of rehabilitation and related services (for example, social care and the voluntary sector), commissioners and providers should design services with whole care pathways in mind, from acute treatment and inpatient rehabilitation through to community provision, including specialised and non-specialised elements.

1.10.2 Ensure collaboration between commissioners from different commissioning bodies to ensure seamless provision, for example, to include specialist community, vocational and educational rehabilitation provision for people after a traumatic injury, including those transferring between children's and adults' services.

1.10.3 Ensure that it is clear locally who has overall designated commissioning

responsibility for rehabilitation services.

1.10.4 Commissioners and providers should ensure that rehabilitation services for people after a traumatic injury:

- meet the needs of people of all ages and at all stages of rehabilitation
- are developed and co-designed in collaboration with the people who use rehabilitation services and the healthcare professionals who work within them
- are outcome-focused and relevant for the people who use them.

1.10.5 Consider commissioning intensive (for example, 3-week) residential or outpatient rehabilitation programmes for people of all ages in addition to existing rehabilitation pathways, for example, as a tertiary service for trauma rehabilitation within the trauma network.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on commissioning.

Full details of the evidence and the committee's discussion are in:

- evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury
- evidence review D.1 (service coordination): inpatient settings for people with complex rehabilitation needs after traumatic injury.

Organisation

1.10.6 Establish care networks (for example, trauma networks) and clear guidance on coordination and communication between rehabilitation settings and services to meet the needs of the local population across different aspects of rehabilitation service commissioning.

1.10.7 Rehabilitation units should maintain an online directory of care pathways, rehabilitation facilities and voluntary sector services (including recreational facilities) so that practitioners have access to up-to-date information and

contact details to pass on to people with complex rehabilitation needs.

1.10.8 If community treatments and services remain uncertain at the point of discharge, give people and their families and carers (as appropriate) information about rehabilitation community and social services available in their local area and from national support networks, and how they can access these.

1.10.9 Offer networking opportunities between different rehabilitation, social care and related services to enhance inter-service awareness and working relationships.

1.10.10 Consider technology-enabled follow-up, support and rehabilitation sessions if people request more local, accessible therapy or if rehabilitation practitioners are not available in their area, for example, in rural areas.

1.10.11 Consider group rehabilitation sessions to allow people to interact with peers, share experiences and to provide valuable support.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on organisation.

Full details of the evidence and the committee's discussion are in:

- evidence review D.1 (service coordination): inpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.3 (service coordination): barriers and facilitators to accessing rehabilitation services following discharge to the community.

Rehabilitation skills, knowledge and expertise in the workforce

1.10.12 Ensure that staff working with people with complex rehabilitation needs have specialist skills, knowledge and expertise in the person's injuries, the complexity of their rehabilitation needs and goals, and the stages of their recovery journey.

1.10.13 Ensure that hospital staff have access to supervision and training to develop their specialist knowledge in the management and rehabilitation of traumatic injuries.

1.10.14 Ensure that community rehabilitation practitioners have access to training expertise, advice or peer support from specialist services, especially where specific rehabilitation interventions or services are not widely available. For example, healthcare professionals such as speech and language therapists, practitioner psychologists and consultants with specialist knowledge of specific injuries and complex rehabilitation could work together with general rehabilitation staff working in community-based rehabilitation services.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rehabilitation skills, knowledge and expertise in the workforce.

Full details of the evidence and the committee's discussion are in:

- evidence review D.2 (service coordination): inpatient to outpatient settings for people with complex rehabilitation needs after traumatic injury
- evidence review D.4 (service coordination): support needs and preferences following discharge to outpatient or community rehabilitation services for people with complex rehabilitation needs after traumatic injury.

1.11 Physical rehabilitation

Physical rehabilitation – early interventions and principles

1.11.1 Provide personalised exercises as soon as possible after a traumatic injury to maintain and improve muscle function, strength and range of movement.

1.11.2 Proactively support people in managing their pain, and ensure that they have adequate analgesia so that rehabilitation can go ahead.

1.11.3 Choose a pain scale appropriate for the person, taking into account a range of factors such as their developmental age, cognitive ability, any communication

difficulties and their first language.

1.11.4 If needed, provide aids, splints or orthotics to maintain range of movement or protect the injury (for example, an ankle-foot orthosis, knee brace or spinal orthosis).

1.11.5 Use clinical judgement and expertise to determine the frequency and dose of the prescribed exercises because this is vital to the success of the interventions, and will differ depending on the individual needs and goals.

1.11.6 Before starting weight-bearing exercises, be aware of the effects of low blood pressure (for example, postural hypotension or vasovagal syncope [fainting]) and monitor the person for hypotensive symptoms when starting therapy.

1.11.7 Minimise adverse effects of low blood pressure and loss of postural reflexes by:

- optimising the person's bed position and using strategies such as thromboembolic stockings
- ensuring adequate hydration
- carrying out a medication review
- using abdominal binders and tilt tables.

1.11.8 Be aware that traumatic injury that requires intubation, or causes facial trauma, oedema or loss of dentition may lead to a voice disorder, decreased speech intelligibility and/or swallowing difficulties. Consider early referral to appropriate professionals as needed; this may include maxillofacial specialists, dental services, ear, nose and throat services, or speech and language therapy.

1.11.9 Promote independence with activities of daily living, in particular personal activities of daily living, and consider referral to occupational therapy if needed.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on physical rehabilitation – early interventions and principles.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Early weight-bearing

1.11.10 The surgical team should define and document the person's weight-bearing status at the earliest opportunity after a traumatic injury, and inform the rehabilitation multidisciplinary team, explaining the reasons for restricted weight-bearing, what limits should be put in place and for how long.

1.11.11 Start a programme of weight-bearing exercises, including exercises through play for children and young people, as soon as possible after a traumatic injury to encourage mobility and maintain postural reflexes, muscle mass, strength and function.

1.11.12 For people with lower limb injuries, start a programme of targeted weight-bearing exercises, including exercises through play for children and young people, to improve range of movement of the affected joint(s), improve muscle activation, and improve strength and balance. Aim to progress the person's function with weight-bearing tasks such as mobility, ability to move from sitting to standing, and ability to lateral step.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on early weight-bearing.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Aerobic and strengthening exercises

1.11.13 As soon as possible after a traumatic injury, start a tailored exercise programme to help with reconditioning, fitness, strengthening, balance, proprioception and

vestibular function, irrespective of the person's age, stage of rehabilitation or combination of injuries. The exercise programme:

- could be self-directed and/or delivered as one-to-one sessions or in a group
- should include resistance training, core strengthening exercises and general aerobic fitness
- should include task-specific balance training if needed
- should be incorporated into the usual play activities for children
- should be tailored to the person's needs and goals (for example, the frequency of the sessions and the exercises involved).

1.11.14 Consider a continued programme of aerobic exercise when agreeing a rehabilitation plan and at appropriate points along the rehabilitation pathway.

1.11.15 For people with limited lower limb mobility or immobility after a traumatic injury, consider a programme of upper body aerobic training or seated exercises.

1.11.16 Tailor the aerobic exercise programme to the person's interests to help with personal commitment and adherence, and depending on the nature of their traumatic injuries.

1.11.17 Do not withhold aerobic exercise programmes from older people after a traumatic injury.

1.11.18 After discharge from hospital after a traumatic injury, offer people a home exercise programme that includes aerobic and strengthening exercises, and review their progress at outpatient clinics or key worker appointments.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on aerobic and strengthening exercises.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Gait training and re-education

1.11.19 For people who are unable to weight-bear (because of clinical restrictions or pre-existing conditions), start an exercise programme as soon as possible after the traumatic injury to reduce the impact of non-weight-bearing and to optimise the transition to gait training when possible.

1.11.20 As soon as possible after a traumatic injury and once weight-bearing can begin, start a gait re-education programme that:

- aims to restore gait patterns
- includes passive stretches and range of movement exercises
- reduces the impact of non-weight-bearing on joints and muscles.

1.11.21 For people who need a non-weight-bearing period after a traumatic injury:

- assess muscle weakness and joint range of movement as soon as possible after the non-weight-bearing period ends and
- start an exercise programme aimed at muscle strengthening and gait progression.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on gait training and re-education.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Manual therapies and maintaining joint range of movement

1.11.22 Provide a programme of passive, active assisted or active range of movement exercises for all affected joints.

1.11.23 Consider a programme of targeted stretching techniques in addition to the standard range of movement exercise programme in recommendation 1.11.22.

1.11.24 If the person is unable to engage in range of movement exercises independently, consider using controlled motion devices to help with range of movement at the

knee and ankle joints.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on manual therapies and maintaining joint range of movement.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Splinting and orthotics

1.11.25 Regularly review the use of splints (as part of donning [putting on] and doffing [taking off]), cautiously increasing the length of time the splint is in use to ensure that it is still appropriate and that there are not complications such as nerve injury or pressure sores.

1.11.26 Ensure that the person, and their families and carers (as appropriate), know how to put on and take off their orthoses and splints, when to wear them and when to seek advice.

1.11.27 For people with lower limb fractures or nerve injuries, consider an orthosis (for example, a dorsi-wedge in a moon boot or an ankle-foot orthosis) if there is a risk of loss of ankle range of movement.

1.11.28 For people with external fixation for lower limb fractures, carry out specialised splinting to maintain ankle range of movement.

1.11.29 Monitor the pressure effects on skin by orthoses or splints, particularly in people with reduced cutaneous sensation and/or recent skin graft or flaps. Seek advice from tissue viability services and/or plastic surgery specialists as needed.

1.11.30 Be aware that spinal orthoses, such as cervical collars and thoraco-lumbar spinal orthoses, may be poorly tolerated by some people, particularly older people or those with delirium, cognitive impairment or dementia.

1.11.31 If spinal orthoses are causing problems (such as pain, pressure sores, or swallowing or breathing difficulties) or are significantly affecting the person's

ability to engage with rehabilitation, inform the relevant surgical team.

1.11.32 If splints or braces are used to immobilise and protect joints, avoid positions that may result in loss of function or complications in the future.

1.11.33 For people with upper limb injuries that affect range of movement in their hands and fingers, offer bespoke (thermoplastic) splints as early as clinically possible to maintain range of movement. Refer people with complex hand injuries to a hand therapy specialist, as appropriate.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on splinting and orthotics.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Management of swelling and oedema, and scars

Swelling and oedema management

1.11.34 Discuss with people what swelling to expect after a traumatic injury. Explain how to monitor swelling on a daily basis, and advise them about signs or symptoms that they should seek medical advice for.

1.11.35 Consider alternative medical causes for unexpected swelling such as deep vein thrombosis, and investigate as necessary.

1.11.36 Start a programme of circulation exercises and elevate the person's affected limb to prevent and reduce swelling after a traumatic injury, for example, by using elevating leg rests for wheelchairs.

1.11.37 Consider providing compression bandaging under specialist supervision, for example, from a specialist in hand therapy.

Scar management

1.11.38 Help the person desensitise themselves to their injury by encouraging them to:

- look at the affected area
- gently touch the affected area
- move their affected limb.

1.11.39 For children and young people, keep their hospital bed as a 'safe' space, and carry out potentially painful scar management techniques such as massage, or other painful treatments, away from their bed if possible.

1.11.40 Reassure people that unpleasant sensations (for example, pain and itchiness) in the area of wounds or skin injuries are normal after a traumatic injury, and may change as recovery progresses.

1.11.41 Discuss and give people information about scar management such as keeping the wound out of direct sunlight for 1 year, and using recommended emollients.

1.11.42 Provide a massage programme for scar tissue after healing, to desensitise the affected area and increase tissue mobility.

1.11.43 Consider referral for specialist treatments for people with problematic scars such as hypertrophy or contracture across joints.

1.11.44 If the person's injuries and scars have had a significant psychological impact on them, consider referral to psychology services and/or signpost to appropriate support groups. See also the section on assessing psychological functioning and the section on psychological rehabilitation.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on management of swelling and oedema, and scars.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

Nutritional supplementation

1.11.45 Monitor the person's intake of adequate food and drink to maintain weight,

taking into account the effects of post-surgical anorexia, pain medications, constipation and nausea, and the increased calorific needs of healing.

1.11.46 Regularly and proactively review the person's nutritional needs and the dietary plan for effective rehabilitation. See recommendations in the NICE guideline on nutrition support for adults.

1.11.47 Following assessment by a dietitian specialising in trauma care, consider supplementation of dietary protein for people who are frail, have gastrointestinal health issues or have multiple injuries.

1.11.48 Involve specialist dietitians when considering dietary protein requirements for people with severe kidney impairment.

1.11.49 For people with a fragility fracture, measure vitamin D levels and consider a supplement. Also see the recommendations in the NICE guideline on osteoporosis: assessing the risk of fragility fracture and the NICE guideline on vitamin D: supplement use in specific population groups.

1.11.50 For people with burns in combination with other traumatic injuries, regularly monitor their weight and involve a dietitian with experience of burns, for example, if the person's weight fluctuates or they are at risk of losing muscle mass and strength.

1.11.51 If there are concerns about safe swallowing and risk of aspiration (see recommendation 1.1.10), keep the person nil by mouth and carry out a swallowing assessment by an appropriately trained healthcare professional as soon as possible. If immediate assessment is not available, maintain hydration and nutrition by non-oral means. Also see the NICE guideline on nutrition support for adults.

1.11.52 Involve a dietitian and nutrition team for treatments to maintain nutritional supply, for example, a nasogastric tube, percutaneous endoscopic gastrostomy (PEG), radiologically inserted percutaneous gastrostomy (RIG) or parenteral nutrition (PN).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on nutritional supplementation.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

1.12 Cognitive rehabilitation

Please note this guideline does not cover assessment or specific rehabilitation interventions for people with traumatic brain injuries. See recommendation 1.2.3 in the section on multidisciplinary team rehabilitation needs assessment.

1.12.1 Reassure people that most trauma-related problems with cognitive functioning are temporary.

1.12.2 Adapt rehabilitation therapy to the person's current cognitive function and emotional needs, taking into account any problems with motor development and skills, and any coexisting neurodevelopmental conditions.

1.12.3 If problems with cognitive functioning persist, get worse or recur, carry out further assessments to understand the cause.

1.12.4 If a person has problems with cognitive functioning after a traumatic injury, provide information:

- using clear language
- with the timing, content and delivery tailored to the person's needs and preferences
- in a suitable format (for example, Easy Read)
- with written plans to aid recall
- that uses pictures, symbols and objects of reference
- with calendar or diary prompts for sessions or appointments.

1.12.5 Share information with family members or carers (as appropriate) so they can help the person understand the key messages and aid recall.

1.12.6 For children and young people:

- ask parents and carers if there are any pre-injury cognitive issues, for example, any known special educational needs
- liaise with their education provider if information about their pre-injury cognitive performance is needed
- inform education providers and teachers, including those in the hospital setting, about the child or young person's needs and any problems with cognitive functioning.

1.12.7 Be aware that after a traumatic injury, people may present with fluctuations in mental capacity, and that this may affect decision making. See the NICE guideline on decision making and mental capacity.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on cognitive rehabilitation.

Full details of the evidence and the committee's discussion are in evidence review B.2: cognitive interventions for people with complex rehabilitation needs after traumatic injury.

1.13 Psychological rehabilitation

1.13.1 Reassure people that short-term psychological problems in the form of an acute stress response are common after a traumatic injury. Symptoms can last for 4 to 6 weeks and may include:

- disturbed sleep
- intrusive thoughts and memories
- nightmares
- bedwetting in children
- flashbacks
- low mood
- anxiety.

1.13.2 Be aware that:

- there is an ongoing risk of low mood in people after a traumatic injury
- psychological problems and mental distress commonly accompany ongoing emotional and psychological adjustments, for example, as a result of life-changing injuries
- psychological problems and mental distress can recur or deteriorate when a person is discharged home or transferred to another setting
- anxiety, depression and post-traumatic stress disorder (PTSD) can occur or recur at any time after a traumatic injury.

1.13.3 Discuss psychological support with the person, and their family members or carers (as appropriate), and offer psychological and emotional support that is tailored to their rehabilitation goals, needs and preferences as part of an overall rehabilitation treatment programme.

1.13.4 If the person's rehabilitation is adversely affected by their psychological problems (for example, if the person is struggling to engage with the rehabilitation process), refer them urgently to psychology services for psychological assessment and treatment, ideally to a practitioner psychologist with appropriate expertise with physical trauma and rehabilitation.

1.13.5 Ask about thoughts of self-harm and suicide regularly, as part of psychological assessment, and particularly at key milestones such as hospital discharge and changes of setting.

1.13.6 The multidisciplinary team should regularly check for signs and symptoms of anxiety, depression and PTSD when reviewing the person's progress against rehabilitation goals and plans.

1.13.7 Treat PTSD, anxiety, and depression in adults, children and young people as part of an overall coordinated rehabilitation treatment package, and in line with the NICE guidelines on:

- post-traumatic stress disorder
- social anxiety disorder

- generalised anxiety disorder and panic disorder in adults
- depression in adults
- depression in adults with a chronic physical health problem
- depression in children and young people
- service user experience in adult mental health.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on psychological rehabilitation.

Full details of the evidence and the committee's discussion are in evidence review B.3: psychological and psychosocial interventions for people with complex rehabilitation needs after traumatic injury.

1.14 Rehabilitation after limb reconstruction, limb loss or amputation

This section covers specific rehabilitation for people after limb reconstruction, limb loss or amputation. The recommendations in this section should be read together with all the recommendations in the rest of the guideline apart from those specific to spinal cord injury, nerve injury or chest injury.

Rehabilitation after limb-threatening injury – early assessment, decision making and support

1.14.1 Discuss limb reconstruction and/or amputation with the person, and their family members or carers (as appropriate), when making decisions about treatment pathways and assessing rehabilitation options. Recognise that, for some people who have had a complex limb-threatening injury, amputation may be the option that best delivers the person's most important rehabilitation goals.

1.14.2 Members of a specialist multidisciplinary team (for example, a limb reconstruction team or prosthetics team) alongside the trauma rehabilitation team should discuss the implications of the following, as part of assessing

rehabilitation needs, as soon as possible with the person, and their family members or carers (as appropriate):

- rehabilitation pathways
- pain management
- recovery timescales
- long-term expectations
- impact on daily life, for example, work, hobbies, activities, education and play.

1.14.3 When amputation is being considered and if time permits before surgery, a member or members of the specialist multidisciplinary team with expertise in prosthetic prescription and rehabilitation should carry out a pre-amputation rehabilitation assessment and consultation.

1.14.4 Offer psychological support before limb reconstruction or amputation (see the section on psychological support).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rehabilitation after limb-threatening injury – early assessment, decision making and support.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Rehabilitation after limb reconstruction

1.14.5 After limb reconstruction, start rehabilitation therapy as early as possible (ideally the day after surgery) to maintain range of movement. This may include:

- splinting
- exercise
- pain management

- swelling and oedema management
- hand therapy
- mobility
- positioning.

1.14.6 Avoid early rapid irreversible loss of range of movement after limb reconstruction by ensuring that the person carries out range of movement exercises for the affected joint and other joints to optimise recovery and avoid contractures.

1.14.7 Continue psychological and emotional support after limb reconstruction (see the section on psychological support).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rehabilitation after limb reconstruction.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Rehabilitation after limb loss or amputation

1.14.8 After limb loss or amputation, refer the person to the amputee and prosthetic rehabilitation service as soon as possible if the referral was not made before the surgery.

1.14.9 After limb loss or amputation, start rehabilitation therapy as early as possible and ideally the day after surgery. This may include:

- pain management (see the section on pain management)
- residual limb oedema and shaping (see the section on residual limb oedema and shaping)

- range of movement and strengthening exercises (see the section on range of movement and strengthening)
- functional independence, including play for children (see the section on functional independence)
- psychological support (see the section on psychological support).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rehabilitation after limb loss or amputation.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Pain management after limb loss or amputation

1.14.10 Plan analgesia with the person before surgery, and ensure that their pain is managed after surgery so that they can effectively participate in rehabilitation therapies.

1.14.11 Manage the different types of pain that can develop, for example, phantom limb pain, neurogenic pain, psychogenic pain, myogenic pain and complex regional pain, and refer the person to a specialist pain team if needed.

1.14.12 Consider visualisation interventions such as graded motor imagery or mirror therapy to manage phantom limb pain in people who have had an amputation or limb loss after trauma.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on pain management after limb loss or amputation.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Residual limb oedema and shaping after limb loss or amputation

1.14.13 Manage residual limb oedema using elevation and compression therapy to reduce swelling and improve shaping in preparation for prosthetics fitting.

1.14.14 For people with a below-knee amputation, keep the limb elevated using a residual limb (stump) board when using a wheelchair.

1.14.15 Avoid residual limb swelling when using walking aids, for example, by using crutches or a frame with the limb in a dependent position.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on residual limb oedema and shaping after limb loss or amputation.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Range of movement and strengthening after limb loss or amputation

1.14.16 Maintain and improve range of movement and strength after limb loss or amputation (particularly in hip flexors, hip abductors and knee flexors) by starting rehabilitation therapy that includes:

- exercise
- mobility, including early walking aids (for example, amputee-specific early walking aids) after surgery when the wound has settled
- positioning.

For a short explanation of why the committee made this recommendation and how it might affect practice, see the rationale and impact section on range of movement and strengthening after limb loss or amputation.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Functional independence after limb loss or amputation

1.14.17 Do not wait for prosthetics to be fitted before starting rehabilitation after limb loss or amputation.

1.14.18 Ensure that wheelchairs:

- are provided as early as possible
- include appropriate accessories (for example, anti-tippers and residual limb [stump] boards)
- are adjusted to accommodate the changes in the person's weight distribution after limb loss or amputation.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on functional independence after limb loss or amputation.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Psychological support after limb loss, amputation or limb reconstruction

1.14.19 Continue psychological support and ensure that the multidisciplinary team has access to a practitioner psychologist with appropriate expertise in physical trauma and rehabilitation, ideally with experience of working with people with

limb loss, amputation or limb reconstruction.

1.14.20 For children, consider play or play therapy when offering psychological and emotional support.

1.14.21 For children and young people, the team around the child should actively monitor for any emerging emotional difficulties as the child or young person grows and develops (for example, moving schools, puberty and emotional relationships).

1.14.22 Take into account the long-term psychological impact of change in body image as a result of injury for all people and the psychological impact for children and young people as they grow.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on psychological support after limb loss, amputation or limb reconstruction.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

Continuing rehabilitation after limb reconstruction, limb loss or amputation and after discharge

1.14.23 When completing a rehabilitation plan (see the section on developing a rehabilitation plan and making referrals) for people after limb reconstruction, limb loss or amputation, ensure that the following are always included in the person's rehabilitation programme:

- exercise and mobility
- psychological and emotional support
- referral and signposting to support groups
- pin-site review (for limb reconstruction)
- frame adjustment (for limb reconstruction)

- prosthetics team review, if relevant.

1.14.24 The specialist multidisciplinary team should offer psychological and emotional support to enable the person to adjust to their altered body image, manage pain and cope with the possibility that they may need further procedures. Psychological and emotional support should involve:

- listening carefully and validating feelings
- supporting reflection and reasoning around realistic goals and care
- supporting planning
- offering feedback about progress towards goals.

1.14.25 Carry out reviews of the rehabilitation plan (for example, equipment, home environment, clothing and footwear needs) at key points, for example:

- at discharge
- when an external-fixation frame is removed
- when weight-bearing status changes
- when prosthetics are changed
- when the person starts to go outside
- when the person starts to return to education, work or community activities
- if the person is readmitted because of complications.

(Also see the section on monitoring progress against the rehabilitation plan, goals and programme of therapies and treatments.)

1.14.26 For children and young people, monitor the impact of growth on the residual limb and prosthetic fitting, and refer without delay for specialist assessment when there are changes.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on continuing rehabilitation after limb reconstruction, limb loss or amputation and after discharge.

Full details of the evidence and the committee's discussion are in evidence review C.1: specific programmes and packages in amputation for people with complex rehabilitation needs after traumatic injury.

1.15 Rehabilitation after spinal cord injury

This section covers specific rehabilitation for people after spinal cord injury. The recommendations in this section should be read together with all the recommendations in the rest of the guideline apart from those specific to limb injury, nerve injury or chest injury.

These recommendations focus on the rehabilitation and supportive needs of people with spinal cord injury (after initial acute assessment) who are not currently in a regional specialist spinal cord injury centre. See also the NICE guideline on spinal injury: assessment and initial management.

Rehabilitation after spinal cord injury – referral, assessment and general principles

1.15.1 For people with a spinal cord injury:

- ensure that ongoing contact with the regional specialist spinal cord injury centre is made in line with the recommendations on communication with tertiary services in the NICE guideline on spinal injury and
- refer using the national spinal injuries database within 24 hours of the diagnosis.

1.15.2 Seek advice from the regional specialist spinal cord injury centre outreach team throughout the person's inpatient stay and at discharge to support their rehabilitation.

1.15.3 A healthcare professional with appropriate clinical skills should complete an assessment using an American Spinal Injury Association (ASIA) chart as soon as possible after a spinal cord injury, and repeat this as clinically indicated.

1.15.4 Be aware that spinal cord injury may affect areas of physical function including

bowel, bladder and sexual function, and seek specialist advice as appropriate (see also recommendation 1.2.6 in the multidisciplinary team rehabilitation needs assessment section).

1.15.5 Refer children and young people with a spinal cord injury:

- to specialist play services to support their emotional and physical development and wellbeing
- to education services to support their ongoing educational development.

1.15.6 For children and young people, monitor growth and nutrition throughout the rehabilitation process.

1.15.7 When discharge planning for children and young people after a spinal cord injury, ensure that meetings take place early and involve the child or young person, and their parents and carers (as appropriate), together with the local education authority, specialist play services and multidisciplinary teams involved in their care.

1.15.8 After hospital discharge, consider ongoing contact between the rehabilitation team and the person, and their family members and carers (as appropriate), with education and a structured review of progress in rehabilitation as part of outpatient follow-up. This could be offered by telephone or video link.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rehabilitation after spinal cord injury – referral, assessment and general principles.

Full details of the evidence and the committee's discussion are in evidence review C.3: specific programmes and packages in spinal cord injury for people with complex rehabilitation needs after traumatic injury.

Bladder and bowel function

1.15.9 Assess and manage bladder function after a spinal cord injury as follows:

- protect upper renal function at all times by maintaining safe bladder emptying (inserting a urinary catheter if necessary), and ensuring that people understand and use bladder management techniques as a key part of their rehabilitation (see also the monitoring and surveillance section in the NICE guideline on urinary incontinence in neurological disease)
- identify acute kidney injury in line with the NICE guideline on acute kidney injury
- identify renal tract stones (see also the NICE guideline on urinary incontinence in neurological disease).

1.15.10 Regularly assess and manage bowel function after a spinal cord injury as follows:

- assess anal tone and sensation
- start and review a bowel management plan that includes laxatives, enemas, suppositories and manual evacuation, depending on the level and severity of the spinal injury.

1.15.11 Keep the person nil by mouth until their bowel function has been assessed because of the risk of neurogenic bowel stasis and aspiration pneumonia. Avoid unnecessary delays to assessing bowel function to avoid prolonged periods of nil by mouth.

1.15.12 For younger children, ask their parents and carers (as appropriate), about their pre-injury continence skills, and take their age and ability into account when assessing and managing bladder and bowel function.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on bladder and bowel function.

Full details of the evidence and the committee's discussion are in evidence review C.3: specific programmes and packages in spinal cord injury for people with complex rehabilitation needs after traumatic injury.

Respiratory function, swallowing and speech

1.15.13 Keep the person nil by mouth until their risk of aspiration has been assessed

(see recommendation 1.11.51).

1.15.14 Be aware that people with cervical spine injuries and those managed on flat bed rest, are particularly at risk of swallowing and speech difficulties and should be assessed early for risk of aspiration.

1.15.15 Assess and manage respiratory function (taking into account age and ability when assessing children and young people) as follows:

- use spirometry to measure vital capacity in line with the NICE guideline on spinal injury
- consider prophylactic respiratory support with, for example, active cycle of breathing techniques, incentive spirometry, intermittent positive pressure breathing (IPPB) or non-invasive ventilation (NIV), to maintain forced vital capacity (FVC) and prevent chest complications
- consider use of cough-assist techniques or devices.

1.15.16 Consider critical care management for people with a high-level spinal injury.

1.15.17 Assess voice quality and refer to a speech and language therapist and/or ear, nose and throat specialist as needed.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on respiratory function, swallowing and speech.

Full details of the evidence and the committee's discussion are in evidence review C.3: specific programmes and packages in spinal cord injury for people with complex rehabilitation needs after traumatic injury.

Preventing complications

1.15.18 Assess skin and pressure care after a spinal cord injury as follows:

- start a 24-hour positioning and turning programme and use a pressure mattress if appropriate (ensuring that the spinal column has been assessed as mechanically stable) or indicated and

- give information about skin protection for people with sensory deficits.

1.15.19 Be aware of the risk of autonomic dysreflexia, and treat it as a medical emergency.

1.15.20 Be aware that most people who have had a spinal cord injury will develop orthostatic hypotension, which can affect their participation in rehabilitation. Consider interventions to optimise blood pressure, for example, medication review, graduated positioning, abdominal binders and compression stockings.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on preventing complications.

Full details of the evidence and the committee's discussion are in evidence review C.3: specific programmes and packages in spinal cord injury for people with complex rehabilitation needs after traumatic injury.

Maintaining mobility and movement

1.15.21 For people with a spinal cord injury who are using a spinal orthosis (for example, cervical collar or thoraco-lumbar spinal orthosis), regularly assess them for complications such as pain, pressure sores, swallowing or breathing difficulties (particularly in older people or those with dementia or delirium).

1.15.22 If spinal orthoses are causing side effects or are significantly affecting the person's engagement with rehabilitation, inform the relevant surgical team.

1.15.23 Maintain joint range of motion after a spinal cord injury and consider early use of splints and orthoses.

1.15.24 Seek specialist advice about hand splints for people with a higher level cervical spinal injury to maintain tenodesis grasp and release ability where indicated; for example, do not splint into wrist extension if there is C6 involvement.

1.15.25 Consider interventions (for example, progressive sitting, tilt table) to increase mobility and aid early sitting as soon as possible after a spinal cord injury.

1.15.26 Consider additional techniques and specialised equipment (for example, functional electrical stimulation, gait orthoses, bodyweight-supported gait training and robotic devices) to promote mobility, upper limb function and independent walking.

1.15.27 Assess people's needs and refer them to specialist services without delay if assistive technology, such as environmental control systems, is needed.

1.15.28 For adults, treat spasticity to prevent losing range of joint movement and avoid contractures.

1.15.29 For adults, consider oral medications to treat spasticity or botulinum toxin type A targeted muscle injections, depending on the clinical circumstances.

In January 2022, botulinum toxin type A was an off-label use for some of the available brands. See individual summaries of product characteristics and NICE's information on prescribing medicines.

1.15.30 Stop oral medications and targeted muscle injections for spasticity if there is no benefit at the maximum tolerated dose. (Explain to the person that special precautions may be needed when stopping certain medicines.)

1.15.31 If spasticity is causing significant impairments in mobility, posture or function, and initial treatments are unsuccessful, refer the person to a multidisciplinary team experienced in the management of spasticity for assessment and treatment planning.

1.15.32 For children and young people, assess spasticity and follow the recommendations in the NICE guideline on spasticity in under 19s.

1.15.33 Be aware that pre-pubertal children have a high risk of early or late onset kyphoscoliosis, so monitor their spinal shape and curvature at regular intervals and refer early for specialist assessment if needed.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on maintaining mobility and movement.

Full details of the evidence and the committee's discussion are in:

- evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury
- evidence review C.3: specific programmes and packages in spinal cord injury for people with complex rehabilitation needs after traumatic injury.

Low mood and psychological support

1.15.34 Be aware that there is significant risk of low mood and psychological trauma for people with spinal injury, and that this may have an impact on rehabilitation.

1.15.35 Consider psychological support after spinal cord injury, and ensure that the multidisciplinary team has access to a practitioner psychologist with appropriate expertise in physical trauma and rehabilitation, ideally with experience of working with people with spinal cord injury.

1.15.36 For children and young people, the team around the child should actively monitor for any emerging emotional difficulties as the child or young person grows and develops (for example, moving schools, puberty and emotional relationships).

1.15.37 Take into account the long-term psychological impact of change in body image as a result of injury for all people and for children and young people as they grow.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on low mood and psychological support.

Full details of the evidence and the committee's discussion are in evidence review C.2: specific programmes and packages in nerve injury for people with complex rehabilitation needs after traumatic injury.

1.16 Rehabilitation after nerve injury

This section covers specific rehabilitation for people after nerve injury. The recommendations in this section should be read together with all the recommendations in the rest of the guideline apart from those specific to limb injury, spinal cord injury or chest injury.

Rehabilitation after nerve injury – general principles

1.16.1 Be aware that nerve injuries may be hidden, particularly if the person:

- has multiple injuries
- has a cognitive impairment or a learning disability
- has a head injury
- is in critical care (adults) or paediatric intensive care (children and young people)
- has a pre-existing neurological condition or injury
- has a complex fracture.

1.16.2 If nerve injury is suspected, assess the peripheral nerves of the affected limb to identify the involved nerve and functional deficit. The surgical team should decide whether early surgical intervention is necessary (see also the section on assessing physical functioning).

1.16.3 Be aware of the risk to tissue viability if there is sensory or motor loss secondary to peripheral nerve injury.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rehabilitation after nerve injury – general principles.

Full details of the evidence and the committee's discussion are in evidence review C.2: specific programmes and packages in nerve injury for people with complex rehabilitation needs after traumatic injury.

Therapies and referral

1.16.4 After nerve injury, start rehabilitation therapy to maintain range of movement and regain function. This may include:

- splinting
- exercise (passive and active range of movement)
- play therapy (for children)
- pain management
- sensory interventions (including mirror therapy, electrical stimulation and hand therapy)
- hydrotherapy (where available)
- functional or vocational therapy.

1.16.5 Regularly assess for signs of nerve recovery and review the programme of therapy as needed.

1.16.6 Consider nerve conduction or a specialist opinion to help determine prognosis and guide future therapy and management if early surgical intervention was not needed and:

- there are no signs of nerve recovery 6 weeks after the injury or
- if recovery is not as expected.

1.16.7 For people who have a poor prognosis for recovery after rehabilitation therapy

and nerve conduction studies, consider referral to a specialist peripheral nerve injury service, for example, for surgery.

1.16.8 Be aware that people recovering from nerve injury may experience low mood, anxiety and lack of motivation because recovery may be a lengthy and ambiguous process (for example, because of uncertainty about the long-term prognosis).

1.16.9 Consider psychological support after nerve injury, and ensure that the multidisciplinary team has access to a practitioner psychologist with appropriate expertise in physical trauma and rehabilitation, ideally with experience of working with people with nerve injury.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on therapies and referral.

Full details of the evidence and the committee's discussion are in evidence review C.2: specific programmes and packages in nerve injury for people with complex rehabilitation needs after traumatic injury.

1.17 Rehabilitation after chest injury

This section covers specific rehabilitation for people after chest injury. The recommendations in this section should be read together with all the recommendations in the rest of the guideline apart from those specific to limb injury, spinal cord injury or nerve injury.

1.17.1 Start rehabilitation after chest injury as soon as possible to optimise respiratory function and prevent deconditioning.

1.17.2 Assess pain regularly and provide adequate analgesia to allow people to be able to breathe deeply, cough, start moving around early and participate in rehabilitation activities.

1.17.3 If oral or intravenous analgesia is inadequate to enable people to breathe deeply, cough or start engaging in rehabilitation, consider early neuraxial (for example, epidural catheter) or regional (for example, paravertebral, erector spinae plane or serratus anterior blocks) analgesia delivered by an appropriately

qualified healthcare professional.

1.17.4 Encourage people with chest trauma to start moving around as soon as it is safe to do so, to optimise respiratory function and prevent deconditioning.

1.17.5 Offer a range of rehabilitation therapies to prevent atelectasis and promote deep breathing and secretion clearance. Therapies may include:

- supported cough to brace chest wall
- active cycle breathing technique
- incentive spirometry
- portable intermittent positive pressure breathing (IPPB) devices.

1.17.6 Be aware that stiffness of the upper limbs is a common complication of chest and rib injury on the affected side.

1.17.7 The multidisciplinary team should discuss the risks and benefits of the use of spinal orthoses in people with a combination of spine injury and rib fracture.

1.17.8 Prevent stiffness of the upper limbs with range of movement exercises and advice about maintaining function. Encourage children to play to maintain their range of movement.

1.17.9 Give people information about what they can do to help themselves return to their normal activities of daily life (for example, how to increase their exercise tolerance), and how to seek help if they are worried about problems such as:

- pain
- shortness of breath
- fatigue
- cough.

1.17.10 Assess adults presenting with rib fractures for their risk of fragility fracture in line with NICE's guideline on osteoporosis.

1.17.11 If people have complex chest injuries that affect communication and swallowing skills, consider referral to speech and language therapy.

1.17.12 Consider assessing children and young people with rib fractures for bone density disorder and for the possibility of non-accidental injury (see recommendation 1.1.13 on safeguarding).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on rehabilitation after chest injury.

Full details of the evidence and the committee's discussion are in evidence review C.4: specific programmes and packages in chest injury for people with complex rehabilitation needs after traumatic injury.

Terms used in this guideline

Complex rehabilitation needs

Complex rehabilitation needs cover multiple needs due to traumatic injury or injuries (polytrauma), and will involve coordinated multidisciplinary input from 2 or more allied health professional disciplines.

Controlled motion device

A device that gently flexes and extends the knee joint (usually after surgery) to allow the joint to bend without the person needing to exert any effort. Sometimes called a continuous passive motion machine.

Key worker

A key worker is a named member of clinical staff (for example, a senior nurse, physiotherapist or occupational therapist) assigned at each stage of the care pathway who coordinates the person's rehabilitation and care; this may continue post-discharge. They act as a single point of contact for the person and their family and carers, and will support liaison with other services, such as social care. The person who fulfils this role may be different along the pathway, for example, following hospital discharge. This role may also be performed by case managers or case coordinators, who would coordinate care as well as liaise with insurers and legal teams, particularly following discharge.

For major trauma, the role of key worker is defined further in recommendation 1.6.3 in the NICE guideline on major trauma: service delivery.

Neurovestibular disorders

Dizziness or problems with balance caused by damage to parts of the inner ear and/or the brain that process the sensory information involved with controlling balance and eye movements.

Orthostatic hypotension

Low blood pressure on changing position from lying to sitting, and sitting to standing.

Practitioner psychologists

The definition of practitioner psychologists is based on the Health and Care Professions Council (HCPC) registration criteria and standards of proficiency.

Pre-amputation rehabilitation assessment and consultation

This follows the principles of the initial rehabilitation assessment in the section on assessment and early interventions for people with complex rehabilitation needs, and also takes into account implications for rehabilitation such as recovery timescales, quality of life and goal setting for different surgical options that may include amputation of all or part of the limb, or reconstructive surgery of the limb. Decisions about surgical interventions would affect the kind of rehabilitation interventions and therapies the person would need, the timescales involved and their personal goals.

Rehabilitation coordinator

Rehabilitation coordinators are rehabilitation specialists, for example, allied health professionals such as physiotherapists, occupational therapists, speech and language therapists, or clinicians who play an active role in the multidisciplinary team. They are usually responsible for decisions about rehabilitation treatment options at the beginning of the pathway and for the implementation of the pathway, including referral or transfer to other services. They are usually part of the team that delivers the rehabilitation care, and the lead contact for the person receiving care.

Rehabilitation plan

This may be in the form of a rehabilitation prescription. It may also come in different versions such

as the rehabilitation passport, which is a patient-held document, and may be a simplified version of the plan. It is carried with the person and also communicated between rehabilitation teams and updated accordingly and used to document information about injuries and rehabilitation treatments in an accessible format.

Single point of contact

A single point of hospital contact following discharge may be a key worker, trauma coordinator or a rehabilitation coordinator, or it may simply be a link to a unit, team or person that formed part of the person's rehabilitation care while in hospital. The point of contact may not be able to offer advice directly but can seek information and input from others if this is needed for a defined period post-discharge.

Specialised rehabilitation services

Specialised elements of care pathways would include options for people with complex rehabilitation needs, for example, level 1, level 2a and level 2b units within a local area.

Strengths-based approach

Strengths-based (or asset-based) approaches focus on the person's strengths (including personal strengths, and social and community networks) and not on their deficits. Strengths-based practice is holistic and multidisciplinary, and works with the individual person to promote their wellbeing.

Team around the child

A group of professionals who work with an individual child or young person with a disability or complex needs who come together to share information and agree a plan – along with parents and carers – to meet the child's needs. The emphasis should be on the needs of the child and the aim is to provide joined-up support.

Trauma coordinator

This person would work closely with the multidisciplinary team to coordinate the patient pathway between relevant specialties involved in the treatment, including acute surgical and medical teams and rehabilitation, from admission to discharge, particularly for people with highly complex traumatic injuries and rehabilitation needs. They offer clinical advice and sometimes this role is performed by a nurse and is sometimes called a nurse coordinator. This role may also include the responsibilities of a key worker, liaising with family and carers, especially in the early stages of the

pathway.

Traumatic injury

This includes multiple, major and severe injuries, sometimes referred to as polytrauma, and any musculoskeletal, visceral, nerve, soft tissue, spinal or limb injury that requires admission to hospital at the time of injury.

Vocational therapy

Focuses on the rehabilitation interventions needed to help people with long-term health conditions or disabilities return to or stay in work, education or training. This may involve adapting working conditions, job roles or retraining.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Effectiveness of intensive rehabilitation in adults

What is the effectiveness and cost effectiveness of intensive rehabilitation programmes in adults with complex rehabilitation needs after a traumatic injury?

For a short explanation of why the committee made the recommendation for research, see the rationale section on intensive rehabilitation programmes.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

2 Effectiveness of intensive rehabilitation in children and young people

What is the effectiveness and cost effectiveness of intensive rehabilitation programmes in children and young people with complex rehabilitation needs after a traumatic injury?

For a short explanation of why the committee made the recommendation for research, see the rationale section on intensive rehabilitation programmes.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

3 Thoracic lumbar sacral orthoses in older people

What are the benefits and harms of using thoracic lumbar sacral orthoses in older people with thoraco-lumbar vertebral fractures?

For a short explanation of why the committee made the recommendation for research, see the rationale section on splinting and orthotics.

Full details of the evidence and the committee's discussion are in evidence review B.1: physical interventions for people with complex rehabilitation needs after traumatic injury.

4 Self-management materials

What is the effectiveness and cost effectiveness of rehabilitation programmes combined with self-management materials, compared with rehabilitation programmes alone, in people with complex rehabilitation needs after a traumatic injury?

For a short explanation of why the committee made the recommendation for research, see the rationale section on guided self-managed rehabilitation.

Full details of the evidence and the committee's discussion are in evidence review B.3: psychological and psychosocial interventions for people with complex rehabilitation needs after traumatic injury.

5 Length of bed rest after spinal cord injury

What is the effectiveness and cost effectiveness of short-term bed rest compared with long-term bed rest on functional outcomes in people with complex rehabilitation needs after traumatic injury that involves the spinal column or spinal cord injury?

For a short explanation of why the committee made the recommendation for research, see the rationale section on maintaining mobility and movement.

Full details of the evidence and the committee's discussion are in evidence review C.3: specific programmes and packages in spinal cord injury for people with complex rehabilitation needs after traumatic injury.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect services.

Initial assessment and early interventions for people with complex rehabilitation needs

Recommendations 1.1.1 to 1.1.13

Why the committee made the recommendations

Rehabilitation can be a long journey, and people will need different interventions and will aim for different endpoints. Because of this, the committee agreed that healthcare professionals should think about each person's individual rehabilitation needs and what is important to them, and take into account their personal strengths, lifestyle and goals, rather than being primarily driven by the nature of the injury.

Psychological and emotional support is important immediately after the injury, to help the person come to terms with their experience and engage with rehabilitation assessment, early interventions and goal-setting discussions.

There was evidence that avoiding delays in acute treatment can improve the effectiveness of early rehabilitation interventions. In the committee's view, early assessments and interventions are also important so that healthcare professionals have up-to-date information and can plan and start rehabilitation promptly. Nutritional assessment (including swallowing safety) is an important factor (particularly in soft tissue healing) but is often overlooked.

The person's longer-term rehabilitation goals should be taken into account when discussing treatment options because these can affect decisions made about the timing and nature of rehabilitation. For example, if a person has upper and lower limb injuries, they might not have surgical treatment of their upper limb injuries because they want to use crutches to help with weight-bearing during rehabilitation for their lower limb injuries.

How the recommendations might affect practice

The recommendations will not involve a major change in practice and are consistent with existing

NICE guidelines. Healthcare professionals might need to spend more time assessing how traumatic injuries affect all aspects of a person's life, and explaining the implications of different medical and surgical treatments on rehabilitation. Spending time on initial assessment and early treatment immediately after a traumatic injury will lead to a better tailored rehabilitation plan and goals, which will save time later on. Generally, all professionals involved in the person's care following a traumatic injury will already be equipped to provide psychological and emotional support.

Return to recommendations

Multidisciplinary team rehabilitation needs assessment

Recommendations 1.2.1 to 1.2.12

Why the committee made the recommendations

There was no evidence in this area, so the committee made recommendations based on their knowledge and experience. They agreed that a comprehensive approach to needs assessment is vital to meet all aspects of the person's care needs, including personal history, usual activities and potential motivations. They also highlighted injuries or conditions that may need to be assessed by specialists who are better equipped to meet complex care needs.

The committee specified the healthcare professionals who should be members of the multidisciplinary team. These members of the multidisciplinary team do not necessarily have to be available all the time, but should be able to contribute when needed.

The committee suggested ways to help people engage in the assessment process because people can have problems with engagement after a traumatic injury. The timing of the needs assessment is also an important aspect of this, because pain, fatigue and confusion can make it difficult for people to understand what is happening. They may need more time than normal to process information and adjust after the trauma. This is particularly important for people with cognitive impairment or brain injuries.

The committee agreed that time was needed for members of the multidisciplinary team to work with clinical teams to fully understand the person's rehabilitation needs and in particular consider the impact of pre-existing conditions so that this could inform a tailored rehabilitation programme. The committee were keen to highlight the importance of validated outcome tools and checklists because these can help identify people who need to be referred to a specialist service early, which can prevent delays in rehabilitation.

How the recommendations might affect services

It is standard practice to have multidisciplinary teams conduct needs assessments. Staff might need additional training on how to use assessment tools, and some extra time might be needed as a result of the recommendations. However, this will be offset by the benefits of appropriate and timely care, increased care coordination, and better outcomes. Overall, the recommendations reinforce current practice and are in line with other guidance.

Return to recommendations

Assessing physical functioning

Recommendations 1.2.13 to 1.2.15

Why the committee made the recommendations

The committee discussed the importance of assessing physical functioning as part of the rehabilitation needs assessment after a traumatic injury. There was no evidence in this area so the committee agreed, based on their knowledge and experience, that the assessment should include both pre-injury and current levels of physical functioning to inform rehabilitation goals. Referrals to specialists may be needed as part of this. The person's current level of physical functioning will serve as a baseline for initial rehabilitation needs and to monitor changes.

How the recommendations might affect services

The recommendations are not expected to have a large resource impact or be difficult to implement, although extra time might be needed to complete the comprehensive assessment. There may also be more referrals to specialist services. However, the involvement of specialist services at the assessment stage will identify needs earlier and reduce unmet care needs.

Return to recommendations

Assessing cognitive functioning

Recommendations 1.2.16 to 1.2.20

Why the committee made the recommendations

There was no evidence in this area. However, the committee believed that recommendations are

needed because problems with cognitive functioning are common after a traumatic injury (even without brain injury). The committee also highlighted some of the cognitive problems the multidisciplinary team should consider as part of the rehabilitation needs assessment, because these may not show up on scans immediately.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice may need to be amended. Some extra time might be needed to complete the comprehensive assessment. There may also be more referrals to specialist services. However, the involvement of specialist services at the assessment stage will identify needs earlier and reduce unmet care needs.

Return to recommendations

Assessing psychological functioning

Recommendations 1.2.21 and 1.2.22

Why the committee made the recommendations

There was no evidence in this area, so the committee made recommendations based on their knowledge and experience. They recommended asking about past risk factors to help inform future rehabilitation goals, and current risk factors to help form a baseline for initial rehabilitation needs and monitor changes.

Some people may need additional support because they react to trauma in different ways, have different barriers to rehabilitation, and may have different responses to psychological and psychosocial interventions. Because of this, the committee recommended referral to a practitioner psychologist with trauma and rehabilitation experience when needed.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended. Some extra time might be needed to complete the comprehensive assessment, and there might also be more referrals to specialist services. However, the involvement of specialist services at the assessment stage will identify needs earlier and reduce unmet care needs.

Return to recommendations

Setting rehabilitation goals

Recommendations 1.3.1 to 1.3.3

Why the committee made the recommendations

Based on qualitative evidence, the committee highlighted the need to agree patient-focused short- and long-term goals with people. They also recommended that these goals are reviewed regularly, to ensure a flexible approach that takes people's concerns into account.

Agreeing small steps as part of long-term rehabilitation goals ensures that efforts are consistently made towards achieving these goals.

The committee highlighted skills and competencies needed by the multidisciplinary team, to ensure that staff have the right training.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended. Some additional professional time might be needed to explore psychological and psychosocial risk factors.

Return to recommendations

Developing a rehabilitation plan and making referrals

Recommendations 1.4.1 to 1.4.11

Why the committee made the recommendations

There was convincing qualitative evidence on patient education, communication between settings, and follow-up. Combining this with their own knowledge and experience, the committee recommended several key components of a successful and comprehensive rehabilitation plan. This should be a single document that can be shared between people undergoing rehabilitation, families or carers, and healthcare professionals. It should be an evolving document, detailing a person's rehabilitation journey and any changes in goals and needs. The committee reflected that it is not always possible or appropriate for people to have access to all of a rehabilitation plan, and therefore recommended that a separate patient-held document be provided if this is the case.

The committee agreed that preventing recurrence of traumatic injury should form an essential component of the rehabilitation plan. Prevention is covered in several other NICE guidelines, so the committee made recommendations that supplement and refer to these guidelines.

There was strong qualitative evidence from both healthcare professionals and people undergoing rehabilitation that reducing delays leads to better coordination of care and rehabilitation outcomes. Based on this, the committee made a recommendation on referrals for parts of the plan that the multidisciplinary team cannot implement themselves. The committee also used their experience to recommend that older people have access to orthogeriatricians, surgical support or perioperative physicians. This is important because the needs of older people with traumatic injuries are complex, and it will prevent delays further on in rehabilitation.

Limited evidence showed that violence intervention programmes might reduce hospital admissions. There was also convincing economic evidence that such programmes represent value for money. The committee agreed that the effectiveness evidence combined with economic evidence was sufficient to support a recommendation on violence reduction interventions.

How the recommendations might affect services

Practitioners should already be producing these rehabilitation plans, but some extra time might be needed to ensure they fulfil the expectations set out in these recommendations. However, this will be offset by reducing problems with the suitability of the plan further down the line, because the more it is tailored for the person, the more effective it will be at helping the person achieve their goals. The recommendations outline good practice points and should make practice more consistent. Having a clear rehabilitation plan will make the whole process more efficient and potentially reduce the amount of extra support people need (for example, asking the team for more information because they do not understand the rehabilitation plan).

Currently, violence reduction interventions are mainly funded by the voluntary sector, so the recommendation on these may represent a change in practice. However, any cost increase will be offset by a potential reduction in future NHS and personal social service costs (for example, readmissions as a result of violent crime).

Return to recommendations

General principles for rehabilitation programmes

Recommendations 1.5.1 and 1.5.2

Why the committee made the recommendations

Evidence showed that rehabilitation programmes should be tailored to a person's needs and rehabilitation goals to maximise their effectiveness. There is no 'one-size-fits-all' programme. Instead, they should be multidisciplinary and developed in conjunction with healthcare professionals and people undergoing rehabilitation, to ensure they are relevant to a person's everyday life. The committee used their knowledge and experience to recommend the content of rehabilitation programmes. There was also evidence on education materials, showing that they can help people learn about their trauma and rehabilitation in their own time, increasing their engagement in the process.

How the recommendations might affect services

The recommendations reinforce current practice and should not be difficult to implement. Education materials on rehabilitation already exist in healthcare settings, but they might need to be changed into a suitable format for people undergoing rehabilitation.

Return to recommendations

Intensive rehabilitation programmes

Recommendations 1.5.3 to 1.5.5

Why the committee made the recommendations

There was no evidence on what to include in an intensive rehabilitation programme. Based on their own experience and expert testimony, the committee made a recommendation on general good practice principles.

There was also no evidence relating to the timing or intensity of rehabilitation. The committee were aware, based on their own experience and expert testimony, that delivering rehabilitation at the right time and providing short blocks of intensive rehabilitation might improve patient outcomes, leading to a quicker recovery and return to work. They gave the example of a 3-week residential rehabilitation programme because economic modelling indicated that this type of programme could be cost effective. However, the committee agreed that an intensive rehabilitation programme would be appropriate only for the most severe injuries and complex needs, when a significant impact on rehabilitation outcomes is likely. Such an approach to rehabilitation may also reduce the health and social care costs associated with longer-term care and rehabilitation.

The expert witness supported the use of education materials before intensive rehabilitation starts, to prepare people for the programme.

The committee made research recommendations on the effectiveness of intensive rehabilitation in adults and the effectiveness of intensive rehabilitation in children and young people.

How the recommendations might affect services

The recommendations are in line with current practice and should have little impact on resources. Intensive rehabilitation is already available for some people (for example, people who have lost a limb). Because rehabilitation services are already being carried out, intensive rehabilitation could be delivered through service redesign and repurposing of existing funds and resources rather than introducing them as completely new resources. Intensive rehabilitation would potentially represent value for money as per the economic model. Also, only a small group of people with the most severe injuries would be eligible for an intensive rehabilitation programme.

On education, existing materials for guided self-management rehabilitation could be used for intensive rehabilitation. This has the potential to reduce the amount of extra support people need, freeing up professionals for other work.

Return to recommendations

Guided self-managed rehabilitation

Recommendations 1.5.6 to 1.5.9

Why the committee made the recommendations

Evidence showed that self-management programmes are appreciated because they give people the flexibility to perform exercises at times most suitable for them. The committee used their experience and knowledge to recommend several possible components of a self-management programme.

Guided self-management rehabilitation was identified in the qualitative literature, as well as expert witness testimony and committee experience, but not in the quantitative literature. The committee made a research recommendation on self-management rehabilitation interventions to better inform future guideline development.

How the recommendations might affect services

Guided self-managed rehabilitation is not provided consistently across the country. In areas where it is not currently provided, extra professional time might be needed for planning, particularly for children, young people and vulnerable adults. There may also be costs from adopting self-managed rehabilitation programmes to different settings.

For trusts that do not like sharing their content using external content-sharing services, there may be costs from hosting programme content on their own server. However, much of the content could be standardised for most people using guided self-managed rehabilitation, so the costs for creating the plans would be mostly one-off. These programmes could be developed at a national level, reducing costs to individual services.

Guided self-managed rehabilitation programmes have the potential to reduce the amount of extra support people need, freeing up professionals for other work.

Return to recommendations

Monitoring progress against the rehabilitation plan, goals and programme of therapies and treatments

Recommendations 1.5.10 and 1.5.11

Why the committee made the recommendations

In the committee's experience, rehabilitation plans and goals can only be helpful to people if progress is monitored consistently and accurately. There are many tools that can be used for this; the choice depends on the person's rehabilitation goals and the type of trauma. Because of this variation, the committee did not recommend specific measurement tools.

For some people, family members and carers will need to be involved in monitoring progress (for example, for young children or vulnerable adults). The paediatric professionals on the committee recommended using a measurement tool that includes both children- and parent-reported measures for this population. Another way to monitor progress is to use the person's own views. There was some evidence that supported asking people to record information to assist discussions and shared decision making while describing subjective measurements that are hard to quantify (for example, their motivation to continue rehabilitation).

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended. Some additional professional time may be needed to complete tools to monitor progress (for example, patient-reported outcome measures [PROMs]).

Return to recommendations

Principles for sharing information and involving family and carers

Recommendations 1.6.1 to 1.6.7

Why the committee made the recommendations

One theme that appeared throughout the evidence was the importance of giving clear and consistent verbal and written information to people undergoing rehabilitation. Evidence showed that this communication should be tailored to a person's injury, needs and goals. If information was too general, people felt poorly prepared and less supported by healthcare staff and services.

People should be given sufficient time to process information in order for them to adjust after trauma and explore their rehabilitation options thoroughly. This is particularly important for people with cognitive impairment or brain injuries, and they may need professionals to repeat information to them.

Along with good evidence, the committee used their knowledge and experience to highlight the central role that families, carers and friends can have in encouraging and supporting people through rehabilitation.

How the recommendations might affect services

The recommendations reinforce current practice and are in line with current guidance and legislation. Some extra time might be needed to consistently involve people and their families and carers in planning. Services might need to develop multiple templates for different communication formats. However, this will be offset by the benefits of people understanding their options, increased engagement and potentially better outcomes.

Return to recommendations

Coordination of rehabilitation care in hospital

Recommendations 1.7.1 to 1.7.10

Why the committee made the recommendations

The committee agreed with the evidence that multidisciplinary teams should be formed early. Evidence showed that delays in rehabilitation can cause poorer outcomes. In order to reduce this, the committee recommended that referrals to specialist rehabilitation services be made as soon as possible. Similarly, the committee recommended follow-up appointments with acute teams when people move to rehabilitation units to further reduce delays.

There was conflicting evidence on how people feel about receiving information from many different specialists. This may be confusing to people, and specialists may have difficulty prioritising different clinical perspectives. The committee believed that named rehabilitation coordinators or key workers are needed to help reduce this confusion. These should be assigned within 72 hours of admission because this is the time limit for starting a trauma prescription for major trauma patients.

There was evidence that providing continuity of staff enhances coordination by building trust and rapport between healthcare staff and the people they are caring for. However, the committee were aware that this is not always possible.

There was good evidence about the importance of prompt and consistent communication when transferring people between inpatient settings. Using their experience and knowledge, the committee agreed recommendations to improve communication between settings, including the use of unique identifiers.

Evidence showed that coordination is improved when a person is educated in their rehabilitation, because they are more engaged. The evidence also showed that coordination is improved when family members and carers receive this information, because they frequently act as a support network for people undergoing rehabilitation. The committee understood the important role that families and friends can fulfil, but were aware of the potential safeguarding concerns around this issue. Therefore, they recommended that this information is only provided to additional people if appropriate, and only with a person's consent.

The committee agreed that families and carers be advised about the support that is available to them at a time that can be confusing and distressing.

How the recommendations might affect services

Multidisciplinary teams are a standard way of working. Having a named rehabilitation coordinator might lead to an increased workload for the coordinator, but this can be limited by daily conversations within the team and delegating responsibilities. Key workers are already routinely assigned to people with complex health and social care needs.

There may be more referrals as a result of involving specialist rehabilitation services earlier in the trauma pathway, but this will ensure timely care with a reduction in disability and will support optimal physical, cognitive and emotional recovery for patients. Most services have established processes and templates for handover. Where this is not the case, services will have to spend time creating them. Additionally, technology might need to be updated to ensure systems are compatible with those used by other services.

Return to recommendations

Coordination of rehabilitation care at discharge

Recommendations 1.8.1 to 1.8.20

Why the committee made the recommendations

Discharge home from inpatient settings is often a time of great stress and apprehension for people with a traumatic injury because they are facing a large reduction in monitoring and support from healthcare staff. The recommendations emphasise the importance of making sure that plans are in place, eventualities are covered and people have all the information they need.

There was evidence that early planning for discharge is needed to take into account the person's needs and preferences, contact relevant services to arrange necessary adjustments, and allow enough time to reassess the rehabilitation plan before discharge. For children and young people returning to education, a meeting between healthcare professionals, education staff and parents or carers should be arranged to discuss new education and support needs. This also gives time to address any potential barriers the person might face in using community rehabilitation services.

There was good evidence on the importance of providing adequate information to people and their families or carers before discharge. This should not be limited to immediate medical information, but should be as comprehensive as possible. The committee used the evidence and their own knowledge and experience to identify information that should be provided. Evidence also showed that including family members and carers in discharge planning can lead to a smoother transition

back into the community. The committee agreed that it is important to include family and carers, but they should only be involved if all parties consent.

There was good evidence, supported by the committee's knowledge and experience, that people who have help with organising their access to rehabilitation services are more likely to use them. In the committee's experience, complex funding is a barrier to receiving equipment that a person may need once discharged. Similarly, there are many different services that a person may need to work with after a traumatic injury (for example, legal services and welfare advice). In order to prevent delays in discharge, information on these organisations should also be provided as soon as possible, to avoid delays in the application process.

There was evidence that people can find a gradual return home helpful, beginning with overnight or weekend visits home before final discharge. This allows people to adjust to being in their home with their new needs, identifying areas that might need further rehabilitation and multidisciplinary team input before permanently going home. The committee acknowledged that this is not appropriate for everyone, but should be discussed as part of discharge planning. Home visits were also identified as being good practice to highlight any potential risks and allow people to have a fully informed discussion about what would benefit them.

The need for flexibility in rehabilitation appointments after discharge was a key theme in the evidence, because people face certain barriers to access (for example, time constraints, or travel to and from rehabilitation appointments). The committee agreed that arranging rehabilitation sessions at home rather than in a clinic or hospital can help, by decreasing travel and waiting times. Based on the evidence and their experience, the committee also recommended alternative consultation formats (for example, phone or video), to increase the flexibility of rehabilitation appointments.

How the recommendations might affect services

Additional time might be needed to compile information and discuss it with people and their support networks. However, by giving comprehensive information before discharge, there will be a decreased need to contact healthcare professionals with rehabilitation questions, and potentially reduced visits and readmissions to inpatient services.

Additional professional time might be needed to cover early discharge planning, checking access to community rehabilitation services, liaising with education providers and organising home visits. The recommendations imply more coordination between inpatient teams and other health and social care services, which will take more time. However, this additional time spent will result in

patients feeling more supported, increasing their confidence in services and improving outcomes. There is a potential resource impact from staggering discharge through overnight or weekend visits home. However, this would only be needed in exceptional cases.

Telephone or video consultations may result in a greater uptake of some services, because people may find remote attendance easier. However, services would have planned to provide in-person consultations for these people anyway, so there should be no overall resource impact.

Return to recommendations

A single point of contact, key contact and key worker after discharge

Recommendations 1.8.21 to 1.8.24

Why the committee made the recommendations

There was good evidence that people benefit from having a single point of contact after discharge from hospital (for example, a discharge coordinator, a phone line or an email contact). Having a team or a professional as a single point of contact can build rapport and trust, increasing the person's confidence in accessing outpatient and community rehabilitation services. It also reduces communication delays or duplication. This contact can also provide injury-specific information and information about local rehabilitation services, help people organise their rehabilitation, and advocate for them. This should be provided for a limited time after discharge in order to provide a secure and safe transition of care. The committee gave an example of 3 months, which was designed to encompass the transition period while still providing a stimulus to ensure healthcare is properly transferred to the appropriate setting.

Based on both the evidence and their own experience, the committee recommended appointing a key contact or key worker for people with continued or complex health and social care needs after discharge. Because of the increased level of support these people might need, a one-to-one relationship will increase trust and rapport, which will benefit patients and healthcare professionals.

How the recommendations might affect practice

Multiple healthcare professionals within the team have access to the relevant patient information and could therefore act as a point of contact, and so this would not need additional resources.

Having a single point of contact may reduce the workload of case managers that are routinely assigned to people with complex healthcare and social care needs.

Key worker roles would be filled by existing healthcare or social care professionals. However, there may be more pressure on their time.

Return to recommendations

Supporting access and participation in education, work and community after discharge (adjustment and goal setting)

Recommendations 1.9.1 to 1.9.12

Why the committee made the recommendations

There was evidence showing that people appreciate psychological and emotional support to adjust to social roles (for example, parenting or other family roles, relationships, intimacy), access meaningful activities for day-to-day living, and return to work, education and training. This is in line with the committee's own knowledge and experience. In the committee's experience, it is difficult to predict the outcome of rehabilitation, and making realistic goals is essential (for example, some people will not be able to return to the same type of work and will need retraining). The committee agreed that it is beneficial for people to continue with their normal activities and hobbies as part of their rehabilitation therapy. Even if adjustments are needed, this improves participation in social activities, counteracts the social isolation people may feel after traumatic injury, and makes rehabilitation goals more tangible. And the longer a person is not undertaking their everyday activities, the more difficult it is for them to return to the same level as before their injury.

There was good evidence on the importance of providing adequate information to people and their families before discharge. Evidence also showed that people often rely on family, carers and friends to help them navigate the multiple appointments and services needed during rehabilitation.

How the recommendations might affect services

More time might be needed to develop a rapport with people, to find out what goals are most important to them and to tailor support needs to them. Additional time may also be needed in order to provide information to employers or education providers.

All team members involved in the care of an individual provide emotional and psychological support, so this would not be an additional cost.

Return to recommendations

Commissioning

Recommendations 1.10.1 to 1.10.5

Why the committee made the recommendations

The qualitative and quantitative evidence identified aspects of planning, commissioning and coordinating that were important to the successful delivery of rehabilitation services. The committee agreed that rehabilitation services should collaborate and use joined-up commissioning approaches to provide a whole pathway rehabilitation. Based on their knowledge and experience, and limited qualitative evidence, the committee identified general principles that commissioners and providers should consider when planning, commissioning and coordinating rehabilitation services. Because these services will have different commissioners, collaboration and good communication will be needed.

There was no evidence on intensity of rehabilitation, so the committee took expert witness testimony on this. They expanded on the points raised by the expert witness to recommend providing an intensive rehabilitation programme. The committee recommended commissioning this as a tertiary service because it would only be appropriate for some people. This way, the service would be best designed to meet the needs of their local population.

Based on the qualitative evidence and their experience, the committee agreed that it is essential for an identified commissioner to have overall responsibility for local rehabilitation services, to avoid confusion and subsequent commissioning and budget errors.

How the recommendations might affect services

The recommendations are in line with current practice and should have little impact on resources. Where practice differs, there may be some resource implications, because services will need to set up frameworks for more collaborative and integrated commissioning. Intensive rehabilitation is already commissioned for some patient groups (for example, people who have lost a limb).

Return to recommendations

Organisation

Recommendations 1.10.6 to 1.10.11

Why the committee made the recommendations

There was qualitative evidence showing that establishing care networks and pathways between different settings encourages conversation, allows services to share advice and support each other, and can help identify gaps in local provision.

There was qualitative evidence on the usefulness of an electronic directory of care pathways, rehabilitation facilities and voluntary sector services. Some trauma units already have these in place, but directories are often out of date or incomplete. Accessing this information is also often difficult.

There was qualitative evidence showing the importance of community and social services for overall rehabilitation and recovery. Non-medical rehabilitative services are wide-ranging and can include social care, housing, home adaptation, transport, and sports and recreational facilities. The committee made a recommendation to make sure that people and their families or carers know these other services exist.

There was qualitative evidence showing that continuity of care increases when various professionals involved are aware of other areas of rehabilitation and can network with each other. There was also qualitative evidence on the importance of professionals in generalised medical settings having access to networking opportunities. This allows greater familiarity between professionals and improves cooperation.

There was qualitative evidence showing that technology and telehealth can be suitable methods of improving flexibility and availability of specialist appointments. This can be particularly useful in rural areas, because qualitative evidence showed that these areas are underserved by specialist rehabilitation services. However, not everyone has the equipment needed for remote consultations, so they cannot completely replace face-to-face consultations.

There was qualitative evidence showing that socialising and interacting with peers can promote rehabilitation uptake and counteract isolation. In the committee's experience, group rehabilitation sessions are a good way for people to get peer support. This was supported by expert witness testimony. However, peer support might not be suitable for everyone (for example, some people may feel discouraged if they are not progressing at the same rate as others).

How the recommendations might affect services

More resources may be needed to establish care networks and pathways. However, there are already examples of this in the NHS. Some trauma units already have electronic directories of care pathways, rehabilitation facilities and voluntary sector services. Services may need to do more to keep these up-to-date.

Most professionals already have opportunities for networking. However, practice may need to change for some services where this is not the case (for example, in rural areas).

Telehealth is becoming more common and does not need any specialist equipment.

Group rehabilitation sessions may represent a change in practice for some services.

Return to recommendations

Rehabilitation skills, knowledge and expertise in the workforce

Recommendations 1.10.12 to 1.10.14

Why the committee made the recommendations

The evidence identified a disparity in access to specialist rehabilitation services, depending on location (for example, rural areas are underserved) and individual needs (for example, if a person is not able to leave their home). A lack of rehabilitation knowledge within non-specialist healthcare services adversely impacts a person's trust in their rehabilitation services. The committee agreed that training is needed to address this. Community rehabilitation practitioners in general healthcare services should also have access to specialist rehabilitation support. This would not need to be full time, and could be provided remotely. Peer support and networking opportunities are also recommended. These will improve communication between professionals in different areas of healthcare and improve coordination for people undergoing rehabilitation.

How the recommendations might affect services

Specialist rehabilitation professionals might need to spend more time providing peer support to general services. This could be done in low-cost ways, for example, virtual meetings. If non-specialist healthcare professionals are better supported, people's needs are more likely to be met

locally and there will be less pressure on specialist services. Time and resources might be needed to provide more training for non-specialists. However, this will also reduce demand on specialist services.

Return to recommendations

Physical rehabilitation – early interventions and principles

Recommendations 1.11.1 to 1.11.9

Why the committee made the recommendations

There was conflicting evidence on the frequency and intensity of prescribed exercises because of the wide range of possible exercises, wide range of trauma and wide range of populations covered by the evidence. The committee agreed, based on their knowledge and experience, that healthcare professionals should set the frequency and intensity of rehabilitation exercises depending on the person's rehabilitation goals, but that these should be started as soon as possible. Analgesia may be needed to allow people to participate in rehabilitation. The committee also highlighted the importance of minimising the effects of low blood pressure when undergoing physical rehabilitation. This risk is increased because the person would need to change positions to perform certain rehabilitation exercises. Independence in performing everyday tasks should be encouraged, to prevent loss of these skills.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended. There may be more referrals to occupational therapy as a result of encouraging independence with activities of daily living. However, occupational therapists are already available in these settings, and this should not have a significant resource impact or be difficult to implement.

Return to recommendations

Early weight-bearing

Recommendations 1.11.10 to 1.11.12

Why the committee made the recommendations

The committee agreed with the evidence and current practice that weight-bearing exercises should be started as soon as possible. In their experience, this is important to encourage mobility and maintain postural reflexes, muscle mass, strength and function.

Decisions about weight-bearing should be led by the surgical team because it will be affected by any potential surgeries. However, bed rest can be harmful to muscle function, skin integrity, postural reflexes and respiratory function (especially in older people), and should be avoided as far as possible for most people with traumatic injury. The surgical team should communicate when a person is able to weight-bear as early as possible to keep bed rest to a minimum and so that weight-bearing can start without delay.

Lower limb injuries will affect a person's mobility, which affects their ability to participate in weight-bearing rehabilitation exercises to a greater extent than upper limb injuries, so the committee recommended a targeted weight-bearing programme. This programme should aim to progress the person's function with weight-bearing tasks such as mobility, ability to move from sitting to standing, and ability to lateral step (which is particularly important for people to maintain independence after discharge).

How the recommendations might affect services

The recommendations reflect current practice and are not expected to need additional resources to implement. Some additional time might be needed for communication between medical and surgical teams.

Return to recommendations

Aerobic and strengthening interventions

Recommendations 1.11.13 to 1.11.18

Why the committee made the recommendations

There was evidence showing the importance of aerobic and strengthening exercises in rehabilitation after traumatic injury. These exercises lead to better rehabilitation outcomes in several different trauma populations. The committee supplemented this evidence with their own knowledge and experience to recommend several aspects that healthcare professionals should consider when designing aerobic and strengthening rehabilitation programmes. The

recommendations cover general components rather than specific exercises because the evidence did not clearly show which exercises were best, and because the recommendations need to be applicable to a wide range of traumatic injuries. The committee also recommended tailoring aerobic and strengthening exercises to each person's interests, to make the exercises more enjoyable and to encourage people to take part.

The committee agreed that the exercise programme should begin as early as possible to limit the loss of muscle tone and physical fitness. Evidence showed that upper body aerobic training can improve rehabilitation outcomes in people with lower limb injuries. The committee discussed how for older people, fitness and strengthening programmes can help to optimise respiratory function, increase endurance when doing rehabilitation exercises, and improve mobility.

Finally, the committee stressed that these exercise rehabilitation programmes should be continued after people are discharged home, to ensure that their physical strength and fitness does not stagnate or decrease. Regular reviews should be carried out during rehabilitation appointments in order to gauge whether the programme components are still appropriate for people's rehabilitation needs, and to change them if not.

How the recommendations might affect services

The recommendations are not expected to have a significant resource impact or be difficult to implement. However, extra time may be needed to tailor exercise programmes to each person's preferences.

Currently, some physiotherapists do not offer aerobic exercise programmes to older people who are frail. For these physiotherapists, there will be a change in practice and there may be a greater uptake of aerobic exercise in older people. Older people would already be working with a physiotherapist, so this will only change the type of exercise used and there will be no additional costs for services.

Return to recommendations

Gait training and re-education

Recommendations 1.11.19 to 1.11.21

Why the committee made the recommendations

Although there was evidence to show that gait re-education did not improve rehabilitation

outcomes, the committee disagreed with these findings. In their knowledge and experience, gait re-education is a very effective rehabilitation tool, particularly for muscle strengthening. In people who are not mobile, gait re-education can still be introduced early but should be focused on reducing the impact of non-weight-bearing. This will maintain the current level of functioning and mobility, so people are ready to undertake weight-bearing gait re-education as soon as possible.

How the recommendations might affect services

At some hospitals, physiotherapists do not get patients into their physiotherapy unit until they can weight-bear fully. These physiotherapists will need to change their practice. Overall, the recommendations are not expected to have a significant resource impact or be challenging to implement.

Return to recommendations

Manual therapies and maintaining joint range of movement

Recommendations 1.11.22 to 1.11.24

Why the committee made the recommendations

There are a variety of range of movement exercises that can be used for rehabilitation, with different levels of assistance depending on ability. Controlled motion devices should be considered if people are not able to perform exercises independently. The committee agreed that range of movement is particularly important during rehabilitation. Targeted stretching is a good method of preventing loss of movement, particularly after exercises, when muscles tighten as a response to activation.

How the recommendations might affect services

The committee were aware of the potential resource impact of recommending specific controlled motion devices to assist range of motion. Generally, these devices are rarely used (and mostly only in hospitals to help with knee injury). However, once acquired, these devices can be used by multiple people. Overall, the recommendations are not expected to have a large resource impact or be difficult to implement.

Return to recommendations

Splinting and orthotics

Recommendations 1.11.25 to 1.11.33

Why the committee made the recommendations

Evidence showed a benefit from orthoses in rehabilitation after trauma. No evidence was found on splinting. The committee combined the available evidence with their experience and knowledge to recommend several specialised splints and orthoses, and to warn about positions known to cause complications and loss of function later on in recovery.

Because of their complexity, the committee recommended bespoke splints for people with hand injuries, as well as referral to a hand therapy specialist. 'Off-the-rack' splints can be ill-fitting and cause lost range of movement in the hands and fingers.

Regular review of splints is recommended because splinting can have adverse effects if not monitored carefully (for example, pressure sores). This risk is increased in people with reduced skin sensation and recent skin graft or flaps, so splints and orthoses may be contraindicated and specialist advice may be needed. People (and families and carers, if appropriate) should receive education on how to wear splints or orthoses to limit adverse effects and when to seek professional advice.

Evidence showed that spinal orthoses can help improve patient rehabilitation outcomes, and they are used in current practice. However, in the committee's experience, not all trauma populations see a benefit (for example, older people) and spinal orthoses can cause adverse events if improperly fitted. Healthcare professionals should be aware that these devices may be poorly tolerated and know when to discuss problems with the surgical team. Because of these issues with the evidence, the committee made a research recommendation on spinal orthoses for older people.

How the recommendations might affect services

The recommendations reflect current practice. Splints and orthoses are commonly used and are all low cost. Bespoke splints are easily made in a treatment room and would not need any additional resources.

Return to recommendations

Management of swelling and oedema, and scars

Recommendations 1.11.34 to 1.11.44

Why the committee made the recommendations

Swelling and oedema management

Swelling is a common side effect of traumatic injury, but there are symptoms that will need treatment from healthcare professionals (for example, signs of deep vein thrombosis). No evidence was found, so the committee used their knowledge and experience to recommend a programme of elevation and exercises to prevent and reduce any swelling associated with trauma. Compression bandages can be used to help this. However, providing appropriate compression is a skill. Therefore, the committee recommended specialist supervision for this.

Scar management

No evidence was found on the psychological aspects of scarring after traumatic injury. Based on their experience, the committee recommended several measures to encourage people to adjust to their new appearance, reassure them of expected recovery sensations and provide information about scar management. For children and young people, the committee recommended performing any painful treatments away from their hospital bed. This encourages them to associate their bed with security, an important factor in their hospital experience.

Evidence was found for massage as a treatment for scar tissue. This will help desensitise the area, and increase tissue mobility (and therefore maintain range of movement).

In the committee's experience, scar management knowledge is not very prevalent in non-specialist healthcare settings. Therefore, they recommended referring people to specialist services if they have scars or skin grafts that need complex treatment (for example, contracture across joints that limits movement).

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Nutritional supplementation

Recommendations 1.11.45 to 1.11.52

Why the committee made the recommendations

The evidence for nutritional supplementation was of very low quality. However, the committee agreed that there is a lack of awareness about the nutritional risks and needs following traumatic injury. People need more calories after traumatic injury, to help with healing. However, they often have complications that can affect eating habits or nutrient absorption. To address these issues and the lack of awareness around nutritional supplementation, the committee made recommendations based on their own experience.

The committee made a specific recommendation for people with burns in combination with other traumatic injuries because they are at increased risk of losing significant muscle mass, weight and strength for a prolonged period, because of the long-lasting effect of the hypermetabolic response.

How the recommendations might affect services

The recommendations are in line with current practice and will not need additional resources to implement.

Return to recommendations

Cognitive rehabilitation

Recommendations 1.12.1 to 1.12.7

Why the committee made the recommendations

There was no evidence in this area. However, in the committee's experience, trauma-related cognitive functioning problems can be upsetting for people and affect their decision making and participation. Because of this, the committee believed it is important to reassure people that these problems are usually temporary. When problems are not temporary, the committee recommended adapting rehabilitation therapy to take account of this and to help the person participate in therapy and assessments.

As another aspect of helping people with cognitive difficulties to participate, the committee highlighted information needs and formats to use. The committee were also keen to emphasise the

need to share this information with the person's family or carers, because they can play an important part in helping the person understand and recall key messages.

The committee agreed on additional steps to follow for children and young people, to ensure that their education providers accommodate their changing needs.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Psychological rehabilitation

Recommendations 1.13.1 to 1.13.7

Why the committee made the recommendations

The committee used their knowledge and experience to make recommendations on psychological rehabilitation. They highlighted the importance of reassuring people that the acute stress response is common and normally temporary, because it can be very distressing. Outside of the acute stress response, the committee identified several other psychological issues, to raise awareness among professionals and encourage good practice.

Because of low quality evidence, the committee based the recommendations on psychological support on their own experience. They agreed that 'one size does not fit all' within psychological and psychosocial therapies and felt it was important to offer psychological and emotional support that is tailored to a person's rehabilitation goals, needs and preferences.

The committee recommended that any treatment for psychological disorders should form part of a complete rehabilitation package, and not be kept separate. This will allow better communication and coordination of physical and mental healthcare.

No evidence of benefit was found for family support interventions. However, in the committee's experience, involving family can be beneficial.

How the recommendations might affect services

The recommendations reinforce current practice and refer to existing NICE guidelines, so should not need additional resources to implement. Most team members specialising in the management of major trauma are equipped to provide psychological and emotional support. Being more aware of psychological problems may result in more referrals to psychology services.

Return to recommendations

Rehabilitation after limb-threatening injury – early assessment, decision making and support

Recommendations 1.14.1 to 1.14.4

Why the committee made the recommendations

There was no evidence in this area. The committee agreed based on their experience who should be involved from the multidisciplinary team and what the discussions needed to cover.

Although no evidence was identified, the committee recommended psychological support before limb amputation because of the life-changing nature of the procedures. Psychological and emotional support can improve outcomes after surgery (such as emotional wellbeing and pain management).

The committee recommended involving limb reconstruction and prosthetic specialists early on, because amputation and limb reconstruction can be life-changing and traumatic.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Rehabilitation after limb reconstruction

Recommendations 1.14.5 to 1.14.7

Why the committee made the recommendations

There was no evidence identified but, based on their own experience, the committee agreed that rehabilitation should start as early as possible after surgery to reduce the risk of complications that may delay the person's recovery, and to maintain range of movement after limb reconstruction. Because of the complexity of limb reconstruction, the committee did not recommend a specific programme but suggested certain interventions that could be used to accomplish this.

The committee also agreed that psychological support should continue after limb reconstruction surgery, to help the person adjust to their appearance and manage pain.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Rehabilitation after limb loss or amputation

Recommendations 1.14.8 and 1.14.9

Why the committee made the recommendations

There was no evidence but, based on their own experience, the committee agreed that rehabilitation should start as early as possible after surgery to reduce the risk of complications that may delay the person's recovery. People should usually be referred to the amputee and prosthetic rehabilitation team before their surgery, but the committee acknowledged that sometimes there is not enough time so they would need to be referred afterwards.

The committee also agreed that psychological support should continue after limb loss and amputation to help the person adjust to their appearance and manage pain (for example, mirror therapy).

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended. More people being referred to amputee and prosthetic rehabilitation before surgery may cause an initial increase in early referrals, but this will be offset by fewer people

being referred later in rehabilitation.

Return to recommendations

Pain management after limb loss or amputation

Recommendations 1.14.10 to 1.14.12

Why the committee made the recommendations

The committee agreed that pain management should be discussed before surgery because pain after limb loss or amputation can be difficult to treat, and managing pain effectively after surgery can increase participation in the rehabilitation process. Additionally, people with poor perioperative pain control have an increased risk of phantom limb pain in the long term. There was also evidence that mirror therapy (a type of graded motor imagery therapy) is an effective and inexpensive non-pharmacological treatment for phantom limb pain after limb loss or amputation.

How the recommendations might affect services

The recommendations enforce current practice and are not expected to be difficult to implement. Mirror therapy is relatively cheap and easy to implement. Other forms of graded motor imagery therapy are less commonly used and should be delivered by staff with appropriate skills, potentially resulting in extra training costs where it is currently not available. There may be an increased level of referrals to specialised pain management teams, depending on the complexity of pain management plans. However, this will be offset by increased participation in rehabilitation after surgery and therefore better outcomes.

Return to recommendations

Residual limb oedema and shaping after limb loss or amputation

Recommendations 1.14.13 to 1.14.15

Why the committee made the recommendations

There was no evidence so the committee based the recommendations on their knowledge and experience. They highlighted the benefit of elevation and compression therapy in managing

residual limb oedema by reducing swelling and facilitating prosthetics fitting. They also agreed that:

- limb swelling should be avoided when using early walking aids because this can delay prosthetics fitting and rehabilitation
- residual limb (stump) boards on wheelchairs can provide support to keep the limb elevated for people with a below-the-knee amputation.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Range of movement and strengthening after limb loss or amputation

Recommendation 1.14.16

Why the committee made the recommendation

The committee used their knowledge and experience to recommend providing range of movement exercises to help prevent complications and optimise functional outcomes.

How the recommendation might affect services

The recommendation reflects current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Functional independence after limb loss or amputation

Recommendations 1.14.17 and 1.14.18

Why the committee made the recommendations

Although there was some evidence identified about waiting until prosthetics had been fitted before

starting rehabilitation, this disagreed with the committee's knowledge and experience. They argued that the best way to maintain and improve the person's range of movement after limb loss or amputation is by starting rehabilitation therapy as early as possible. Rehabilitation should not be delayed by waiting for prosthetics to be fitted because the maintenance and improvement of range of movement will help prevent complications and optimise functional outcomes.

The committee also agreed that wheelchairs should be provided early, along with appropriate accessories such as anti-tippers and residual limb (stump) boards. Wheelchairs should be adjusted to accommodate the changes in the person's weight distribution after limb loss or amputation. By providing appropriately fitted and adjusted wheelchairs as early as possible, a person's independence and mobility will be increased and they will be better able to engage in activities of daily living. There was no evidence, so the committee used their knowledge and experience to make the recommendation on wheelchairs.

How the recommendations might affect services

There might be an increased number of referrals to physiotherapists and occupational therapists in order for wheelchairs to be individually fitted and adjusted. However, the committee discussed that the increased mobility and independence will result in an increased engagement with rehabilitation, leading to better rehabilitation outcomes. Overall, the recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Psychological support after limb loss, amputation or limb reconstruction

Recommendations 1.14.19 to 1.14.22

Why the committee made the recommendations

Although there was no evidence, the committee used their experience and knowledge to discuss how continuing psychological support after limb reconstruction, loss or amputation can help the person come to terms with their appearance and manage pain.

The committee recommended actively monitoring children and young people for emerging emotional and psychological impact. This is because childhood and young adulthood is a period of change for anyone, and children who have had limb reconstruction, loss or amputation may

experience it differently to the general paediatric population (for example, altered body image may become more important during puberty).

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Continuing rehabilitation after limb reconstruction, limb loss or amputation and after discharge

Recommendations 1.14.23 to 1.14.26

Why the committee made the recommendations

The rehabilitation plan should be reviewed at key points to ensure it is updated with any changes in the person's goals, circumstance or needs. For children and young people, physical growth may cause complications around the residual limb or prosthetic fitting. The committee recommended referral to specialist assessment when this occurs, in order to prevent any adverse effects.

Based on their experience, the committee recommended psychological and emotional support after trauma to help a person adjust to their altered body image, manage pain and cope with the possibility of further procedures.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Rehabilitation after spinal cord injury – referral, assessment and general principles

Recommendations 1.15.1 to 1.15.8

Why the committee made the recommendations

The committee discussed their experience with early treatment of traumatic spinal cord injury in emergency departments and how this can affect rehabilitation. Studies involving spinal cord injury treatment in the emergency department were not included in the evidence reviews because of an existing NICE guideline on spinal injury: assessment and initial management. However, the committee highlighted several areas of acute treatment that can affect rehabilitation after traumatic injury.

Because of competing clinical interests, certain aspects of spinal cord injury management are often overlooked in emergency healthcare settings. The committee highlighted the importance of timely contact with regional specialist spinal cord injury centres and the national spinal injuries database to establish a partnership of care with specialist healthcare professionals that will continue throughout the rehabilitation journey. An American Spinal Injury Association (ASIA) chart should also be completed early to identify a current reference point for future assessments.

The committee reflected on the additional issues that people encounter after spinal cord injury because of the chronic nature of the injury and resulting disabilities (for example, bowel, bladder and sexual function). External support networks are very important during spinal cord injury rehabilitation, with family members (and carers or friends, if appropriate) being invited into healthcare discussions and rehabilitation goals. Vocational, educational, recreational and home adjustments may be needed after discharge. By starting these conversations and arrangements early in the rehabilitation process, any modifications can be in place and rehabilitation can be better tailored to an individual, creating a smoother transfer back into the community. Ongoing contact with hospital rehabilitation teams should be maintained to ensure a continued progress review to inform outpatient rehabilitation planning.

The committee discussed the additional complications that children and young people might experience after spinal cord injury because they are still growing. Spinal growth patterns, skeletal growth and nutrition need to be closely monitored in children and young people. Complications in any of these areas can cause additional barriers to rehabilitation, and will become more difficult (if not impossible) to treat as the child or young person stops growing.

How the recommendations might affect practice

The recommendations reinforce current practice and are in line with the NICE guideline on spinal injury. The benefits of increased care coordination will offset the extra time that professionals might need to follow the recommendations. ASIA charts can be difficult to administer reliably, and staff with appropriate skills should complete assessments, potentially resulting in some extra

training costs.

Return to recommendations

Bladder and bowel function

Recommendations 1.15.9 to 1.15.12

Why the committee made the recommendations

The committee agreed that bladder and bowel management is important because the medical consequences from undetected bladder and bowel malfunction can be severe. Complications include renal tract damage, bowel perforation and respiratory distress. The committee used their knowledge and experience to recommend several measures to monitor and maintain bladder and bowel function. Although keeping people nil by mouth is a common practice while assessing bowel function, the committee highlighted that delays in this assessment should be minimised in order to prevent issues with nutrition and discomfort during rehabilitation.

How the recommendations might affect practice

There is variation in bladder and bowel management, so the recommendations should lead to greater consistency and improve care. Monitoring bladder and bowel function will involve additional time, but should have benefits in reducing complications, avoiding delays in starting and continuing rehabilitation, and improving patient outcomes.

Return to recommendations

Respiratory function, swallowing and speech

Recommendations 1.15.13 to 1.15.17

Why the committee made the recommendations

Spinal cord injury can cause problems with speech and swallowing, so the committee agreed that people should be nil by mouth until they have been assessed for aspiration risk. They used their expertise to highlight groups of people that are at a particularly high risk, and should be assessed early. Referral to specialists may be needed.

Maintaining respiratory function is essential after a spinal cord injury because the injury may have

damaged the chest muscles used in respiration. Without treatment, this could lead to respiratory failure and severe complications. It can also delay rehabilitation until the person is clinically stable enough to start it, and may mean they also need chest physiotherapy to be added to their care plan. Respiratory function should be assessed in line with the NICE guideline on spinal injury to determine baseline function and mark progress. The committee highlighted that children and young people can find it difficult to complete these assessments (particularly forced vital capacity [FVC]), and these should be performed and interpreted in accordance with their age and ability. The committee used their experience to recommend several protective interventions to assist with respiratory function after spinal cord injury.

How the recommendations might affect services

Monitoring respiratory function after a spinal cord injury will involve additional time, but should have benefits in preventing complications caused by compromised respiratory function, avoiding delays in starting and continuing rehabilitation, and improving outcomes. Prophylactic respiratory support will potentially reduce the need for additional chest rehabilitation further down the pathway.

Return to recommendations

Preventing complications

Recommendations 1.15.18 to 1.15.20

Why the committee made the recommendations

The extended periods of bed rest and immobilisation following spinal cord injury can lead to a wide variety of complications, which can delay rehabilitation. There was no evidence so the committee based the recommendations on their knowledge and experience.

Skin management is a particular area of concern because of decreased mobilisation coupled with reduced physical sensation. People can develop deep pressure ulcers very quickly, which need to be treated before rehabilitation can start.

Blood pressure monitoring is important after spinal cord injury because people are at risk of developing autonomic dysreflexia (in high-level spinal cord injury) and orthostatic hypotension. Autonomic dysreflexia has severe consequences (for example, strokes, encephalopathy, brain haemorrhages and heart attacks) and should be managed as a medical emergency. Orthostatic hypotension has less severe complications but, because it is triggered when changing positions, can

affect engagement with rehabilitation exercises.

How the recommendations might affect services

The recommendations reinforce current practice and should not need additional resources to implement. Additional education might be needed for healthcare professionals on the best way to inform people with spinal cord injury about skin and pressure management.

Return to recommendations

Maintaining mobility and movement

Recommendations 1.15.21 to 1.15.33

Why the committee made the recommendations

The committee agreed that it is important to maintain mobility and range of motion after a spinal cord injury. However, they also recognised that the large variety of spinal cord injury disabilities and needs means that this should be considered on a case-by-case basis. Because of this complexity, the committee stressed that specialist advice should be sought when needed (for example, the appropriateness of wrist splints for people with a spinal cord injury involving C6). Spinal orthoses have conflicting results in different people, and can hinder certain rehabilitation programmes. Therefore, the committee recommended referring to surgical teams in these cases, to explore other avenues of treatment.

There was some evidence on the benefit of specialist equipment and rehabilitation techniques to maintain mobility and range of motion. The committee agreed that these should be considered on a case-by-case basis, aligning interventions with rehabilitation needs and goals.

Spasticity is an important area to treat for people with spinal cord injury, to prevent losing range of joint movement and contractures. There was some evidence on baclofen (an oral antispastic medication) and botulinum toxin type A to manage spasticity after a spinal cord injury. Referral to a multidisciplinary team specialised in spasticity management may be needed.

Length of bed rest after spinal cord injury varies throughout different NHS trusts, and is an area that the committee were keen to standardise. However, because of the lack of evidence identified, they were unable to make any strong recommendations and made a research recommendation on the optimal length of bed rest to inform future guideline updates.

How the recommendations might affect services

More people with spinal cord injury might be referred to specialist services. Any additional cost will be offset by more people achieving their long-term rehabilitation goals because of earlier specialist input. There might be some additional costs for training healthcare staff, and some services might need to procure specialist equipment to help with mobility, upper limb function and independent walking. Although some equipment, like robotics, can be expensive, the committee agreed a range of effective interventions. There is flexibility within the recommendations about the use of a range of assistive devices and techniques.

Return to recommendations

Low mood and psychological support

Recommendations 1.15.34 to 1.15.37

Why the committee made the recommendations

There was conflicting quantitative evidence on using psychosocial interventions after spinal cord injury, with some studies reporting beneficial outcomes and some finding no difference. The committee argued that this was low quality evidence, and that their experience and expertise agreed with the beneficial impact of psychological interventions. However, because they have already made recommendations on psychological interventions for rehabilitation after traumatic injury, they used this section of the guideline to make recommendations that are specific to people with spinal cord injury.

People with spinal cord injury have increased rates of low mood and psychological trauma, and this can affect engagement with rehabilitation. Access to a psychologist with experience in traumatic spinal cord injury and rehabilitation is not guaranteed outside of specialised spinal units, so the committee made a recommendation to address this. Active monitoring is recommended for children and young people because childhood and young adulthood is a period of change for anyone, and children and young people with a spinal cord injury could be affected in different ways to the general paediatric population (for example, altered body image becoming more important during puberty).

How the recommendations might affect services

The recommendations reinforce current practice and should not need additional resources to implement. If multidisciplinary teams are more aware of low mood and psychological trauma in

people with a spinal injury, they may make more referrals for psychological support.

Return to recommendations

Rehabilitation after nerve injury – general principles

Recommendations 1.16.1 to 1.16.3

Why the committee made the recommendations

Nerve injuries may be hidden; for instance, when the person has multiple injuries, a cognitive impairment, a head injury, is in critical care or has a pre-existing neurological condition. These obvious injuries could distract clinicians from recognising subtler nerve injury, and neurological deficit caused by nerve injury can be mistakenly assumed to be due to a pre-existing neurological condition. In addition, diagnosis of nerve injury may not be possible if the person is unconscious, and nerve function cannot be assessed on limbs that are splinted. The committee highlighted the need to assess the peripheral nerves of the affected limb to identify the informed nerve and functional deficit.

The committee highlighted the importance of assessing the risks to tissue viability if there is sensory or motor loss secondary to peripheral nerve injury, to manage the risk and not jeopardise the person's functional recovery.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice might need to be amended.

Return to recommendations

Therapies and referral

Recommendations 1.16.4 to 1.16.9

Why the committee made the recommendations

Based on the evidence and their experience, the committee emphasised the need to start rehabilitation therapy to maintain range of movement and regain function after nerve injury. This is because nerve injury can cause the joint to rest in an unnatural position and lead to fixed deformity

from contracture of the capsule and muscle. Providing vocational therapy while the recovery is ongoing can help the person return to normal activities such as work.

Nerve function should be assessed regularly for symptoms of recovery, which will affect the components and intensity of the nerve rehabilitation programme. It should not be a static programme. For people who have a poor prognosis, a referral to a specialist peripheral nerve injury service should be made because these services are better equipped to deal with the complex needs of peripheral nerve injury.

People recovering from nerve injury may experience low mood, anxiety and lack of motivation, because recovery may be a lengthy process. To ensure that specialist psychological support is available for people who may need it, the rehabilitation team should have access to a psychologist with trauma and rehabilitation experience.

How the recommendations might affect practice

Sensory interventions (including mirror therapy) and hydrotherapy are not widely available and this could have some resource implications. However, hydrotherapy would only be offered if pool facilities were available, and mirror therapy and other sensory interventions are relatively inexpensive and easy to implement. All of the above interventions can play a part in stimulating and aiding functional recovery, and can lead to a quicker recovery, help with pain management, and improve the person's health-related quality of life.

Healthcare professionals may need training to conduct nerve conduction studies reliably, but this will save costs further down the care pathway. There may be more referrals to specialist peripheral nerve injury services.

Return to recommendations

Rehabilitation after chest injury

Recommendations 1.17.1 to 1.17.12

Why the committee made the recommendations

There was no evidence identified. However, the committee discussed the importance of starting rehabilitation as soon as possible to avoid further complications. They also discussed the need for regular assessment of pain and highlighted pain management options. This is because pain is a contributing factor for much of the morbidity associated with chest injury, and the appropriateness

of pain management options may vary between people with chest injury.

For people with chest trauma, the committee highlighted the need for movement in order to optimise their respiratory function and prevent deconditioning. They further highlighted a range of rehabilitation therapies to use in preventing respiratory difficulties because this is a key component of chest trauma rehabilitation. The committee are aware that the availability of these therapies may differ between services, and different therapies may be preferred by different people.

Because of the concerns over possible injury causes and underlying pathologies, the committee highlighted the need to assess people with rib fractures, in order to inform future treatment and prevent recurrence. The committee recognise stiffness of the upper limbs as a common complication and discussed measures to prevent compromised function.

The committee recommended referring people with complex chest injuries that affect communication and swallowing skills to speech and language therapy to prevent speech decline and swallowing difficulties.

The committee also recommended providing information that will help people to return to normal life and explain how to seek help for different problems that may arise because rehabilitation for chest injuries can take a long time, causing stress and worry.

How the recommendations might affect services

The recommendations reflect current practice, but where there are regional variations, practice will need to be amended.

Return to recommendations

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE webpage on injuries, accidents and wounds.

For full details of the evidence and the guideline committee's discussions, see the evidence reviews. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

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Accreditation

NICE National Institute for Health and Care Excellence

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NICE guideline

Babies, children and young people's experience of healthcare

NICE guideline

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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

Overview

This guideline describes good patient experience for babies, children and young people, and makes recommendations on how it can be delivered. It aims to make sure that all babies, children and young people using NHS services have the best possible experience of care. It is recognised that parents and carers play a key role, and where appropriate, we took their views into account when developing the recommendations.

NICE has also produced a guideline on patient experience in adult NHS services for people aged 18 and over.

See a visual summary setting out how to use NICE guidelines on babies, children and young people's experience of healthcare.

Who is it for?

- Healthcare professionals, commissioners and providers of NHS or local authority healthcare services
- Non-clinical staff who come into contact with patients (for example, receptionists, clerical staff and domestic staff)
- People aged 17 and under using healthcare services, their families and carers, and members of the public

Introduction from the young people involved in the development of this guideline

When babies, children and young people access healthcare, it is important that their experience is as positive as possible. This guideline has been written with children and young people who know what it's like to be a patient. It has been an opportunity to share what has and has not worked, and hopefully improve the healthcare experience of many babies, children and young people in the future.

Adults often see children and young people as passive recipients of healthcare. This can lead to children and young people not being listened to, having a lack of understanding of their own condition and may lead to problems that can affect future care (for example, finding it difficult to trust healthcare professionals or feeling very anxious before procedures). However, having a positive experience can make a child or young person feel confident, empowered and supported to manage decisions about their own health and healthcare, and can improve their perception of their diagnosis and treatment. This positive experience should also ensure that babies, children and young people are treated as individuals with a life outside healthcare, and not just as their condition or diagnosis.

This guideline aims to improve the healthcare experience of babies, children and young people with the hope that this can improve their health outcomes and their wellbeing.

Context

Optimising patient experience has long been recognised as an integral part of effective healthcare for adults. The healthcare experience of babies, children and young people has received less attention in the past, despite the legal rights of children to participate in decisions that affect them. Unfamiliar environments, and having to meet and interact with a range of healthcare professionals, can be particularly unsettling for babies, children and young people, and may lead to anxiety and distress.

Many NHS providers of healthcare services for children and young people currently carry out user surveys directly with children and young people as well as with their parents or carers, and some run focus groups to obtain feedback from children and young people and their parents or carers, with a view to improving the provision of services and the experience of healthcare. However, surveys of children and young people's healthcare experiences have identified that feedback from children themselves is generally less positive than their parents' responses, with a third of children in 1 survey reporting that they did not always understand what staff said, and over half feeling they were not involved enough in making decisions about their care or treatment.

Although there are some examples of good practice and initiatives to improve babies, children and young people's experience of healthcare, there is variation in practice across the country.

This guideline covers babies, children and young people (aged 17 and under) accessing NHS physical or mental health services, or local authority-commissioned healthcare services. Babies, children and young people are entitled to always receive the same high-quality healthcare experience, and so the recommendations in this guideline apply to all healthcare experiences and settings. For some babies, children and young people, interaction with healthcare services may be limited to visits to a dentist or GP, whereas other babies, children and young people may have medical conditions that need frequent interactions, inpatient stays and an ongoing healthcare relationship with professionals, so a personalised approach to implementation is needed.

The guideline provides evidence-based information for healthcare professionals, children, young people and their parents or carers about communication, information, support, the healthcare environment, access and continuity of care. It also provides guidance on maintaining usual activities because babies, children and young people need the opportunity to grow, learn and develop alongside their peers, despite their healthcare needs.

Recommendations

Healthcare professionals should involve children and young people in decisions about their healthcare in ways that are appropriate to their maturity and understanding. Some children and young people will be able to give informed consent themselves, some will be able to contribute to the discussion, and others may not be able to be involved at all. For more information, see NICE's information on making decisions about your care.

A parent or carer, who has parental responsibility for a child (as defined by the Children's Act 1989), will have a key role to play in planning and making decisions about their child's health and care, particularly when they are young. As children grow older and develop the maturity and understanding to make decisions for themselves, that role will diminish, particularly if the child wants it to. Where relevant, parents and carers should be given information and support to enable them to do this, as set out in the NHS Constitution and summarised in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding that should be used alongside this guidance.

1.1 Overarching principles

Safeguarding

1.1.1 Adhere to all relevant legislation and follow all national and local safeguarding policies and professional guidelines when implementing these recommendations and when planning and delivering healthcare services for all babies, children and young people, in any setting. See further guidance in the NICE advice on safeguarding and the Children's Act 1989 (and subsequent updates).

Disabilities

1.1.2 Adhere to all relevant legislation relating to the rights of disabled babies, children and young people to access healthcare, and make reasonable

adjustments as required by legislation to enable this access. See the Equality Act 2010.

Competence

1.1.3 Involve all children and young people in decisions about their healthcare, unless they do not wish (or are unable) to be involved (see recommendations 1.1.4 to 1.1.7). Recognise that:

- Young people aged 16 or 17 years with mental capacity to make decisions about their healthcare are entitled to do so, and to consent to treatment. There is a presumption that a person above the age of 16 has capacity unless and until assessed otherwise.
- Children and young people under 16 years can make decisions about their healthcare and consent to treatment if they are assessed by a healthcare professional to be Gillick competent. The conclusion that a child or young person is competent relates to that specific healthcare decision.

Age- and developmentally appropriate care

1.1.4 Ensure that all methods of communication, information and discussions are tailored for the age, developmental stage and level of understanding of the baby, child or young person.

1.1.5 Recognise that needs and preferences may change as children mature, and that it is necessary to revisit these needs and preferences on a regular basis and to adapt support, information and complexity of discussions accordingly.

Changes in needs and preferences

1.1.6 Recognise that children and young people's needs, preferences and engagement with healthcare professionals and healthcare services (for example, how much they would like to be involved in decision making or how much support they need) may vary from day to day, at different encounters or may be affected by other factors (for example, how unwell they are feeling).

1.1.7 Ensure that previously expressed needs, preferences or engagement levels are revisited, and give additional or alternative opportunities for discussions or decisions, particularly if personal or clinical circumstances have changed.

Digital access

1.1.8 Recognise that not all children and young people, or the parents or carers of babies and young children, are able to access digital resources (for example, online information, messaging or video-calling, apps or other digital tools).

1.1.9 Ensure that non-digital methods of attending appointments, communicating, and providing information are available, and provide an equal level of service, for anyone who cannot access (or prefers not to use) digital methods.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on overarching principles.

Full details of the evidence and the committee's discussion are in:

- evidence review A: planning healthcare and making shared decisions
- evidence review C: consent privacy and confidentiality
- evidence review D: providing information
- evidence review E: understanding the risks and benefits of healthcare decisions
- evidence review F: involving parents or carers in healthcare and healthcare decisions
- evidence review G: support from healthcare staff
- evidence review M: healthcare environment.

1.2 Communication and information

Communication by healthcare staff

1.2.1 Ensure that children and young people, and their parents or carers have a positive experience by:

- introducing yourself and anyone else present

- asking them how they wish to be addressed (for example, their preferred name and pronouns)
- putting the child or young person and their parents or carers at ease by being friendly and welcoming (for example smiling, saying hello, using eye contact)
- building a rapport to develop trust
- encouraging children, young people and the parents and carers of babies and young children to contribute to, and be active participants in, discussions and decisions about their care.

See also the section on support from healthcare staff.

1.2.2 Communicate with children and young people and their parents or carers with:

- kindness, compassion and respect
- cultural sensitivity
- a non-judgemental attitude.

1.2.3 When communicating with babies, children and young people, particularly those with ongoing health needs, develop an understanding of them as individuals, not only based on their health condition or diagnosis (for example, referring to the baby, child or young person by name, asking them what is important to them in their healthcare).

1.2.4 Take time to listen to and address the concerns and fears of children and young people, and of the parents or carers of babies and young children and:

- treat their concerns and feelings (such as fear and embarrassment) with empathy and understanding
- give reassurance that these concerns are very common and are nothing to feel embarrassed or upset about (for example, by saying 'it's OK to be scared').

1.2.5 Identify who is the most appropriate person to communicate with a child or young person, or the parent or carer of a baby or young child (for example, this could be a healthcare professional or other member of the multidisciplinary team, or another professional such as a youth worker or social worker). When

deciding on the person, take into account:

- the clinical circumstances
- the subjects to be discussed
- the preferences of the child or young person.

1.2.6 Identify the child or young person's preferred forms of communication and use these when communicating with them. Ask their advice, or ask their parents or carers what these are. Take into account that:

- English may not be their first language
- these may be non-verbal (for example, sign language, Makaton)
- identification of a 'yes' or 'no' response (which might be non-verbal) can allow a direct conversation between a child or young person and a healthcare professional
- these might need additional resources (for example, foreign language or sign language interpreters, picture boards, computer-based systems)
- individuals with additional communication needs might need more time and specialist support for alternative forms of communication (for example, augmentative and alternative communication).

1.2.7 Be aware that parents or carers may have communication preferences and needs of their own that may affect their ability to discuss their baby or child's care.

1.2.8 Use developmentally appropriate creative and interactive tools to help effective communications with babies, children and young people (for example, play dough, pictures, diagrams and writing).

1.2.9 Help engage babies, children and young people in communication by:

- using both verbal and non-verbal methods (for example, sitting at the same level as them, using body language to show attentive listening, reassuring babies by positive touch or containment holding before or during procedures)
- pausing and allowing time for responses.

1.2.10 When communicating with children and young people, always check they have taken the information in and understood it (for example, by asking children or young people to explain back to you in their own words).

1.2.11 If a child or young person is uncomfortable or having difficulty communicating, try alternatives that may help. This may include:

- trying again at a different time
- trying again in a different, quieter or more private setting (see recommendations 1.4.8 and 1.4.9)
- seeing them without their parents or carers
- involving a different person (for example, another healthcare professional or an adult trusted by the child or young person)
- using a different means of communication.

1.2.12 Respect times when children and young people do not wish to communicate, and be aware that their wish to communicate may vary at different times.

1.2.13 In urgent or emergency situations when time may be limited, give children and young people opportunities to communicate whenever possible, and the opportunity to discuss afterwards.

1.2.14 Be aware that babies, children and young people may not communicate pain, distress or anxiety verbally so you may need to:

- ask parents or carers what is usual behaviour for their child or young person
- be alert to physical cues (for example, lack of or abnormal movements to reduce pain) or behavioural cues (for example, crying, refusing to speak or pushing away, or behaviour that appears aggressive such as anger, defiance or biting).

1.2.15 All staff involved in providing healthcare services to babies, children and young people should have skills and competencies in relevant communication skills.

1.2.16 For guidance on communicating with children with life-limiting conditions, see the NICE guideline on end of life care for infants, children and young people with life-limiting conditions.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on communication by healthcare staff.

Full details of the evidence and the committee's discussion are in evidence review B: communication by healthcare staff.

Providing information

1.2.17 Ask children and young people, and the parents or carers of babies and young children, about the quantity and type of information they wish to receive, and how they wish to receive it. This should include, but not be limited to, details of:

- their condition and any treatment options and issues related to these (including diagnosis, possible side effects, long-term outcomes, and symptoms they may experience)
- any preventative action or lifestyle changes they can make
- where they will be seen
- likely timescales and waiting times for their treatment, including keeping them informed about waits or delays at appointments
- who will be involved in providing their healthcare
- what will happen at key points in their care (for example, on transfer from one healthcare setting to another, when being referred to a different healthcare team).

  Follow the recommendations on age and developmentally appropriate care and the recommendations on changes in needs and preferences.

1.2.18 When giving information to the child or young person, or the parents or carers of babies and young children:

- use their preferred method whenever possible; this may be in person face-to-face or other methods (for example email, phone call, text message or video call)
- take into account that the child or young person's preferences for, and ability to access, digital resources may differ from those of their parents and carers

- provide written and digital information to back up and supplement face-to-face contact, telephone calls or video calls and to refer to later.

1.2.19 Ensure information for children and young people is provided privately when appropriate, for example:

- without their parents or carers present if this is what they would prefer
- by telephoning or texting them directly
- by addressing letters to children or young people themselves, and not their parents or carers.

1.2.20 Discuss with children and young people if there is information that should be provided to their parents or carers, to help their parents or carers support them or look after them (for example, dietary information, post-operative care, or symptoms to look out for).

1.2.21 Provide information for children and young people or the parents or carers of babies and young children that is:

- in simple, clear language that is easy to understand, avoiding jargon and explaining any medical terms used
- evidence based
- appropriate for their individual needs
- culturally sensitive
- not judgemental
- presented in accessible formats and language that can be understood by them (for example, through an interpreter, translated into another language, or as an easy-read version using pictures and symbols)
- given consistently by all members of the healthcare team
- in line with the NHS Accessible Information Standard.

1.2.22 Provide written or digital information (for example leaflets, websites, apps) for children and young people that is:

- created in partnership with children and young people
- engaging for children and young people (for example, containing appealing images, video, audio or animations).

1.2.23 Provide information at a suitable time, place and pace, for example:

- when possible, at regular, predictable times such as during ward rounds or clinic reviews
- in stages if necessary, so children, young people, parents or carers are not overloaded with too much information at one time.

1.2.24 When children, young people, parents or carers have had time to absorb and reflect on information they are given:

- check they have understood it, and how it applies to them (see recommendation 1.2.10)
- allow time to discuss the information again
- actively encourage them to ask questions
- make sure they know what to do if they do not understand, or have questions about their healthcare that come up later on.

1.2.25 When giving information to children and young people about their care, take into account:

- the possible emotional impact of any information provided (for example, children and young people may be upset by what they have been told)
- that support might be needed to help them think about and process the information
- that they may feel intimidated by the healthcare professional providing information (if they feel that individual is in a position of authority), and might need reassurance and support.

1.2.26 Warn children and young people, parents or carers that some of the medical information available which they have not been directed to by the healthcare team (for example, online, on social media or from friends) may be inaccurate or have a limited evidence base.

1.2.27 Support children and young people to identify reliable sources of information related to their care or condition, and ensure that recommended sources are:

- up to date
- professional, credible and evidence based (for example, NHS resources, charities and support groups).

1.2.28 Advise children and young people to check the validity of information with their healthcare professional if they are unsure about its accuracy.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on providing information.

Full details of the evidence and the committee's discussion are in evidence review D: providing information.

1.3 Planning healthcare

Shared decision making

1.3.1 Respect and support the right of children and young people to be involved in making decisions about their healthcare. This should include:

- ensuring early and ongoing involvement in discussions about their healthcare
- providing opportunities for them to share their opinions
- supporting them to make decisions independently
- taking into account previous discussions or decisions, and checking if their decisions have changed
- including them in any decisions when there is a choice of options, including where there is no impact on health or treatment outcomes (for example, what colour plaster cast they would prefer, whether they prefer their medicine as liquid or tablets).

1.3.2 When involving children and young people in decision making, take into account that:

- the extent and level of their involvement may vary, between individuals and on different occasions; follow the recommendations on changes in needs and preferences
- on occasions, some children and young people might not wish to be involved in shared decision making, and that this choice should be respected
- they might wish to have help from their parents or carers, or another person or advocate, for support, to help understand information or to help make decisions
- they might need time to think about decisions, so planning discussions in advance to allow for this might be helpful.

1.3.3 When discussing and making decisions about treatment options with children and young people:

- follow the recommendations on communication by healthcare staff and the recommendations on providing information
- clearly articulate the options, and adapt the description of the treatment options so they are understood by the child or young person you are talking to
- use alternative methods for discussions and decisions if necessary (for example, children and young people might prefer to write down or pre-record questions or opinions if they are not comfortable talking about them)
- consider using decision aids to support complex decisions, or if children and young people are having difficulty making a decision.

1.3.4 Involve parents or carers in discussions and decisions relating to the care of their baby or young child (for example, for inpatient care, by allowing parents to be present at ward rounds when their baby or child's care is discussed whenever possible). Follow the same principles as shown in recommendations 1.3.1 to 1.3.3.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on shared decision making.

Full details of the evidence and the committee's discussion are in evidence review A: planning healthcare and making shared decisions.

Risks and benefits

1.3.5 Offer children, young people and the parents or carers of babies and young children information about the potential risks and benefits of healthcare options to allow them to make informed decisions. Follow the recommendations on communication by healthcare staff and the recommendations on providing information.

1.3.6 Ensure this information is:

- provided in a way they can understand, and they can see how it applies to them
- relevant to their individual needs and personal circumstances (for example, health setting, health status, age and developmental stage).

1.3.7 Discuss with children and young people how much information they would like about risks and benefits, and take this into consideration. Recognise that some children and young people:

- might not want to know more about the risks than is needed for informed consent
- might not want to know about risks on a particular occasion
- might need additional opportunities to think about and discuss risks and benefits
- might benefit from alternative methods of communicating risks and benefits
- might need to take a break when discussing risk, and to come back to the topic later
- might want to discuss the risks and benefits without their parents or carers present.

1.3.8 When discussing the risks and benefits of healthcare options with the child or young person, parent or carer:

- check their understanding of what the risks mean to them and what the benefits to them would be (see recommendation 1.2.10)
- ask them if they have any particular concerns or worries they would like to talk about (for example, fear about procedures such as injections, or children may want to ask about the risk of death, however unlikely this may be)
- answer any questions they may have and address any concerns.

1.3.9 Reconfirm understanding of risks and benefits on an ongoing basis. Follow the recommendations on changes in needs and preferences.

1.3.10 Explore, acknowledge and respond to any concerns that children and young people or their parents or carers have about risk, and provide opportunities to discuss concerns and what will be done to reduce risk.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on risks and benefits.

Full details of the evidence and the committee's discussion are in evidence review E: understanding the risks and benefits of healthcare decisions.

1.4 Consent, privacy and confidentiality

1.4.1 Discuss consent, assent, privacy and confidentiality directly with children and young people if:

- they are able to understand what these concepts mean (with appropriate explanation)
- they can relate them to their own situation.

1.4.2 When discussing consent, assent, privacy and confidentiality:

- ensure that children and young people, and parents or carers, understand their rights and responsibilities
- explain when parents or carers might have to make decisions on behalf of children and young people.

1.4.3 For detailed advice on best practice around consent, privacy and confidentiality, refer to relevant professional guidance (for example, the General Medical Council's ethical guidance for doctors on decision making and consent and the 0–18 years: guidance for all doctors, the Nursing and Midwifery Council's Code and the guidance on consent in the General Dental Council's standards for the dental team).

Consent

1.4.4 Support children and young people to make informed decisions to assent to, consent to or refuse treatment, taking into account their individual capacity or competence (which may be different for different decisions).

1.4.5 Provide children and young people with clear explanations about why treatment in their best interests had to go ahead if it is not possible to obtain their consent or assent before treatment (for example, in an emergency situation).

1.4.6 If there is a difference of opinion about consent, assent or refusal for a procedure (for example, if the views of the child or young person are different from those of their parents or carers, or the views of the child, young person or parent or carer are different from those of healthcare professionals):

- recognise that all discussions and decisions should focus on what is in the best interests of the baby, child or young person
- consider involving others, such as another member of the multidisciplinary team, another healthcare professional, an independent advocate, or a named or designated professional for child protection
- discuss with the child, young person and their parent or carer that you would like to involve other people
- ensure that the child, young person and parent or carer are offered support.

1.4.7 Reconfirm a child or young person's understanding and consent decisions on an ongoing basis. Follow the recommendations on changes in needs and preferences.

Privacy and confidentiality

1.4.8 Maintain privacy and dignity during discussions, examinations and care. Take into account individual preferences, circumstances and cultural sensitivities whenever possible.

1.4.9 Discuss potentially sensitive topics in places where they are less likely to be overheard, when possible, for example, in a clinic room or side room rather than behind bed space curtains.

1.4.10 When using digital or virtual methods for consultations or discussions:

- ask if the child or young person is able to speak without being overheard to discuss potentially sensitive topics
- confirm with them that they are able to talk freely, or if they would prefer an alternative time or method of communication.

1.4.11 Be aware that information sharing, privacy and confidentiality laws also apply to babies, children and young people. Only share their information:

- with their consent for the purposes of care and treatment or
- when in the baby, child or young person's best interests to do so or
- when otherwise required to do so by law.

1.4.12 Offer children and young people the opportunity to see and talk to a healthcare professional without the presence or involvement of their parent or carer, and explain that this discussion will be confidential.

1.4.13 If children and young people who usually rely on their parents or carers for help communicating want to have private conversations with healthcare professionals without the presence or involvement of their parent or carer, ensure additional support is provided (for example, by determining mechanisms to enable children and young people to express a 'yes' and 'no' response (which may be non-verbal), or including other people in conversations and meetings). See recommendation 1.2.6.

1.4.14 Explain to children and young people that it may be necessary to share confidential information without their consent in certain circumstances (for example, if they or others may be in danger).

For a short explanation of why the committee made these recommendations, see the rationale and impact section on consent, privacy and confidentiality.

Full details of the evidence and the committee's discussion are in evidence review C: consent, privacy and confidentiality.

1.5 Advocacy and support

Involvement of parents or carers

1.5.1 Involve parents or carers in discussions and decisions about the care of babies and young children, and recognise that parents or carers will be their principal caregivers and advocates.

1.5.2 Give all children and young people opportunities to express their opinions about their health needs independently, including:

- asking them about the extent to which they want their parent or carer to be involved in their healthcare
- offering to see them separately from their parents or carers for part of the consultation.

1.5.3 Be aware that their wish for parental involvement may depend on the circumstances (for example, what the appointment is about, if they have to have any procedures) or may vary. Follow the recommendations on changes in needs and preferences.

1.5.4 Encourage children and young people to develop their confidence in making decisions for themselves (for example, by giving them opportunities to do this), and encourage their parents or carers to support them with this.

1.5.5 Encourage parents and carers to talk to their child or young person about how they will be involved in decisions about their healthcare. This might include:

- finding out whether the child or young person would like to know more about what will happen at appointments (for example, what healthcare procedures might take place), even if the parent or carer might feel they should leave out details so as not to worry them
- the parent or carer reassuring their child or young person that they can have part or all of an appointment without them being present if they would prefer that
- regularly confirming with their child or young person that they can change their mind at any time about how involved they want them to be.

1.5.6 Ensure that children or young people who do not have a parent or carer to support them, or whose parents or carers are not able to support them, are offered other sources of support (for example, a family member, advocate, social worker, youth worker, nurse or play specialist). Young people may wish to be supported by a friend or partner.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on involvement of parents or carers.

Full details of the evidence and the committee's discussion are in evidence review F: involving parents or carers in healthcare and healthcare decisions.

Support from healthcare staff

1.5.7 All staff involved in providing healthcare services to babies, children and young people should uphold children's rights in accordance with the United Nations Convention on the Rights of the Child.

1.5.8 Advise children and young people about how they can be supported by healthcare staff in a specific setting and encourage them to express their preferences about the support they would find helpful.

1.5.9 Be aware that some children and young people may need more support from healthcare staff than others and that this support may change over time. Follow the recommendations on changes in needs and preferences.

1.5.10 When building a healthcare relationship with children and young people:

- introduce yourself, explain your role and how you can help support them
- listen to and be seen to believe their experiences (for example, symptoms such as discomfort, how they are feeling)
- reassure them that you will take their concerns seriously
- provide calm and positive emotional support and encouraging words
- discuss with them how you will act on what they have said.

1.5.11 Help children and young people to speak up about things that matter to them, and their views and preferences by:

- advocating for them and upholding their preferences if they are unable or unwilling to do this themselves
- acting as a trusted person for them to talk to when they feel their concerns are not being listened to.

1.5.12 Encourage children and young people to ask for the support they need to help with their healthcare experiences or encourage them to use coping techniques they have already developed. These could include:

- their parent or carer to be with them or someone's hand to hold
- music to listen to, a soft toy to cuddle, playing a game on a phone or tablet, a support animal or pet to stroke
- individual coping techniques.

Ask them if these techniques help or if they would like to try other techniques.

1.5.13 Provide advice about and access to other forms of support available (for example, from the education or voluntary sector).

For a short explanation of why the committee made these recommendations, see the rationale and impact section on support from healthcare staff.

Full details of the evidence and the committee's discussion are in evidence review G: support from healthcare staff.

Self-advocacy

1.5.14 Facilitate self-advocacy in children and young people. This may include:

- allowing enough time in consultations and appointments
- providing confidential and private spaces
- providing information on their rights to advocate for themselves

- establishing and using the child or young person's preferred method of communication, paying particular attention to those who do not communicate verbally (see recommendation 1.2.6 and recommendation 1.4.13).

1.5.15 Assume that all children and young people have views and opinions about their own healthcare, and actively encourage them to express what matters to them. In particular:

- do not make assumptions that certain groups of children or young people will not want or will not be able to advocate for themselves
- recognise that children and young people from different backgrounds may have different levels of confidence or skills to advocate for themselves.

1.5.16 Empower children and young people to advocate for themselves by:

- providing information so they can develop an understanding of their own condition and health needs
- making them central to discussions about their healthcare
- agreeing with them when and how they would like their parents or carers included in discussions and decision making, and ensure this agreement is followed
- working collaboratively with them to discuss healthcare needs and treatment options and include them in decisions about their care
- taking into account their own culture, experiences, needs, wishes and feedback
- considering the use of age- and developmentally appropriate healthcare-management applications, such as smartphone apps; apps should meet the criteria specified in the NICE evidence standards framework for digital health technologies; see the NHS Apps library for details of NHS approved apps.

1.5.17 Support children and young people to develop skills in advocating for themselves by offering opportunities to be involved in feedback, service design or improvement or other engagement activities (see recommendations 1.7.1 to 1.7.9).

For a short explanation of why the committee made these recommendations, see the rationale and impact section on self-advocacy.

Full details of the evidence and the committee's discussion are in evidence review H: empowering children and young people to advocate for themselves.

Independent advocates

1.5.18 Children and young people must have access to an independent advocate in line with statutory requirements. This includes the Mental Health Act 2007, the Care Act 2014 and the Mental Capacity Act 2005.

1.5.19 Where children and young people are eligible, inform them that, they can have another person, known as an independent advocate, present with them when speaking to healthcare professionals, rather than their parent or carer. See also recommendation 1.3.2 about support from other people for shared decision making.

1.5.20 Provide children and young people who are eligible for support from an independent advocate with information about independent advocates. Include:

- the role of an independent advocate (including confidentiality and independence from the healthcare team)
- the option to express a preference for an advocate of a particular gender, or how to change advocate.

1.5.21 Support eligible children and young people to meet with an independent advocate (for example, by providing a private space and time to meet).

1.5.22 Independent advocates should work with eligible children and young people to support and empower them in discussions and decisions about their healthcare. This should include:

- identifying and using the child or young person's preferred method of communication and using additional support to communicate if necessary (see recommendation 1.2.6)
- building a trusting relationship, ensuring continuity where possible

- ensuring confidentiality
- providing guidance on healthcare systems, pathways and processes, where necessary
- providing explanations of medical information and terminology, where necessary
- empowering children and young people to make their own decisions.

1.5.23 Independent advocates should provide a mechanism for children or young people to give feedback on the advocacy service and to check that the relationship is working effectively for the benefit of the child or young person.

1.5.24 Commissioners should consider expanding the availability of independent advocates services to support children or young people who are not eligible under legislation, but who are not adequately represented by their parents or carers or other professionals.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on independent advocates.

Full details of the evidence and the committee's discussion are in evidence review I: independent advocacy in healthcare for children and young people.

1.6 Improving healthcare experience

Food

1.6.1 Ensure babies, children and young people who are inpatients have access to food that meets their needs. This should include:

- a balanced healthy diet that will help with their recovery
- a choice of food options at every meal that are culturally and dietetically appropriate and will appeal to a range of tastes
- flexibility in availability of food, for example access to snacks outside meal times

- food choices and menus that have been developed in conjunction with children and young people.

  For babies who are breast or bottle fed, ensure there are suitable facilities to support this.

Pain-related anxiety

1.6.2 Reduce the fear and anxiety about pain that may be experienced by babies, children and young people during healthcare interventions by:

- preparing them with information about interventions or procedures (for example, blood tests and injections)
- being honest about possible pain and what will be done to alleviate pain
- using therapeutic play and distraction techniques and creating a calm environment before, during and after interventions or procedures that are likely to be painful
- upholding children and young people's experiences of pain, showing them they are believed, and avoiding language that minimises the child or young person's experience of pain (for example, do not say a procedure they found painful "didn't really hurt").

1.6.3 Ensure adequate pain assessments are carried out and acted on. See NICE guidelines for the management of pain in specific conditions, such as the NICE guideline on cerebral palsy for under 25s for advice on assessing pain in verbal and non-verbal children and young people, the NICE guideline on end of life care for infants, children and young people with life-limiting conditions and the NICE guideline on sickle cell disease.

Staff uniforms and healthcare clothing

1.6.4 Ensure children and young people, and parents or carers of babies and young children can easily identify members of staff. This could include:

- visible name badges with easy to understand job roles or titles
- recognisable uniforms, particularly if they help differentiate between professions.

1.6.5 Be aware that healthcare clothing (for example gowns, masks or visors) can be frightening for babies, children and young people and they may be unable to

recognise staff or see their facial expressions or smiles. This is particularly important for children who rely on lip reading or facial cues for communication.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on improving healthcare experience.

Full details of the evidence and the committee's discussion are in evidence review J: improving experience of healthcare.

1.7 Involvement in improving healthcare experience

Design of healthcare services

1.7.1 When designing services that will be used by babies, children and young people:

- involve children and young people and obtain their views, or for babies and young children, involve their parents or carers
- actively seek out children and young people (or the parents or carers of babies and young children) from under-represented groups (for example, black, Asian and minority ethnic groups, people with physical, sensory or learning disabilities, people from a disadvantaged background, LGBT+ people, people who have not been able to, or have chosen not to, use the services before, looked-after children).

1.7.2 Assume that all children and young people have relevant opinions on services they use and their care, and will give them if asked in a suitable way.

1.7.3 Make it as simple as possible for children and young people to contribute to service design by:

- using appropriate methods to engage them, capture their views and enable them to contribute (for example, internet surveys, social media, forums and groups)
- addressing any practical issues that could be barriers to involvement (for example, transport, timing, language, travel costs, disabilities or communication difficulties).

1.7.4 Ensure that feedback about the design of services from children, young people and parents or carers is shared and used. Explain how their input has shaped design of services (for example, using social media or posters to describe

methods such as 'Ask Listen Do' and 'You Said We Did').

For a short explanation of why the committee made these recommendations, see the rationale and impact section on design of healthcare services.

Full details of the evidence and the committee's discussion are in evidence review K: design of healthcare services.

Measuring experience

1.7.5 Collect feedback (for example, using questionnaires or surveys) directly from children and young people at different points in their healthcare experience. Collect feedback for babies and young children from their parents or carers.

1.7.6 Actively seek out feedback from children and young people (or the parents or carers of babies and young children) from under-represented groups (for example, black, Asian and minority ethnic groups, people with physical, sensory or learning disabilities, people from a disadvantaged background, LGBT+ people, people who have not been able to, or have chosen not to, use the services before, looked-after children).

1.7.7 Make it easier for people to give meaningful feedback by using tools that:

- have been co-produced with the appropriate age group
- are appropriate for, and selected together with, the intended group (including taking into account any disabilities or communication preferences)
- are provided at a convenient time and place, and by a convenient method, for respondents (for example, voting systems in a healthcare setting, or an online survey to be completed at home).

1.7.8 Ensure that the feedback on healthcare experiences from children, young people and parents or carers is shared and used. Explain how their input has been used to improve healthcare experiences (for example, using social media or posters to describe methods such as 'Ask Listen Do', 'You Said We Did').

1.7.9 Inform children and young people, and the parents or carers of babies and

young children, of their right to complain. Ensure that it is easy for children and young people to make a complaint if they need to.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on measuring experience.

Full details of the evidence and the committee's discussion are in evidence review L: measuring experience.

1.8 Healthcare environment

1.8.1 Care for babies, children and young people in an environment that:

- meets their clinical and personal needs
- takes into account their preferences about their place of care (or the preferences of parents or carers for babies or young children)
- is appropriate for their age and developmental stage, is physically accessible and has adaptations available, if needed.

1.8.2 Provide a healthcare environment that supports:

- privacy and dignity
- confidence in healthcare delivery (for example, equipment is available when needed)
- family-centred care for inpatients (for example, the option for a parent or carer to stay and sleep, including in non-paediatric areas)
- parents or carers to give developmentally appropriate care to their children (for example, changing their baby's nappy, helping children wash and dress)
- other family members, siblings, or those important to the child or young person to be present (if this is what they would like)
- easily accessible, age-appropriate play and recreation for children and young people, including to reduce boredom and anxiety while waiting for appointments or interventions

- children and young people who are inpatients to mix with friends, peers or partners (for example, flexible visiting times, access to social media, spaces away from clinical areas to meet)
- a feeling of safety (for example, easy access to call bells or other means of summoning help, knowing that someone is around to help).

1.8.3 Provide a healthcare environment that:

- is clean, comfortable and feels homely
- is calm, with as little disturbance from background noise as possible
- separates treatment areas from those for play and recreation
- is designed and decorated in a suitable way for the age group it is for (including use of colours, layout, lighting and clear signs)
- in an inpatient setting is quiet enough for rest and sleep, particularly at night.

1.8.4 Provide children and young people who are inpatients with information about the facilities and routine on the ward (for example, where the bathrooms are located, what times meals are served, where play and recreation facilities are located and how they can be accessed, where there are quiet areas), and answer any questions they may have.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on healthcare environment.

Full details of the evidence and the committee's discussion are in evidence review M: healthcare environment.

1.9 Maintaining usual activities

1.9.1 Give children and young people ongoing opportunities to identify aspects of their lives that are important to them (for example, physical, social and recreational activities, schooling and education, their developmental, cultural and emotional needs).

1.9.2 Discuss with children and young people, particularly those with ongoing health needs:

- how their health condition and their healthcare will impact on their ability to engage in usual activities
- what their expectations and goals may be for their future involvement in usual activities, and how they can be helped achieve them.

1.9.3 Ensure that babies, children and young people are able to continue with their usual activities of daily life with minimal disruption while receiving healthcare and, when clinically appropriate, make reasonable adjustments to their environment to support this (for example, providing a quiet space for studying).

1.9.4 In an inpatient setting, ensure free internet access over Wi-Fi, and that any Wi-Fi codes or passwords are freely available so that children and young people can maintain their usual contacts and networks.

1.9.5 Advise children and young people that use of social media or technology (for example, phones, noisy computer games) must not compromise the privacy or the environment of other people.

1.9.6 Recognise that the wishes and needs of each baby, child and young person to engage in the activities they have identified as important to them will vary between individuals and over time. Integrate these needs into the delivery of healthcare.

1.9.7 Make sure that the baby, child or young person's usual support networks (for example, parents and carers, siblings, partners and friends) can be involved in maintaining activities of daily living (for example, changing nappies, washing, getting dressed, eating) and other usual activities.

1.9.8 Ensure coordination between healthcare, education and social care to maintain an individual's usual activities, including education and learning. This could include education support roles, Early Help or making adjustments such as scheduling treatment appointments around school commitments.

1.9.9 Help children and young people to use cultural, spiritual or religious beliefs that they find helpful in their lives as a source of support if they wish. This could

include facilitating religious activities such as prayer time, or letting them know about chaplaincy services or other religious support available.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on maintaining usual activities.

Full details of the evidence and the committee's discussion are in:

- evidence reviews N: supporting participation in usual activities
- evidence review J: improving experience of healthcare.

1.10 Accessibility, continuity and coordination

Accessing healthcare

1.10.1 Provide children and young people with targeted information about:

- when an illness or condition means they should seek medical help
- what services are available (for example, using the NHSGo app)
- when and how they can access services.

Follow the recommendations on providing information.

1.10.2 Reassure children and young people that:

- healthcare services are there to help them
- feeling afraid or embarrassed about asking for help is normal but healthcare professionals will understand and provide support.

1.10.3 Develop information about healthcare and healthcare services with input from children and young people themselves, and in collaboration with healthcare professionals (for example, play specialists, child psychologists) and other sectors (for example, education, social care, the voluntary sector).

1.10.4 Provide information for parents and carers to support them in accessing

healthcare services for their baby or child (for example, the eRedbook app).

1.10.5 Actively seek out groups of parents or carers who may face barriers accessing healthcare services for their children (for example, those who would benefit from translated materials or those who may have limited internet access), to ensure they have accessible information about what care their children can receive, and are encouraged to use those services.

1.10.6 Provide information to children and young people on:

- what services they can access with or without their parents or carers
- whether their parents or carers will need to be told if they access services.

1.10.7 Take into account the views of children and young people, and for babies and young children the views of their parents and carers, when designing or redesigning healthcare services. Include:

- personal factors, such as the age range, gender and developmental stages of the children and young people using the service
- social factors, such as the religious, cultural or social background of the children and young people using the service.

  See recommendations 1.7.1 to 1.7.4 on involving children and young people in design of healthcare services.

1.10.8 Provide children and young people with support and help to access the healthcare system. Ensure additional support, such as one-to-one support from a named healthcare or social care professional, is available for those who need it (for example, children with learning disabilities, looked-after children, children in institutional care, care leavers).

1.10.9 Take into account access needs specific to children and young people. This might include:

- accommodating preferences about the gender of the healthcare professional who they see

- offering flexible appointments that meet an individual's and family's needs, for example minimising regular appointments during school hours
- providing services in locations that are easier for children and young people to access, or co-locating with other services that children and young people access (for example, youth centres and schools).

1.10.10 Use flexible methods where clinically appropriate, agreed with the child or young person to deliver healthcare services (for example, telephone or video calls, digital media such as websites and apps) as alternatives to in person face-to-face services to help overcome access difficulties, such as travelling to appointments or relying on parents for transport.

1.10.11 Use feedback from children and young people to improve the accessibility of healthcare services. See recommendations 1.7.5 to 1.7.9 on measuring experience of care.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on accessing healthcare.

Full details of the evidence and the committee's discussion are in evidence review O: accessing healthcare.

Continuity and coordination of care

1.10.12 Maintain continuity of care by providing healthcare from the same professionals or teams when clinically appropriate.

1.10.13 Ensure clear and timely exchange of relevant patient information:

- between healthcare professionals and children and young people or the parents or carers of babies and young children
- between healthcare professionals
- between healthcare, education and social care professionals.

1.10.14 Pay particular attention to communication between healthcare professionals and services and the coordination of ongoing care:

- at key points in care (for example, on transfer from one healthcare setting to another, or when being referred to a different healthcare team)
- for children and young people who might need additional support (for example, children with learning disabilities, looked-after children, care leavers, young people who are homeless).

  For advice on transition to adult services, see the NICE guideline on transition from children's to adults' services.

1.10.15 Ensure systems are in place so that children and young people and the parents or carers of babies and young children do not need to unnecessarily repeat their healthcare history when being seen by different healthcare professionals (for example, by using health passports or digital health records).

1.10.16 Ensure children and young people and the parents or carers of babies and young children have access to their healthcare records. Access must meet the requirements of the Access to Health Records Act 1990.

1.10.17 Provide contact information so that children and young people know how to obtain advice from the same service or team in the future.

For a short explanation of why the committee made these recommendations, see the rationale and impact section on continuity and coordination of care.

Full details of the evidence and the committee's discussion are in evidence review P: continuity of care.

Terms used in this guideline

This section defines terms that have been used in a particular way for this guideline. For other definitions, see the NICE glossary.

Accessible

Something (for example, a service or information format) designed in a way so that people who have a disability or impairment are able to use it with a similar level of time, effort and skill needed as someone who does not.

Assent

Agreement given by a child or young person to a course of action or procedure, when they are not legally empowered to give consent.

Consent

Agreement (which can be verbal, non-verbal or written) to a course of action or procedure, after a discussion of the risks and benefits, when they are legally empowered to give consent.

Containment holding

Placing both hands firmly but gently on a baby and holding the position very still, to provide reassurance and comfort.

Cultural sensitivity

Knowledge, awareness and respect for other people's cultural background, identity and differences, without making assumptions about them.

Focus and reference groups

A series of focus and reference groups with children and young people were held to obtain their views and opinions. These views and opinions were considered by the committee as part of their review of the evidence.

Gillick competent

Children under the age of 16 can consent to their own treatment if they're believed to have enough intelligence, competence and understanding to fully appreciate what's involved in their treatment. Also see the NHS website on consent to treatment – children and young people.

National surveys

A review of recent national surveys of children and young people's views on healthcare was carried out. The findings of these surveys were considered by the committee as part of their review of the evidence.

Non-judgemental

Not criticising or demonstrating a negative attitude about another person's feelings or actions, based on personal opinions or personal biases.

Parents or carers

Parents or carers refers to the primary caregivers for a baby or child at any given time. This can include birth or adoptive parents with parental responsibility, other members of the extended family who provide care such as siblings, grandparents, aunts and uncles, others nominated by the parents, or legal guardians. For looked-after children or those who lack mental capacity, it can also include those acting instead of parents such as a social worker, key worker, foster carers or guardians. It does not refer to nurses, healthcare assistants or other healthcare professionals who are acting in their professional capacity.

Positive touch

Human touch that aims to give babies the experience of touch that is not for a clinical purpose, but is given tenderly, lovingly and gently, and that which responds to and does not ignore their behaviour.

Usual activities

Activities that form part of a baby, child or young person's daily life and which may be disrupted by illness or the need to access healthcare services. This may include activities of daily living (bathing, showering, eating), interactions with family and friends, social and emotional development, education and schooling, sports, hobbies and interests, social activities and use of social media.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Risks and benefits

What decision aids are the most cost effective and acceptable when explaining the risks and benefits of healthcare interventions to children and young people?

For a short explanation of why the committee made this research recommendation, see the rationale section on risks and benefits.

Full details of the evidence and the committee's discussion are in evidence review E: understanding the risks and benefits of healthcare decisions.

2 Independent advocacy

How can the views of babies, children and young people be best represented by independent advocates?

For a short explanation of why the committee made this research recommendation, see the rationale section on independent advocates.

Full details of the evidence and the committee's discussion are in evidence review I: independent advocacy in healthcare for children and young people.

3 Improving healthcare experience

What elements of healthcare matter most to babies, children and young people to create positive experiences of healthcare?

For a short explanation of why the committee made this research recommendation, see the rationale section on improving healthcare experience.

Full details of the evidence and the committee's discussion are in evidence review J: improving experience of healthcare.

4 Measuring experience

How can the experience of babies, children and young people be measured so as to improve their experience of healthcare?

For a short explanation of why the committee made this research recommendation, see the rationale section on measuring experience.

Full details of the evidence and the committee's discussion are in evidence review L: measuring experience.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice.

Overarching principles

Recommendations 1.1.1 to 1.1.9

Why the committee made the recommendations

The committee were aware, based on their own knowledge and experience, that safeguarding is an important consideration that applies to all aspects of healthcare services, and so made an overarching recommendation to state this. Similarly, the committee were aware that it is necessary for all services to make reasonable adjustments as required by legislation in order to meet the needs of disabled babies, children and young people, and so made an overarching recommendation to state this.

Based on stakeholder feedback, the committee added an overarching recommendation to clarify the rights of children and young people to make decisions about their healthcare and to consent to treatment.

There was evidence from a number of reviews: that all discussion, support and information need to be suitable for the age, developmental stage and level of understanding for an individual child or young person; that, as children develop and mature, their healthcare needs and preferences change; and that determining needs and preferences is not a static one-off decision.

As a number of recommendations throughout the guideline relate to the use of digital resources, the committee clarified that alternative methods should be available as access to these digital resources is not universal.

How the recommendations might affect practice

The recommendations are in line with current practice and should have little impact on resources, but may mean extra time is needed to revisit needs and preferences on a regular basis, or to provide alternatives to online information.

Return to recommendations

Communication by healthcare staff

Recommendations 1.2.1 to 1.2.16

Why the committee made the recommendations

There was good evidence that children and young people like healthcare professionals to communicate in a friendly, compassionate and respectful manner, reading behavioural cues, giving them sufficient time, listening to them and getting to know them on a personal level.

There was good evidence that different methods of communication should be used when appropriate, and this includes using verbal and non-verbal communication, and identifying the best way to communicate for individuals, particularly those who have additional communication needs.

The committee were also aware of the need for healthcare professionals to ensure that different methods of communication are used if necessary to meet the requirement of the Mental Capacity Act 2005 that a person is not to be treated as unable to make a decision unless all practicable steps to help them to do so have been tried.

How the recommendations might affect practice

Healthcare professionals might need more time to communicate with children and young people and this could mean some consultation times are longer, which would create a resource impact for the NHS. Additional help to communicate may be needed (for example, use of foreign language or sign language interpreters) and that may also have a resource impact for the NHS.

Ensuring that all staff are competent to communicate effectively might also need additional time and resources for training and skill development.

Return to recommendations

Providing information

Recommendations 1.2.17 to 1.2.28

Why the committee made the recommendations

There was good evidence from the systematic literature review on the preferred sources of information, with in person face-to-face information provided by a healthcare professional one of the preferred and most trusted forms of information. The evidence showed that healthcare professionals should provide information clearly in a way that is easy for children and young people to understand, and that it is important that healthcare professionals consider when and how to deliver information, as sufficient information needs to be provided, but this should not be overwhelming. The evidence also showed that children and young people, and the parents of babies and young children, want information in a variety of formats, including written materials, websites and smartphone applications and any other digital sources, and that these sources should be clear and easy to understand and relevant.

There was evidence that children and young people would want their parents or carers to have information tailored to their condition and needs in order to provide support and look after them.

There was evidence that whatever the format, information should be age- and developmentally appropriate, and should be available in different versions (for example, easy-read versions) and languages to allow as many people to access it as possible.

The evidence from the focus and reference groups and some limited evidence from the national surveys reinforced the systematic literature review evidence, showing that the quantity of information should not be overwhelming, and that there is a need for clear, understandable verbal and written information.

How the recommendations might affect practice

The recommendations may mean additional time and resources are needed to deliver and produce information in suitable formats (for example leaflets, websites, apps) in partnership with children and young people. However, it was acknowledged that many services are already using a variety of alternative ways of proving information to children or young people and the overall resource impact in this area will be modest.

Return to recommendations

Shared decision making

Recommendations 1.3.1 to 1.3.4

Why the committee made the recommendations

There was evidence from the systematic literature review, focus and reference groups and from the national surveys that most children and young people want to be involved in making shared decisions about their healthcare, but that the level of preferred involvement may vary between different children, on different occasions and may change as children get older.

The committee were also aware of the requirement of the Mental Capacity Act 2005 that a person is not to be treated as unable to make a decision unless all practicable steps to help them to do so have been taken without success. Healthcare professionals therefore need to tailor their approach to discussions (with advice from other specialists or those who know the person well if necessary) to ensure this.

There was some evidence on children and young people's preferences for how the shared decision-making process should be undertaken, for example by starting discussions as soon as possible, making sure information is presented clearly, tailoring its complexity, providing it at a suitable pace and using decision aids if they are available.

The committee also used their knowledge and experience to make additional recommendations to adhere to these principles when making shared decisions with parents and carers on behalf of babies and young children.

How the recommendations might affect practice

Additional time may be needed to carry out meaningful discussions around shared decision making. Ensuring that all staff are competent to implement shared decision making effectively might also need additional time and resources for training and skill development.

Return to recommendations

Risks and benefits

Recommendations 1.3.5 to 1.3.10

Why the committee made the recommendations

There was limited evidence that decision aids improve knowledge about risks and benefits and reduce decisional conflict, but as there was insufficient evidence to allow the committee to give advice on their use, a research recommendation was made on this topic (see research

recommendation 1). There was some evidence from the focus and reference groups that children and young people vary in their views about how much information they like to receive on risks. Based on this evidence, and on their knowledge and experience, the committee made recommendations on the best ways to discuss risk and benefits with children and young people, including pacing this information, having discussions without parents and carers, and ensuring understanding.

How the recommendations might affect practice

The recommendations might mean additional time and resources are needed to help children, young people and the parents or carers of babies and young children understand the risks and benefits of healthcare decisions. Ensuring that all staff are competent to discuss risks and benefits effectively might also need additional time and resources for training and skill development.

Return to recommendations

Consent, privacy and confidentiality

Recommendations 1.4.1 to 1.4.14

Why the committee made the recommendations

No evidence relating to consent was found, but the committee discussed that children and young people have the legal right to consent to, or refuse, treatment as set out in UK law and the UN Convention on the Rights of the Child. These rights are dependent on their age and competence and as the committee agreed it was such an important principle, they included these details in an overarching recommendation at the beginning of the guideline.

The committee used their experience and expertise to make recommendations on how children and young people could be best supported to make decisions on consent. The committee also used their knowledge and experience of how differences of opinion over consent, assent or refusal of treatment should be approached. This could include involving other healthcare professionals, but the committee also recognised that the child, young person, parents or carers should be offered support so that they did not feel outnumbered in discussions.

There was some low-quality evidence on privacy and confidentiality, which showed that children are aware of the risks to anonymity and privacy with digital information applications, but that they also recognised that in some cases, it was valuable to share information (for example, with parents, or to allow peer-to-peer support). The committee therefore also used their experience and

expertise on best practice at maintaining privacy (particularly when using digital or virtual methods for consultations, or with children or young people who needed additional support to communicate without their parents or carers), discussing private and confidential information with children and young people, and the sharing of information with parents or carers.

How the recommendations might affect practice

There are already examples of good practice across the NHS concerning consent, privacy and confidentiality, and these recommendations are designed to increase consistency throughout the NHS. Implementing these recommendations might mean extra time is needed for healthcare professionals to discuss and explain issues surrounding consent, privacy and confidentiality with children and young people. There may also be a need to consider the environment in which healthcare is delivered to provide privacy and ensure confidentiality.

Return to recommendations

Involvement of parents or carers

Recommendations 1.5.1 to 1.5.6

Why the committee made the recommendations

There was evidence that children and young people want to be able to express their opinions independently from their parents, but they also value their parent or carers' presence or support. There was evidence that the extent of support they want varies depending on the circumstances and the child or young person, and that it should be discussed between parents or carers and their children. The committee were aware from their knowledge and experience that certain groups of children and young people did not have parents or carers to support them, and that it is particularly important that these children and young people should be offered alternative support.

How the recommendations might affect practice

The recommendations are in line with current practice and should have little impact on resources, but may need extra time to have these discussions, and to see children with their parents or carers and separately.

Return to recommendations

Support from healthcare staff

Recommendations 1.5.7 to 1.5.13

Why the committee made the recommendations

There was evidence that children and young people have differing preferences for the support they wish to receive from healthcare professionals, so this should be personalised based on their preferences at any time (as these preferences can change depending on different factors). There was also evidence around needing to build a trusting relationship. Based on their knowledge and experience, the committee agreed that it was essential that healthcare professionals support children and young people's rights and advocate for them where necessary. There was also evidence that children and young people appreciate support to identify and use coping techniques, and to be advised on other sources of support.

How the recommendations might affect practice

Additional time may be needed to build trust, discuss and provide the support according to the preferences and needs of children and young people.

Return to recommendations

Self-advocacy

Recommendations 1.5.14 to 1.5.17

Why the committee made the recommendations

There was evidence from the systematic literature review and the focus and reference groups for strategies that would enable children and young people to advocate for themselves with respect to their healthcare and related decisions. This includes providing time, space and adequate information.

There was evidence that some children and young people felt as though healthcare professionals have a preconceived idea of their ability and motivation to engage with healthcare decisions. This often results in missed opportunities to encourage vulnerable children and young people to engage in their care and advocate for their choices.

The evidence also showed that engaging children and young people in feedback, service design and

other activities could improve and facilitate their self-advocacy skills.

Based on the evidence and their knowledge and experience, the committee identified approaches to empower children to advocate for themselves.

How the recommendations might affect practice

Additional time may be needed to discuss and provide the adequate support to children and young people so they can be empowered to advocate for themselves.

Return to recommendations

Independent advocates

Recommendations 1.5.18 to 1.5.24

Why the committee made the recommendations

The recommendations reflect current UK legislation in respect of access to independent advocates in certain situations for children and young people. Based on their knowledge and experience, the committee recognised the potential benefits to children and young people of independent advocacy in wider healthcare situations, not currently covered by the legislation. These benefits include support to understand healthcare processes and procedures, to express views and opinions, and with decision making.

There was evidence from an expert witness and the focus and reference groups that eligible children and young people may have limited knowledge about independent advocacy services. Therefore, they should be provided with this information and supported throughout the process.

There was evidence from the expert witness and the focus and reference groups about the role of independent advocates, which involves supporting children and young people in decisions about their healthcare and that, in order to be most effective, independent advocates should take time to build a trusting and confidential relationship with children and young people.

As there was no evidence from the systematic review of the literature for this review, the committee made research recommendation 2.

How the recommendations might affect practice

The recommendations on access to an independent advocate are in line with current UK legislation, with little additional impact on resources. However, the suggested expansion of this service to children and young people who are not adequately represented by parent and carers may lead to an increase in the number of independent advocates needed by NHS services, which will need an increased level of funding. There may be an increased amount of time for healthcare professionals to facilitate this use of independent advocates.

Return to recommendations

Improving healthcare experience

Recommendations 1.6.1 to 1.6.5

Why the committee made the recommendations

The qualitative and quantitative evidence identified 4 aspects of healthcare that were important to children and young people but which were not covered in other evidence reviews. These were food, pain-related anxiety, staff uniforms and healthcare clothing, and religious, cultural and spiritual support. Based on their expertise and experience, the committee made additional recommendations on these topics. The committee agreed that the recommendations on religious support related to maintaining usual activities, and therefore they placed this recommendation in that section of the guideline.

As there was limited quantitative evidence on the elements of healthcare that matter most to babies, children and young people to create a positive experience of healthcare, the committee made research recommendation 3.

How the recommendations might affect practice

The recommendations reflect best practice and may reduce variation in practice.

Return to recommendations

Design of healthcare services

Recommendations 1.7.1 to 1.7.4

Why the committee made the recommendations

There was some evidence that children and young people are keen to contribute to the design of healthcare services, and appreciate the opportunity to do so. There was also evidence that the children and young people recognise there could be practical difficulties with involvement (for example, time, travel, number of events, and content not being age- or developmentally appropriate). There was evidence that ways to obtain feedback should be age- and developmentally appropriate. There was evidence that children and young people want their views to be taken seriously, and that they appreciate being told how their input had changed practice.

The committee and stakeholders identified that there may be particular groups who may be less likely to be involved in the design of healthcare services and so recommended that the views of these groups should be actively sought. However, the list is not exhaustive and other groups may be identified according to local circumstances or demographics.

How the recommendations might affect practice

There are already examples of good practice across the NHS, but practice is inconsistent. These recommendations aim to standardise how children, young people, parents and carers should be involved in the design of services, to encourage more consistent practice across the whole NHS.

Implementing this across the NHS might mean increased resources are needed to develop the tools, identify participants, aid involvement, and evaluate and feedback the results.

Return to recommendations

Measuring experience

Recommendations 1.7.5 to 1.7.9

Why the committee made the recommendations

There was some evidence from the focus and reference groups that children and young people are keen to provide feedback, that they are willing to use a variety of methods to do this, and that surveys should be quick and easy to complete. The evidence also showed that children and young people prefer giving their feedback at or towards the end of treatment but based on their knowledge and experience, the committee agreed this should be at various points in treatment. There was a very small amount of evidence from the national surveys on the problems children and young people had had using complaints systems. The committee also used their own knowledge

and experience on helping people give feedback to optimise responses.

The committee and stakeholders identified that there may be particular groups who may be less likely to be involved in providing feedback on healthcare services and so recommended that the views of these groups should be actively sought. However, the list is not exhaustive and other groups may be identified according to local circumstances or demographics.

As there was very limited evidence from the systematic review of the literature on measuring children and young people's experience, the committee made research recommendation 4.

How the recommendations might affect practice

Experience may already be measured in a number of different ways across the NHS and these recommendations will increase measurement of experience, reinforce best practice and make practice more consistent.

Implementing this across the NHS might mean more resources are needed to co-produce the tools, identify participants, aid involvement and evaluate and feedback the results.

Return to recommendations

Healthcare environment

Recommendations 1.8.1 to 1.8.4

Why the committee made the recommendations

There was some evidence from young people about their preferences, and from parents of babies in neonatal units, and the committee agreed that all babies and young children (represented by their parents), children and young people, should be able to express views about the preferences for place of care. The committee used this and their own knowledge and experience to agree how settings should be appropriate, comfortable, welcoming and acceptable to the people who need to use them. There was evidence that young people prefer their care environment to be age-appropriate, and that they may feel uncomfortable in paediatric settings aimed at young children. There was also evidence that they like to be able to meet visitors in an appropriate space, to have areas for recreation facilities, to have adequate signs, and for there not to be too much noise. They also expressed wanting to feel safe in healthcare environments.

There was evidence from parents or carers of babies about the need for privacy, comfortable

furniture and furnishings, and facilities so they have the option to stay with their babies. Although there was no evidence about privacy for children and young people, the committee agreed that offering privacy is important, based on their knowledge and experience.

How the recommendations might affect practice

The recommendations aim to make best practice more consistent across the NHS. Some changes to improve the healthcare environment might be easy to make, but changing or redesigning healthcare environments can be an expensive process, and some of the recommendations could need considerable resources to implement.

Return to recommendations

Maintaining usual activities

Recommendations 1.9.1 to 1.9.9

Why the committee made the recommendations

Based on their knowledge and experience, the committee made recommendations on the importance of determining what usual activities were important to children and young people, and making adjustments to allow these to continue. The committee agreed that providing support to continue with usual activities would need to be personalised to account for different needs, preferences and developmental stages. The committee recognised the benefits to the wellbeing of children and young people of continuing with usual activities, which may include a reduction in boredom, anxiety and distress. There was evidence that some children prefer to receive help with personal care from their family, as would happen if the child were at home. There was also evidence that children and young people want to continue with social activities and keeping in touch with their friends. There was no evidence from the systematic literature review specifically about Wi-Fi access but the committee agreed that the ability to instantly contact friends was a part of everyday life for most children and young people and this was reinforced by evidence from the focus and reference groups and the national surveys.

The evidence on educational support reinforced the committee's experience that maintaining educational provision and liaison with education services is very important.

There was evidence that some children and young people found religious or spiritual support or beliefs helpful when they were unwell. Other aspects from this evidence are reflected in the recommendations on improving healthcare experience, where this evidence is described in more

detail.

How the recommendations might affect practice

The recommendations aim to reduce variation in practice across the NHS, and might mean extra staff time or changes in practice are needed to implement them.

Return to recommendations

Accessing healthcare

Recommendations 1.10.1 to 1.10.11

Why the committee made the recommendations

There was evidence from the systematic review of the literature about factors that could be barriers for children and young people to access health services. This included factors relating to practical aspects of accessing healthcare such as location and timing of appointments, as well as trust and relationships with healthcare professionals and lack of knowledge about when to access healthcare, and what services to access. The focus and reference groups also provided evidence about the perceived barriers and these included fear and embarrassment, being too busy to access healthcare or not wanting to miss out on school or social activities, and being aware of the capacity issues within the NHS. The committee then used this evidence to make recommendations designed to overcome these barriers. The evidence from the national surveys also identified that certain groups of children and young people may need additional help and support to access and navigate the health system.

How the recommendations might affect practice

Additional resources may be needed to promote and deliver accessible and flexible services.

Return to recommendations

Continuity and coordination of care

Recommendations 1.10.12 to 1.10.17

Why the committee made the recommendations

There was good evidence that children and young people prefer to see the same healthcare professionals whenever possible, and that this promotes improved engagement and continuity of care. The committee were aware that children and young people prefer to be able to contact their healthcare professionals or teams directly.

There was good evidence that children and young people do not want to have to repeat their healthcare history on multiple occasions, and that good and timely communication between healthcare professionals, services, and children and young people and the parents or carers of babies and young children could help with this. There was also some evidence for the use of different methods to help improve communication and continuity of care, and in particular the use of electronic health records.

How the recommendations might affect practice

There are some electronic and paper methods to improve communication already in use, including electronic health records. Implementing more integrated systems to share information with and between healthcare professionals, other services and children and young people or the parents and carers of babies and young children will have resource implications for the NHS. In addition, there may be a need for improved administration support to help with the sharing of information, which will also have some resource implications.

Return to recommendations

Finding more information and committee details

You can see everything NICE says on this topic in the NICE Pathway on babies, children and young people's healthcare.

To find NICE guidance on related topics, including guidance in development, see the NICE webpages on infants and neonates and children and young people.

For full details of the evidence and the guideline committee's discussions, see the evidence reviews. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

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Accreditation

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs
2.	**Associated appraisal body & Summary of ruling** NICE Technology Appraisal guidance TA711 (June 2021) Guselkumab (Tremfya®), alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them, only if they have: • peripheral arthritis with 3 or more tender joints and 3 or more swollen joints • moderate to severe psoriasis (a body surface area of at least 3% affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10) • had 2 conventional DMARDs and at least 1 biological DMARD. Guselkumab is recommended only if the company provides it according to the commercial arrangement. Assess the response to guselkumab from 16 weeks. Stop guselkumab at 24 weeks if psoriatic arthritis has not responded adequately using the Psoriatic Arthritis Response Criteria (PsARC; an adequate response is an improvement in at least 2 of the 4 criteria, 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria). If PsARC response does not justify continuing treatment but there is a PASI 75 response, a dermatologist should decide whether continuing treatment is appropriate based on skin response.
3.	**Number of people in Northern Ireland expected to take up service/therapy** Guselkumab is one of a number of NICE-approved medicines for this patient group. Implementation of this guidance offers an additional treatment option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. The NICE resource impact statement indicates that the guidance is not expected to have an impact on resources. This is because the technology is a further treatment option and is available at a similar price to the current treatment options.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Janssen) has a commercial arrangement. This makes guselkumab available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	**Infrastructure Requirements** It is anticipated that infrastructure requirements will be minimal. Infrastructure requirements for the delivery of all biologics are reviewed annually as part of the routine commissioning arrangements for supporting growth in the provision of these therapies.
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements** This drug will be formally commissioned by HSCB/PHA via the Specialist Services Commissioning Team initially on a cost per case basis.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the quarterly monitoring of all biologic therapies (activity/cost and waiting times) and this regime will be included within the routinely provided return. All monitoring returns for biologics are reviewed by the specialist services commissioning team quarterly.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case. The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act.

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Ravulizumab for treating atypical haemolytic uraemic syndrome
2.	**Associated appraisal body & Summary of ruling** NICE Technology Appraisal guidance TA710 (June 2021) Ravulizumab (Ultomiris®)is recommended, within its marketing authorisation, as an option for treating atypical haemolytic uraemic syndrome (aHUS) in people weighing 10kg or more: • who have not had a complement inhibitor before or • whose disease has responded to at least 3 months of eculizumab treatment It is recommended only if the company provides ravulizumab according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** By extrapolation from the Resource Impact Statement provided by NICE, it is estimated that 8 patients per year in Northern Ireland will be eligible for treatment with ravulizumab for this indication
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Alexion Pharmaceuticals) has a commercial arrangement (simple discount patient access scheme). This makes ravulizumab available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of this medicine for this indication will be dealt with as part of the routine commissioning process.
6.	**Expected implementation period** There is no impediment to implementation of this guidance.
7.	**Commissioning arrangements** This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost per case basis initially. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.

8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monthly monitoring of all biologic therapies (patient numbers and waiting times), and this regime will be included within the routinely provided return. All monitoring returns for biologics are reviewed by the Specialist Services Commissioning Team monthly.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.

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HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency
2.	**Associated appraisal body & Summary of ruling** NICE Technology Appraisal guidance TA709 (June 2021) Pembrolizumab (Keytruda®) is recommended as an option for untreated metastatic colorectal cancer with high microsatellite instability (MSI) or mismatch repair (MMR) deficiency in adults, only if: • pembrolizumab is stopped after 2 years and no documented disease progression, and • the company provides pembrolizumab according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** According to the NICE Resource Template that accompanies NICE TA709, it is predicted that 10 people per year in Northern Ireland will be treated with pembrolizumab for this indication and in line with this Technology Appraisal.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Merck Sharp and Dohme) has a commercial arrangement. This makes pembrolizumab available to the NHS with a discount. The size of the discount is commercial in confidence. HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the commercial agreement.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements** This regimen with be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.
8.	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Ofatumumab for treating relapsing multiple sclerosis
2.	**Associated appraisal body & Summary of ruling** NICE Technology Appraisal guidance TA699 (May 2021) Ofatumumab (Kesimpta®) is recommended as an option for treating relapsing–remitting multiple sclerosis in adults with active disease defined by clinical or imaging features. This is only if the company provides ofatumumab according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** In discussion with clinical colleagues locally, it is estimated that the number of people likely to eligible for treatment will be in the region of: • 20 in 2021/22; and • Approximately 70 per year thereafter
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Novartis) has a commercial arrangement in place. This makes ofatumumab available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	**Infrastructure Requirements** The use of ofatumumab is not expected to result in additional service requirements. It is self-administered at home via a pre-filled auto injector pen (following initial healthcare professional guidance during the first injection), increasing convenience for people who use it and may save costs. The use of ofatumumab may also free up healthcare professional capacity compared to treatments administered by intravenous infusions in hospital. Infrastructure requirements for the delivery of all Disease Modifying Therapies (DMTs) for MS are reviewed annually as part of routine commissioning arrangements for supporting growth in the provision of these therapies.
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements** This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-care (CPC) basis.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monitoring of patients on disease modifying therapies (activity/cost and waiting times) and this regime will be included within the routinely provided return. All monitoring returns for disease modifying therapies are reviewed by the specialist services commissioning team quarterly.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case. The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act.

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Ravulizumab for treating paroxysmal nocturnal haemoglobinuria (PNH)
2.	**Associated appraisal body & Summary of ruling** Ravulizumab (Ultomiris®) is recommended, within its marketing authorisation, as an option for treating paroxysmal nocturnal haemoglobinuria in adults: • with haemolysis with clinical symptoms suggesting high disease activity, or • whose disease is clinically stable after having eculizumab for at least 6 months, and • the company provides it according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** According to the NICE Resource Impact Template that accompanies NICE TA698, it is expected that by year 5 patient numbers will be as follows: • 10 people in the prevalent population will be on treatment each year • 1 person from the incident population will start treatment each year Hence, at steady state, 11 people will be treated with ravulizumab for PNH each year.
4.	**Patient Access Scheme Availability** (**Yes**/No) The list price of ravulizumab is £4,533.00 per 300mg/3ml concentrate for solution for infusion vial; £16,621.00 per 1,100mg/11ml concentrate for solution for infusion vial (excluding VAT). The company (Alexion Pharmaceuticals) has a commercial arrangement. This makes ravulizumab available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of this medicine for this indication will be dealt with as part of the routine commissioning process.
6.	**Expected implementation period** There is no impediment to implementation of this guidance.
7.	**Commissioning arrangements** This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost per case basis initially. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monthly monitoring of all biologic therapies (patient numbers and waiting times), and this regime will be included within the routinely provided return. All monitoring returns for biologics are reviewed by the Specialist Services Commissioning Team monthly.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case. The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act.

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Carfilzomib with dexamethasone and lenalidomide for previously treated multiple myeloma
2.	**Associated appraisal body & Summary of ruling** NICE Technology Appraisal guidance TA695 (April 2021) Carfilzomib (Kyprolis®) plus lenalidomide and dexamethasone is recommended as an option for treating multiple myeloma in adults, only if: • they have had only 1 previous therapy, which included bortezomib, and • the company provides carfilzomib according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** It is estimated that 13 people per year in Northern Ireland would be expected to take up treatment with this regimen.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Amgen) has a commercial arrangement. This makes carfilzomib available to the NHS with a discount. The size of the discount is commercial in confidence. HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the commercial agreement.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements** This regimen with be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.
8.	**Monitoring arrangements**
	The HSCB cost per case process will generate quarterly reports on the number of applications. HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy.
2.	**Associated appraisal body & Summary of ruling** NICE Technology appraisal guidance (TA687), Published: 31 March 2021 www.nice.org.uk/guidance/ta687 Ribociclib plus fulvestrant is recommended as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer in adults who have had previous endocrine therapy only if: • exemestane plus everolimus is the most appropriate alternative to a cyclin-dependent kinase 4 and 6 (CDK 4/6) inhibitor, and • the company provides ribociclib according to the commercial arrangement
3.	**Number of people in Northern Ireland expected to take up service/therapy** Ribociclib plus fulvestrant was recommended for use in the Cancer Drugs Fund (CDF; TA593). The uptake of ribociclib plus fulvestrant is not expected to change significantly when it moves into routine commissioning. Referring to NICE TA593 it was estimated that up to 100 people per year in Northern Ireland will be expected to take up this therapy.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Novartis) has a simple discount patient access scheme for ribociclib. This makes ribociclib available to the NHS with a discount. The size of the discount is commercial in confidence. HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the patient access scheme.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements**
	This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.
8.	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology appraisal guidance (TA683) Published: 10 March 2021 www.nice.org.uk/guidance/ta683 Pembrolizumab with pemetrexed and platinum chemotherapy is recommended as an option for untreated, metastatic, non-squamous non-small-cell lung cancer (NSCLC) in adults whose tumours have no epidermal growth factor receptor (EGFR)-positive or anaplastic lymphoma kinase (ALK)-positive mutations. This is only if: • it is stopped at 2 years of uninterrupted treatment, or earlier if the disease progresses and • the company provides pembrolizumab according to the commercial arrangement.
3.	**Number of people in Northern Ireland expected to take up service/therapy** This guidance updates and replaces NICE technology appraisal guidance TA557 on pembrolizumab with pemetrexed and platinum chemotherapy (pembrolizumab combination) for untreated, metastatic, non-squamous NSCLC, which was available through the Cancer Drugs Fund. According to the Resource Impact Template that accompanies TA683 NICE estimate in Northern Ireland: • Around 96 people with non-squamous non-small cell lung cancer (NSCLC) are eligible for treatment with pembrolizumab with pemetrexed and platinum chemotherapy each year. • Around 70 people will receive pembrolizumab with pemetrexed and platinum chemotherapy from year 2023/24 onwards once uptake has reached 73%
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Merck Sharp & Dohme) has a commercial arrangement in place. This makes pembrolizumab available to the NHS with a discount. The size of the discount is commercial in confidence. HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the commercial arrangement.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated will be dealt with as part of the

	routine commissioning process.
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements** This regimen with be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.
8.	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.

HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Baricitinib for treating moderate to severe atopic dermatitis
2.	**Associated appraisal body & Summary of ruling** NICE Technology Appraisal guidance TA681 (March 2021) Baricitinib is recommended as an option for treating moderate to severe atopic dermatitis in adults, only if: • the disease has not responded to at least 1 systemic immunosuppressant, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are not suitable, and • the company provides it according to the commercial arrangement Assess response from 8 weeks and stop baricitinib if there has not been an adequate response at 16 weeks, defined as a reduction of at least: • 50% in the Eczema Area and Severity Index score (EASI 50) from when treatment started and • 4 points in the Dermatology Life Quality Index (DLQI) from when treatment started. When using the EASI, take into account skin colour and how this could affect the EASI score, and make appropriate clinical adjustments. When using the DLQI, take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI, and make any appropriate adjustments.
3.	**Number of people in Northern Ireland expected to take up service/therapy**

Estimated number of people in Northern Ireland receiving baricitinib

		22/23	2034/24	2024/25	2025/26
		10%	15%	20%	25%
		11	11	11	11
weeks because of		-3	-3	-3	-3
People continuing	8	8	8	8	8
People continuing with treatment from previous	0	8	17	25	34
treatment		**16**	**25**	**33**	**42**

4.	**Patient Access Scheme Availability** (**Yes**/No)
	The company (Eli Lilly and Company Ltd) has a commercial arrangement. This makes baricitinib available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of this medicine for this indication will be dealt with as part of the routine commissioning process.
6.	**Expected implementation period** There is no impediment to implementation of this guidance.
7.	**Commissioning arrangements** This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost per case basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monthly monitoring of all biologic therapies (patient numbers and waiting times), and this regime will be included within the routinely provided return. All monitoring returns for biologics are reviewed by the Specialist Services Commissioning Team quarterly.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case. The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act.

Health and Social Care

Internal Ref. No.:
_____

DATA ACCESS AGREEMENT

IT IS IMPORTANT THAT YOU READ THIS SECTION BEFORE COMPLETING THE DATA ACCESS AGREEMENT (DAA) FORM

This Data Access Agreement (DAA) template should be completed ONLY where personal identifiable data is to be shared for a secondary purpose.

'Identifiable' means data which could lead to any individual being identified and includes pseudonymised data. (See Section A). A secondary purpose is a reason other than the initial purpose for which the data was collected

A DAA is NOT appropriate for the following purposes:

- When only anonymous (non-identifiable) data is to be shared
- Where identifiable data is to be shared for a primary purpose e.g. for a purpose linked to the direct care of the patient or service user; or a purpose linked directly to a staff member's employment. Contact your IG Department for further advice.
- Research (see below re Research Governance Framework)
- Software maintenance contracts (will be covered by the appropriate contract)
- Internal audits (seek advice from the Audit Department)
- Where a legally binding contract is more appropriate (e.g. with a 3rd party supplier)

When information is required for a secondary purpose other than those included above, it is important that you consider what type of data meets your requirements and that you complete section A before proceeding with this DAA.

Please note that the purpose of a DAA is only to address any data protection issues associated with the sharing of personal data. Any other issues regarding the availability or interpretation of data and arrangements or resources required to comply with the request should be discussed separately with the relevant Service / Information Dept. staff within the Trust(s).

Introduction

All Health and Social Care (HSC) organisations must ensure that when sharing HSC data for non-direct care (secondary purposes), assurances are provided by the requesting organisations that they comply with data protection (DP) legislation and that staff are aware of the relevant DP policies and procedures in place.

Researchers undertaking studies and who require access to patient identifiable information and / or anonymous HSC data should follow the research protocol (Research Governance Framework for Health and Social Care in Northern Ireland). There is no need for an additional DAA to be completed.

Please be aware that it may be more appropriate to make use of the Honest Broker Service (HBS) rather than completing a Data Access Agreement. The HBS will enable the provision of anonymised, aggregated and in some cases pseudonymised health and social care data to the Department of Health (DoH), HSC organisations and in the case of anonymised data for approved Health and Social care related research.

Arrangement for access to personal data for a secondary purpose may already be covered by a contract (e.g. a contract for supplier support on an information system) therefore organisations need to be clear that any proposed data sharing is either covered adequately by that contract or make sure that a Data Access Agreement is completed.

The following Data Access Agreement must be completed and signed by any organisation wishing to access HSC identifiable data for a secondary purpose not already covered by a contract or research application. It must be considered for approval and signed by the owner organisation's Personal Data Guardian or Senior Information Risk Owner (SIRO).

In the event of a breach of this agreement which results in a financial penalty, claim or proceedings, the parties agree to co-operate to identify and apportion responsibility for the breach and the defaulting party will accept responsibility for any such claim.

Please refer to Appendix 2, 'Principles Governing Information Sharing' for guidance.

The form is divided into Sections (A-I) as detailed below:

Section A: Classification of data required
Section B: Title of Agreement / Details of Organisations to which the data will be shared
Section C: Details of Identifiable Data Items required and rationale
Section D: Consent or other Lawful Basis for accessing personal data
Section E: Data Protection arrangements (of receiving organisation)
Section F: Measures / Controls to prevent inappropriate disclosure of information
Section G: Data Retention
Section H: Declaration: Organisation to which data will be shared
Section I: Declaration: Owner Organisation

Appendix 1: Data Destruction Notification
Appendix 2: Principles Governing Information Sharing
Appendix 3: Definitions
Appendix 4: Contact Details

*****IMPORTANT*****

PLEASE REVIEW AND COMPLETE SECTION A BEFORE PROCEEDING

(A) Classification of data required (for secondary purpose)		
Identifiable data	The data to be shared with our organisation will contain Client Identifiable Details i.e. any of the following: Name, Address, Full Postcode, Date of Birth, HSC Number; Case-note Number; or other unique identifier that would link the data to identifiable details	Yes ☐ Please complete ALL sections of this DAA
Pseudonymous data	The data to be shared with our organisation contain no personal identifiers (as described above); however a unique code or key will be included that allows the possibility of linking this in future to a specific data subject. The pseudonymisation process will be completed at source by the HSC organisation who alone will securely retain the key to re-identify the data.	Yes ☐ Please complete sections B, C, and H of this DAA
Anonymous data	The data to be shared with our organisation will contain **NO** identifiable data items (as described above). At no stage will any party be able to link the data to an identified or identifiable natural person.	Yes ☐ A DAA is not required

When a DAA is appropriate, please ensure that the completed / signed form is returned to the relevant contact in each organisation (**see attached Appendix 4 for contact details**)

Please note that the completed Data Access Agreement will be immediately returned unless the receiving organisation has signed section H.

(B) Title of Agreement / Organisations to which the data will be shared

Title of Agreement	
Date of Request	

Please indicate as follows, by ticking the relevant box. This is:-

a) A New application ☐

b) Extending an earlier Agreement with no changes to what was previously agreed ☐

c) An update of an earlier Agreement with changes to what was previously agreed ☐

Please ensure that any changes from a previous agreement are clearly highlighted at Section C.

Date Access to Begin: _____

Date Access Ends: _____

2 yearly review date if on-going agreement:_____

Details of the Organisation the data will be shared with	
Name of Organisation:	
Name of Authorised Officer requesting Access to Trust Data	
Position/Status	
Address Postcode	
Telephone Number	
Email Address	
Name and Telephone Number of Organisation's Personal Data Guardian/Caldicott Guardian	

If you require the data to carry out work **on behalf of another organisation**, please complete the additional Table below. If not, please go straight to section (C).

Commissioning Organisation (if relevant)	
Name of Commissioning Organisation	
Contact Name	
Title	
Contact Number	
Email Address	

(C) Details of Identifiable Data Items required and rationale (NB. only minimum identifiable data should be requested for the required purpose)	
Please provide a list of data items that can identify an individual (e.g. Name, Address, Full Postcode, Date of Birth, HSC Number; Case-note Number; or other unique identifier that would link the data to identifiable details).	Please indicate the reasons for requiring each of these data items
1 _____ 2_____ 3 _____ 4_____ 5_____ 6_____ 7_____ 8_____ 9_____ 10_____ Continue on separate sheet if necessary	1_____ 2 _____ 3_____ 4 _____ 5_____ 6 _____ 7_____ 8 _____ 9_____ 10_____ Continue on separate sheet if necessary

Processing of information
Please complete all sections below to explain how information will be processed - *complete all sections using language easily understood by lay reviewers* - *continue on a separate sheet if necessary or attach any relevant documentation*
A <u>brief</u> description of the data flow(s):
The purpose for which the data is required:
How you propose to process the data once received:
Details of any record linking or matching to other data sources:
Other relevant information:

Please list the System(s) from which data is to be extracted (if known) for Example PAS, SOSCARE, PARIS, NIECR, etc. Please also include sites or geographical locations (if known):	
Frequency of transfers (*Please Tick*)	Once ☐ Other ☐ (Please specify) _____

(D) Consent or other Lawful Basis for accessing personal data	
If you are requesting personal identifiable/special category data for a secondary purpose, there is an expectation that you will have explicit written consent from the service user(s) or another lawful basis for accessing their information. When relying on consent as the lawful basis, this means offering individuals genuine choice and control. This will require a very clear and specific statement of consent, which should be in writing and held on the service user's file. It should be clear to the individual what they are consenting to and who will have access to their information. It should be easy for individuals to withdraw consent and they should be made aware that they can do this at any time.	
Do you have the individuals' **informed consent** for their data to be shared for the purpose specified in this DAA?	Yes ☐ No ☐ If yes, please provide a copy of the Consent Form with this application
If you are NOT obtaining informed consent, what other **lawful basis** are you relying on to obtain the data for this purpose? *(please discuss with your Data Protection Officer / IG department regarding relevant legislation and GDPR conditions – see Appendix 3 below re lawful basis under article 6 and article 9)*	
In the absence of consent or any other lawful basis, it will only be appropriate to share anonymous data or pseudonymous data (data pseudonymised at source). Please refer back to Section A.	

(E) Data Protection arrangements of the Organisation receiving the identifiable data – to provide assurance that the data shared is processed and stored securely by you, please answer the following questions:	
You must be registered with the Information Commissioner's Office (ICO) to process personal data. Please provide your **ICO registration number**	
Do you have a confidentiality / privacy policy which complies with Data Protection legislation?	Yes ☐ No ☐
Are confidentiality clauses included within contracts of all staff with access to the person identifiable information?	Yes ☐ No ☐
Are all staff trained and aware of their responsibilities under Data Protection legislation and adhere to the Data Protection principles?	Yes ☐ No ☐
Do you have an ICT security policy?	Yes ☐ No ☐
Have you conducted a Data Protection Privacy Assessment (DPIA)? (please see App. 3 for further details on when a DPIA is necessary)	Yes ☐ No ☐ If yes please include a copy with this form.

(F) Measures / Controls in place by the receiving organisation to prevent the inappropriate disclosure of <u>Person Identifiable Information</u>	
How do you require the information to be securely transferred to your organisation?	
Describe the physical security arrangements for the location where **person identifiable data** is to be: - processed; and - stored	
Provide details of access and/or firewall controls implemented on the system, and measures to encrypt which are in place.	

Will this data be accessed or transferred by you to another organisation; or shared with another organisation?	Yes ☐ No ☐
If applicable, how will you secure information provided being transferred by you to another organisation?	
Is a separate agreement in place to ensure the security of the data held by the 3rd party?	Yes ☐ No ☐
If the data is to be stored or shared outside the UK please provide details (e.g. country):	

(G) Data Retention – **Please indicate how long the receiving organisation will retain identifiable data**	
Please state the date by which you will be finished using the identifiable data. If this is not applicable you need to explain why?	
If the data retention period for identifiable data is greater than two years, please indicate the reasons for this. (**The maximum data retention period is 2 years, after this time a review of this agreement is required**)	
Describe the method of data destruction you will employ when you have completed your work using person identifiable data	

When appropriate, please ensure that the Data Destruction Notification (Appendix 1) is completed within the specified retention period and returned to the appropriate contact person (see Appendix 4).

(H) Declaration: Organisation to which data will be shared

Please note that the completed Data Access Agreement will be immediately returned unless the receiving organisation has signed section H.

Data Protection Undertaking on Behalf of the Organisation Wishing to Access the Data

My organisation requires access to the data specified and will conform to Data Protection legislation; the Information Commissioner's Data Sharing Code of Practice; and the guidelines issued by the Department of Health in *"The Code of Practice on Protecting the Confidentiality of Service User Information (updated April 2019)".*

I confirm that:

- The information requested and any information extracted from it is for a specified, explicit and legitimate purpose
- It is adequate, relevant and limited to the stated purpose
- It will be processed fairly and lawfully and used only for the stated purpose
- It will be processed and stored in a manner that ensures appropriate security
- It will be held no longer than is necessary for the stated purpose
- It will be disposed of fully and in such a way that it is not possible to reconstitute it
- All measures will be taken to ensure identifiable data is not disclosed to third parties
- Where appropriate, the Health and Social Care organisation will be informed of the identifiable data being deleted / destroyed (see Appendix 1)
- In the case of pseudonymised data, the process of de-identifying data will be completed at source. The key to re-identification will be held only by the data controller and at no stage will the data we receive be attributed to an identified or identifiable natural person
- Any loss, theft or corruption of the shared data by my organisation will be immediately reported to the Personal Data Guardian / SIRO of the owning organisation and we will assist fully in any investigation. I understand that any serious breaches, data loss, theft or corruption will be reported to the ICO within 72 hours of the breach first being discovered.

As the Authorised Officer of the organisation to which data will be shared, I declare that I have read and understand my obligations and adhere to the conditions contained in this Data Access Agreement.

Signed: _____
(Personal Data Guardian / Caldicott Guardian / Authorised Officer)

Signed: _____
(IAO/SIRO)

Date: _____

(I) Declaration – HSC Owner Organisation

DATA ACCESS AGREEMENT

I CONFIRM THAT:

The _____ (HSC owner organisation) consents to the disclosure of the data specified, to the organisation identified in Section B of this form. The disclosure of the data conforms to the guidelines issued by the Department of Health Code of Practice on Protecting Confidentiality of Service User Information (updated April 2019); and the Information Commissioner's Data Sharing Code of Practice.

Signed: _____ ____ *(HSC Organisation internal use)*
(Information Governance and / or ICT Security)

Signed: _____
(Personal Data Guardian) OR (Senior Information Risk Owner SIRO)

Date: _____

Please note that this organisation has the right to inspect the premises and processes of the requesting organisation to ensure that they meet the requirements set out in the agreement.

Appendix 1

Data Destruction Notification

(to be completed on all occasions when data is transferred external to HSC NI)

Authorised users of the person identifiable data have, under the terms and conditions of the Data Access Agreement, a requirement to destroy the data on or before the retention date stated in Section (G).

This form should be completed on destruction of the data, and returned to the relevant Trust contact (see Appendix 4):-

Data Destruction Notification	
Name of Organisation	
Name of Authorised Officer (please print)	
Position/Status	
Address	
Telephone Number	
Mobile Number (Optional)	
Fax Number	
Email Address	
Title of Agreement	
Date Declaration Signed	
Date Data Received	
Date Data Destroyed	

Signature	
Date	

Appendix 2 - Principles Governing Information Sharing[1]

Code of Practice Principles	GDPR Principles	Caldicott Principles[2]
The Code of Practice is principally concerned with identifiable service user information. The nature of the obligation to protect confidentiality can be expressed in terms of three core principles: • individuals have a fundamental right to the confidentiality and privacy of information related to their health and social care; • individuals have a right to control access to and disclosure of their own health and social care information by giving, withholding or withdrawing consent; • when considering whether to disclose confidential information, health and social care staff should have regard to whether the disclosure is necessary, proportionate and accompanied by any undue risks. Particular care is needed on the part of health and social care staff to ensure that the right to privacy of vulnerable people – specifically adults with incapacity and children – is respected and that the duty of confidentiality owed to them is fulfilled. https://www.health-ni.gov.uk/publications/code-practice-protecting-confidentialityservice-user-information	**1.** processed lawfully, fairly and in a transparent manner **2.** Purpose limitation - collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes **3.** Data minimisation - adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed **4.** Data Quality - accurate and, where necessary, kept up to date **5.** Storage Limitation - kept for no longer than is necessary. **6.** Integrity and Confidentiality - processed in a manner that ensures appropriate security of the personal data **7.** Overarching Accountability principle –take responsibility for what you do with personal data and how you comply with the other principles, having appropriate measures and records in place to be able to demonstrate your compliance. Principles relating to individuals' rights and overseas transfers of personal data are specifically addressed in separate GDPR articles.	**1.** Justify the purpose(s) for using confidential information. **2.** Only use it when absolutely necessary. **3.** Use the minimum that is required. **4.** Access should be on a strict need-to-know basis. **5.** Everyone must understand his or her responsibilities. **6.** Understand and comply with the law. **7.** The duty to share information can be as important as the duty to protect patient confidentiality

[1] These principles must be followed by health and social care organisations when considering use and disclosure of service user information.
[2] PDG Principles are adopted from the Caldicott Principles (revised September 2013) established in England and Wales.

Appendix 3- Definitions

Personal Data
'Personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;

Consent
'Consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;

Processing
'Processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

Pseudonymisation
'Pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person;

Data Controller
'Controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;

Data Processor
'Processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

Third party
'Third party' means a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data;

Data Protection Impact Assessment (DPIA)
A Data Protection Impact Assessment (or DPIA) is part of the accountability obligations under the GDPR and is an integral part of the 'data protection by default and by design' approach. It is a process to help you identify and minimise the data protection risks of a project

A DPIA is mandatory when introducing a new system or process that is likely to include a high risk to the privacy of the individuals involved. An effective DPIA will document the data flows and help to identify and fix problems at an early stage, demonstrate compliance with data protection obligations, meet individuals' expectations of privacy and help avoid reputational damage which might otherwise occur. For further information please see:

https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments/

Lawful Basis
You must have a valid lawful basis in order to process personal data. The conditions for processing personal data are included under article 6 of GDPR and for processing special category personal data under article 9.

There are six available lawful bases under Article 6 for processing personal data. No single basis is 'better' or more important than the others and the most appropriate basis to use will depend on your purpose and relationship with the individual. Most lawful bases require that processing is 'necessary' for a specific purpose. You must determine your lawful basis before you begin processing, and you should document it.

For full details of Article 6 lawful basis for processing personal data please refer to: https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/

In order to lawfully process 'special category data'*, you must identify both a lawful basis under Article 6 (in exactly the same way as for any other personal data); however you will also need to satisfy a specific condition under Article 9.

For full details of Article 9 lawful basis for processing personal data please refer to: https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/

Special Category Data*
Special category data is personal data which the GDPR says is more sensitive, and so needs more protection. This type of data could create more significant risks to a person's fundamental rights and freedoms. For example, by putting them at risk of unlawful discrimination.

Special category data is information about an individual's:

- race;
- ethnic origin;
- politics;
- religion;
- trade union membership;
- genetics;
- biometrics (where used for ID purposes);
- health;
- sex life; or
- sexual orientation.

Appendix 4 - Contact details

Belfast Health and Social Care Trust

Gillian Acheson - Senior Data Protection Manager

Information Governance Dept | 1st Floor Admin Building | Knockbracken Health Care Park | Saintfield Road | Belfast BT8 8BH

Email: Personal Information redacted by the USI

Northern Health and Social Care Trust

Nicola Lyons - Information Governance Manager

Information Governance Department | Causeway House | Route Complex | 8E Coleraine Road | Ballymoney BT53 6BP |

E-mail: Personal Information redacted by the USI

South Eastern Health and Social Care Trust

Lynda McAree - Head of Information Governance & Directorate Support

Information Governance Department | Lough House | Ards Community Hospital | Newtownards BT23 4AS

Email: Personal Information redacted by the USI

Southern Health and Social Care Trust

Peter McManus - Information Governance Manager

Ferndale | Bannvale Site | 10 Moyallen Road | Gilford BT63 5JY

Email: Personal Information redacted by the USI

Western Health and Social Care Trust

Jeremy Foster - Head of Records and Information Governance,

Trust Headquarters | MDEC Building | Altnagelvin Hospital site | Glenshane Road Londonderry BT47 6SB

Email: Personal Information redacted by the USI

Public Health Agency

Karen Braithwaite - Senior Operations Manager (Delivery)

Public Health Agency | Tower Hill | ARMAGH | BT61 9DR

Email: Personal Information redacted by the USI

Health and Social Care Board

Ken Moore | Information Governance Manager

Corporate Services | Health and Social Care Board | Towerhill | Armagh | BT61 9DR | Northern Ireland

Email: Personal Information redacted by the USI

Business Services Organisation

Alan McCracken - Data Protection Officer (DPO)

Business Services Organisation Headquarters | 2 Franklin Street | Belfast | BT2 8DQ

Email: Personal Information redacted by the USI

Southern Health and Social Care Trust

Clinical and Social Care Audit Registration Form

Audit Title:

Directorate: Acute Services ☐ Children & Young People ☐ Older Persons & Primary Care ☐
Mental Health & Disability ☐ Corporate request ☐

Division:

Auditor's name: **Contact details:** **(email)**	**Audit Supervisor's Name :**

Is this a: National audit ☐ Regional audit ☐ Trust audit ☐ International audit ☐

Proposed audit commencement date …/…/… Proposed audit completion date …/…/….

Rationale for the audit (please tick all that apply)

Topic is included in the Directorate's clinical audit work-plan	☐	Compliance with standards & guidelines	☐
National Healthcare Quality Improvement Partnership (HQIP) audit	☐	Regional RQIA/GAIN audit	☐
Other national / international audit	☐	Trust based audit topic important to team/division	☐
Clinical risk	☐	Recommendation from national / regional report	☐
Serious Adverse Incident or Adverse Incident review	☐	Clinician / personal interest	☐
Incident reporting	☐	Educational audit	☐

Other – please specify ……

Priority levels for clinical audit (please see criteria overleaf)

Level 1 ☐ **Level 2** ☐ **Level 3** ☐ **Level 4** ☐

Audit approval process

Has this audit been approved based on the priority level? Yes ☐ No ☐

Level 1 - Approval required by Associate Medical Director or Clinical Director or Directorate Governance Forum
Level 2 - Approval required by Associate Medical Director or Clinical Director or Directorate Governance Forum
Level 3 – Approval required by Supervising Consultant
Level 4 – Approval required by Supervising Consultant
Please be advised that the audit cannot proceed without approval as above.

Information Team Requests

Please Note: The Information Team have advised they will not release data to the requestor unless the clinical audit has been approved as above.
The clinical audit team will also advise contact with Information Governance for any advice required.

Trust's M&M and Clinical Audit team contacts

The clinical audit team can be contacted via:
Email: Personal Information redacted by the USI

Tel:	Fiona Davidson	Personal Information redacted by the USI	Sandra McLoughlin	Personal Information redacted by the USI
	Raymond Haffey	Personal Information redacted by the USI	Mary Markey	Personal Information redacted by the USI
	Terri Harte	Personal Information redacted by the USI	Roisin Feely	Personal Information redacted by the USI
	Philip Sullivan	Personal Information redacted by the USI		

In submitting this audit registration form, I agree to share the audit findings, recommendations and audit summary template with:the Audit Supervisor, appropriate Divisional/Directorate Committee and the Trust's Clinical audit team

Please submit your audit registration form to: Personal Information redacted by the USI

Priority levels for clinical audit

Level	Audit type - projects identified through	
Level 1 audits, "external must dos" (where the service is applicable to SHSCT)	• National audits (NHS England Quality Accounts List (HQIP), including the National Confidential Enquiry into Patient Outcomes and Deaths (NCEPOD) / Other Confidential Inquires	1
Level 2 audits, other national audits and 'internal must dos'	• National audits not contained within the HQIP list, or other clinical audits arising from: • Clinical risk • Serious untoward incident / internal reviews • National Institute of Clinical Excellence Standards & Guidelines • Complaints • Re-audit • Regional audits initiated by RQIA / GAIN	2
Level 3 audits, 'divisional priorities'	• Local topics important to the division	3
Level 4 audits	• Clinician / personal interest • Educational audits	4

Southern Health and Social Care Trust
Quality Care - for you, with you

Southern Health and Social Care Trust

M&M: Combined Surgery, Anaesthetics

January – December 2022

Day	Date	Month	Time	M&M
Thursday	13th	January	PM	Speciality specific
Friday	18th	February	AM	Speciality specific
Friday	11th	March	PM	Combined
Tuesday	12th	April	AM	Speciality specific
Tuesday	17th	May	PM	Speciality specific
Wednesday	15th	June	AM	Combined
Wednesday	20th	July	PM	Speciality specific
Thursday	18th	August	AM	Speciality specific
Thursday	15th	September	PM	Combined
Friday	14th	October	AM	Speciality specific
Friday	18th	November	PM	Speciality specific
Tuesday	13th	December	AM	Combined

Agenda
Patient Safety Meeting / M&M Meeting Urology
Friday 18th February 2022 AM session

1. **Welcome , attendance and apologies received by Chair**:

2. **Review of Previous Minutes / Verification of last meeting report**
    a. Matters Arising / outstanding issues

3. **Deaths within 30 days Discharge**

FOR INFORMATION
DEATHS OUTSIDE H

4. **Mortality Reporting**

    See NIECR

5. **Morbidity**

Personal Information pdf

6. **Local incident themes : Ward / Unit issues**

7. **Pharmacy issues, incidents and medicine safety alerts**

8. **Shared learning from Complaints / SAI/ IR1 forms / Other meetings / Learning Letters**

9. **Shared learning from Litigation / Coroners cases / PM reports / Ombudsman**

10. **Safety alerts and Circulars (Safety Quality Reminder) sent to M&M chairs**

    a. Safety and Quality Reminders
    b. E-Alerts
    c. PHA Letters

Issued Standards & Guidelines Circulars: for Dissemination, Review & Implementation

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G
PALIVIZUMAB_RSV in At Risk Preterm Infants *Provision of Palivizumab passive immunisation to the existing and additional cohorts should be stopped at the end of January 2022. Updates and replaces letter issued on 16/07/2022*	28/01/2022	HSS MD 03 2022	CMO Correspondence	n/a	31/01/2022
Inducing Labour *Updates and replaces CG 70 that was previously issued on 01/07/2009*	27/01/2022	NG 207	NICE Clinical Guideline	27/04/2022	27/01/2023
Sodium Zirconium Cyclosilicate_Hyperkalaemia	26/01/2022	TA 599	NICE Technology Appraisal Update	n/a	26/04/2022
Glaucoma Diagnosis and Management *Clinical Guideline was initially endorsed by DOH on 21/12/2017*	26/01/2022	NG 81	NICE Clinical Guideline Update	n/a	26/04/2022

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	Deadline Date for Implementation
Management HSC Staff_Confirmed Cases COVID 19 *Previous version of this CMO letter was issued on 21/01/2022* The Trust's COVID19 Toolkit (Version 4) [click here] has been updated to reflected these recent changes from the Chief Medical Officer. It may now be possible to return to work after 5 days of isolation after testing positive for COVID 19 provided staff adhere to stringent lateral flow testing.	25/01/2022	HSS MD 02-2022 (revised)	CMO Correspondence	With Immediate Effect
Updated guidance_Care Homes_COVID 19	25/01/2022	n/a	PHA Correspondence	With Immediate Effect
PHA Letter - Testing for HCAI	24/01/2022	n/a	PHA Correspondence	With Immediate Effect

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	Deadline Date for Implementation
Managing COVID	27/01/2022	NG 191	NICE COVID-19 Rapid Guideline Update	n/a

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G
Antenatal care (updates and replaces CG62)	13/01/2022	NG 201	NICE Clinical Guideline	13/04/2022	13/01/2023
Foreign Body Aspiration During Intubation, Advanced Airway Management or Ventilation *Regional Circulation – Clear Your Clutter Poster*	12/01/2022	HSC (SQSD) 17/20	Patient Safety Alert	n/a	n/a

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	Deadline Date for Implementation
Visiting with Care – A Pathway	14/01/2022	n/a	CNO Correspondence	N/A

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G
Budesonide_Eosinophilic Oesphagitis	11/02/2022	TA 708	NICE Technology Appraisal	11/05/2022	11/11/2022
Andexanet alfa_Reversing anticoagulation_Apixaban_Rivaroxaban	11/02/2022	TA 697	NICE Technology Appraisal	11/05/2022	11/11/2022
Bempedoic Acid with Ezetimibe	11/02/2022	TA 694	NICE Technology Appraisal	11/05/2022	11/11/2022
Dapagliflozin_Chronic Heart Failure	11/02/2022	TA 679	NICE Technology Appraisal	11/05/2022	11/11/2022
Mepolizumab_Severe Eosinophilic Asthma	11/02/2022	TA 671	NICE Technology Appraisal	11/05/2022	11/11/2022
Naldemedine for treating opioid-induced constipation	11/02/2022	TA 651	NICE Technology Appraisal	11/05/2022	11/11/2022
NOT RECOMMENDED_Fostamatinib_Chronic Immune Thrombocytopenia	10/02/2022	TA 759	NICE Technology Appraisal	n/a	10/03/2022
Updated DoH Guidance_Death Certification *Previous HSS MD 01/2019 has been superceded* *Recipients of this circular must ensure that all Medical Practitioners are informed of this updated guidance which can be found at 'Guidance surrounding Death' under the heading 'Death Certification and Completing a MCCD'. Refer to link below:*	09/02/2022	HSS MD 07/2022	CMO Correspondence	n/a	n/a

Guidance surrounding Death | Department of Health (health-ni.gov.uk)					
TERMINATED - Pembrolizumab_Metastatic Urothelial Cancer	01/02/2022 (SHSCT did not receive this notification hence delay in issue)	TA 674	NICE Technology Appraisal	Not Applicable to SHSCT	

Title of Correspondence	Date of Issue from External	Reference	Guidance Type	Deadline Date for Implementation

	Agency			
Updated_HSS MD 06-2022_nMABs_non hospitalised patients with COVID *Please note the published Interim Clinical Commissioning Policy 'Antivirals or neutralising monoclonal antibodies (nMABs) for non-hospitalised patients with COVID-19' and associated clinical guide have been updated since the issue of the above letter on 1 February 2022.*	11/02/2022	HSS MD 06-2022	CMO Correspondence	n/a
Updated_HSS MD 04-2022 COVID 19 Alert_antivirals nMABs_treatment of COVID patients *Please note the published Interim Clinical Commissioning Policy 'Antivirals or neutralising monoclonal antibodies (nMABs) in the treatment of COVID-19 in hospitalised patients' and associated clinical guide have been updated since the issue of the above letter on 31 January 2022.*	11/02/2022	HSS MD 04-2022	CMO Correspondence	n/a
Updated PHA Guidance_Testing to reduce HCAI *Updates guidance issued on 24/01/2022 and 09/02/2022*	11/02/2022	n/a	PHA Correspondence	With Immediate Effect

Title of Correspondence	Date of Issue from External	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G

	Agency				
Revised HSCB Letter_Nivolumab Ipilimumab Chemotherapy_untreated metastatic non-small-cell lung cancer - NOT RECOMMENDED *There was an error in the previous HSCB letter dated 20/12/2021 (wrong cancer type stated). Assurance has been already provided that the Trust is compliant with the recommendation not to recommend this regime for the treatment of this condition*	21/01/2022	NICE TA 724	NICE Technology Appraisal	n/a	n/a
Pentosan Polysulfate Sodium_ Bladder Pain Syndrome	21/01/2022	NICE TA 610	NICE Technology Appraisal	21/04/2022	21/10/2022
Xeomin_Treating chronic sialorrhoea	21/01/2022	NICE TA 605	NICE Technology Appraisal	21/04/2022	21/10/2022
Updated Never Events Guidance - Never Event Number 4	20/01/2022	HSC SQSD 04-22	CMO Correspondence	n/a	n/a
Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management *(Updates and replaces NICE CG 53 previously*	19/01/2022	NG 206	NICE Clinical Guideline	19/04/2022	19/01/2023

endorsed on 31/08/2008)					
MBRRACE UP Perinatal Mortality Surveillance Report Jan to Dec 2019	18/01/2022	n/a	MBRRACE	n/a	n/a
MBRRACE UK Learning from Standardised Reviews when Babies Die	18/01/2022	n/a	MBRRACE	n/a	n/a
Rehabilitation after Traumatic Injury Forms part of the regional Equality Screening consultation process (6 weeks)	18/01/2022	NG 211	NICE Equality Screening Questionnaire	n/a	28/02/2022
Children Young Persons experience of Healthcare	17/01/2022	NG 204	NICE Clinical Guideline	18/04/2022	18/01/2023

NICE Technology Appraisals Issued by the HSCB (29th January to 4 February 2022)

Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G
Guselkumab_Active psoriatic arthritis after inadequate response to DMARDs	31/01/2022	TA 711	NICE Technology Appraisal	30/04/2022	31/10/2022
Ravulizumab_Atypical Haemolytic Uraemic Syndrome	31/01/2022	TA 710	NICE Technology Appraisal	30/04/2022	31/10/2022
Pembrolizumab_Metastatic Colorectal Cancer with High Microsatellite	31/01/2022	TA 709	NICE Technology Appraisal	30/04/2022	31/10/2022
Ofatumumab_Relapsing Multiple Sclerosis	31/01/2022	TA 699	NICE Technology Appraisal	30/04/2022	31/10/2022
Ravulizumab_Paroxysmal Nocturnal Haemoglobinuria	31/01/2022	TA 698	NICE Technology Appraisal	30/04/2022	31/10/2022
Carfilzomib with dexamethasone and lenalidomide_Multiple Myeloma	31/01/2022	TA 695	NICE Technology Appraisal	30/04/2022	31/10/2022
Ribociclib_Advanced Breast Cancer after Endocrine Therapy	31/01/2022	TA 687	NICE Technology Appraisal	30/04/2022	31/10/2022
Pembrolizumab with Pemetrexed and Platinum Chemotherapy_ NSC Lung Cancer	31/01/2022	TA 683	NICE Technology Appraisal	30/04/2022	31/10/2022
Baricitinib_Moderate to severe Atopic Dermatitis	31/01/2022	TA 681	NICE Technology Appraisal	30/04/2022	31/10/2022

11. **Local Audit reports/Quality Improvement**

a) All clinical audits to be registered via clinical audit registration form. DAA form to be completed also.


Data Access Agreement (v4.0) Ju


Clinical And Social Care Audit Registrati

12. **Consultant outcome data (NCEPOD / National / Regional / Speciality)**

13. **Any Other Business**

14. **Date of Next Meeting -** Friday 11th March 2022, PM, Combined

15. **Calendar 2022**


1.Combined Surgical Anesthetics MM [redacted]

Health and Social Care Board

Belfast Health and Social Care Trust

caring supporting improving together

27 March 2019

To: All Medical Staff

Dear Colleagues

On occasion, colleagues may have concerns regarding the conduct, health or performance of a colleague in any part of the health and social care system. You will be familiar with the guidance from the GMC in Good Medical Practice (paragraph 25 point C).

> *"If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague, your defence body or us. If you are still concerned you must report this, in line with our guidance and your workplace policy, and make a record of the steps you have taken".*

It is essential that such concerns are communicated in a timely manner, so that they can be appropriately considered.

Where you have a concern regarding the conduct, health or performance of a doctor, you should contact your Responsible Officer who will then forward the concern to the relevant Responsible Officer.

In the case of doctors working in primary care or at the following Trusts, you should contact the Medical Director and Responsible Officer:-

General Practitioners	Dr Margaret O'Brien Assistant Director of Integrated Care, Head of GMS and Responsible Officer	Personal Information redacted by the USI
Belfast HealthTrust	Dr Cathy Jack Medical Director	Personal Information redacted by the USI
Northern HealthTrust	Mr Seamus O'Reilly Medical Director	Personal Information redacted by the USI
South East Health Trust	Mr Charles J Martyn Medical Director	Personal Information redacted by the USI
Southern Health Trust	Dr Maria O'Kane Medical Director	Personal Information redacted by the USI
Western HealthTrust	Dr Dermot Hughes Medical Director	Personal Information redacted by the USI

In addition, you should contact the GMC or other regulatory body directly in the following circumstances:

- if you cannot raise the issue with the responsible person or body locally because you believe them to be part of the problem;

- if you have raised your concern through local channels but are not satisfied that adequate action has been taken;

- if there is an immediate serious risk to patients, and a regulator or external body has responsibility to act or intervene if you are unable to contact the relevant RO.

On behalf of all Trust Medical Directors and Responsible Officers we hope this clarification is helpful but should you have any queries, please do not hesitate to contact our respective offices.

Yours sincerely

Personal information redacted by USI

Personal information redacted by USI

Dr Margaret O'Brien
Assistant Director of Integrated Care
Responsible Officer, HSCB

Dr Cathy Jack
Deputy Chief Executive
Medical Director, BHSCT

Southern Health and Social Care Trust

Quality care – for you, with you

GOVERNANCE COMMITTEE COVER SHEET

Meeting Date	12th May 2022		
Agenda item	Quarterly Mortality Report July 2020 – June 2021		
Accountable Director	Dr Maria O'Kane, Medical Director		
Report Author	Name	Suzanne Barr	
	Contact details	Personal Information redacted by the USI	
This paper is presented for: Assurance			
Links to Trust Corporate Objectives	√	Promoting Safe, High Quality Care	
	☐	Supporting people to live long, healthy active lives	
	☐	Improving our services	
	☐	Making best use of our resources	
	☐	Being a great place to work – supporting, developing and valuing our staff	
	☐	Working in partnership	

	This report cover sheet has been prepared by the Accountable Director. *Its purpose is to provide the Trust Committee with a clear summary of the paper being presented, with the key matters for attention and the ask of the Committee.* *It details how it impacts on the people we serve.*

1. Detailed summary of paper contents:

There are three different sources of information contained within the report:

- CHKS Data: July 2020 – June 2021
- CAH ICU ICNARC: 1st April 2021 – 31st December 2021
- SHMI & VLADs: SHMI: July 2020 – June 2021
- Data Quality Assurance: July 2020 – June 2021

- For the reporting period of July 2020 – June 2021, there were 1,183 deaths within the Southern Trust.

- **A red alert has been generated by the Crude Mortality rate compared to both regional and national peers for the Southern Trust, however, these are inclusive of the COVID-19 deaths. The Trust Risk Adjusted Mortality rate indicators, has not generated any alerts and compare favourably with regional and national peers. These exclude COVID-19 deaths. The Risk Adjusted Mortality Indicators offer clear assurance to the Trust.**

- It should also be noted that risk adjusted measures such as RAMI are not designed for pandemic activity such as that observed during 2020. It is anticipated that at least 12 months full year activity will be required for sufficient data to be available to begin considering the development of risk adjusted mortality relating to Covid-19. As a result, the present RAMI measure cannot accurately calculate an expected deaths figure for records with Covid-19 coding using the present methodology. Risk adjusted reporting in this report therefore excludes any activity with Covid-19 diagnoses codes, specifically ICD-10 codes Confirmed Covid-19 U07.1 & Suspected Covid-19 U07.2. *No exclusions are applied to crude mortality indicators*

2. Areas of improvement/achievement:

- The Trust crude mortality rate was 1.50% compared to 1.12% for the 2019/20 period. In comparison with the UK peer, the mortality rate is similar (UK peer 1.48%) whilst the trust RAMI is lower (UK peer 93.39).
  There was a significant increase in mortality for April 2020 before reducing in May and returning to within control limits for June 2020. The Mortality rate increased again in November/December 2020 above control limits (Chart 1 & chart 2, pages 12 & 13) and both episodes reflected deaths from COVID 19. These have been reflected and presented within previous Mortality Reports for the relevant timeframe.

- The RAMI 2019 score for the 2020/21 period was 79.03 compared to 78.83 2019/20. In comparison with the UK peer, the mortality rate is similar (UK peer 1.48%) whilst the trust RAMI is lower (UK peer 93.39). RAMI is rebased each year to address changes in data capture and it is worth noting that the RAMI used in this report Is RAMI 2019.

- The RAMI Risk Adjusted mortality between April and November 2019 notes there were 7 consecutive points below the mean which were noted with special cause variation indicating a significant decrease. This trend has not been maintained and has returned to normal variation.

- The trust monthly RAMI is within the control limits for the period under review; May 2020 reports as highest index score by monthly value (117.53). The lowest RAMI score is observed in March 2020 (64.5). The overall RAMI index score for the trust over the period April 2018 to March 2021 is 81.81. For the 12 month reporting period April 2020 to March 2021 the overall RAMI index score is 79.03. (Chart 3)

- For specialist mortality indicators, there was no statistically significant alerts generated during the analysis period. Note that as numbers of deaths are at low confidence intervals they tend to be wide. Small changes in absolute numbers may lead to large percentage annual change causing some to be presented as a red alert

- The performance in the trust relating to the rate of deaths within 30 days of an emergency admission with a myocardial infarction is lower than peer (trust 0.38%, peer 3.3%) presented in Table 4.

- The performance relating to the rate of deaths in hospital within 30 days of an emergency admission with a stroke was better than peer, (trust 8.5%, peer 11.6%). The overall rate has decreased for this indicator in comparison with the same period last year (9.8% 2019/20) presented in Table 5.

- The rate of deaths for non-elective surgical patients within 30 days of surgery performance is similar in comparison to the previous 12 month period (0.50% 2019/20 to 0.52% 2020/21). There were 38 deaths associated with this indicator. Trust performance compares favourably with the peer (1.6% peer). (Table 6)

- The rate of deaths for elective surgical patients within 30 days of surgery is similar to the previous 12 month period (0.08% 2019/20 to 0.06% 2020/21). There was 1 death associated with this indicator. Trust performance compares favourably with the peer (0.18% peer). (Table 7)

- The rate of deaths in low mortality CCS groups is similar in comparison to the previous 12 month period (0.087% 2019/20 to 0.082% 2020/21). There were 9 deaths associated with this indicator. Trust performance compares positively to peer (0.14% peer) for the analysis period. (Table 8)

- ICNARC outcomes for the period 1st April 2021 to 31st December 2021 indicate that the Trust is performing on par in relation to all other NHS general critical care units peer and all similar peer units (Pages 17 -22).There were no alerts, with the Trust observed percentage lying within the predicted range (95%)

- The overall data quality index score for the trust for the July 2020 – June 2021 period was 95.70. This compared favourably to the NI peer (peer 93.29; note: the data quality index is a composite score made up of a series of data quality indicators including depth and completeness of coding. A score of 100 is the maximum score and is the most favourable position).

- Using both the regional methodology for mortality (SHMI pages 22 – 24) and the national CHKS methodology, the Southern Trust SHMI was "lower than expected" with Daisy Hill Hospital in the "lower than expected group".

3. **Areas of concern/risk/challenge:**

- As previously noted there was a red alert has been generated by the *Crude Mortality rate* compared to both regional and national peers for the Southern Trust, however, these are *inclusive of the COVID-19 deaths*. The Trust *Risk Adjusted Mortality rate* indicators, has not generated any alerts and compare favourably with regional and national peers. *These exclude COVID-19 deaths*. The Risk Adjusted Mortality Indicators offer clear assurance to the Trust.
- There were no significant areas of concern, risk or challenge noted from this quarter.

4. Impact: Indicate if this impacts with any of the following and how:

Corporate Risk Register	no
Board Assurance Framework	no
Equality and Human Rights	no

CHKS
Insight for better healthcare

The Southern Health and Social Care Trust

Quarterly Mortality Review: July 2020 to June 2021

Report to the Governance Committee, 12th May 2022

- CHKS Data: July 2020 – June 2021
- CAH ICU ICNARC: 1st April 2021 – 31st December 2021
- SHMI & VLADs: SHMI: July 2020 – June 2021
- Data Quality Assurance: July 2020 – June 2021

2 About CHKS

CHKS is a leading provider of healthcare intelligence and quality improvement products and services. Over the last 32 years our team of NHS data experts, clinicians and quality managers have worked with more than 400 healthcare organisations around the world to improve population health.

We enable providers and commissioners to make better decisions at patient, service, organisation and population level and deliver sustainable improvements in care quality, patient outcomes and service efficiency along the entire patient pathway.

Our services include:

- **Healthcare benchmarking and analytics** – we identify what to improve and model the impact of change at patient, organisation and population level;
- **Clinical coding, data quality and costing services** – we ensure data used for payment and decision making accurately reflect the care delivered;
- **Care quality, assurance and accreditation** – we work to the latest international standards of best practice within a proven framework of continuous improvement.

Head office:

6190 Knights Court
Solihull Parkway
Birmingham Business Park
Birmingham
B37 7YB
T: 0333 241 2323

www.chks.co.uk

3 Introduction

3.1 Background

The SHSCT Mortality Report is at the core of the trust's clinical and quality indicator suite. The trust continues to develop, refine and validate mortality reporting mechanisms.

The Directorate of Performance and Reform and the Medical Directorate have established a number of matrices which draw upon CHKS benchmarked data in the analysis and review of the raw statistics of hospital deaths.

Death in hospital can be both an accepted fact of medical care delivery and a cause for organizational reflection and continuous assessment. Some unexpected deaths might be prevented if all the factors that contribute to them are better understood.

Hospital death rates, appropriately adjusted for variables such as population characteristics and diagnoses can serve as important quality indicators, and are an essential starting point in a journey to improve care and reduce mortality.

Good governance requires that trust managers and clinicians work together to distinguish between preventable deaths and deaths from other causes.

The mortality review has been designed in response to stakeholder comments which indicated that previous quarterly mortality reports were too detailed but did not provide an easily understandable picture of mortality.

3.2 Interpretation of mortality measures

Hospital Standardised Mortality Ratios (SMRs) are indicators of healthcare quality that measure whether the number of deaths at a hospital are higher or lower than expected based on the risk derived from case mix, given the type of patients admitted to the hospital.

A high SMR does not necessarily mean that there is a quality of care issue, or that unsafe services are being provided. It is not always possible to distinguish between deaths which could potentially have been preventable and those which were not. Therefore, a high SMR is regarded as a trigger for further investigation.

SMRs and mortality rates vary between trusts and fluctuate over time. This is especially true if SMRs or mortality rates are monitored frequently over short periods of time. The degree of fluctuation will be higher with smaller numbers of deaths in shorter time periods, simply because the effect of change is greater when the numbers are smaller. Equally, a single figure cannot be looked at in isolation and

must be examined in the context of a trend, and other sources of information on quality and safety. The two main mortality indicators used by CHKS in this report are as follows:

- Crude mortality – this is the proportion of patients treated in a hospital/site who died. It is calculated as $\frac{Total\ deaths\ x\ 100}{Total\ discharges+deaths}$ and
- Risk-Adjusted Mortality Index (RAMI) – this indicator uses the characteristics of the patients treated in hospital to calculate a number of expected deaths and then compares this to the number of actual (observed) deaths. RAMI is then calculated as $\frac{Observed\ deaths\ x\ 100}{Expected\ deaths}$ and expressed as an index, base 100 e.g. 210 observed deaths vs 200 expected = RAMI 105. If the number of observed deaths is higher than the number of expected deaths, RAMI will be greater than 100; if observed deaths are lower than expected, RAMI will be below 100.

The methodology behind the RAMI is limited to just six factors, each of which is known to have a significant and demonstrable impact on risk of death. They are:

- Age - six groups;
- Admission type - elective or non-elective;
- Primary clinical classification - 260 CCS groups;
- Sex - defaults to female if not known;
- Length of stay - specific groups only; and
- Most significant secondary diagnosis - list covers 90% of all diagnoses mentioned in patients who died.

The first five of these are defined as primary factors. Each is known with greater certainty and recorded with greater consistency than secondary diagnoses. For this reason the methodology uses these factors first. Secondary diagnoses which most significantly and consistently increase risk of death are then also used in the model.

RAMI is rebased each year to address changes in data capture. The RAMI used in this report is RAMI 2019.

3.3Analysis and Reporting

The analysis completed in this report uses the CHKS benchmarking tool (iCompare) using data supplied by the trust, other NI trusts and NHS Digital. This review covers mortality for all admissions in SHSCT for the period July 2020 – June 2021 (inclusive) based on the data extract submitted by the trust in January 2022.

The peer groups used in this review for the purposes of benchmarking trust performance are the NHS England HES Acute Trusts peer and Northern Ireland Health and Social Care Trusts, (see Appendix 3).

Reporting includes funnel plot and statistical process control charts. Funnel plot charts show the volume of activity being analysed (along the x-axis) and the performance against the indicator (along the y-axis) for the trust and comparative peer group sites. The curved lines show the control limits, i.e. which data points are within the expected range of natural variation. Smaller datasets are more prone to the effect of natural variation, so that the control limits narrow as the volume of activity increases.

Statistical process control charts show variation over time. Upper and lower control limits have been included at +/- 3 standard deviations. These show which data points are within the expected range of natural variation. It should be noted that the number of deaths in any given month is small and as such, it is important not to over-interpret fluctuations in the data month on month. In charts, the trust is identified in blue and peers are identified in green.

The benchmark report scorecards included in this report set out the performance of the trust for the reporting period. There are two sets of information to review:

- The change in the trust performance between the two years under review-

Improvement of more than 5%

Stable within ±5%

Deterioration of more than 5%

- Comparison in performance to the peer (HES acute peer). The peer value is the average and the 25th and 75th percentiles are shown. The performance key is:
    - Diamond represents Trust
    - Whiskers either side of Trust represent 95% confidence intervals
    - Vertical dotted line is peer mean
    - Horizontal grey box is peer percentile range from lower quartile to upper quartile
    - Low scores always on left/high scores on right.

All analysis is based on discharge attribution.

It should also be noted that risk adjusted measures such as RAMI are not designed for pandemic activity such as that observed during 2020/21. This is because this activity is not recorded in the reference data to which RAMI makes its adjustments. It is anticipated that at over 12 months full year coded activity will be required for sufficient data to be available to begin considering the development of risk adjusted mortality relating to Covid-19. As a result, the present RAMI measure cannot accurately calculate an expected deaths figure for records with Covid-19 coding using the present methodology. Risk adjusted reporting in this report therefore excludes any activity with Covid-19 diagnoses codes, specifically ICD-10 codes Confirmed Covid-19 U07.1 & Suspected Covid-19 U07.2. No exclusions are applied to crude mortality indicators.

3.4Trigger points

In applying this analysis the following trigger points for further investigation have been agreed (incorporating agreed trigger points with the HSC Board).

- A value higher than the upper confidence limit on a single or multiple occasions;
- A risk adjusted score / index higher than 100 on six or more successive occasions;
- Six or more consecutive increases, regardless of the starting level (a rising trend) across any indicator.

The trust trigger point activation protocol is detailed in Appendix 1.

4 Findings

4.1 Mortality measures

The findings in this section of the report focus on the following measures of mortality:

- Crude mortality including trended in a SPC (statistical process control chart) against the trust's own upper and lower confidence limits;
- CHKS Risk Adjusted Mortality Index (RAMI 2019) including trended in a SPC (statistical process control chart) against the trust's own upper and lower confidence limits;
- The rate of deaths within 30 days of an emergency admission with a myocardial infarction (age 35 to 74);
- The rate of deaths within 30 days of an emergency admission with a stroke;
- The incidence of mortality for non-elective surgical patients within 30 days of surgery;
- The incidence of mortality for elective surgical patients within 30 days of surgery; and
- Rate of deaths in low mortality clinical classification groups.

4.2 Mortality analysis

The following charts, graphs and tables are taken from the CHKS iCompare system, using the trust's own data. This allows the organisation to review key components of its performance either over time in trend analysis or comparatively against peer hospitals.

The SHSCT Mortality Table – UK Peer (Table 1) and the SHSCT Mortality Table – NI Peer (Table 2) show the trust RAMI and mortality rate performance for the trust for the July 2020 – June 2021 reporting period and the same period the previous year. For the reporting period, there were 1,183 deaths; the trust crude mortality rate was 1.50% compared to 1.12% for the 2019/20 period. The RAMI 2019 score for the 2020/21 period was 79.03 compared to 78.83 2019/20.

In comparison with the UK peer, the mortality rate is similar (UK peer 1.48%) whilst the trust RAMI is also lower (UK peer 93.39).

Table 1: SHSCT Mortality, UK Peer, July 2020 – June 2021

Description	Local Numerator	Local Denominator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Performance	25th Percentile	75th Percentile	Alert
Mortality Rate	1183	78704	1.5031%	1.1241%	33.72%	1.4803%		1.3439%	1.8145%	-
RAMI (Risk adjusted mortality index) 2019	816	1033	79.03	78.83	0.24649%	93.39		85.10	101.23	-

The trust crude mortality rate is higher than the NI peer of 1.42%. .While this change creates a 'red' alert, it is in line with UK peers. The crude mortality rate includes Covid 19 deaths. The trust RAMI is lower than the NI peer of 91.37 which excludes Covid 19 deaths.

Table 2: SHSCT Mortality, NI Peer, July 2020 – June 2021

Description	Local Numerator	Local Denominator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Performance	25th Percentile	75th Percentile	Alert
Mortality Rate	1183	78704	1.5031%	1.1241%	33.72%	1.4210%		1.2226%	1.3641%	Red
RAMI (Risk adjusted mortality index) 2019	816	1033	79.03	78.83	0.24649%	91.37		84.95	93.41	-

Table 3 shows that there were 351 recorded deaths with a confirmed Covid-19 diagnosis and 16 with a suspected Covid-19 diagnosis. The SHSCT has had more Covid related deaths in this period than the NI peer.

Table 3: SHSCT Mortality, NI Peer, July 2020 – June 2021

Description	Local Numerator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Alert
Total Deaths with Covid-19	351	351	54	550%	275	-
Total Deaths with Suspected Covid-19	16	16	16	0%	17.8	-
Total Deaths without Confirmed or Suspected Covid-19	816	816	989	-17.5%	1177	-

Chart 1 illustrates the trended monthly average mortality (crude) for the trust for the period July 2018 to June 2021 and shows that performance for the trust falls within the upper and lower control limits up to April 2020 before reducing in May and returning to within control limits for June 2020; mortality rate performance also increases above the upper control limit from November 2020 through to February 2021. The range for the period is between 0.75% (August 2018) and 3.3% (January 2021). *The chart shows significant findings as an upper confidence breach and 'special cause variation' (decrease from April 2019 to November 2019 which was previously reported on), the upper confidence breaches are most likely to be the Covid-19 fatalities previously noted.*

Chart 1: Average Monthly Mortality (Crude) SPC, July 2018 – June 2021

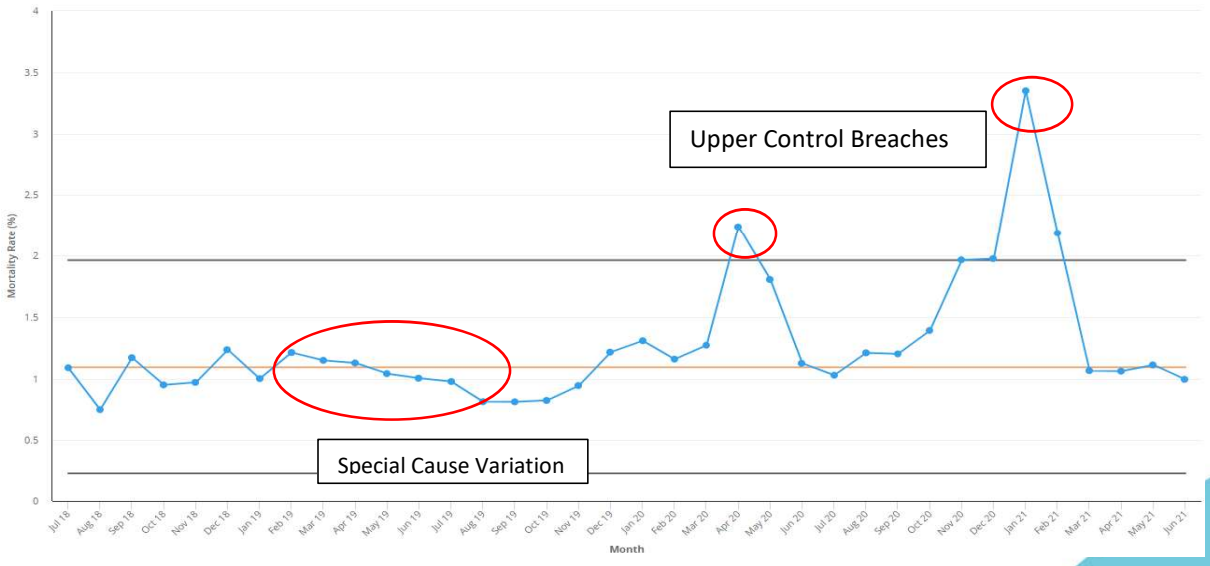
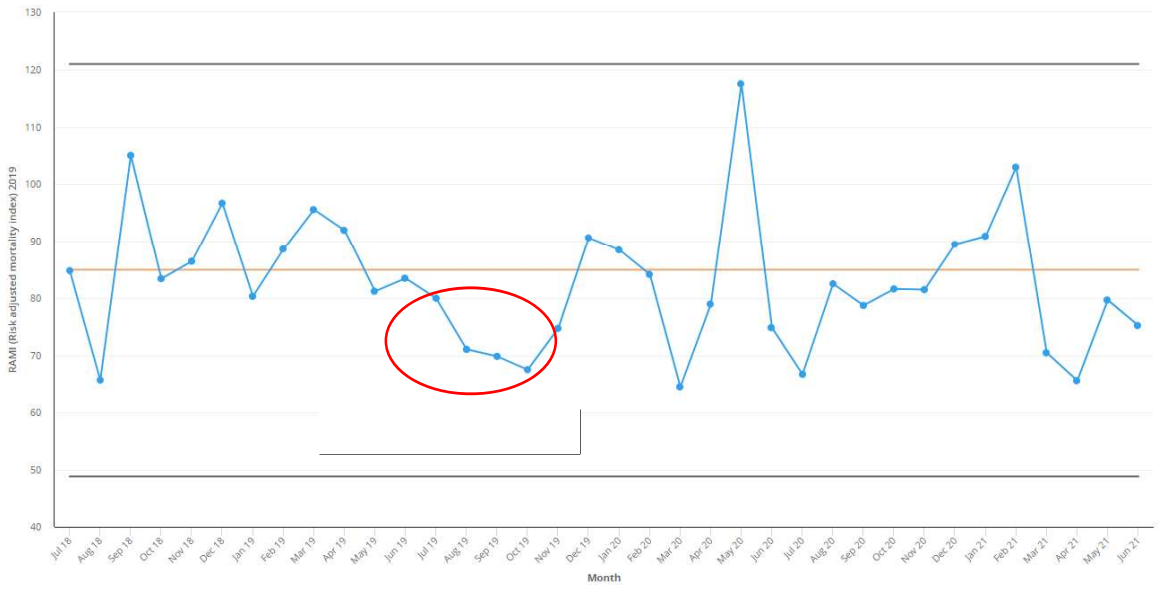


Chart 2 (below) illustrates the trended position for RAMI over the July 2018 to June 2021 period.

Chart 2: Monthly Risk Adjusted Mortality (RAMI) SPC, July 2018 – June 2021

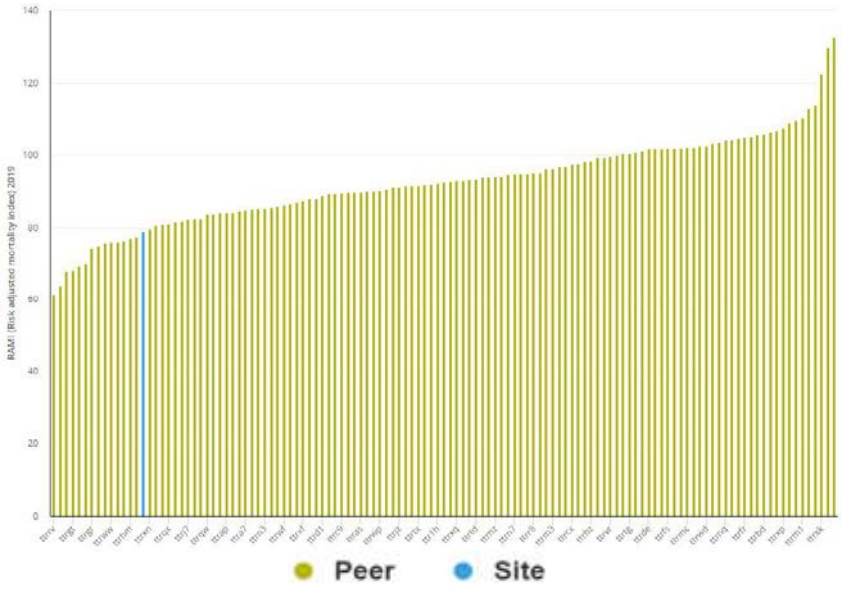


The trust monthly RAMI is within the control limits for the period under review; May 2020 reports as highest index score by monthly value (117.53). The lowest RAMI score is observed in March 2020 (64.5).

The overall RAMI index score for the trust over the period April 2018 to March 2021 is 81.81. For the 12 month reporting period April 2020 to March 2021 the overall RAMI index score is 79.03.

The trust's position relative to the UK HES Acute peer for the July 2020 to June 2021 period is represented by the blue bar in Chart 3 below.

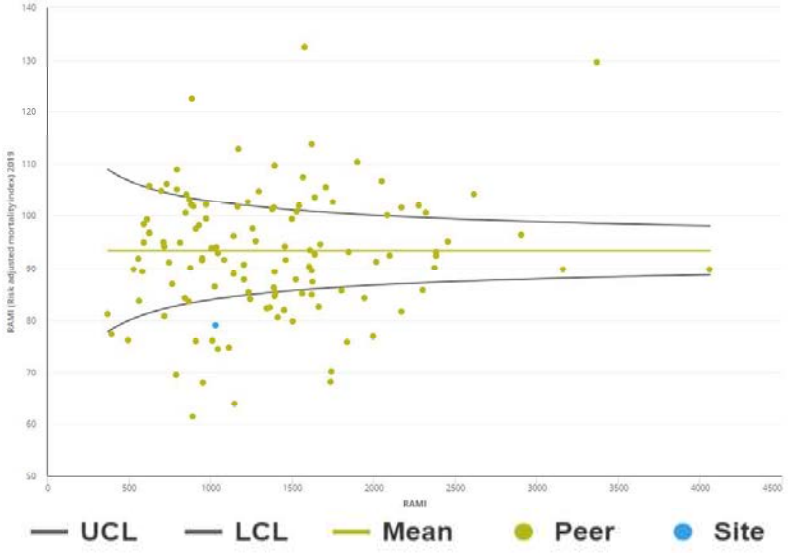
Chart 3: RAMI compared to UK peer, July 2020 – June 2021



In comparison with the UK peer, the trust RAMI score of 79.03 falls into the lower range of the peer.

Funnel plot analysis (see Chart 4 below) shows the trust position relative to individual UK peer sites. HSCB guidelines indicate that a position above the upper confidence limit in a funnel plot would require further investigation; this is not the case for the trust as it is sitting below the peer mean average and lower confidence limit. This means that the Trust has a statistically lower than expected mortality rate.

Chart 4: RAMI funnel plot, UK peer, July 2020 – June 2021



4.3 Specialist mortality indicators

The following section sets out a number of key areas where the incidence of mortality may be exceptional and as such a review of these cases could identify areas of concern and learning for the trust where the rate of mortality is greater than expected. Definitions for these indicators can be found in Appendix 4.

The trust has developed a specialist mortality indicators assurance process which was ratified by the SHSCT Mortality and Morbidity Monitoring Group – see Appendix 5 for further details.
The following tables show trust performance in relation to the peer average (HES Acute peer) for the period July 2020 to June 2021. No statistically significant alerts are generated relating to trust performance for these indicators during the analysis period.

Table 4. Rate of deaths within 30 days of an emergency admission with a myocardial infarction, UK Peer, July 2020 – June 2021

Description	Local Numerator	Local Denominator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Performance	25th Percentile	75th Percentile	Alert
% Mortality in hospital within 30 days of emergency admission with a heart attack (MI) aged 35 to 74	1	260	0.3846%	2.0478%		3.266%		1.9553%	3.781%	-

The performance in the trust relating to the rate of deaths within 30 days of an emergency admission with a myocardial infarction is lower than peer (trust 0.38%, peer 3.3%).

1 death was recorded against this indicator. This case was subject to the Trust M&M screening process, however was not selected for detailed review.
This represented a rate decrease for the trust in comparison with the same period last year (2.0% 2019/20).

Table 5. Rate of deaths in hospital within 30 days of an emergency admission with a stroke, UK Peer, July 2020 – June 2021

Description	Local Numerator	Local Denominator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Performance	25th Percentile	75th Percentile	Alert
Rates of mortality in hospital within 30 days of emergency admission with a stroke	47	553	8.499%	9.790%		11.598%		10.374%	13.732%	-

The performance relating to the rate of deaths in hospital within 30 days of an emergency admission with a stroke was better than peer, (trust 8.5%, peer 11.6%). 47 deaths were recorded against this indicator. The overall rate has decreased for this indicator in comparison with the same period last year (9.8% 2019/20).

There were 47 deaths recorded against this indicator of June 2020 – July 2021, all of these deaths were subject to Trust M&M screening processes, with 10 cases being discussed in detail at a Trust M&M Meetings. For this report there was 18 cases not previously reported on within the last quarterly report - 2 of these cases have Covid-19 noted and therefore learning from these cases is awaited. There was no learning outcomes noted from the other cases reviewed.

Table 6. Rate of deaths for non-elective surgical patients within 30 days of surgery, UK Peer, July 2020 – June 2021

Description	Local Numerator	Local Denominator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Performance	25th Percentile	75th Percentile	Alert
Rate of Mortality in hospital within 30 days of Non elective surgery	38	7246	0.5244%	0.5037%	4.106%	1.6050%		1.2095%	1.8761%	-

The rate of deaths for non-elective surgical patients within 30 days of surgery performance has increased in comparison to the previous 12 month period (0.50% 2019/20 to 0.52% 2020/21).

There were 38 deaths associated with this indicator. Trust performance compares favourably with the peer (1.6% peer).

Of the 38 deaths associated with this indicator, all were subject to Trust M&M screening processes, with 4 waiting to be signed off by an M&M Chair (2 cases with Urology Consultant to review, 1 case with General Surgery and 1 outstanding due to no Gynae M&M Chair however this has been escalated to Divisional AMD).

24 of these cases were discussed in detail at Trust M&M Review Meetings. Following detailed reviews, 18 cases were deemed to have no learning outcomes and care provision was determined to be appropriate. One case is being reviewed as an SAI and at point of writing, remains ongoing.

There was no learning outcomes noted from the **new** cases reviewed at Trust M&M meetings.

Table 7. Rate of deaths for elective surgical patients within 30 days of surgery, UK Peer, July 2020 – June 2021

Description	Local Numerator	Local Denominator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Performance	25th Percentile	75th Percentile	Alert
Rate of Mortality in hospital within 30 days of elective surgery	1	1967	0.05084%	0.06614%		0.16476%		0.06983%	0.20859%	-

The rate of deaths for elective surgical patients within 30 days of surgery has decreased in comparison to the previous 12 month period (0.07% 2019/20 to 0.05% 2020/21).

There was 1 death associated with this indicator. Trust performance compares favourably with the peer (0.16% peer). This case was previously commented on within the last quarterly report.

Table 8. Rate of deaths in low mortality CCS Groups, UK Peer, July 2020 – June 2021

Description	Local Numerator	Local Denominator	Jul 20 - Jun 21	Jul 19 - Jun 20	Change	Peer Value	Performance	25th Percentile	75th Percentile	Alert
Deaths in Low Mortality CCS Groups	9	10989	0.08190%	0.08660%		0.13907%		0.09039%	0.17232%	-

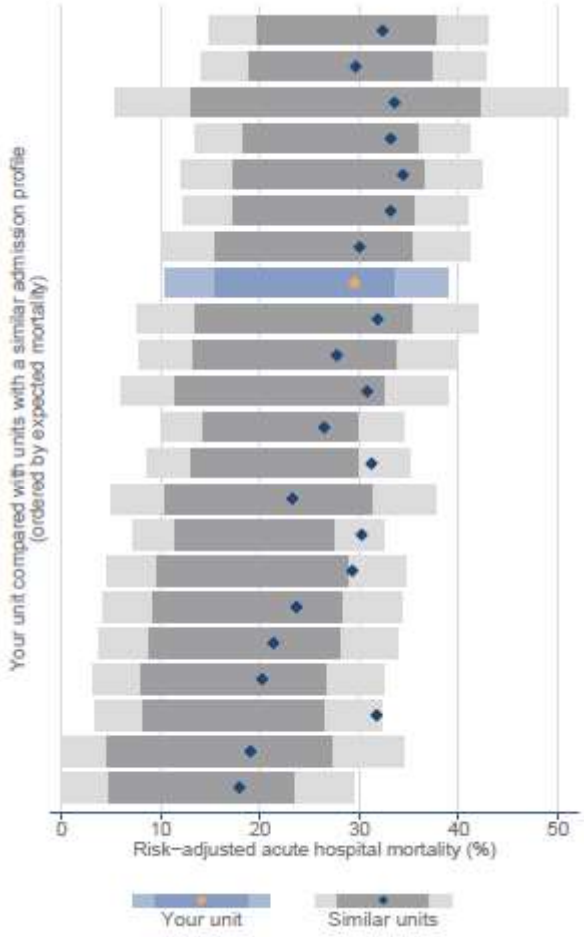
The rate of deaths in low mortality CCS groups is similar in comparison to the previous 12 month period (0.087% 2019/20 to 0.082% 2020/21).

There were 9 deaths associated with this indicator. Trust performance compares positively to peer (0.14% peer) for the analysis period. None of these cases are new cases and have been previously commented on within previous quarterly Mortality reports.

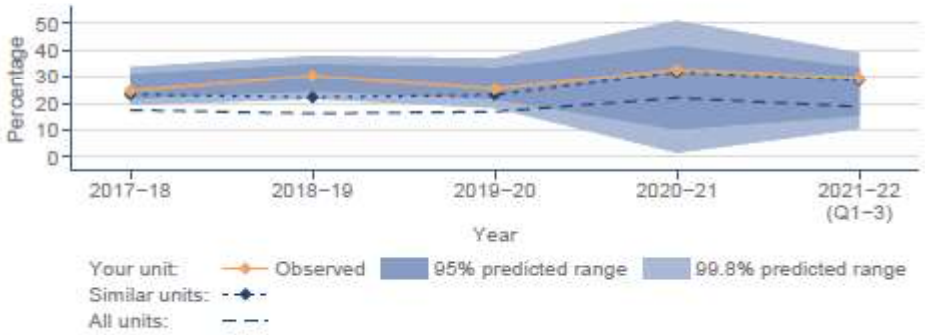
4.4 Intensive Support Unit, Craigavon Area Hospital (1st April 2021 – 31st December 2021)

The Trust participates in a UK wide audit of Intensive Care Outcomes - ICNARC Case Mix Programme (CMP). ICNARC is an audit of patient outcomes from adult, general critical care units (intensive care and combined intensive care/high dependency units) covering England, Wales and Northern Ireland. [Appendix 7]. This information will also feature in the Trust National Audit Assurance Report.

Chart 5: Chart of Risk Adjusted Acute Hospital Mortality – ICNARC 2018 Model [All and Similar Units] Compared with all other NHS general critical care units (1st April – 31st December 2021)



	N	Eligible	Observed percentage	Expected percentage	95% predicted range	99.8% predicted range	
Quarter 1	113	112	21.4	19.7	(12.1, 26.8)	(8.4, 31.5)	
Quarter 2	138	133	27.8	23.8	(10.5, 36.3)	(3.8, 44.4)	
Quarter 3	122	114	39.5	30.5	(12.9, 47.0)	(3.8, 57.4)	
Quarter 4							
Year to date	373	359	29.5	24.6	(15.4, 33.5)	(10.5, 39.0)	

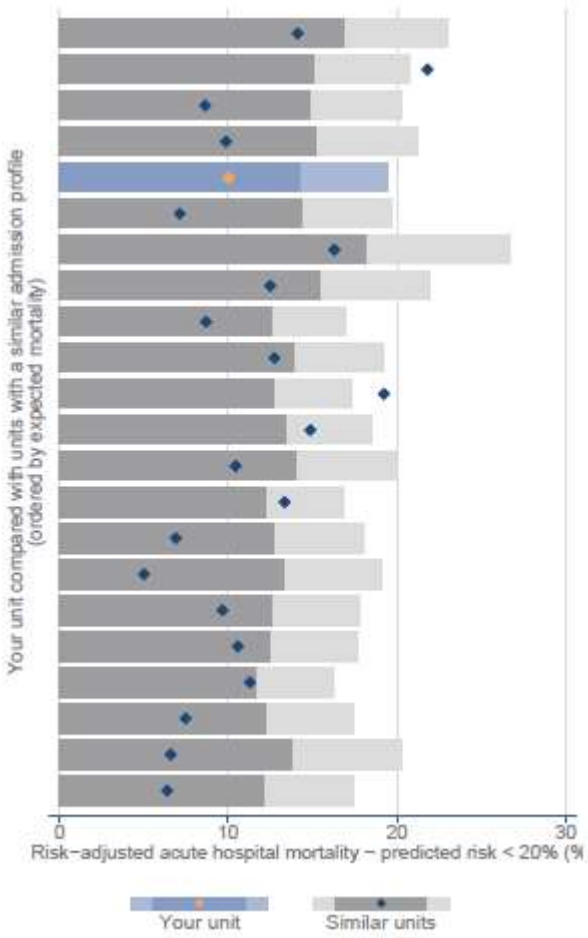


Definition

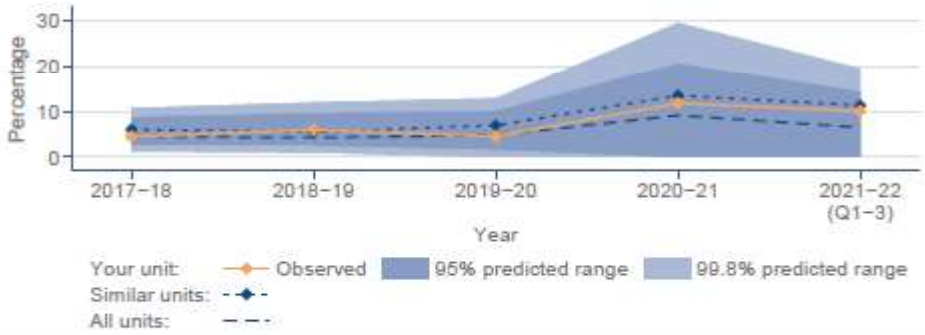
- Eligible: All critical care unit admissions, excluding readmissions, patients dead on admission and those admitted to facilitate organ donation
- Observed percentage: The percentage of eligible admissions that died before ultimate discharge from acute hospital
- Expected percentage: The expected percentage of acute hospital deaths among eligible admissions, calculated as the mean predicted risk of death from the ICNARC$_{H-2018}$ model for eligible admissions to your unit
- Predicted range: We expect a unit's observed percentage to lie within the 95% predicted range 19 times out of 20 and within the 99.8% predicted range 998 times out of 1000

Chart 5 and the charts above illustrate the CAH ICU ICNARC 1st April – 31st December 2021 score on a plot compared to all other ICNARC participating units. The position of the Southern Trust is indicated by the orange marker and compares on par to peer sites. The Trust observed percentage lies within the 95% predicted range.

Chart 6 – Chart of Risk Adjusted Acute Hospital Mortality [Predicted Risk <20%) – ICNARC 2018 Model [All and Similar Units] Compared with all other NHS general critical care units. 1st April – 31st December 2021



	N	Eligible	Observed percentage	Expected percentage	95% predicted range	99.8% predicted range
Quarter 1	113	80	6.3	5.5	(0.4, 10.5)	(0.0, 14.3)
Quarter 2	138	79	10.1	6.3	(0.0, 16.8)	(0.0, 24.9)
Quarter 3	122	60	15.0	8.5	(0.0, 24.9)	(0.0, 37.5)
Quarter 4						
Year to date	373	219	10.0	6.6	(0.0, 14.2)	(0.0, 19.5)



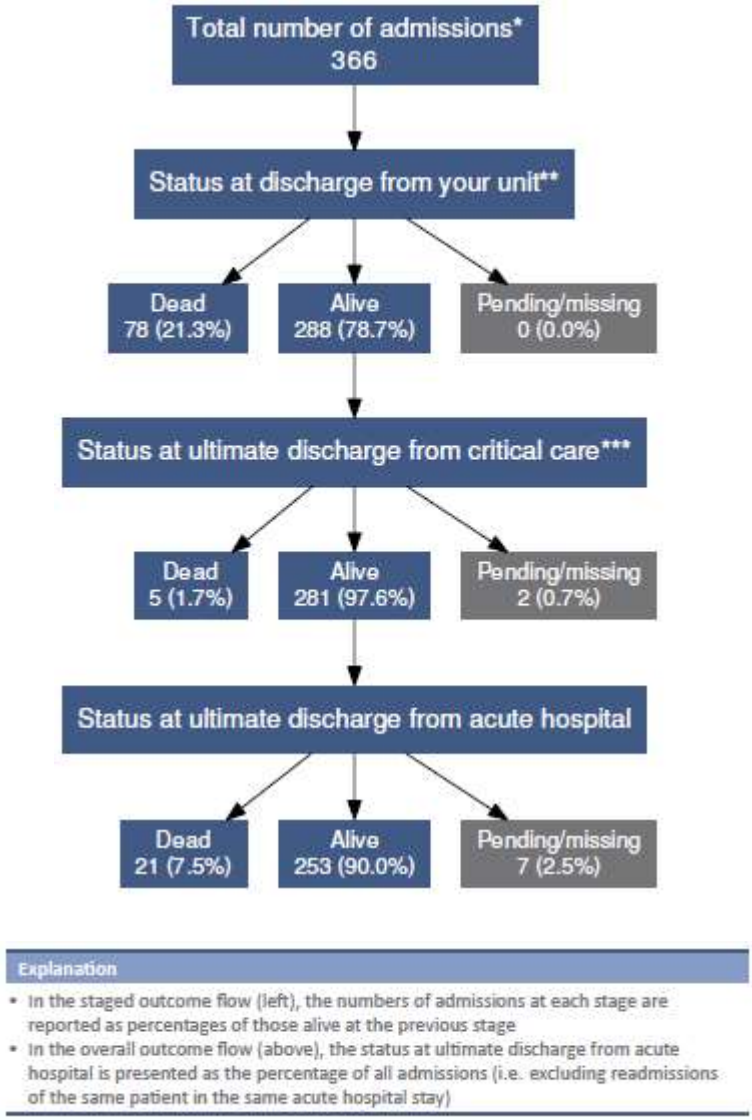
Your unit: Observed 95% predicted range 99.8% predicted range
Similar units:
All units:

Definition

- Eligible: All critical care unit admissions with a predicted risk of death < 20% on the ICNARC$_{H-2018}$ model, excluding readmissions, patients dead on admission and those admitted to facilitate organ donation
- Observed percentage: The percentage of eligible admissions that died before ultimate discharge from acute hospital
- Expected percentage: The expected percentage of acute hospital deaths among eligible admissions, calculated as the mean predicted risk of death from the ICNARC$_{H-2018}$ model for eligible admissions to your unit
- Predicted range: We expect a unit's observed percentage to lie within the 95% predicted range 19 times out of 20 and within the 99.8% predicted range 998 times out of 1000

Chart 6 and the charts above illustrate the CAH ICU ICNARC April 2021 – December 2021 score on a plot compared to other similar ICNARC participating units. The position of the Southern Trust is indicated by the orange marker. This shows that the Trust lies within the 95% predicted range.

Chart 7 – below provides detailed outcomes for admission into ICU from 1st April – 31st December 2021



The above chart gives comprehensive and detailed data on the admissions and outcomes of those in the Southern Trust ICU throughout 1st April – 31st December 2021.

4.5 Summary Mortality Hospital Information (July 2020 – June 2021)

The Summary Hospital-level Mortality Indicator (SHMI) compares the actual number of patients who die following hospitalisation at a Trust, with the number that would be expected to die on the basis of average Northern Ireland figures, given the characteristics of the patients treated there. SHMI analysis is provided to all HSCTs by the Department of Health Information Analysis Directorate.

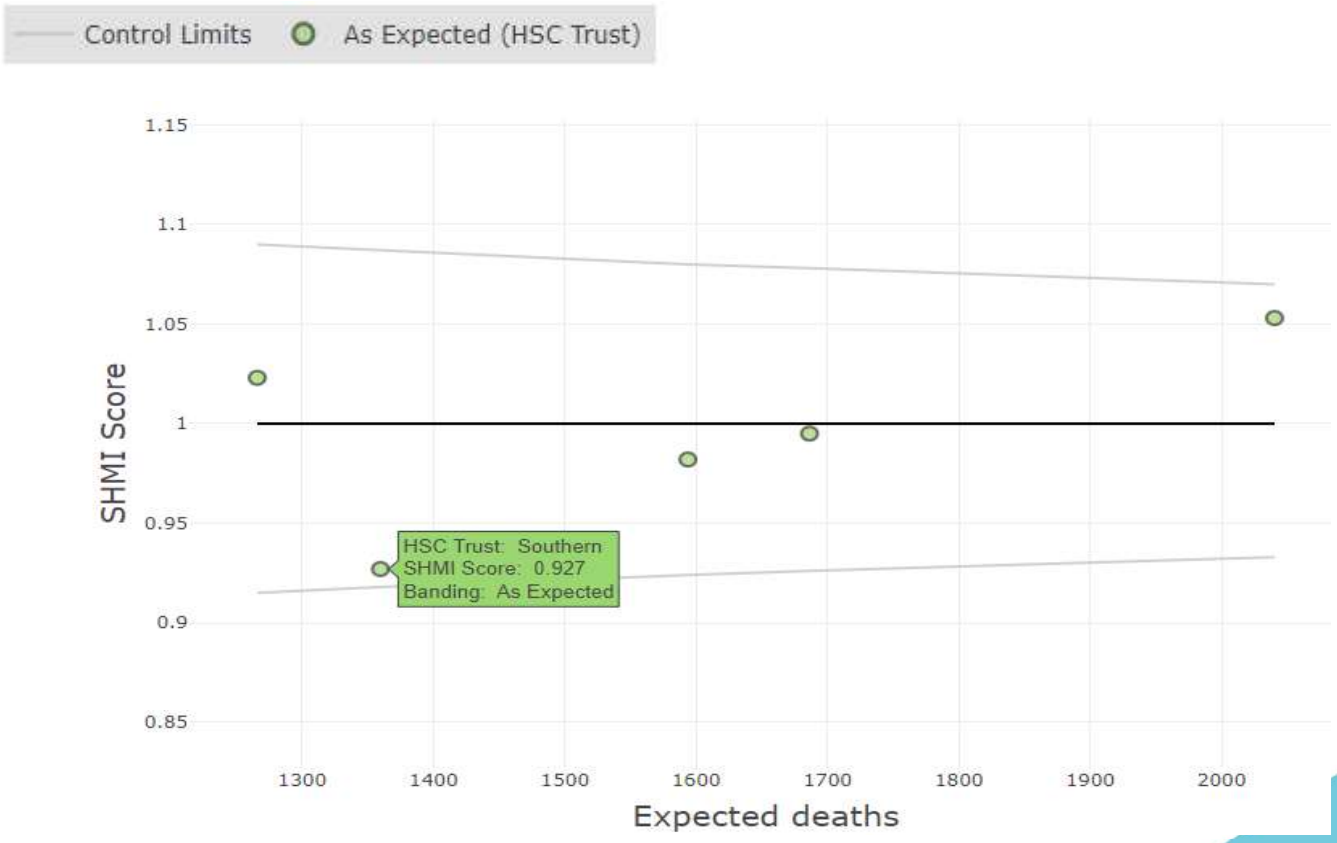
For any given number of expected deaths, a range of observed deaths is considered to be 'as expected'. If the observed number of deaths falls outside of this range, the Trust in question is considered to have a higher or lower SHMI than expected.

The SHMI includes deaths which occur in hospital or within 30 days of discharge and is calculated using Patient Administration System (PAS) data linked to General Registry Office (GRO) death registrations data.

The expected number of deaths is estimated using the characteristics of the patients treated; age, sex, method of admission, current and underlying medical condition(s). It covers patients admitted to hospitals in Northern Ireland who died either while in hospital or within 30 days of being discharged.

Scatter plots showing results at Trust and Hospital Level are included below. As shown on the chart, the Southern Trust overall has a risk adjusted mortality rate that significantly lies below the expected range.

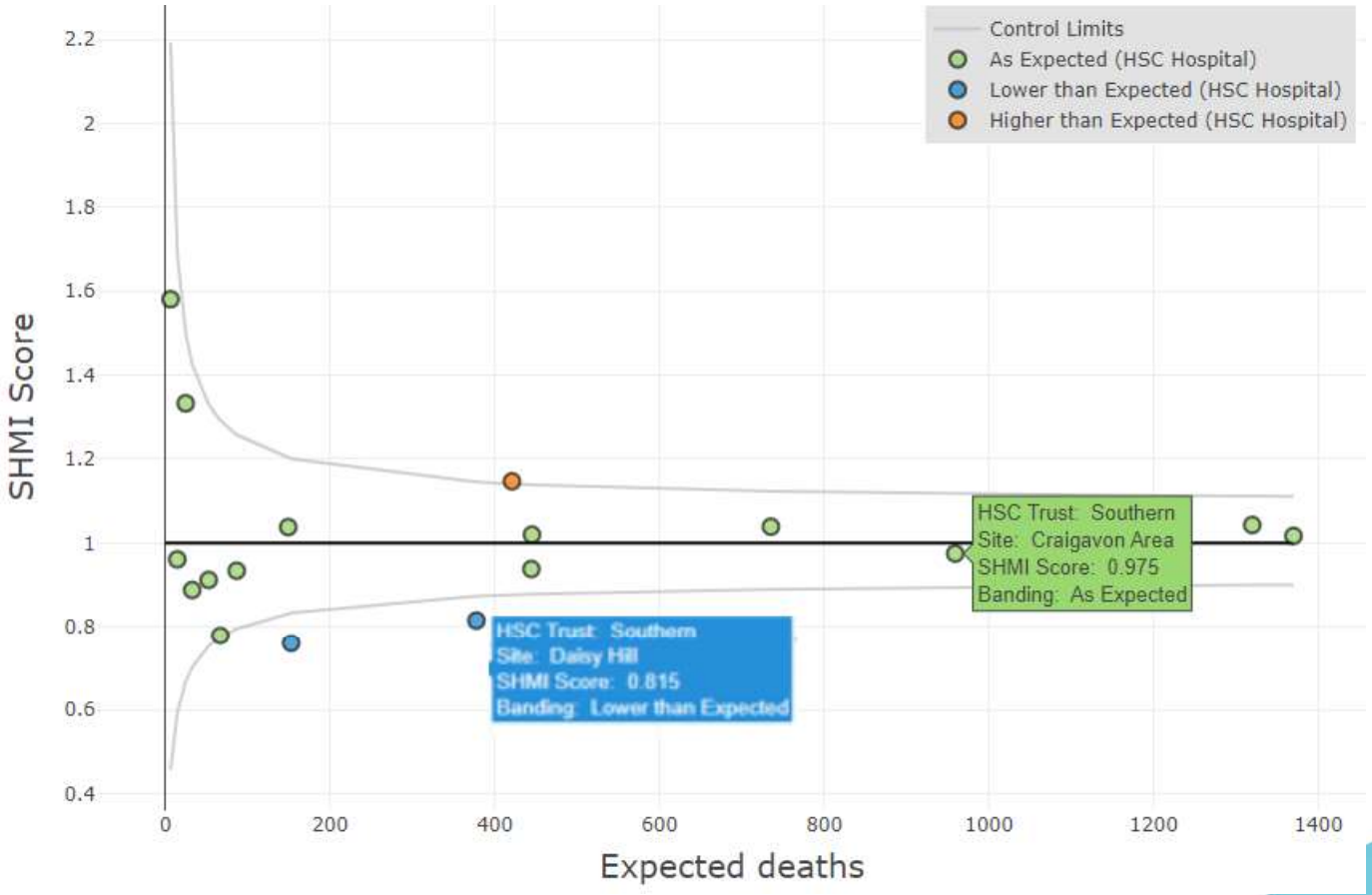
Chart 8 – Funnel Plot of Summary Hospital Level Mortality Indicator [Trust Level] July 2020 – June 2021



HSC Trust	Deaths	Risk	SHMI Score	Admissions	SHMI Banding
Belfast	2,148	2,040	1.053	60,233	As Expected
Northern	1,678	1,686	0.995	42,693	As Expected
South Eastern	1,565	1,593	0.982	41,419	As Expected
Southern	1,260	1,359	0.927	43,324	As Expected
Western	1,295	1,265	1.023	36,992	As Expected

The funnel plot and table above illustrates the Trust score compared to all other NI Health and Social Care Trusts. The position of the Southern Trust is labelled on the funnel plot with all Trusts presenting as expected.

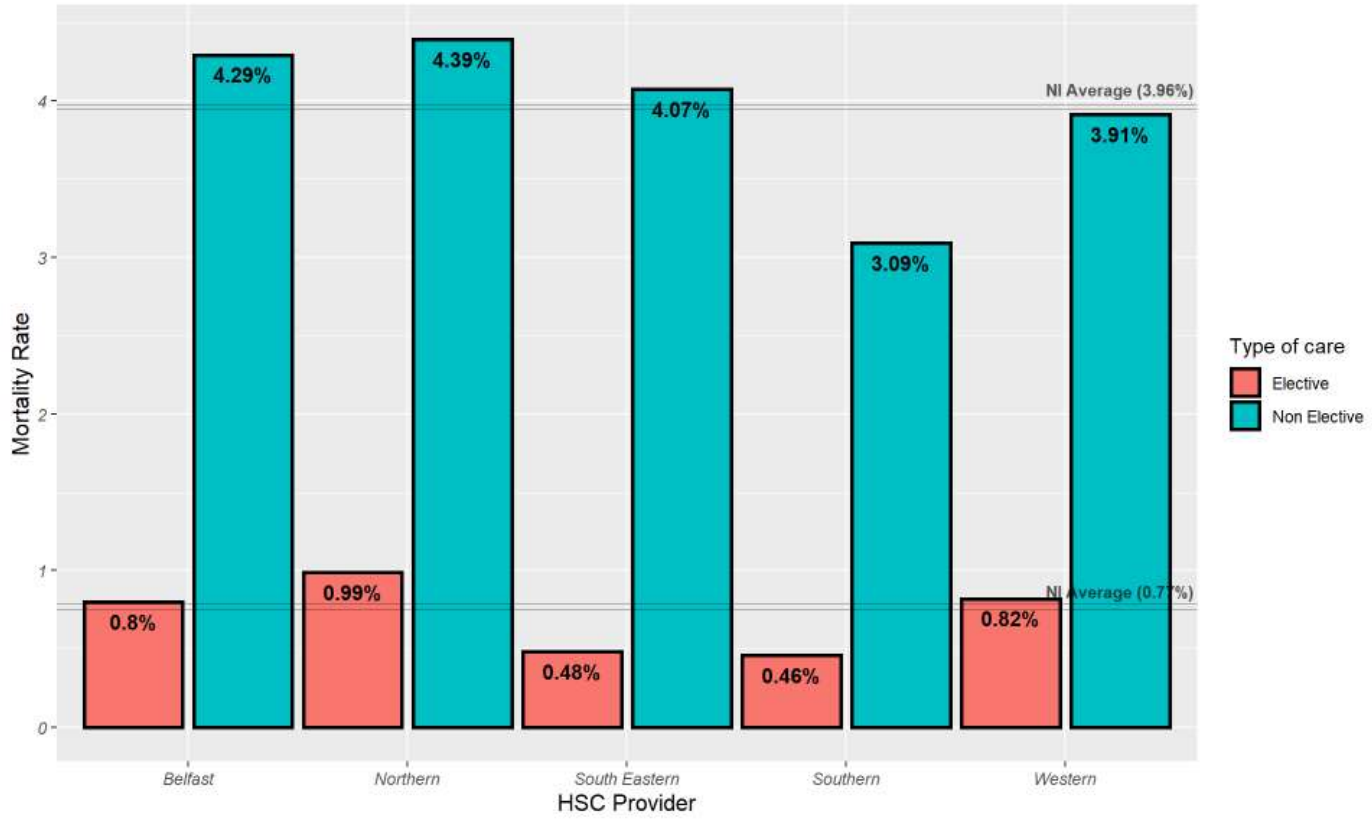
Chart 9 – Funnel Plot of Summary Hospital Level Mortality Indicator [Hospital Level] July 2020 – June 2021



Southern	Craigavon Area	935	959	0.975	27,993	As Expected
Southern	Daisy Hill	308	377	0.815	14,404	Lower than Expected

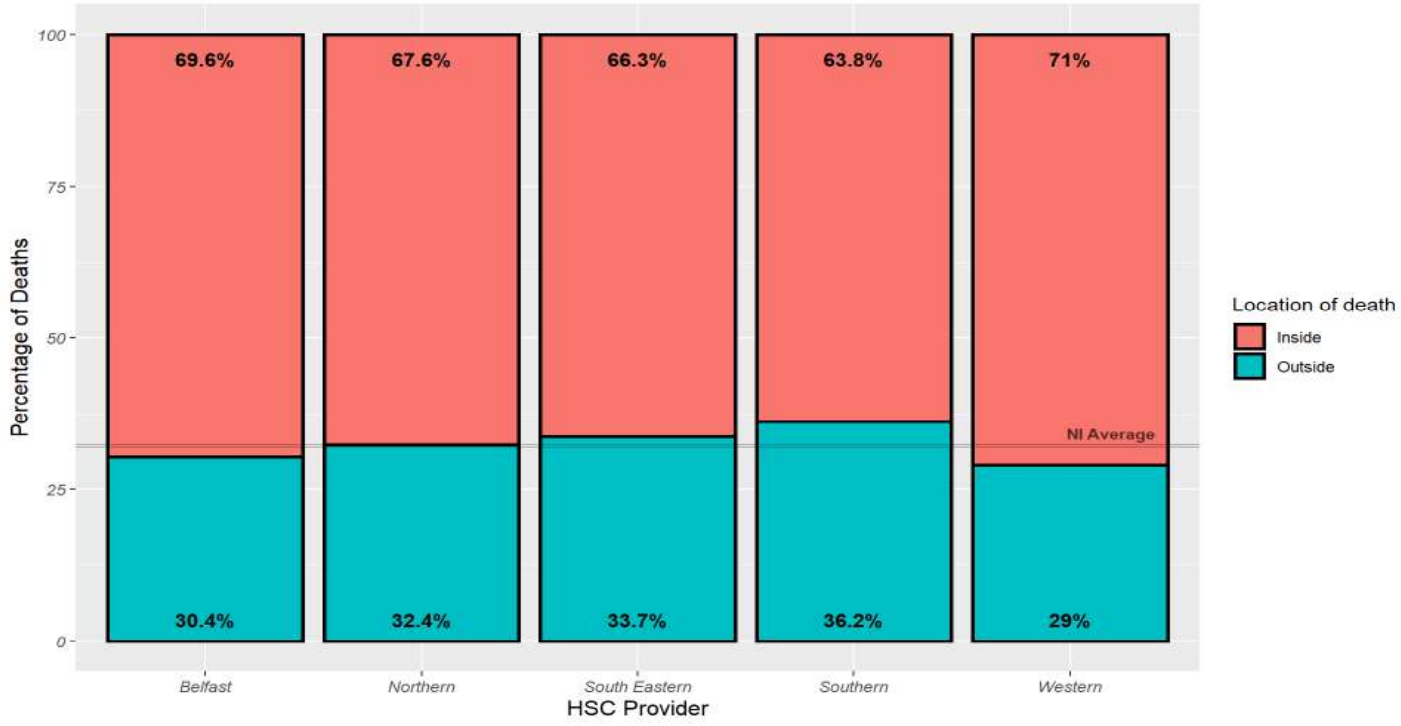
Chart 9 illustrates the Trust Hospitals score on a funnel plot. The position of two Hospitals in the Southern Trust are labelled, with Craigavon Area Hospital 'as expected' compared to peer organisations, with Daisy Hill Hospital SHMI score 'lower than expected' as also presented on the table above.

Chart 10 –Summary Hospital Level Mortality Indicator – Percentage of Deaths Elective / Non-Elective Care July 2020 – June 2021



The chart above indicates Southern Trust performance compared with other NI Trusts with regards elective and non-elective deaths. The Southern Trust ranks lower than average for both elective and non-elective deaths for the period. Trust non-elective (3.09%) and elective (0.46%) deaths are the lowest for the region.

Chart 11 –Summary Hospital Level Mortality Indicator – Location of Patient Deaths July 2020 – June 2021



The chart above indicates the Southern Trust's position regarding the location of patient deaths (i.e. inside and outside of hospital). This chart shows the percentage of deaths in each category. The rate of deaths occurring outside of hospital is higher in the Southern Trust than in the other NI HSC Trusts (Southern Trust 36.2%). The Southern Trust has the least number of deaths inside hospital (63.8%) in comparison with its peers. Several factors will influence the Trust's ratio of in-hospital and outside hospital deaths, including support for palliative care services at home and Acute Care at Home services which are embedded within the Trust.

Chart 12 –Summary Hospital Level Mortality Indicator – Percentage of total deaths coded as Palliative July 2020 – June 2021

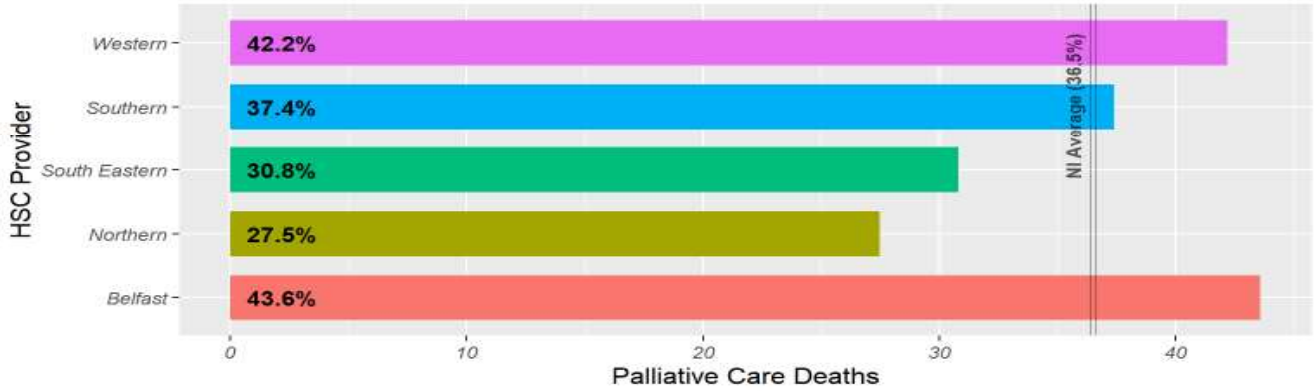


Chart 12 highlights the total percentage if deaths coded as Palliative; this considers deaths that occurred **both** in and outside of hospital settings. The Southern Trust percentage (37.4%) is higher than the regional average (36.5%).

4.6 Variable Life Adjusted Displays (VLADS)

A VLAD is a visual representation of treatment outcomes for selected diagnosis groups which itself is a subset of the SHMI methodology. It displays trends over time within a hospital and identifies unexpected runs of outcomes. Each plotted point on the line represents an episode of care. The outcome (0 = Survived, 1 = Died) of that episode is subtracted from the expected score for that episode (Risk). If a patient survives, the line moves up, if a patient dies, the line moves down. The extent of movement up or down is dependent on the difference between the expected and the observed outcomes. If any chronological run of outcomes is greater than is deemed statistically probable, the line will move above or below its control limit and the chart will flag this as a control limit breach. These charts can be created for any of the 140 SHMI diagnosis groups but currently are created for 11 SHMI Diagnosis groups which show high levels of activity and SHMI Model stability by the Department of Health Information Analysis Directorate. The 11 groups are listed below:

- Septicaemia
- Cancer of Bronchus
- Secondary Malignancies
- Fluid and Electrolyte Disorders
- Acute Myocardial Infarction
- Pneumonia
- Acute Bronchitis
- Gastrointestinal Hemorrhage
- Acute and Unspecified Renal Failure
- Urinary Tract Infection
- Fractured Neck of Femur (Hip)

The below table indicates the VLAD that experienced control limit breaches for SHMI group during this reporting period. None of the remaining VLADs experienced any breaches during the reporting period July 2020 – June 2021

SHMI Group	SHMI Description	Upper Limit Breaches	Lower Limit Breaches
73	Pneumonia (excluding TB/STD)	1	0

Chart 14 – Variable Life Adjusted Display Control Limit Pneumonia (excluding TB/STD) – June 2020 – July 2021

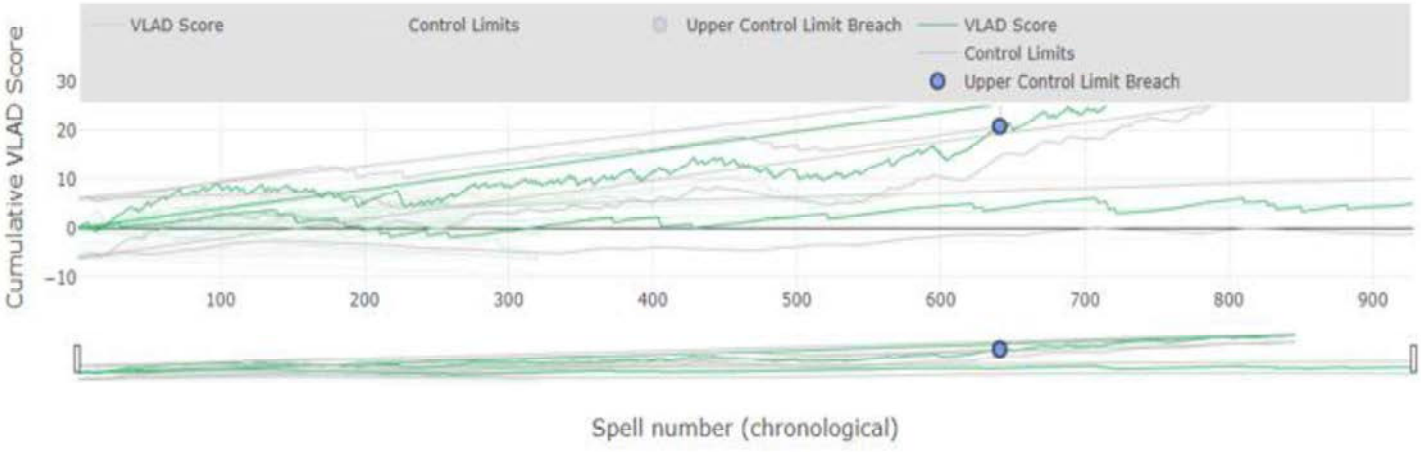


Chart 14 above details the upper limit breach regarding Pneumonia (excluding TB/STD) which occurred in the case of one patient within this reporting period.

4.7 Data quality assurance

The analysis of any case mix / risk adjusted scoring relies heavily on the accuracy and completeness of the coded data. The data quality index within iCompare is derived from a number of indicators including the volume of un-coded activity and the depth of coding as more codes can give a more comprehensive view of the individual patient's condition and treatment.

A number of indicators are monitored against the peer in relation to coding quality; these are:

- Trust data quality index score;
- Blank (un-coded) diagnosis rate;
- Depth of coding, (the average number of diagnoses recorded against each episode of care);
- Use of palliative care diagnosis code Z51.5

The overall data quality index score for the trust for the July 2020 – June 2021 period was 95.70. This compared favourably to the NI peer (peer 93.29; note: the data quality index is a composite score made up of a series of data quality indicators including depth and completeness of coding. A score of 100 is the maximum score and is the most favourable position).

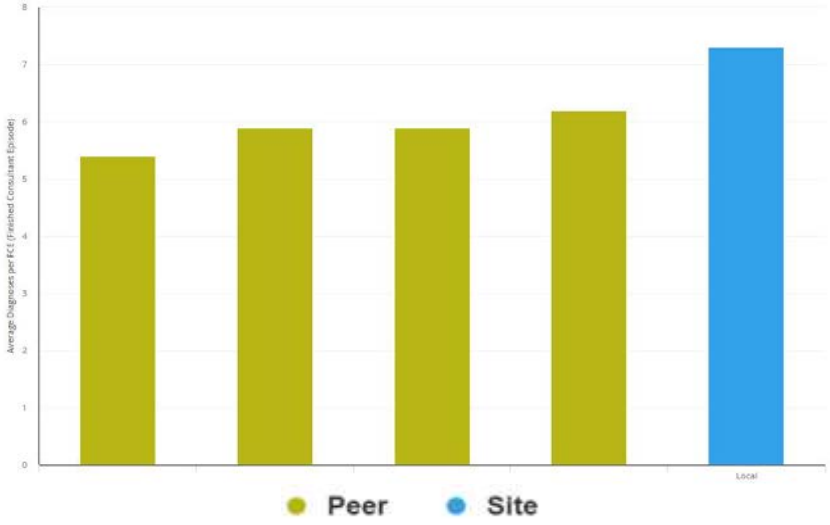
Chart 5a. Trust data quality index by month compared to NI peer, July 2020 – June 2021

Chart 5b. Trust % blank diagnosis codes (Finished Consultant Episode), NI peer comparison, July 2020 – June 2021

Chart 5a shows that the trust data quality index score is higher over the analysis period in comparison with peer. Chart 5b shows higher levels of % blank diagnosis codes to peer throughout reporting period with the exception of March 2021.

In relation to depth of coding, Chart 6 shows the trust average diagnosis codes are highest compared to NI peers for the analysis period (trust depth of coding is 7.3 for the July 2020 – June 2021 period, peer 5.8).

Chart 6. Average diagnosis codes per FCE, NI peer, July 2020 – June 2021



The final data indicator reviewed relates to the level of palliative care codes associated with the caseload of the trust. Consistent and appropriate use of palliative care codes are important to ensure that differences in performance to the peer are not due to variation in recording practices. The following table highlights the trust position is higher than the NI peer for the percentage of episodes with a palliative care code and the percentage of deaths with a palliative care code.

Table 8. Palliative care coding, July 2020 – June 2021

Indicator	Southern Trust	Benchmark NI Peer
Number of FCEs with palliative care code Z51.5	2734	N/A
% of all episodes with palliative care code	2.3%	1.2%
FCE deaths in hospital with palliative care code	455	N/A
FCE deaths with palliative care code	38.72%	34.52%

5 Appendices

Appendix 1. Trust trigger point protocol

The HSCB have defined the following trigger points which would suggest that there is a high possibility that the pattern of data has not arisen by chance alone.

- The Risk Adjusted HSMR score if higher than the upper control limit on a single occasion
- The Risk Adjusted HSMR score is higher than 100 on six or more successive occasions
- The trend of Risk Adjusted HSMR scores shows six or more consecutive increases, regardless of the start level.

Trigger Point Escalation

For HSCB Board Regional Mortality Report the following process will be followed by the Trust Medical Director/Director of Public Health:

- Inform HSCB/Trust Chief Executive and relevant members of HSCB/Trust SMT
- Liaise with Trust Medical Director to establish a HSCB SMR Incident Team
- Inform Chief Medical Officer and t
- he DHSSPS through the early alert system
- Report progress to the HSCB and Trust SMT, Governance Committee and Board
- Escalate immediate concerns to Chief Executive Level as and when required.

For Internal Patient Safety Mortality Review/ Clinical Specialty Mortality Review the following process will be followed by the Trust Medical Director.

- Inform Trust Chief Executive and relevant members of Trust SMT
- Escalate immediate concerns to Chief Executive Level as and when required.

Review Structure

For HSCB Board Regional Mortality Report a SMT Incident Team will be established.

For internal Reports the Trust M&M Oversight Group will establish a SMR Response team.

Actions to be undertaken

Step 1 Check for data analysis errors

- Was raw data from the correct data period used?
- Is any raw data missing?
- Was additional data included in error?
- Were the correct expected death rates applied?
- Was the right peer group used as the comparator?

Step 2 Check for artefacts, specifically

- Did the data quality change significantly compared to the previous period or compared to other Trusts in NI/peer?
- Did the Trust change other aspects of its coding practice?
- Did any new specialised units open or close in the Trust since the last reporting period?
- Did the denominator change significantly since the last reporting period?

Step 3 Check the source of the trigger, specifically

- Is it a generalised increase in deaths, or limited to 1 or 2 specialties?
- If limited, have there been any special features or changes in those areas that might explain the change in SMR?

Step 4 Check other measures of quality and safety of care in the areas affected, specifically:

- What do other assurance systems show, e.g. M and M meetings, clinical audits, nutritional audits, environmental cleanliness audits, Confidential Enquiry reports or Sentinel audits?
- Has there been any notable change in adverse events or complaints?
- Has there been any increase in HCAIs [as a proxy for good care]?
- Have there been any concerns about the performance of individual medical, nursing or other staff?
- Have there been any qualitative concerns raised about safety/quality?

Step 5 Instigate more detailed analysis and monitoring, including, but not limited to:

- Senior doctors, nurses/other relevant staff review a substantial sample of deaths including coding of these details. Widen the size of the review if the first phase identified cause for concern [This may be done by staff external to the Trust]
- Conduct short, immediate specific audits to examine any areas of concern in more detail
- Monitor SMRs more frequently or at a more detailed level where valid

Step 6 Address any issues identified, specifically

- The Trust SMR Response Team will develop and implement an action plan to ensure that all identified issues are addressed. They will report to the Safety Monitoring Committee and HSCB Incident Team [where appropriate].

Step 7 Next Steps

- If SMRs do not improve, or further analysis identified other substantive issues of concern, the situation will be escalated to Chief Executive level.

Appendix 2. Funnel Plots & Statistical Process Control Charts

The funnel plot shows the distribution of RAMI scores of the peer group, and includes confidence limits at 99.8%. A RAMI score outside the confidence limits is unlikely to have arisen due to normal variation or fluctuation. Instead, it is considered to be a 'special cause' variation which requires further investigation.

A rising trend associated with trended values, or persistently higher RAMI or other score that is still within confidence limits, is also considered to be unlikely to have arisen by chance, and therefore would require further investigation.

SPC charts compare performance of a single Trust over time. They therefore do not provide any assurance of performance relative to other sites. They need an absolute minimum of 1 years' worth of data. The control limits are centred around the Trust mean and set to 3 standard deviation above and below.

Appendix 3. CHKS Top Hospital Peer

The 'CHKS Top Hospital Peer' is based on the evaluation of 22 indicators of clinical effectiveness, health outcomes, efficiency, patient experience and quality of care. Peer hospitals included are:

West Suffolk NHS Foundation Trust

Shrewsbury And Telford Hospital NHS Trust

Surrey And Sussex Healthcare NHS Trust

East Cheshire NHS Trust

Homerton University Hospital NHS Foundation Trust

Royal Surrey County Hospital NHS Foundation Trust

Kingston Hospital NHS Foundation Trust

Western Sussex Hospitals NHS Foundation Trust

Ashford And St Peter's Hospitals NHS Foundation Trust

Airedale NHS Foundation Trust

South Warwickshire NHS Foundation Trust

Norfolk And Norwich University Hospitals NHS Foundation Trust

Taunton And Somerset NHS Foundation Trust

Wrightington, Wigan And Leigh NHS Foundation Trust

Dorset County Hospital NHS Foundation Trust

Weston Area Health NHS Trust

Harrogate And District NHS Foundation Trust

Southern Health and Social Care Trust (*Note: excluded as a peer in analysis*)

Chelsea And Westminster Hospital NHS Foundation Trust

Northumbria Healthcare NHS Foundation Trust

Wirral University Teaching Hospital NHS Foundation Trust

Bedford Hospital NHS Trust

The Hillingdon Hospitals NHS Foundation Trust

Cambridge University Hospitals NHS Foundation Trust

Poole Hospital NHS Foundation Trust

Imperial College Healthcare NHS Trust

Yeovil District Hospital NHS Foundation Trust

The Dudley Group NHS Foundation Trust

The Royal Bournemouth And Christchurch Hospitals NHS Foundation Trust

Gateshead Health NHS Foundation Trust

Countess Of Chester Hospital NHS Foundation Trust

Gloucestershire Hospitals NHS Foundation Trust

The Whittington Hospital NHS Trust

The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust

Burton Hospitals NHS Foundation Trust

Derby Teaching Hospitals NHS Foundation Trust

George Eliot Hospital NHS Trust

Barking, Havering And Redbridge University Hospitals NHS Trust

Salford Royal NHS Foundation Trust

West Hertfordshire Hospitals NHS Trust