Urology Services Inquiry

USI Ref: Notice 68 of 2022

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Note: S21 Notice No. 68 of 2022 can be found at WIT-82399 to WIT-82657.
Addendum No. 1 can be found at WIT-98807 to WIT-98808.
Annotated by the Urology Services Inquiry.

Addendum Witness Statement of: MR AIDAN O'BRIEN

I, Aidan O'Brien, wish to make the following statement as an addendum to my existing response, dated 2 November 2022 and addendum dated 31 July 2023.

Section 1 – The Retained Swab, DARO and Outpatient Waiting Times

1. At paragraphs 132 to 135 of my witness statement of 02 November 2022, I related the concerns that I had concerning DARO (Discharge Awaiting Results – Outpatients) [WIT-82447 to WIT-82448]. At paragraph 135, I referred to email correspondence on 06 February 2019 when I was advised for the first time that any patient who had any investigative test requested on or after completion of a clinical episode, was not to be placed on any waiting list until after the result or report of the requested investigation was reviewed by the requesting clinician, and even when that requesting clinician had already determined the next step in the patient's management at the time of requesting the investigation [AOB-07566 to AOB-07567]. I was alarmed to learn that patients were being completely discharged from the service even though the clinician had already determined the next step in the patient's management and requested that it would be implemented. As exemplified by the case which I described in my email dated 06 February 2019 the report of the CT scan which had been requested was important, but of secondary importance to review of the patient. I was most concerned to learn that DARO would have prevented the patient being placed on the waiting list for review until the report of the scan had been reviewed. I was concerned that test results would not be viewed for whatever

reasons and patients would not be reviewed at all as a consequence of having been discharged from the service.

2. Since then, I have reviewed the disclosure from the Public Health Agency (PHA). I have appreciated that the genesis of DARO lay in the Findings of the RCA of SAI Ref-514 dated October 2010; the case of the retained swab relating to Patient 95 [PHA-00616]. The report recommended a more robust and reliable system of counting and for accounting of all swabs used during operative procedures to minimise the risk of recurrence of having a swab retained, and that all outpatient waiting times be reduced [PHA-00626 to PHA-00627].

3. Dr Diane Corrigan, Consultant in Public Health Medicine with the PHA, communicated by email in April 2011 with Dr McAllister, the author of the Findings of the RCA, advising that she knew that outpatient review appointments were behind in general, but that she had been unaware that:

"*something like a first review post major complex cancer surgery could be deferred from early Dec and not yet seen by the following July"* [PHA-00630 to PHA-00631].

4. She proceeded to raise her concern that test results were not being reviewed until patients were being reviewed, as had been reported in the Findings of the RCA.

5. Dr Corrigan subsequently wrote to Ms Debbie Burns, then Assistant Director of Clinical & Social Care Governance at the Southern Trust, in November 2011 [PHA-00632 to PHA-00633]. In her letter, she wrote that the:

"RCA report identifies that, due to a backlog in outpatient reviews, in fact the patient was not seen at outpatients in the 12 months after surgery, at which stage she was admitted as an emergency. The recommendation relating to this issue was that outpatient backlog reviews should be cleared. This recommendation is reasonable, albeit not necessarily easy for the Trust to implement given the resources required to do so. However, this aspect of the SAI does raise

a wider cause for concern which has not been addressed directly in the RCA or the recommendations".

6. Dr Corrigan proceeded to enquire of Ms Burns whether the issue of reviewing test results had been taken forward:

"*for example by considering whether there is a need for a formal Trust policy, such as review of all test results by medical staff before filing, whether or not the patient is awaiting outpatient review."*

7. In an unsigned letter of 02 August 2012, probably from Ms Margaret Marshall [PHA-00639], Dr Corrigan was advised that:

"*The communication system used within the Trust to manage patient appointments and patient episodes, including the Discharge of patients awaiting results is PAS. PAS provides a function to alert Secretaries of patients who are discharged but still await results. This function has now been activated within the PAS system and Consultant's Secretaries have been trained in the Management of the function."*

8. In a further communication by email on 23 April 2014, addressed to Ms Margaret Marshall and to Dr John Simpson [PHA-00652], Dr Corrigan advised that:

"My reading of this is that these arrangements only deal with patients discharged from the ward, so would not apply to results following outpatient investigation."

9. Discharge Awaiting Results – Outpatients (DARO) was clarified by the Governance Office in email correspondence to Dr Corrigan in July 2014, in so far as the tracking and review of test results were concerned [PHA-00658 to PHA-00659]. However, there was no mention of outpatient review appointments. There was no clarification of the relationship of DARO to

review appointments or the fact that patients had been discharged from review as a consequence. Dr Corrigan emphasised this point in her reply of 21 July 2014 [PHA-00662]. The Trust further confirmed to Dr Corrigan by email in December 2014 that secretaries had confirmed that they did not file results without them first being viewed by the consultant [PHA-00665].

10. In a final emailed correspondence in November 2017 relating to this issue [PHA-00709], Dr Corrigan remained of the view that DARO appeared to be a robust system of ensuring that there were no delays in tests being conducted but remained unconvinced of:

"Trust protocols to ensure results are then seen by a member of medical staff in a reasonable timescale and before being filed away, or left on a file awaiting an outpatient review which may be delayed (as happened in this case)."

11. Dr Corrigan's comments would imply that she had not appreciated that patients had been discharged from review while awaiting a test and while awaiting the result being viewed by a member of medical staff who would then decide whether outpatient review or other actions were indicated.

12. There has been no documentary evidence that Dr Corrigan was provided with the draft Standard Operating Procedure of November 2010 [TRU-98341] that clearly stated at paragraph 3 [TRU-98343] that:

"If a patient is awaiting results prior to a decision regarding follow up treatment being made, they must be recoded as a discharge (DIS) ***and not*** *added to the OP Waiting List for review"*

13. The instructions in the email of 30 January 2019 [AOB-07567] from Ms Collette McCaul to secretaries were clearly at variance with those of the Standard Operating Procedure of November 2010. I believe that it was appropriate for me to raise my concerns as I did on 06

February 2019 [AOB-07566]. It remains unclear whether Dr Corrigan would have shared those concerns if she had been fully informed of the Standard Operating Procedure of November 2010.

14. Whether she would have, there was no evidence of her enquiring of any progress on the part of the Trust in implementing the recommendation of the Findings of the RCA of October 2010 that all outpatient review waiting times be reduced. She acknowledged that doing so would not be easy in view of the resources required to do so. There did not appear to be any acknowledgement by Dr Corrigan or by the Trust of the difficulty, or the possibility, with which DARO, either in its original format of 2010 or in its later format of 2019, could be implemented with the same resources. In effect, all responsibility had been transferred to clinicians without the additional resources required.

Section 2 – Intravenous Fluids, Antibiotics Therapy & Cystectomy

15. I provided comments on the above issues in my Section 21 statement dated 2 November 2022 [paragraphs 417 – 429]. However, since preparing that statement, I have had sight of disclosure from the Public Health Agency to the Inquiry [primarily PHA-00430 – PHA-00553] and wish to make additional comments on this issue.

16. The disclosure referred to above between PHA-00430 and PHA-00553 provides an insight into how the Trust attempted to address and manage the above issues. It is implicit in the early communications from Dr Loughran [see, for example, PHA-00441] that he was advised of the reasons and rationale for the elective admissions of patients for intravenous hydration and antibiotic therapy, which essentially was to prevent their subsequent acute admissions in worse clinical condition, requiring the same management for longer periods of time. I can assure the Inquiry that I left Dr Loughran in no doubt concerning the reasons and rationale for the elective admission of these patients. While it is important to emphasise that the majority of patients acutely admitted did not suffer urosepsis, a minority did. Nevertheless, it is remarkable that those reasons and rationale were absent in communications.

17. At PHA-00440 there is a note of a call with me dated 22 April 2009. It is stated that "*Aob wants an in depth look at the cohort…. not just telephone contact with specialists*." I wanted a complete investigation of this cohort of patients, including review of the patients by external experts as well as their consultation with Mr Young and myself, and preferably with the patients involved, so as to ensure that they were fully informed.

18. Rather than having a full, in-depth review as indicated above, I received a letter from Dr Loughran dated 18 May 2009 [PHA-00441] advising that he had spoken to Mr Mark Fordham and inviting me to meet him immediately and to reflect upon the possibility of changing the management of these patients to oral therapy with frequent urinary cultures performed at the hospital. Dr Loughran essentially requested an immediate meeting to change the management of these patients to that which we had found to be unsuccessful, based upon a telephone conversation with Mr Fordham and with Dr Jean O'Driscoll.

19. It was stated by Dr Loughran in his letter to me dated 2 June 2009 [PHA-00445] that I would "*accept an independent assessment of this IV therapy*." That is an unusual choice of words where I had in fact specifically asked for an in-depth review to take place previously.

20. Mr Fordham was then asked to review the clinical records of five patients who had had ileal conduit urinary diversions performed, with or without cystectomy, even though the majority of patients in the cohort of patients managed by elective admission for intravenous hydration and antibiotic therapy had not had ileal conduit urinary diversions performed. The reason for the selection of these specific patients, or their identities, was not shared with Mr Young or me. On the basis of the email from Mr Fordham to Roberta Wilson dated 23 October 2009 [PHA-00448] it does not appear that he was aware that the majority of patients in this cohort had not had cystectomy and ileal conduit urinary diversions performed. Moreover, there was no description of the reason and purpose of elective admission of these patients for intravenous hydration and antibiotic therapy which was to prevent their imminent and acute admissions with severe clinical deterioration.

21. It is my view that, that an independent review process would have been considerably more robust had the Trust provided the independent reviewers with an opportunity to consult with the clinicians who managed these patients who would have accurately informed the experts of the reason and purpose of their management. It remains incomprehensible to me how any responsible clinicians could deny to patients an effective form of treatment to prevent their worsening conditions requiring their acute admissions for the same treatment for longer periods of time, all other usual preventative treatments having been found to be ineffective. In that regard, I found it concerning that Dr Loughran could advise that "*admission to the ward is possible but only if outpatient or day case management fails – usually in cases of severe sepsis*" [PHA-00174].

22. It is also concerning that Dr Corrigan et al did not appreciate that radical pelvic urological surgery was a term used throughout the world to refer to surgery for malignancy, such as radical cystectomy and radical prostatectomy [PHA-00453]. The use of the adjective 'radical' by the urologists working in the Southern Trust was not sophistry, nor was it due to a lack of common sense as she attributed to us [PHA-00490]. Instead, she instructed that simple cystectomy would no longer be performed in the Southern Trust before she had even validated the data, never mind attempting to understand the reasons for simple cystectomies being performed.

23. I believe that the manner in which these issues were addressed was an example of personnel providing opinions and making decisions without being fully informed and, more importantly, without having any intent or making any effort to be fully informed by consulting with the clinicians directly involved in the issues, and most importantly, consulting with the patients directly involved.

Section 3 – Bicalutamide

24. The management of prostate cancer by androgen deprivation consisted of bilateral orchiectomy and/or stilboestrol until the 1980s when surgical achievement of castrate levels of serum testosterone was progressively replaced by the administration of LHRH agonists with the advantage that castration was reversible if no longer indicated. However, castration did not completely eliminate stimulation of prostate cancer as 3% to 7% of serum androgens was produced by the adrenal gland. This led to the development of antiandrogens capable of blocking receptors to engagement with androgens produced by the adrenal glands. The first antiandrogens, Flutamide and Nilutamide, became available in 1985.

25. Bicalutamide was first introduced in and around 1995, replacing Flutamide which had previously been used in the UK and Ireland. Flutamide had a short elimination half-life, requiring it to be taken three times daily, and was accompanied by troublesome, gastrointestinal side-effects, particularly diarrhoea. By 1995, it was replaced by a metabolite, Bicalutamide, which had a longer elimination half-life of 7 to 10 days, meaning that it could be taken once daily, and had a significantly improved tolerability profile.

26. These developments coincided with an appreciation that serum prostate specific antigen (PSA) levels were not only a more reliable indicator of the extent of prostate cancer than were serum acid phosphate levels, previously used to monitor response of prostate cancer to androgen deprivation, but that they may also be surrogate predictors of outcome in prostate cancer management. It had been reported that patients who presented with advanced prostate cancer and who were treated with primary androgen deprivation therapy had a significantly longer time to disease progression and had a clear survival advantage if their serum PSA levels normalised.

27. From 2006 the possibility of increased cardiovascular risks associated with LHRH agonists became more widely known. Since then, there has been a significant number of population-based, observational studies of cardiovascular risks associated with LHRH agonists compared

to surgical castration, combined androgen blockade and to anti-androgens. The overriding findings have been that treatment with LHRH agonists has been found to be associated with significantly increased risks of incident diabetes, incident coronary heart disease, myocardial infarction, sudden cardiac death, stroke, peripheral vascular disease and venous thromboembolism. Apart from some findings of increased incidence of heart failure, oral antiandrogen monotherapy has not been associated with increased incidence or risk of adverse outcomes. Indeed, a number of observational studies have found that treatment with Bicalutamide has been associated with decreased cancer specific and overall mortality.

28. Concurrent with the comparative assessment of the efficacy of LHRH agonists or Bicalutamide combined with radical radiotherapy in the management of non-metastatic prostate cancer, there has been strong evidence that nadir PSA levels prior to radiotherapy are strongly predictive of significantly improved oncologic outcomes, and usually more significantly than any other factors, if not entirely independent of all other characteristics, or combinations of characteristics. The significance of nadir PSA levels is such that strategies have been proposed to manipulate androgen deprivation therapies or their duration, or alternatively to escalate radiation doses to compensate for inadequate PSA suppression, particularly in patients with higher risk disease. Further research is required to define the watershed nadir PSA levels in low and intermediate risk disease to determine whether it is as necessary to achieve nadir levels as low as is required in high-risk disease.

The disease, the management and the patient

29. There has been remarkable progress in the diagnosis and management of prostate cancer during the past 80 years since Huggins and Hodges reported its dependence upon androgens.

30. It has been a journey of ongoing discovery which continues. I believe that few would disagree with the consensus that there have been negative features along the journey. It is probably the case that all clinicians have contributed to varying degrees to the overdiagnosis and overtreatment of early prostate cancer.

31. I believe that we now have a much more detailed knowledge of the side-effects and risk profile of LHRH agonists than we did have previously. Yet, there persists a lack of clarity resulting from the fact that there have been no randomised, controlled trials (RCT) prospectively performed with stratification of cardiovascular status a priori and with cardiovascular end-points, in order to provide first degree evidence of cardiovascular risks, rather than the post-hoc studies of RCTs with oncologic stratification and outcomes. Therefore, we have been dependent on real world, 'big data', population based, observational studies to assess the risks associated with varying forms of ADT.

32. Such considerations apart, the patient should be the most important consideration for all those informing, advising, offering and providing diagnosis, assessment, management and support. The foundation of that consideration is the process of informing the patient of his condition. That process includes advising the patient of the limitations of our knowledge of his condition at any point in time and at any stage in the gathering of information. It involves listening to the patient, to learn of his appreciation of his condition, the deficits etc. Patient participation in management decision making arises from and develops from that process. Patient participation in management decision making requires time, both for those informing and the patient who is learning.

33. The assessment of the patient should be and needs to be holistic. The assessment of any patient diagnosed with prostate cancer should include as a minimum an assessment of lower urinary tract symptomatic status and of sexual function. It may well be that one patient may be bothered by urinary symptoms which do not cause another any bother at all. Nevertheless, the patient should be informed of the risks of worsening of their lower urinary tract symptoms due to the varied treatment options and be offered assessment and management of their urinary symptoms as recommended by NICE guidelines [NG131]. Similarly, in my experience erectile function can be more important to the sexually inactive and the celibate than to those who have enjoyed a life of sexual activity. In any case, and particularly in considering management options of localised disease when the differences in oncologic outcomes of management

options may be minimal, the risks of adverse effects are often the deciding factors, provided that the patient is adequately informed and has been provided with the time to consider his options. That is a dynamic process in most cases. Rarely do decisions have to be made this month or indeed necessarily this year.

34. Most importantly of all, it is the prerogative of the patient to decide, in conjunction with the clinician and the multidisciplinary team, and the patient can only choose that management option which is best aligned with his priorities, wishes and concerns if he is fully informed, advised, supported and provided with the time to do so. I have always endeavoured to facilitate that process. In doing so, I have experienced varied reasons for choosing to prescribe the anti-androgen, Bicalutamide, rather than a LHRH agonist, in the management of non-metastatic prostate cancer.

35. For example, I prescribed Bicalutamide 150 mg daily for Patient 1 at review in September 2019. Patient 1 had a family history of cardiovascular disease, had a diagnosis of hypertension since 2003 and was found to have hyperlipidaemia when diagnosed with ischaemic heart disease in 2004. He had a myocardial infarct in 2016 when he had triple coronary arterial stenting performed and since when he remained on related medication. In addition, he remained on antiglycaemic medication since 2017 when he was found to have type II diabetes. In view of all of the evidence of the increased risks of a further major adverse cardiovascular event, I would have considered it indefensible to have subjected him to such risks by prescribing a LHRH agonist for his prostatic carcinoma while awaiting conventional staging.

36. When he reported side effects in October 2019 potentially attributable to the Bicalutamide 150 mg daily or to the tamoxifen 10 mg daily which had also been prescribed, or to the combination, and to the extent that he had concerns about driving, I believe that it was entirely rational to advise him to discontinue taking both, and to resume taking Bicalutamide alone at a daily dose of 50 mg from 01 November 2019. The efficacy of the Bicalutamide taken to date was reflected in his serum PSA level decreasing to 3.84ng ml by 11 November 2019. Having persuaded him

to remain on 50 mg daily while going Personal Information redacted by the on holiday in December 2019, his serum PSA level had decreased further to 2.23ng/ml by 07 January 2020.

37. If I had prescribed a LHRH agonist in November 2019, I believe that Patient 1 would have been at significantly increased risk of suffering a major cardiovascular event, including a thromboembolic event in view of the additionally increased risk of such an event associated with air travel.

38. Patient 4 was 84 years old when found to have high-risk Gleason 5+5 prostatic carcinoma on histopathological examination of prostatic tissue resected to relieve bladder outlet obstruction in June 2019. Patient 4 had been diabetic since 1987. His diabetes had become insulin dependent in 2011. He had hypercholesterolaemia since before 2006 when he was also found to be hypertensive. He was frail upon initial assessment in January 2019 and appeared more so at review following surgery in August 2019. His serum PSA level had been 2.79ng/ml in December 2018 and was found to be 1.66ng/ml at his postoperative review in August 2019.

39. In view of his frailty, his known cardiovascular risk factors, his unknown cardiovascular status, his low serum PSA and testosterone levels, I considered it appropriate to initiate androgen deprivation by prescribing Bicalutamide 50 mg daily while staging was completed. If he had been found to have evidence of metastatic disease, he could then have been prescribed a LHRH agonist. In any case, the efficacy of Bicalutamide 50 mg daily was reflected in his serum PSA level decreasing to 0.86ng/ml by December 2019 by which time he had achieved relief of his significant urinary symptoms by performing self-catheterisation twice daily.

40. I believe that this frail, 84 year old man would have been exposed to significantly increased risk of a cardiovascular morbidity if he had been prescribed a LHRH agonist in August 2019 without any significant additional oncologic benefit in the absence of evidence of metastatic disease by December 2019, until when it would have been inappropriate to consider radical radiotherapy without further assessment and management of persistent, lower urinary tract symptoms, as recommended by NICE guidelines (NG131, published 09 May 2019).

41. In the case of Patient 6, I prescribed Bicalutamide 50 mg at his review in July 2019 due to his anxiety and concern that his presumed prostate cancer would progress while awaiting prostatic biopsies later that month. Though prescribed prior to histopathological confirmation of prostate cancer, the off-licence indication was similar to that recommended by BAUS in March 2020 to relieve the similar anxieties and concerns of men whose definitive treatment was deferred due to Covid 19. Its efficacy was reflected in his serum PSA level having decreased from 13.44ng/ml in July 2019 to 8.4ng/ml by September 2019.

42. Concern regarding compromise or loss of erectile function has been a significant issue for many patients embarking upon androgen deprivation therapy. For example, it was the reason for initially prescribing tadalafil for a period of three weeks prior to prescribing Bicalutamide 50 mg daily for Patient 35 in February 2013 in the hope of maintaining his erectile function which he was so keen to preserve.

43. Most importantly, when the patient has been optimally informed of the anticipated benefits of differing management options and of the comparative risks associated with those options, it has been my experience that a great proportion of men, probably the majority, were most keen to embark upon a journey to achieve the benefits while incurring the least risks. It has been in that context that androgen deprivation using Bicalutamide has been prescribed, irrespective of the dose initially used.

44. I have never initiated ADT of any form for any patient with non-metastatic prostate cancer with the intent that it would be their sole, indefinite management. Bicalutamide was always initiated with the intent that it would be a prelude to radical radiotherapy to which the patient had agreed in principle. However, on numerous occasions, when patients were informed of the biochemical response to ADT, I have been asked whether they were obliged or compelled to proceed with radiotherapy at that time. I advised them that they were of course under no such obligation. It was for that reason that ADT, using Bicalutamide, initiated with neo-adjuvant intent, incrementally became long-term monotherapy. Such was the case of Patient 139 who had a

progressive reduction in serum PSA levels over a period of ten years since being prescribed Bicalutamide 50 mg daily in 2010.

45. I believe that this has been most eloquently described by the reviewer of the records of Patient 48 [TRU-182393] who wrote as follows:

"This is an interesting case.

At initial diagnosis, the case was reviewed at MDT as a T3N0M0 high risk Gleason 4+4 with capsular invasion on MRI. It would be standard practice to recommend hormones and radiotherapy for this case as was the conclusion of the MDT. This was not followed which would be regarded as 'poor' practice. Active surveillance would not be recommended because of the apparent high-risk nature of the disease. Instead, monotherapy with bicalutamide was given – which in this case would be on licence but not first choice.

As it transpires, the PSA has been extremely well controlled over the 10 year period and the patient has remained well. For the last two years, the hormone therapy has been stopped, and the PSA has risen only slightly to 0.19ng/ml. In an 88 year old patient, it is extremely unlikely that the disease would advance quickly and if it did, hormones could be reintroduced as suggested by Mr Haines. The patient has done very well – and has not had the risk of complications from radiotherapy.

The question therefore is whether he has had 10 years of hormones unnecessarily? The answer to this is almost certainly 'no'. had he not had the bicalutamide, I suspect that the tumour would have progressed in the 10 year period, being already locally advanced at diagnosis.

In this instance we must ask whether he had been better off having the hormone therapy for 10 years, the side effects of bicalutamide being minimal compared with the alternative LHRH

partial agonists; or whether he would have been better off having radiotherapy – with its potential well recognised side effects?

This man was fortunate in that his tumour, though advanced, was, and remained, hormone sensitive over the 10 year period. I therefore believe, with hindsight, he had the correct treatment. Evidence would suggest however that this would not be the case for the majority.

Did AOB know something that we don't? I find it difficult to mark this as 'poor' care on this form when the patient has, admittedly with hindsight, had the better treatment. I have therefore marked it as adequate."

46. While I do not have the benefit of having been provided with Patient 48's clinical records, or having access to them or the patient, I believe that I have known from my experience of caring for men with prostate cancer since 1985 that a significant portion of my knowledge has derived from those patients themselves. This man was presumably satisfied to remain on Bicalutamide in the knowledge of its ongoing oncologic effect rather than proceeding to radiotherapy, or worse still, LHRH agonists and radiotherapy. It was not solely a matter of hindsight. It was a continuum of hindsight and foresight, informed by the preferences of the patient. I believe that his overall care was more than adequate.

47. It is the case that men with non-metastatic prostate cancer have their pathologies and conditions discussed by MDTs at MDMs, without having a complete appraisal of the patients and their preferences and priorities. It is not possible for patients to formulate those preferences and priorities until they themselves have been fully informed of their pathologies and prognoses, management options, benefits and risks. It has been my experience that the patient may then choose to follow a course of management from which much can be learned by both patient and clinician.

Section 4 - Issues raised by Mr Chris Hagan

48. I note that Mr Chris Hagan, Consultant Urologist and then Medical Director of the Belfast Health and Social Care Trust, provided a witness statement to the Inquiry [WIT-98839] dated 9 August 2023 and then gave oral evidence to the Inquiry on Day 61. I further note that Mr Hagan stated at WIT-98839 that his direct experience of working with me was over a 6-month period over 20 years ago (between February 2000 and August 2000) accepting that he did not have a full and complete recollection of that period simply due to the passage of time. (Mr Hagan also raised issues pertaining to 2010 and to 2016).

    I have a very minimal recollection of Mr Hagan's presence as a specialist registrar during the period February 2000 to August 2000 that he describes in his witness statement.

49. Mr Hagan raises a number of separate issues from that period of time in 2000 in his witness statement, and I would like to address these specifically. I cannot fully address all of them due to lack of access to clinical records, but if the Inquiry wishes to seek my comments on any of the allegations made by Mr Hagan which are not dealt with here to its satisfaction, I will endeavour to do so if clinical records are provided.

Intravenous Fluids and Antibiotic Therapy

50. At WIT-98845, Mr Hagan recalls that:

    "*There was a group of patients that seemed to me to be being regularly admitted to the ward for antibiotics and IV fluids by Mr. O'Brien. My recollection is that these patients would make contact with Mr. O'Brien in some way and be admitted directly to the ward as an inpatient for treatment. When I asked about this practice the ward nurses referred to this treatment as "Mr. O'Brien's regime". I would do an unaccompanied ward round every morning during my 6 months rotation when I would come across these patients. It was often not clear to me the reason for this approach, or the evidence base for the treatment. I considered patients who fell into this category could have been managed as outpatients, as they could eat and drink. I did not encounter this approach in any other urological unit that I worked in before or since."*

51. I have provided comments on the use of IV fluids and antibiotic therapy in my Section 21 response dated 2 November 2022 at paragraphs 417-423 [WIT-82547 – WIT-82550], as well as further comments on this issue at Section 2 in this additional statement, and do not propose to repeat same here. I do note, however, that Mr Hagan did not report in his witness statement that he raised this issue with me. If he had, I would have explained the rationale to him.

Cystectomy and Orthotopic Neobladder Formation

52. At WIT-98846 Mr Hagan recounts his recollection of a patient under my care who he alleges underwent a cystectomy and neobladder to treat recurrent urinary tract infections. Mr Hagan said as follows in his statement to the Inquiry:

"The predominant indication for cystectomy and neobladder is for treatment of bladder cancer and I was disturbed that this major procedure had been undertaken for recurrent UTIs in a young woman. I could find no evidence base in the literature for this. At the end of a ward round, where I had accompanied Mr. O'Brien, I challenged him as to why he had carried out such a radical and life changing operation on this young woman in the context of recurrent UTIs. He remarked that someone else had said that to him, and he justified it to me by telling me he had specifically discussed this case with a Urologist in the United States of America (USA) who agreed it had been a reasonable course of action. I felt, as a second-year surgical trainee, inevitably anxious about challenging an experienced consultant, that I had expressed my view and Mr. O'Brien had provided an explanation that was hard to dispute at the time. I think this was the only case of this type that I myself saw during my rotation, but I cannot say if there were others with whom this approach was taken. I did speak to Mr. Young during my rotation about various concerns I had about Mr. O'Brien, but I cannot now say whether this was one of the matters that I spoke to Mr. Young about. I may have, but I cannot say that I did. Looking back on this now, with 17 years' experience as a Consultant Urological Cancer Surgeon, I can see no justification for the operation."

53. If it was indeed the case that this operation, namely a cystectomy and orthotopic neobladder formation, was performed on any patient for recurrent urinary tract infections alone, without any lower urinary tract dysfunction or other pathology, I would entirely agree with Mr Hagan that that would not be a justification for such surgery. However, I have no recollection of ever performing such surgery for recurrent urinary tract infection alone or having seen such surgery performed for that reason by any other surgeon.

54. It is therefore difficult to comment in any more detail without access to the relevant clinical records and information in respect of this patient.

Trans Urethral Resection of the Prostate (TURP)

55. Mr Hagan provides comments under the above heading at WIT-98847. In particular, Mr Hagan said as follows:

"I was therefore disturbed as a trainee in CAH when a TURP that Mr. O'Brien was carrying out involved a resection that lasted significantly greater than 1 hour. The case I recall involved resection time approaching 2 hours, and the anaesthetist and nursing staff expressing concerns to Mr. O'Brien about the length of operating time, but Mr. O'Brien continued. I thought this was a patient safety issue because it was putting the patient at what I considered to be unnecessary risk. I expressed that view to Mr. O'Brien. Mr. O'Brien's view, as far as I recall it, was that resection time was not the significant issue I considered it to be. I believe I did speak to Mr. Young about this issue (I did speak to him a number of times during my rotation about different issues) and my recollection is of him saying "that's just Aidan".

56. Again, I have not been provided with any evidence of this particular event, or any medical records regarding the patient. It is therefore impossible to comment on this in terms of the specific procedure that took place. However, I would be surprised if Mr Hagan is correct that the resection time was approaching two hours. Such a prolonged resection time implies that the prostate gland was particularly large or that there was difficulty in achieving satisfactory

haemostasis, or a combination of both. If I considered after 30 minutes of resection that optimal resection of a large prostate would require a prolonged resection time, it was my usual practice to limit the resection, such as to one lateral lobe +/- the median lobe of the prostate. It was also my usual practice to request serum biochemistry to be performed if I was approaching one hour's resection time. If the serum sodium levels were normal, and I felt I could complete the procedure within 15 minutes, my normal practice was to continue to complete the procedure. I have no recollection of any TURP procedure coming close to the two hours resection time as alleged by Mr Hagan. Moreover, the audit of the incidence of hyponatraemia complicating TUR prostate and bladder tumours undertaken in 2014 found no correlation between resection time and glycine absorption [TRU-396014 – TRU-396017].

57. The only severe TUR syndrome that I have ever been aware of was a complicated resection of a very large prostate by a consultant urologist in Dublin in 1987 when I was a registrar in urology there. The patient suffered pulmonary oedema from which he made a complete recovery with no lasting consequence. I had performed over 400 prostatic resections prior to appointment as a consultant urologist in 1992. By 2000, when Mr Hagan was hoping to increase the number of TURP operations he had performed towards a target of 100 during his six months' rotation, I had already performed over 1,000 prostatic resections. I have performed over 3,000 TURP operations throughout my career. I would estimate that I may have experienced a maximum of three or four potentially symptomatic cases of TUR syndrome during my consultant career. I believe that such a low incidence has been attributable to much improved operative techniques, such as the use of video magnification and continuous intraoperative irrigating resectoscopes, as well as increasing experience. These patients had transient symptoms which resolved completely in the recovery ward. I cannot recall ever having been aware of any severe TURP syndrome affecting any patient under my care, or under the care of any colleague. I have never known of a mortality associated with glycine absorption complicating TURP. I am unaware of any evidence that my practice in respect of TURP procedures was associated with any more complications than any other consultant.

58. I note that Mr Hagan states in his statement that he believes he spoke to Mr Young about this issue [WIT-98847 – WIT-98848]. I further note that Mr Young had no recollection of that discussion [TRA-09684 – TRA-09690 & WIT-103607 – WIT-103609].

59. With regard to TURP syndrome, Mr Hagan further stated in his witness statement at paragraph 59 [WIT-98867] that he:

"*was contacted by phone by Dr Charlie McAllister, a consultant anaesthetist in CAH. I cannot be sure when exactly I received this call, but I believe it was sometime between 2017 and 2019. Dr McAllister wished to discuss TUR surgery, TUR syndrome and use of bipolar resection. He explained that they had an issue in CAH with an individual carrying out prolonged TURP resections with glycine and some "bad" TUR syndromes. He did not name the surgeon specifically. He wanted to know my experience with introducing TURP in saline. I explained that the experience in Belfast was good, that the technique was similar to monopolar TURP with glycine and that with modern equipment, in my view, it was unjustified and unsafe to continue to use glycine due to the safety profile of it as an irrigating fluid."*

60. In a further Section 21 Notice sent to Dr McAllister on 12 October 2023, he was asked to provide full details of the telephone conversation referred to by Mr Hagan. He was specifically asked whether he agreed that Mr Hagan's account of the telephone call was accurate. Dr McAllister replied at paragraph 2.01 [WIT-103755] as follows:

"*No. I have no memory of this telephone call as characterized by Mr. Hagan so I am unable to agree that Mr. Hagan's account is accurate"*

61. In paragraphs 2.02.(1-6), Dr McAllister explained in detail how it was not possible for such a phone call to have been made by him to Mr Hagan, hence he stated at paragraph 2.03 [WIT-103756] as follows:

"I have no memory of contacting Mr. Hagan regarding this matter following the introduction of The Policy on the Surgical Management of Endoscopic Tissue Resection HSS(MD)14/2015 because I believe that it did not happen."

Ureteric Stones

62. Mr Hagan in his statement at WIT-98848 raised two separate issues under the above heading. I will deal with these separately:

63. Issue 1

(i) Mr Hagan said the following at WIT-98848:

"Mr. O'Brien's approach to ureteric stone management was very different and his preference was to intervene surgically at a very early stage. When discussing patient management with Mr. O'Brien, I challenged him in relation to this approach, as I felt that suitable stones should be allowed to pass naturally. This is because intervention carries risks, including sepsis and ureteric perforation. Mr. O'Brien however referred to his training in Tallaght Hospital in Dublin, and that this was how he managed stones. Generally, I found Mr. O'Brien to be dismissive of me when I raised concerns. He was clear that it was an appropriate course of treatment."

(ii) Again, I have no recollection of any patients whom Mr Hagan considered were inappropriately managed and have not been provided with any details and / or medical records relating to any such patients to assist me in responding to Mr Hagan's comments. I have no recollection of Mr Hagan ever discussing this issue with me at any time.

(iii) I do not accept that I had a preference to intervene surgically at a very early stage, other than when clinically indicated. The criteria for early endoscopic management of ureteric calculi are well established. It may be the case that Mr Hagan's understanding of this treatment at the time was simplistic given his position as a trainee.

(iv) I further note that Mr Hagan referred to my training at Tallaght Hospital in Dublin. I was trained in the endoscopic management of ureteric stones at St. James's, Meath, Beaumont and Mater Hospitals in Dublin from 1985 to 1991. It may be of interest to the Inquiry to note that I never undertook any training at Tallaght Hospital. Moreover, Tallaght hospital did not open until 1998, which was six years after I commenced my employment with the SHSCT in Craigavon.

64. Issue 2

(i) At paragraph 31.iv (WIT-98848), Mr Hagan stated that:

"The second issue related to the energy source used in the destruction of stones. Destruction of ureteric stones requires an energy source. In 2000, there were a number of sources commonly used when operating on the ureter, such as laser and pneumatic devices (such as the swiss lithoclast). Both these types of energy sources had good safety profiles. Mr. O'Brien's preference however was to use an electrohydraulic (EHL) energy source. It was powerful and unpredictable. EHL has uses for large bladder stones and kidney stones, where its use is safe, but, in the ureter, it carries a very high risk of ureteric perforation. I discussed this risk with Mr. O'Brien, as I felt this was a high-risk energy source to use in the ureter, with real safety risks. I described my experience with the lithoclast, which has a zero risk of perforation, and questioned why he would not use it, as it was very cheap technology. Again, I found Mr. O'Brien to be dismissive of my concerns. Mr. O'Brien did not accept my view. Unfortunately, when carrying out a left ureteric stone case, with Mr. O'Brien directly supervising me, he told me to use the EHL probe to break up the stone. As instructed, I did this and the discharge of the energy source caused a very large perforation in the upper third of the ureter. Mr. O'Brien took over the case and was unable to negotiate a ureteric stent into the kidney due to the size of the defect. This then required the patient to have an open surgical repair of his ureter. I was very distressed by this complication, as I felt very much to blame for it, even though I had carried out the

instructions of the supervising Consultant. Mr. O'Brien spoke to the patient afterwards, as he was ultimately responsible for the operation. I was not present. I don't know what Mr. O'Brien said to the patient. With hindsight, it is clear to me that the direction I received from the supervising Consultant, to use the EHL, was not appropriate in the situation and that this was an entirely avoidable complication."

(ii) The Inquiry has since been advised on 19 December 2023 that the Trust has investigated this issue and has been able to locate the chart and the operation note in respect of the person the Trust believes to be the patient in question [TRU-320239 – TRU-320241]. The Trust has provided redacted copies of the operation note written by Mr Hagan on 06 May 2010 [TRU-320247) and the discharge summary dictated by me on 03 August 2010 [TRU-320245 – TRU-320246]. There was no record in the operation note of my being present at all during the operation and there was no record of my supervising the operation. On the contrary, Mr Hagan recorded at the end of the operation that I was informed of the proceedings.

Note: As per email (WIT-107947) received on 8th April 2024 the dates highlighted at paragraph 64 (ii) should read "06 May 2000" and "03 August 2000" instead of 2010. Annotated by the Urology Services Inquiry.

(iii) Moreover, the Trust has established that alternative energy sources were unavailable at that time, the Holmium YAG Laser not available until April 2006 and the Swiss Lithoclast not available until March 2014 [TRU-320243 – TRU-320244].

Paediatric Urology

65. At WIT-98849, Mr Hagan relates his surprise to finding that I had acquired a set of paediatric cystoscopes. Having been a Clinical Fellow in Paediatric Urology in Bristol from 1991 to 1992, I appreciated the diagnostic value of being able to examine the lower urinary tract endoscopically. I was for that reason that I acquired a paediatric cystoscope and a resectoscope. They were rarely used, and if used they were usually used for treating older children.

66. Mr Hagan sets out his recollection of another patient, a child, who he alleges I was of the view required invasive testing such as urodynamic studies for nocturnal enuresis. Mr Hagan sets out his view that he felt this was over-investigating, although he accepts that he cannot recall whether the invasive testing actually took place. Mr Hagan again states that he disagreed with me on the course to be undertaken.

67. I have no recollection of Mr Hagan ever discussing this patient with me. I have no recollection of the patient that he refers to. I have not been provided with any clinical details or medical records to allow me to properly comment on the allegation.

Radical Prostatectomy and High PSA

68. At WIT-98850, Mr Hagan relates the concerns he had in 2010 with regard to my performing radical prostatectomies for prostate cancer on men who had very high serum PSA levels at the time of diagnosis.

69. I note that he implies that my patients may not have had staging performed by MRI scanning prior to surgery. In fact, I had staging undertaken by MRI scanning for all patients considered for radical prostatectomy. I was able to have MRI scanning performed at the Royal Victoria Hospital in Belfast for years prior to MRI scanning becoming available at Craigavon Area Hospital.

70. Moreover, staging by MRI scanning was undertaken prior to any patients being prescribed neo-adjuvant androgen deprivation therapy which was not initiated in order to reduce serum PSA levels but instead to prevent disease progression while awaiting surgery.

Priapism and Penile Disassembly

71. At WIT-98851 Mr Hagan provides details of a patient suffering from a priapism. He states the following:

"Andrologists (physicians who specialise in treating men's reproductive-related issues) in Great Britain were recommending early referral to London for insertion of artificial penile prosthesis for management of this rare condition. However, in the case I remember, Mr. O'Brien took the patient to theatre and performed what I can only describe as a penile disassembly by separating the corporal cavernosum and spongiosum tissues. I was not myself "scrubbed" in for the procedure along with Mr. O'Brien, and whoever was assisting him, but I just remember being present in the theatre at some point and wondering what Mr. O'Brien was trying to achieve. I remember being concerned that the procedure could risk compromising the vascular supply to the penis. I remember leaving the theatre as I did not want to watch what was happening. I never found a description of the procedure in any text. My recollection is that when the patient returned to the ward there was concern in respect of ischaemia of parts of the penis. I do not know the final outcome for this patient as I left CAH to return to BCH as part of the urology rotation. This patient will have been on the Urology ward for a period of time post his operation, so it may well be Mr. Young or others will recall the case because of its unusual features."

72. I have no recollection of this case, nor have I been provided with any clinical details or medical records in respect of this patient to assist my recollection. I note that in his evidence to the Inquiry, Mr Young had no recollection of this incident ever being raised with him by Mr Hagan [TRA-09686 & WIT-103605].

Outpatient Practice

73. At WIT-98851, Mr Hagan describes his efforts to discharge patients from outpatient review when he considered that they did not require to remain under review. In doing so, he recalls:

"one specific patient who I discharged from clinic in Banbridge for this reason, but who was then back at the clinic the following month. His symptoms had not deteriorated or changed and I asked him how he had been re-appointed. The patient told me that he had phoned Mr.

O'Brien's wife (who I believe assisted Mr. O'Brien with his private patients) who arranged (presumably with the clinic's appointment secretary) for him to be re-instated on the clinic. I was very surprised that this had happened but was concerned that perhaps something would be said to me for having discharged the patient in the first place. Mr. O'Brien never mentioned it to me. As I reflect on this now for the purposes of this statement, I realise that was an unusual practice that was occurring."

74. I have no recollection of this event or this patient. Nevertheless, I both strongly resent and refute the allegation that this, or any, patient phoned my wife with a view to having a review appointment re-arranged, or even more importantly, that she arranged it. It was not a rarity for patients to attempt to contact me by phoning my home as my telephone number was not ex-directory. While it was the case that patients contacted my home to arrange private appointments, patients waiting long periods of time for review or for admission, would also have done so. If I was not at home, as I usually was not, my wife would have answered the phone. She would have taken a message and contact details so that I could deal with the issue. My wife never arranged any review or any other service of any kind for any patient who contacted me by calling my home; my wife would simply take a message and contact details.

75. It may have been that a patient was dissatisfied by some aspect of his review by Mr Hagan. It may be that I requested that another review be arranged for him. In any case, I have no recollection of either patient or event.

Administration Delays

76. At WIT-98852, Mr Hagan looks back on my administrative processes as appearing disorganized and chaotic. Perhaps they only appeared so. He is of the view that the contributory factors may have included a tendency to over investigate patients. I have not previously been aware of any other person's consideration that I over investigated patients.

77. Mr Hagan also expresses the view that I wrote, what seemed to him, extremely long letters which often seemed to struggle to get to the point. He considers that it is obviously important, when writing letters to GPs, that they are timely, and that the diagnosis and management plan are succinct and clear.

78. I do appreciate that others may consider the length of a letter, such as that which I dictated to the GP of the patient who suffered the left ureteric perforation in addition to a ureteric stenosis requiring surgical repair, to be long or too long [TRU-320245]. However, I believe that such a letter was an appropriate record of the patient's diagnoses and management at that time. I do not believe that it struggled to get to the point, as I believe the point was to provide the GP with a record of the patient's management, and to have such a record for future reference by others. It may be that it did contribute to administrative delays, but I considered it better to have a properly informative record than to have one that was timely but not adequately informative.

Transfer of Patients for Radical Pelvic Cancer Surgery in September 2010

79. At paragraphs 40 to 43 [WIT-98856 to WIT-98863], Mr Hagan relates the sudden and unexpected transfer of five patients from the Southern Trust to the Belfast Trust for radical pelvic surgery in September 2010, three for bladder cancer and two for prostate cancer. Mr Hagan raises concerns regarding the three patients who were transferred for radical surgery for bladder cancer.

80. At paragraph 43.1 [WIT-98857], he relates the history of this male patient who had been found to have non-muscle invasive, non-metastatic, sarcomatoid carcinoma of his urinary bladder in July 2010. I recall this patient well as I continued to review him until my employment with the Southern Trust terminated in July 2020. Mr Hagan stated that:

"the presence of high grade, aggressive, sarcomatoid bladder cancer should have triggered immediate discussion about cystectomy irrespective of there being no detrusor muscle in the

specimen. However, the patient underwent another TURBT in August 2010 which confirmed the same pathology."

81. Mr Hagan would appear to imply that there had not been a discussion regarding management by radical cystectomy following the histopathological examination, and presumably with the patient. I am unaware upon which evidential basis he has made this implication.

82. With regard to the other two patients, I have no recollection of these patients and hence am unable to comment upon the concerns which Mr Hagan describes. However, I would be happy to do so if provided with their complete clinical records, if that would be of assistance to the Inquiry.

Delay in Referral of Patients from CAH

83. At paragraphs 52 to 55 [WIT-98865 to WIT-98866], Mr Hagan describes the case of a patient who had a bladder tumour resected in February 2016 but had not been referred for cystectomy until June 2016. He relates that he considered the patient to be not fit for surgery when he met her in June 2016, but that it would have been July 2016 before her surgery could have been performed if she had been considered fit for surgery, a period of five months since diagnosis, during which time there would have been an increasing risk of metastasis. Mr Hagan shared his concerns with Dr Mitchell who referred the matter to the Southern Trust by emailing both Ms Shauna McVeigh, MDT Cancer Tracker, and myself, suggesting that we conduct a review of her case with a view to determining whether there was any local or regional learning to be derived from it [WIT-98869]. I note that Mr Hagan considers that I may also have been 'head' of the local MDT at the time.

84. In her response of 19 December 2023 to a Section 21 Notice sent to her by the Inquiry on 13 December 2023, Ms McVeigh had no recollection of having read the email sent to me and copied to her and had no recollection of the case being discussed at MDM [WIT-105874]. I

note at paragraph 1.08 that she was, perhaps understandably but mistakenly, of the impression that the patient had been under my care [WIT-105874].

85. I clearly recall having the case discussed at MDM following receipt of the email from Dr Mitchell. The patient was a 78-year-old lady under the care of Mr O'Donoghue. She had a flexible cystoscopy and bladder mucosal biopsies performed on 16 February 2016 in the investigation of lower urinary tract symptoms of a storage nature, and of recurrent urinary tract infections. Histopathological examination of the biopsies was in keeping with a diagnosis of poorly differentiated, squamous cell carcinoma. On discussion at MDM on 10 March 2016, it was recommended that she would be reviewed by Mr O'Donoghue, that she have staging CT and bone scans requested and that her suitability for radical cystectomy be assessed, followed by regional MDM discussion of her further management [AOB-76767 – AOB-76768].

86. When subsequently reviewed by Mr O'Donoghue, the prospect of radical cystectomy was discussed with her. Mr O'Donoghue considered her to be reasonably fit and was sure that she was a candidate for surgery. There was no convincing evidence of metastatic disease on bone scanning on 04 April 2016 or on CT scanning on 19 April 2016. However, when the images were discussed at MDM on 28 April 2016, it was considered that there was increased uptake of radioisotope in the left shoulder on bone scanning. It was recommended that she be reviewed by Mr O'Donoghue to have plain radiography of her left shoulder requested, to recommend radical cystectomy followed by regional MDM discussion as previously intended. At review, Mr O'Donoghue again considered her reasonably fit for surgery [AOB-77254 – AOB-77255].

87. When discussed at Regional MDM on 12 May 2016, it was advised that the patient have a CT scan of her left shoulder and scapula performed [AOB-77307]. When again discussed at Regional MDM on 09 June 2016, it was concluded that there was no evidence of metastatic disease. She was referred directly to the urologists at Belfast City Hospital by inter-Trust transfer [AOB-77466].

88. I clearly recall having the case discussed at MDM for a number of reasons. We acknowledged and accepted the criticism that bone scanning was not recommended in the staging of bladder cancer, though we noted the irony that it gave rise to delay in her referral due to the local MDM recommendation to have plain radiography of her left shoulder performed, and the regional MDM recommendation to have CT scanning of her left shoulder and scapula performed. As we assumed that we were the only MDT to learn not to have bone scanning performed, I did not consider it necessary to confirm to Dr Mitchell that we had undergone that learning.

89. The second reason for my clearly recalling discussion of the case was that we noted that Mr Hagan concluded at her outpatient review that she was unfit for surgery, even though Mr O'Donoghue had considered her fit for surgery, having reviewed her on two occasions. At MDM discussion, we doubted whether Mr Hagan's assessment of her fitness for surgery would have been any different if her referral had not been delayed.

Section 5 – Clinical Nurse Specialists and Key Workers

90. While my Section 21 statement dated 2 November 2022 provided some comments in respect of Clinical Nurse Specialists (CNSs), in response to specific questions from the Inquiry in its Section 21 Notice 68 of 2022, I believe that it would be helpful to provide a more extensive commentary on the history of that role, the relevant policies associated with the role, as well as my further comments on the allegations against me relating to the perceived failure to make appropriate use of CNSs and/or Key Workers within my practice.

91. There are a number of descriptive definitions of CNSs, to some degree depending upon the specialism and country. Whether by varied combinations of qualification, training and experience, they commonly are regarded as nurses who have attained a level of advanced expertise to enable them to practice in the care of patients suffering from specific conditions, such as cancer.

92. In 2004, the National Institute for Health and Care Excellence (NICE), produced its Guidance 'Improving Supportive and Palliative Care for Adults with Cancer', in recognition of evidence that patients with cancer required support across a range of domains, benefited when that support was provided and the realisation that the need for support was all too often neither assessed or provided. One of its recommendations was that teams (whether hospital, hospice or primary care based) may wish to consider nominating (with the agreement of each patient) a person to act as 'Key Worker' and that this person might be, for instance, a community nurse, allied health professional, nurse specialist or social worker, and that the role might involve:

- orchestrating assessments to ensure patients' needs are elicited
- ensuring care plans have been agreed with patients
- ensuring findings from assessments and care plans are communicated to others involved in a patient's care
- ensuring patients know who to contact when help or advice is needed, whether the 'Key Worker' or other appropriate personnel
- managing transitions of care

93. While it had been considered in 2004 that professionals other than nurses, or CNSs, could fulfil the Key Worker role, advances in nurse practitionership during the next decade resulted in a general acceptance, ten years later, that CNSs were best qualified to undertake the role. Indeed, in 2015, Macmillan Cancer Support [WIT-81066 – WIT-81079] stated that Cancer CNSs support health care professionals in delivering effective, efficient services and in improving the quality of care for cancer patients. It further stated that the high-level activities of Cancer CNSs can be separated into five main functions:

- Using and applying technical knowledge of cancer and treatment to oversee and coordinate services, personalise 'the cancer pathway' for individual patients and to meet the complex information and support needs of patients and their families
- Acting as the key accessible professional for the multidisciplinary team

- Undertaking proactive case management and using clinical acumen to reduce the risk to patients from disease or treatments
- Using empathy, knowledge and experience to assess and alleviate the psychosocial suffering including referral to other agencies or disciplines as appropriate
- Using technical knowledge and insight from patient experience to lead service redesign, to implement improvements and make services responsive to patient needs

94. While not all CNSs involved in the management of cancer patients undertake a Key Worker role, nevertheless the above description details the main functions of the CNS as a Key Worker.

95. In Northern Ireland, the concept of the Key Worker had become so well established during the decade since 2004 that the Northern Ireland Cancer Network (NICaN), in its Key Worker Policy, advised multidisciplinary teams (MDTs) in developing Key Worker Policies that "*there should be an operational policy whereby a single named Key Worker for the patients' care at a given time is identified by the MDT for each individual patient and the name and contact number of the current Key Worker is recorded in the patients' case notes. The responsibility for ensuring that the Key Worker is identified should be that of the nurse MDT member(s)*" [TRU-99578 – TRU-99584]. The policy stipulated that the Key Worker must be a core member of the MDT, and listed the responsibilities of a Key Worker within Northern Ireland as follows:

- to achieve continuity of care, that the patient knows who to contact for information and support
- to introduce themselves proactively to the patient and provide contact details
- to be present, whenever possible, when the patient is given their diagnosis
- to ensure that a holistic assessment is carried out of the patient's needs
- to ensure that a holistic needs assessment is repeated at regular intervals to maintain an up-to-date picture of the patient's needs
- to ensure that a care plan is drawn up, in conjunction with the patient and based on information obtained from the initial assessment

- to ensure that patients are given the opportunity to participate in decision making.
- to ensure that the care plan is updated at regular intervals
- to ensure that patients' preferences and choices are elicited, especially in relation to end of life care
- to ensure that these preferences and choices are documented
- to assess the patient's response to their diagnosis and monitor how they are coping
- to refer on for specialist psychological support where appropriate
- to provide opportunities for the patient to discuss the progress of their disease and treatment
- to establish and maintain contact with the patient's GP so that they are kept informed of key developments in treatment and prognosis
- to provide timely information to meet needs expressed by the patient, family members and carers
- to provide general emotional and psychological support, both proactively and as requested by the patient, family members and carers

96. There was little doubt by 2015 that CNSs were considered the most suitable professionals to undertake the Key Worker role, even though they remained inadequate in number in Northern Ireland. While the Southern Trust employed two Urology CNSs, Mrs Kate O'Neill and Mrs Jenny McMahon, in 2015, only Mrs O'Neill was a Urology Cancer CNS. As the Southern Trust's Urology MDT Lead Clinician, I drafted the Urology Cancer Service Operational Policy in preparation for National Peer Review in June 2015. In order to provide cover for annual leave and other absence, both Mrs O'Neill and Mrs McMahon were named as MDT Core Nurse Members. However, by the time the Operational Policy was updated in September 2016, two Band 6 practitioners, experienced in urodynamic studies and the provision of intravesical chemotherapy, had been appointed. Mrs O'Neill was therefore nominated as the MDT Core Nurse Member whose responsibility it was to oversee the responsibilities of all Nursing Practitioners / Key Workers involved in the ongoing assessment and management of cancer patients as outpatients. The role and responsibilities of the Core Nurse Member were listed in

the updated Operational Policy in September 2016 [TRU-105240 – TRU-105241]. They included:

- acting as the Key Worker or be responsible for nominating the Key Workers for patients under the care of the MDT, dealing with the team in line with the Trust Key Worker Policy
- ensuring that a holistic assessment is undertaken of the needs of each patient following a diagnosis of a urological cancer, in order to provide specific expert nursing care, advice, support and counselling and where necessary onward referral for specialist input and support

97. For the purpose of the Policy, the Key Worker was defined as 'the person who, with the patient's consent and agreement, takes a key role in co-ordinating the patient's care and promoting continuity, ensuring the patient knows who to access for information and advice'. It stated that it was the joint responsibility of the MDT Clinical Lead and of the MDT Core Nurse Member to ensure that each urology cancer patient has an identified Key Worker and that this is documented in the Record of Patient Management. The identification of the Key Workers was the responsibility of the designated MDT Core Nurse Member. The Operational Policy stated that in the majority of cases, the Key Worker would be a Urology CNS (Band 7) or Practitioner (Band 6).

98. The Operational Policy listed the main responsibilities of Key Workers. These included:

- acting as the main contact person for the patient and carer at a specific point in the pathway
- offering support, advice and providing information for patients and their carers, accessing services as required
- ensuring that the patient and carer have their contact details, that these contact details are documented and available to all professionals involved in that patients care

- supporting the patient in identifying their needs, reviewing these as required and co-ordinating care accordingly

99. In recognition of the shortage of optimally qualified and experienced nurses to undertake the Key Worker role, two additional Band 6 CNS posts were advertised in late 2016. As documented by one of the applicants, Mrs Leanne McCourt, in her witness statement at paragraphs 1.7 and 1.10 [WIT-85914 to WIT-85915], both she and the second applicant, Mr Jason Young, learned at interview that the posts for which they were being interviewed were Clinical Sister posts rather than CNS posts. She was subsequently advised by Mrs Corrigan, Head of Service, that there had been an element omitted from the job description or criteria and that the jobs had to be changed at the last minute. After careful consideration, she took up the Clinical Sister in April 2017, a post which was predominantly concerned with managerial and organisational duties, rather than nurse practitionership facilitating Key Workership. Mr Jason Young also took up the second Clinical Sister/Charge Nurse post in 2017. I believe that his appointment was allied to the development of practitionership allied to non-cancerous urological patient care.

100. Mrs McCourt subsequently applied for and took up the post of Band 7 Urology CNS role in March 2019. However, she was still responsible for managerial duties until 2021, resulting in her nurse practitionership being considerably curtailed until then. As she stated at paragraph 26.1.i) of her witness statement [WIT-85943], absence or reduced CNS provision meant that fewer patients had a named Key Worker and for those that did, access to the Key Worker would have been on a more limited basis. She stated that this could have resulted in less support and advice for patients and their families, leading to a more disjointed journey for them.

Genesis of the Allegations

101. During the course of the Root Cause Analysis of the nine cases considered to have met the threshold for review as Serious Adverse Incidents (SAIs), the Review Team reported

that it found that none had had a CNS appointed or allocated to them as a Key Worker, and presumably had not had Holistic Needs Assessments (HNAs) conducted or been provided with the contact details of their allocated Key Workers. It has been inferred that this failure in their care was during the periods when each of them was under my care. It remains unclear whether any or all of them remained without allocated Key Workers when their care was taken over by other consultant urologists from July 2020.

102. The following is a review of the notes, taken by Mrs Patricia Kingsnorth, of the meetings which Dr Hughes had with various professionals, focussing on the issue of CNSs and Key Workers.

103. At the SAI Urology Review meeting with Mr Glackin, Lead Clinician of the Urology MDT, on 30 November 2020, Dr Hughes advised that each of the families had not been involved with a CNS [TRU-162250]. Mr Glackin said that nurses were available in the acute setting but not at outreach clinics, that his patients had access to a CNS and were referred to palliative colleagues for support. Mr Glackin described me as a 'holistic physician/clinician'. Mr Glackin and colleagues would work with multidisciplinary teams, they would deal with the surgical management but would refer to medical colleagues.

104. At the SAI Urology Review meeting with Dr Shahid Tariq on 29 December 2020, Dr Hughes referred to patients not having access to a specialist nurse / Key Worker and that I chose not to involve other professionals in the patients' care, and that the specialist nurses were used by all the clinicians except one [TRU-162256].

105. At the meeting with Mr David McCaul on 04 January 2021, Dr Hughes was noted to have said that none of the nine patients had access to a Key Worker / specialist nurse and that this was unique to this consultant [TRU-162261]. Dr Hughes advised that the peer review document in 2017 provided assurances to the Board that all patients had access to a Key Worker / specialist nurse but that this had not happened.

106. At the SAI Urology Review meeting with Mrs Martina Corrigan on 18 January 2021, Mrs Corrigan was noted as stating that I never involved a specialist nurse and that had always been the case since she started in the Trust [TRU-162263]. She advised that she had worked in the Trust for 11 years and confirmed that during that time, I never recognised the role of Clinical Nurse Specialists. She stated that I never involved them in my oncology clinics. She stated that she was aware that some of the Clinical Nurse Specialists asked to be at my clinics but that I never included them. She also advised that two of the Clinical Nurse Specialists did report that they did regularly challenge me, asking me if I needed them to be in the clinic to assist with the follow-up of patients, but it had got to the stage where staff were getting worn down by no action and they gave up asking as they knew that I would not change. She also advised that I could be quite arrogant and that was a big part of the perceived issues with my practice.

107. At that meeting, Dr Hughes was recorded as having asked Mrs Corrigan: *"at no stage were specialist nurses allowed to share patient care with Mr O'Brien?"* Mrs Corrigan confirmed that that was correct. She also confirmed that all of the other consultants saw the benefit of using a CNS and that they included them in all of their clinics.

108. In the meeting with Mr Ronan Carroll on 18 January 2021, Mr Carroll advised that the consensus was that I was a very strong personality who could be spiteful and even vindictive and that many of the CNSs were afraid of me [TRU-162265]. Mr Carroll advised that he had been unaware that CNSs had been excluded from seeing my patients. Dr Hughes explained that some of the patients were not referred on for palliative care when their disease progressed. In turn, Mr Carroll speculated about me that there was a sense of arrogance / commanded respect, almost *"God like"* when I walked the corridors.

109. In the meeting with Mr Mark Haynes on 18 January 2021, Dr Hughes advised that I did not work with specialist nurses [TRU-162267]. In turn, Mr Haynes advised that I did not involve the CNSs and that I had a different view of their work [TRU-162268].

110. Dr Hughes did not meet the CNSs until 22 February 2021 due to Covid [TRU-162269]. In a draft record of that meeting, it was noted that Mrs Kingsnorth, Acute Clinical Governance Co-ordinator, advised the meeting that CNS care was not being brought into question. Dr Hughes provided an overview of the nine SAI patients, all of whom should have had input from nurse specialists. Mrs O'Neill advised concerning the inadequacy of CNS staffing relative to the need. Dr Hughes advised that patients were not given phone numbers and that he needed to know whether I had an issue working with nurse specialists or was it a deficit.

111. Again, Dr Hughes advised that he needed to know whether it was a deficit due to work or whether it was 'this particular doctor'. Mrs McMahon advised that she was not sure why I did not invite CNSs into the room and felt that this was a question I needed to answer. She recalled me having oncology review clinics on Fridays, but she was not asked to attend. Dr Hughes asked whether it was reasonable to say that resources were made available. Mrs McMahon confirmed that they would have been made available if support was needed on the day but advised that nurse specialists were not invited to attend appointments.

112. Dr Hughes advised that there were nine patients in the review, and they were not referred to nurse specialists and that three had died. Mrs McMahon agreed that contact details should have been given. She conceded that there may not have been anyone available on the day, but patients should have been given contact details. Dr Hughes advised that he wanted to be able to say that resources were available but that patients had not been referred.

113. Dr Hughes advised that there was no criticism of nurse specialists. The issues are with "the person not referring patients which was best practice, and that these issues were not of the nurse specialists doing". Mrs O'Neill enquired if this would be reflected in the report. Both Dr Hughes and Mrs Kingsnorth replied "yes". Mrs McMahon reiterated that in 2019, all resources were there and that it was indefensible not to provide contact details. Dr Hughes advised that the report would be written without any criticism of the nurse specialists, but that it would highlight resource issues.

114. Dr Hughes lastly met with Mrs Heather Trouton, Executive Director of Nursing, on 23 February 2021 [TRU-162283]. It was noted that Dr Hughes explained to Mrs Trouton that the main concern was around the patient's access to a cancer nurse specialist. He advised that none of the nine patients received the services of a cancer nurse specialist. Dr Hughes explained that as part of the review, the quality of care provided (presumably by clinical nurse specialists) was not in question, as patients did not receive any care. He further explained that the NICaN guidance recommended that every patient with a cancer diagnosis was provided support from a cancer nurse specialist. This assurance was provided to the peer review in 2017 that additional specialist nurses were resourced to provide this service, but that the reality was that my patients were not given access to a specialist nurse.

115. Mrs Trouton advised that, as a Director of Nursing, she would have expected any nurse to provide care in their professional role. Dr Hughes advised her that he did not have an issue with the standard of care that the specialist nurses provided. His issue was that they did not receive any referrals from me and therefore did not provide any care. Mrs Trouton asked whether Dr Hughes thought the specialist nurse should have sought referrals. He replied that they should not but that there should have been checks and balances in place to ensure that my patients were being referred.

116. Mrs Trouton also advised that she in turn had been advised that all of the information regarding accessing a specialist nurse, and all of the leaflets and phone numbers, were visible in every consulting room to ensure that doctors had the information to give to patients. Mrs Trouton reported that the issue of specialist nurse referrals had never been escalated to her.

117. Dr Hughes advised that he had spent two days talking to families, advising them that the resources for specialist nurses were in place, but that they and their loved ones did not get access to one. He reported that all of them wanted to know how this was allowed to happen.

118. The Overarching Report into the nine SAIs was completed and signed off by Dr Hughes, Responsible Lead Officer and Chair of the SAI Review Team, three days later, on 26

February 2021 [TRU-163304]. In the description of its review methodology, the report stated that prior to it being finalised, the Lead Reviewer would ensure that the Review Team apply Trust quality assurance processes to ensure compliance with regional guidance prior to delivery of the final report to the Review Commissioner who would also seek assurance that the quality assurance process had been completed [TRU-163306]. It remains unclear whether either occurred.

119. The Report noted that the MDT Guidelines indicated that "*all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner*" [TRU-163318]. The Report concluded that none of the nine patients had access to a Key Worker or Cancer Nurse Specialist.

120. The Report stated that the Review Team considered whether this was endemic within the Multidisciplinary Team and concluded that it was not, and that patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.

121. It also reported that statements to the Urology Cancer Peer Review in 2017 indicated that all patients had access to a Key Worker / Urology Nurse Specialist. However, this was not the case and was known to be so [TRU-163318].

122. The Report also stated that the Review Team regarded the absence of a Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and Professional Leads. It stated that, while this was the primary responsibility of the referring consultant, there was a responsibility on the Trust to know about it and address it [TRU-163318].

123. The Clinical Nurse Specialists subsequently submitted comments regarding the 'Final' Report [TRU-172135]. They specified that where a CNS was not available for a results clinic,

this task was delegated to either a Clinical Sister or a Charge Nurse or an Experienced Staff Nurse. The Review Team replied with the comment that the issue was that patients were not referred to the service for subsequent discussion and telephone numbers were not made available.

124. The Clinical Nurse Specialists also commented upon the statement in the Report that the Review Team had been informed that I had excluded all CNSs from the care of patients at my clinics [TRU-172139]. The CNSs commented that this was not an accurate representation as they would have been introduced to patients when there was a need for interventions such as catheter changes, nephrostomy tube management, dressings and onward referrals to community continence, district nursing and other AHP services. The Review Team replied with the comment that the review findings were based upon the experiences of the nine patients, in that they did not have access to specialist nurses for the responsibilities detailed by the specialist nurses, namely the responsibilities of Key Workers.

125. In commenting upon the finding of the Review Team that the use of CNSs was common for all other urologists, the Clinical Nurse Specialists also stated that, with recent expansion, the CNS team was more readily available to provide this resource in person, if required, but that this had not always been the case due to other services running in parallel and to competing demands on CNS time. However, if a CNS was unavailable on the day, the Key Worker contact number or the Thorndale Unit contact number would have been available for all urologists to provide. The Clinical Nurse Specialists referred to the reference in the Report that it was the primary responsibility of the consultant to enlist the support of the CNS.

126. The comments were considered at a further meeting of the Review Team on 12 April 2021, when it was recorded that Dr Hughes explained that the Clinical Nurse Specialists had highlighted that they were never given an opportunity to be involved in patients' care and that they would like this to be reflected in the Report [TRU-172133]. All agreed to change the wording in the Report to highlight that nurses were not given an opportunity to be part of patient care and were not the ultimate failsafe in the patients' pathway / journey.

Comments

127. I believe it is reasonable to state that the allegation regarding my appreciation of specialist nurses, whether related to cancer services or otherwise, my usage of them, my engagement with them, my exclusion of them, or my not involving them in the care of my patients, has probably caused me more hurt since 2020 than any other allegation. I believe that the hurt is understandable in view of the contribution that I have made to the development of specialist nurse practice since 1992.

128. As has been stated previously, I found upon arrival as a consultant urologist in July 1992 that the knowledge, expertise and experience of nursing staff related to urology was rudimentary. That improved significantly during the next few years and was much assisted by the leadership of the Ward Manager, Mrs Eileen O'Hagan. However, the development of specialist nursing practice in urology was further boosted by the foundation of CURE by Mrs Roberta Brownlee in 1996. This enabled the development of relationships with academic departments in Ulster University and Queen's University, Belfast. One crucial advance was my success in having a Lecturer Practitioner in Urology jointly appointed by Ulster University and Craigavon Area Hospital Group Trust in 1998. This led to the establishment of modules in urology for undergraduate and postgraduate degrees in nursing. CURE also funded nurses attending urological courses and conferences, further reinforcing their specialist nursing practices. I believe it reasonable to claim that I contributed significantly to a process without which our specialist nurses would not have attained the knowledge, expertise and experience they have since gained.

129. I have never excluded a nurse of any status from the care of any of my patients throughout my career, apart from any occasion when a patient requested privacy or confidentiality, or when I detected or suspected that they did so, on which occasions I would have done professionally and tactfully. Rather, I have frequently engaged with nurses in all

locations, from the student to the clinical nurse specialist [see attachment]. I have found the allegation of their exclusion by me to be profoundly offensive.

130. I believe that there has been a fundamental lack of appreciation of the role of the Key Worker in the care of any cohort of patients, as in this case, patients with a diagnosis of cancer. I believe that it is evident that there has been a fundamental lack of awareness of the original need of cancer patients for a Key Worker. The term 'Key Worker' is not interchangeable with the term 'clinical nurse specialist' or any other nursing role or job description. However, the term has been repeatedly used interchangeably with 'clinical nurse specialist', 'specialist nurse' and others by those interviewed by the SAI Review Team, by the Review Team itself, by counsel to the Inquiry and perhaps most importantly, by the Urology Cancer Clinical Nurse Specialists themselves.

131. Upon reviewing the witness statements of Mrs O'Neill and Mrs McCourt, I do believe that there was a varied awareness of the fundamental reasons for Key Workers, namely, those health care professionals whose primary purpose was, according to the Operational Policy, to assess, with their consent, the needs of cancer patients, their families and carers, across a range of domains, with a view to providing them with that support or referring them to those agencies that would be able to do so.

132. In addressing Question 11 [WIT-80914 – WIT-80915] concerning interchangeability of the terms Keyworker, Specialist Nurse, Cancer Nurse Specialist, Urologist *(sic)* Nurse Specialist, Mrs O'Neill stated that she would "*determine that a Keyworker is part of the Urology CNS role for those engaging in Oncology activity",* whereas the remaining terms were essentially interchangeable. Mrs McCourt on the other hand indicated that the terms were broadly used interchangeably, and that she had also noted other terms for Key Worker, such as Macmillan nurse and named nurse [WIT-85929, paragraphs 11.1 and 11.4]. I believe this to be indicative of a varied recognition of the primary function of a Key Worker.

133. It is apparent from her witness statement that Mrs O'Neill was aware of the need to assess the support needs of patients. She stated that *"an attempt was made to allocate all patients with a Key Worker, but the CNS resource issue meant that a solution was challenging and remained so. While consideration was given to plan for Holistic Needs Assessment the staffing deficit meant that this was not resolved until more recently*" [WIT-80947, paragraph 31.4].

134. She further stated that "*the most recent introduction of Holistic Needs Assessment (HNA) has enhanced the approach to patient care further by offering an online or face to face appointment when the patient and CNS discuss the patient's physical, psychological, spiritual and social needs. The focus is on the patient as a whole, the discussion is led by them and for them, and an action plan is completed to address their top concerns*" [WIT-80914 paragraph 10.5]. It is noteworthy that the primary purpose of the Key Worker for urological cancer patients has only recently been made possible by the provision of adequate numbers of CNSs to undertake the role.

135. It is nevertheless reassuring to note that "*a holistic approach to care is provided at all nurse-led services, encompassing the physical, emotional, psychological and social aspects of patient need' and that 'Patients are given a direct contact number, with a named practitioner (their Key Worker) whom they can liaise with throughout their diagnostic and treatment journey*" [WIT-80913 paragraph 10.3].

136. As indicated above, it is possible that Mrs McCourt did not distinguish between the practices of CNSs and the specific role of the Key Worker. At paragraph 54.2, she stated that she was the Key Worker for a number of my patients but that she had "*no insight as to how Mr O'Brien selected which patients needed or received CNS input"* [WIT-85963]. I frequently identified those patients who needed CNS input for a variety of reasons, requested that input and it was always given, as detailed by the Clinical Nurse Specialists in their comments upon the Overarching Report of the nine SAI patients [TRU-172139].

137. Conversely, Mrs McCourt wrote in her witness statement that she had no understanding as to how Mr O'Brien decided which patients he referred for Key Worker input. If, on occasion, I considered that a patient and/or family/carers required and would benefit from an immediate holistic needs assessment, I requested that it be undertaken, whether by request in advance of a patient attending, or on the day of attendance, or following review, as I did in relation to Patient 4 on 01 March 2020 [AOB-82774]. Otherwise, I expected that all patients would be contacted by their allocated Key Worker with a view to holistic needs assessment and support for any identified needs, if they had been allocated Key Workers and if they had the time and resource to do so.

138. It is probable that the persistent, severe inadequacy of CNSs and other nursing staff able to undertake the role of Key Worker was such as to render it so difficult as to be impossible, and it may be that impossibility undermined the ability to have all patients allocated a Key Worker who then undertook the primary functions of the Key Worker. In any case, I have no doubt that the resources available to the CNSs and other nursing staff capable of being Key Workers was such as to render it impossible to be all that would have been expected of them as Key Workers for all patients. Nevertheless, I believe that it was incumbent upon Key Workers to make every attempt to ensure that their basic responsibilities of ensuring that a holistic needs assessment was undertaken and of ensuring that patients had their contact numbers so as to advise of their changing needs.

139. It is worthy of note in this regard that a workshop was held in March 2022 to discuss "*the need for CNS keyworker role and focus on Holistic Needs Assessment. The pending launch of the Cancer Strategy will reference the need for all patients with a cancer diagnosis to have a CNS keyworker. The nurse should also be part of the local MDM"* [PHA-00320]. I believe that this confirms my contention that the basic responsibilities of the Key Worker were indeed to undertake a Holistic Needs Assessment, having gained the consent of the patient, with the obvious corollary that contact details should be provided so that the patient and/or family/carers may remain in contact with the Key Worker to advise of changing needs.

140. Both CNSs described the consequences of the lack of resources in the provision of both CNS and Key Worker services. Mrs O'Neill stated at paragraph 50.1 [WIT-80960] that "*there were many competing challenges with the service and the availability of a CNS at every results clinic was not possible*" and described at paragraphs 50.2 – 50.6 [WIT-80960 to WIT-80963] the differing practices of consultant urologists in response, bearing in mind that the oncology review clinics undertaken by Mr Michael Young and by myself on Fridays were the least resourced. Such was the competing demand upon inadequate nursing staff on Fridays that they expressed their appreciation that I was able to manage without their assistance.

141. It has been explicitly repeated in the Operational Policies of the Urology Cancer Service that it was the responsibility of the MDT Core Nurse Member, Mrs O'Neill, to be, or to allocate Key Workers, to all newly diagnosed cancer patients. Mrs O'Neill has explained that it was not possible to allocate Key Workers at each MDM as she could only do so at a later time when she knew which nursing staff were allocated to individual clinics. If a Key Worker was allocated to the patients attending an individual clinic, it was then their responsibility to be the Key Worker for those patients attending. It was the responsibility of the Key Worker allocated to proactively introduce themselves to patients, seeking their consent to be their Key Worker, as explicitly expressed in the NICaN policy.

142. Mrs McCourt related the occasion when she advised me that she would be the Key Worker for patients attending my clinic that afternoon [WIT-85957 – WIT-85958, paragraph 50.1]. I recall this occasion very well. I believe that it was actually prior to a New Patient clinic on a Tuesday afternoon, when there may have been new patients attending with either a diagnosis or suspicion of cancer. I indulged in some word play, asking her whether Key Workers were people who worked with keys. I intended it to be nothing other than harmless fun. However, interestingly, I believe that I am correct in asserting that in all of the years conducting cancer clinics in the Thorndale Unit, that was the only occasion when a nurse of any standing presented him or herself at a clinic as the Key Worker for the patients attending that day. However, Mrs McCourt stated that the presence of a Key Worker in the actual

appointment or an introduction after the appointment was by *"invitation only*" [WIT-85957, paragraph 50.1].

143. I believe that such 'invitation only' comment is indicative of a misunderstanding that the role of a Key Worker was somehow predicated upon an invitation to be so. It was not, and never was so. I refute the assertion of Dr Hughes that it was the primary responsibility of the consultant clinician to ensure that patients had Key Workers appointed or that Key Workers undertook their basic responsibilities to the patients to whom they had been allocated. I am unaware of any indication or inference, never mind explicit expression, in any documentation pertaining to Key Workers that it was the primary responsibility of the consultant clinician, to use, engage or refer patients to Key Workers as has been persistently repeated. I know whose responsibilities it was, as I wrote the Operational Policies which were formally adopted by the Trust.

144. It is however the primary responsibility of the consultant clinician to ensure that the patient is fully informed of their condition, its assessment, its natural history, its likely prognosis, its management options, the risks and benefits of management options and the patient's assessment of fitness to undergo management options. It is the primary responsibility of the consultant clinician to ensure that the patient has been able to evaluate that information. It is the primary responsibility of the clinician to enquire of and listen to the patient's wishes and priorities, and to provide time for the patient to formulate those wishes and priorities, so that they may fully participate in management decisions, in order to minimise the risk of management regret, particularly when management options are available and/or recommended, as in many patients with small renal masses or prostate cancer. I believe that the presence of or subsequent participation of a Key Worker should be an adjunct to that primary responsibility of the clinician, rather than a replacement of it.

145. It has always been understood, and explicitly stated, that the involvement of a Key Worker in the care of a patient must be with the consent of the patient. The NICaN policy concerning Key Workers advised that they proactively introduce themselves to the patient, with

the inference that in so doing they would request their consent to their participation in their care, and, perhaps most particularly, to their presence during any consultations with the clinician. Alternatively, the clinician may have requested their consent, if a Key Worker had been allocated and available. I certainly have had the experience of many patients who were and would have been uncomfortable in the presence of a Key Worker during a consultation, particularly male patients in the presence of a female Key Worker.

146. Lastly, it remains unclear whether any or all of the nine patients had Key Workers appointed or allocated to them at any stage during their cancer journeys, either during or after they remained under my care.

147. Patient 1 was one of many cancer patients who attended my clinic at South West Acute Hospital in Enniskillen. Why did his attending my clinic at South West Acute Hospital prevent a Key Worker contacting him by telephone to seek his consent to involvement in his care, to undertake a holistic needs assessment, to offer and arrange support, and to provide contact details by telephone? Nevertheless, Patient 1 documented his contact with nursing staff on two occasions [PAT-001382], and with Mrs McCourt on one of those occasions [PAT-001385]. Why did neither of these contacts precipitate Patient 1 having a Key Worker allocated? Why did he not have a holistic needs assessment undertaken as a consequence? Did he meet a CNS at his review on 14 July 2020? Did he/she undertake the Key Worker role then? Did he/she undertake a holistic needs assessment then? If so, why did Patient 1 and his family experience such difficulty accessing services thereafter?

148. As detailed above, I specifically requested a holistic needs assessment of Patient 4 on 01 March 2020. Did he have it undertaken? Did he have a Key Worker appointed at that time? Was he and his family provided with the contact details of a Key Worker?

149. Mrs O'Neill advised the SAI Review Team on 22 February 2021 that she had met Patient 5 when he attended for review by Mr Haynes in the late summer of 2020 [TRU-162269]. If so, did he have a holistic needs assessment performed then and support offered if needed?

Was he provided with contact details then? Did Mrs O'Neill remain as his Key Worker, or did she appoint another in her stead?

150. At the Urology Service User Group Meeting of 18 November 2021, I note that Patient 2 asked if the process of a consultant passing a patient to a CNS was a lengthy one [TRU-163475]. Mr Carroll advised that this was the process of an MDM. "*The entire MDT are present including a CNS and it is the responsibility of that nurse to link".* Did Patient 2 have a Key Worker allocated by then? Who allocated the Key Worker and when was the Key Worker allocated? Who was the Key Worker? Had he had a holistic needs assessment undertaken and contact details by telephone provided?

Concluding Remarks

151. The role of the Key Worker, indeed its job description, has been well established. It can theoretically be fulfilled by any adequately qualified and experienced, health care professional, but has understandably and appropriately become the preserve of nurses, and particularly of clinical nurse specialists. Its need and purpose, its role or job description are not interchangeable with those who take on that role. They are appointed or allocated by the MDT Core Nurse Member. They are not appointed or allocated by usage, engagement or referral by a consultant clinician.

152. In many health care jurisdictions, Key Workers have become so established and adequately resourced as to enable them to be the hub in the centre of the wheel of patient care, requesting investigations, referring patients for pre-operative assessment etc. When the complement is so inadequate as to render it impossible to have all cancer patients effectively allocated a Key Worker, it renders it impossible for those Key Workers to fulfil even the primary purposes of the role, which have been, and remain, the holistic assessment of the needs of the patient, their families and carers, offering them support, while ensuring they are able to remain in contact as they progress along their cancer journey.

Section 6 – Job Plans / Administration Time

153. At various sections in my Section 21 Statement dated 02 November 2022, I referred to job plans and the inadequacy of the amount of time allocated to me for administrative tasks. I have since then heard evidence from various witnesses in respect of the issue of administrative time and I wish to make some further comment on this issue.

154. Mark Haynes sent an email to Esther Gishkori on 5 October 2018 [TRU-163343 – TRU-163345] when considering resigning from his role as Associate Medical Director (AMD). In that email, he included his working week schedule. He indicated that on a typical week he started administrative work at 5.15 am 5 to 6 days each week, as well as Sunday evenings. On the basis of the schedule he presented, he spent approximately 15 hours each week on administration [TRU-163344]. That is the equivalent of two standard working days each week solely on administration.

155. It resonated very much with me as similar to the amounts of time that Michael Young and I recorded when we were awarded job plans of 15.5 PAs in 2006 [AOB-00047].

156. If you then compare that to the amount of time allocated to administration in my proposed job plans from March 2012 until the end of my employment, while it varied annually, it was approximately 0.8 PAs, the equivalent of approximately 3 hours per week. It was one fifth of that which Mark Haynes required. How can it be reasonable to expect an employee to meet the employer's expectations with regard to administration by providing 3 hours per week to do so, if another employee has demonstrated that it has required 15 hours to meet those expectations?

157. See my Section 21 Statement dated 02 November 2022 for analysis at WIT-82527 – WIT-82528. And my job plans at 2012 0.80PA [TRU-102235 – TRU-102243], 2013 0.80PA

[TRU-102244 – TRU-102252], 2015 0.667PA [AOB-00795 – AOB-00799], 2016 0.476PA [AOB-01072 – AOB-01076], 2017 0.577PA [AOB-01408 – AOB-10413], 2018 0.77PA [TRU-102253 – TRU-102260].

158. I have noted that my former colleagues have since been allocated PAs for specific roles in their more recent job plans. I have noted that the Lead Clinician of the Urology MDT has been allocated 1 PA, four hours, per week for that role. I was not allocated any time in any proposed job plans for the role of Lead Clinician of the Urology MDT from April 2012 until December 2016. It is worthy of note that the Lead Clinician is currently allocated more time for that role than I was offered for all administration from March 2012 onwards. Moreover, Mark Haynes is allocated 2 hours per week for his role at NICaN [TRA-00824], a role for which I was not allocated any additional administrative time.

Section 7 – Two out of Ten Patients

159. At paragraphs 6-20 of my Section 21 Statement dated 2 November 2022 I set out my concerns regarding the information that was provided to the Minister and / or Department of Health which led to Mr Robin Swann MLA making a statement to the Northern Ireland Assembly on 24 November 2020 [WIT-82401 – WIT-82405]. The Minister's statement referred to an allegation that 2 out of 10 patients listed for surgery under my care were not on the hospital's Patient Administration System at that time. I set out in my original statement the basis upon which this allegation was unfounded and have provided medical records establishing this allegation to be unfounded to the Inquiry. The individual who made the allegation, Mr Mark Haynes, has since confirmed in his own evidence that it was incorrect [TRA-01360 – TRA-01369]. However, I remain concerned, in light of the evidence that has been heard, that this allegation continues to be repeated without any reference to the fact that it has been established as untrue.

160. In the evidence of Dr Maria O'Kane at TRA-01467 she stated the following:

"*Mr. O'Brien retired from the Trust on 17th July. When we had discovered the difficulties after – I think I was informed on 11 June and the Clinical team, principally Mr. Haynes and Mrs Corrigan had been working on an email that they had received that suggested there was a discrepancy in two waiting lists, and that caused them a bit of concern. When they worked their way through that they realised there wasn't a discrepancy, but what they also discovered on the back of those explorations were the concerns then around the cancer multi-disciplinary team meeting."*

161. In his own evidence, Mark Haynes has accepted that the allegation relating to the 2 out of 10 patients was incorrect [TRA-11397]. He was not clear in his evidence specifically when he discovered that the allegation was untrue [TRA-11398]. However, Dr O'Kane informed the Inquiry that that it was her recollection that the realisation that there was in fact no discrepancy occurred in and around late September [TRA-1159].

162. My concern is that, notwithstanding this allegation being untrue, and having been accepted by Mr Haynes as untrue, it has been repeated on countless occasions by various bodies. I have stated above that the allegation was repeated by the Minister for Health when making his statement to the NI Assembly on 24 November 2020. More recently, the RQIA published a report dated July 2023 entitled 'Interim Report on Findings in Respect of Terms of Reference 1. RQIA Review of Southern HSC Trust Urology Services and Lookback Review'. In that report, at WIT-106548, it is stated that the Trust became aware that "*two out of 10 patients listed for surgery under the care of the consultant had not been recorded on the hospital's patient administration system at that time."* That allegation is repeated by the RQIA in July 2023 notwithstanding that the allegation was untrue and was certainly known by the Trust to be untrue long before July 2023. The RQIA report makes no reference to the allegation having been untrue. On discovering that this allegation was untrue, why has the Trust not been clear with other organisations that the allegation was untrue? Why has the Trust facilitated the continuing repetition of this allegation by bodies such as the RQIA in July 2023 in circumstances where it has been established that the allegation was untrue?

163. It remains of significant concern to me that the Trust was aware long ago that the allegation was untrue but has apparently taken no steps to address this and has permitted this allegation to persist and be repeated as if it was true.

164. I would further question why Mr Haynes was appointed to assist the Trust with the subsequent review in respect of the screening for Serious Adverse Incidents and SCRRs, patient reviews etc., in circumstances where his analysis of the 2 out of 10 patients was significantly flawed and where a more independent reviewer would have been preferable.

Section 8 - Retirement

165. Throughout the course of the Inquiry there have been countless references to my having 'retired' from clinical practice. I wish to clarify that I did not retire.

166. I had a meeting with Malcolm Clegg of Human Resources ("**HR**") in 2018 to discuss my options in respect of my future retirement, mainly in terms of the tax implications of retiring. During that meeting, we discussed the option of my retiring from full time employment and returning to part time employment with the SHSCT. While it was emphasised by Mr Clegg that there was no right to return to part-time employment with the SHSCT, he felt that in the context of an inadequately resourced service he could not foresee any reason why I would not be able to avail of that option. There was no mention at this meeting of any practice or policy of not re-engaging people with ongoing HR issues.

167. Later, in January 2020, I made the decision that I wanted to spend more time at home and decided to look further into the prospect of retirement. I decided to further explore the idea of retiring from full-time employment and returning to the SHSCT as a part-time employee. I discussed this idea initially with Michael Young, and subsequently with Mark Haynes and

Martina Corrigan. Indeed, in my discussions with Mark Haynes, we discussed the nature of the work that I would like to do on returning as a part-time employee of the SHSCT.

168. Following those discussions, I decided to retire from full-time employment on 30 June 2020, and to return to part-time employment on 3 August 2020. I requested the relevant forms for drawing down my pension from HR on 13 February 2020. I did not announce my intended retirement at that time. I returned the completed forms to HR on 6 March 2020. I subsequently advised Martina Corrigan in writing later in March 2020 of my intention to retire from full-time employment on 30 June 2020 and to return to part-time employment from 3 August 2020 [AOB-02373].

169. I received a text message from Mark Haynes on 8 June 2020 to enquire whether I would be available at 15.00 later that day for a call with him and Ronan Carroll. I was concerned that Ronan Carroll was to be included on the call, and for that reason I made the decision to record the call, otherwise I would not have done so [AOB-56494 – AOB-56496]. Following that call, I rescinded my intention to retire on 9 June 2020, and confirmed that I had done so with the Chief Executive and the Chair of the Trust Board on 10 June 2020. Accordingly, while I subsequently left the employment of the SHSCT, I did not do so voluntarily and did not retire.

170. It has been repeatedly stated by various witnesses throughout the Inquiry, and in documentation relating to the Inquiry, that I retired. I did not retire, and I wish to be absolutely clear with the Inquiry that I did not retire.

Section 7 - Miscellaneous Issues

171. In the oral evidence of Ms Esther Gishkori [TRA-03092] she stated that Mr Mackle said to her that I was "*creating havoc within the theatres*." At TRA-06998 – TRA-06999, the exchange between Mr Hanbury and Ms Gishkori was as follows from line 128:

Q: "Thank you. You also made a comment about his practice causing havoc. Again, what do you mean by that? Is that an organisational thing or what? Why did you choose those words?

A: I chose those words because he wasn't a team member. He would have, as you saw in one of the complaints, told somebody to come in the night before but nobody else knew about that. So, the gentleman turned up at the ward 'I am here for my operation', 'well, what operation'. That's the sort of havoc I am talking about. And because he went on so late, then others had to go off the list that were due to be done that day and then there had to be found time for them again. Things like that.

Q: So it was more a scheduling thing and perhaps overruns?
A: Just scheduling and him, I suppose, not toeing the line, as everybody else, did that caused havoc."

172. I entirely reject the notion that I caused havoc in the theatre, whether that relates solely to scheduling or otherwise. No evidence has been provided indicating that my theatre sessions went on any later than any other consultant, and I do not accept that that was the case. On the contrary, I was so regularly prevented from starting my operating session on Wednesdays at 1.00 pm due to Mr O'Donoghue's morning operating session overrunning that I had to reduce the number of patients scheduled for my sessions to avoid similarly overrunning or having patients cancelled. I worked with many theatre nurses, anaesthetists, and other surgeons during my career and no issues were ever raised with me regarding my conduct within the theatre or in respect of scheduling patients for surgery. I am unaware of any theatre staff having been asked by the Inquiry for information or evidence in support of this allegation. I am unaware of any evidence that I caused havoc in theatre due to administrative scheduling of operation lists. I note that, in particular, in the evidence of Mr Suresh, consultant urologist, at TRA-08699 – TRA-08700, he confirmed that he had no experience of my causing havoc in theatre.

173. Somewhat related to the above allegations, Mrs Corrigan made reference in her witness statement to her raising "*concerns regarding Mr. O'Brien bringing patients in from home on the week when he was consultant urologist of the week, thereby adding more pressure to an already pressured system"* [WIT-26294]. In her evidence to the Inquiry, she clarified that these were patients who were on an elective inpatient waiting list [TRA-07292]. I have found it remarkable that Mrs Corrigan had not been aware that we were encouraged to avail of any vacated elective operating sessions when Urologist of the Week (UOW) and that the sessions were secured by arranging for one or two patients to be admitted electively for each of those sessions. These arrangements were agreed in advance at our monthly scheduling meetings, and it was my understanding that Mrs Corrigan would have been aware of these arrangements as it was she who notified the Theatre Manager of the arrangements.

174. Indeed, Mrs Corrigan went further in giving evidence to the Inquiry in June 2023 by asserting that the patients scheduled for emergency surgery during the weekend of 15 and 16 July 2017 had included patients who had been on an elective list [TRA-07292]. It was evident from her evidence that she was uncertain of the date of the meeting when this issue arose. There was no meeting held on 07 July 2017. Instead, I was on annual leave on 14 July 2017 when I received a telephone call from Personal information redacted by USI, locum consultant urologist, advising me that he wished to admit a patient suffering ureteric colic due to an obstructing ureteric stone that day, asking if I would agree to my operatively managing the patient the following day, Saturday 15 July 2017, as I was the Urologist of the Week (UOW) over the weekend. I agreed to do so. However, on arrival the following morning, I found that the patient had not been added to the emergency list, whereupon I did so. Thankfully, the audio transcription of the recorded meeting of 25 July 2017 did not record any allegation that any of the patients scheduled that weekend had been on any elective list of mine [AOB-56218 – AOB-56219, page 9-10]. Instead, I found it sinister that it had been suspected that I had arranged for a patient to be admitted electively for emergency surgery, just because I found on 15 July 2017 that an acutely admitted patient had not been added to the emergency operating list. This allegation made in evidence six years later would have gone unchallenged but for the recording of the meeting of six years earlier.

175. I strongly refute the allegation made by Mrs Corrigan that I refused to discharge patients who would have been fit for discharge to assist with patient flow [TRA-07273 – TRA-072741]. If any patient was fit to be safely discharged, they were discharged. If I considered that it was unsafe to discharge patients, I did not agree to do so.

176. Similarly, I repudiate Mrs Corrigan's allegation that I was regularly late for morning ward rounds which would be almost completed by the time that I arrived [TRA-07295]. Consultant-led ward rounds began at 9 am, apart from the Grand Round each Thursday morning which I initiated on the appointment of Mr Baluch as the second consultant in January 1996 and which began at 10 am. The ward rounds conducted by registrars, and to which Mrs Corrigan refers and describes, were indeed logistic ward rounds resulting from handover from those on duty during the previous night, and which were concentrated on requesting laboratory and radiological investigations as well as placing patients on emergency operating lists, if any of these were not already undertaken. A clinical ward round of 20 to 35 patients could not conceivably be adequately conducted in 30 minutes. Prior to the introduction of UOW, I may not have been able to perform a morning ward round at all, if 'on call', as I may have been in theatre or at a clinic, beginning at 9 am. Following the introduction of UOW in November 2014, I similarly may not have been able to undertake a ward round at 9 am if I were operating in emergency theatre. Otherwise, I did, ensuring that a proper and adequate ward round was conducted.

177. With regard to outpatient clinics, I have no memory of any clinic having ever overrun until 8pm, as such an overrun would be memorable. Indeed, I recall on one occasion in December in the late nineties, when we had come under pressure to accommodate increased numbers of new and review outpatient attendances, conducting a clinic at which approximately 68 patients had been appointed at Armagh Community Hospital with the assistance of two registrars and a clinical research fellow. As all four of us left the Hospital at 6.45 pm, I pledged not to have such an overrun happen again.

178. I note that Dr Rankin reported in her evidence to the Inquiry that the allegation of my clinics at Banbridge Polyclinic overrunning until 7 pm emanated from Mrs Corrigan (Day 50, Page 57). In her own evidence (WIT-26314, para 70.5) Mrs Corrigan asserted that my clinics did not finish until 8 pm. However, I am unaware of the Trust having disclosed any evidence of any outpatient clinic overrunning until 8 pm and I do not accept that was the case.

179. Mrs Corrigan also related an occasion when I was angry at the admissions of one or two patients being cancelled by a recently appointed Patient Flow Manager for procedures arranged to be undertaken the day following admission [TRA-07291]. One patient was severely disabled, requiring transport by ambulance to the hospital, for which reason his admission on the day prior to the procedure had been arranged, as it had been our experience that the ambulance service could not be relied upon to have the patient admitted on the day of the procedure in time for the procedure. If I recall correctly, the procedure was one of interventional radiology. I went to Mrs Corrigan's office to speak to her. The Patient Flow Manager was present. They both then appreciated that the patient's circumstances had not been considered. Mrs Corrigan subsequently advised me that the Patient Flow Manager had undertaken the cancellation, that I was correct to bring it to her attention and that it was understandable that I was annoyed on behalf of the patient as all of the logistics of elective readmission on another occasion would have to be rearranged. I have found it concerning to read Mrs Corrigan's evidence six years later that she had sought the advice of Mr Young who would not have been familiar with the patient's circumstances and who advised admission the following day [ref].

180. Mrs Corrigan also related that I had spoken rudely to Mr O'Donoghue for having begun discussion of patients at the Urology MDM prior to the usual starting time of 2.15 pm [TRA-07279 – TRA-07280]. I do recall this episode very clearly. It did not occur in 2019 as indicated by Mrs Corrigan in her evidence but in April 2020. It had been our usual practice for the Chair of MDM to wait for a few minutes after 2.15 pm to ensure that MDT members who were expected to attend could be present for discussion of all the patients listed. As we were well into Covid lockdown by this stage, I linked in remotely by Zoom at 2.15 pm to realise that three patients had already been discussed, one of whom was under my care. I shared my view that

it was inappropriate for Mr O'Donoghue, who was chairing, to have commenced the meeting prior to the usual starting time, resulting in patients being discussed without all members present.

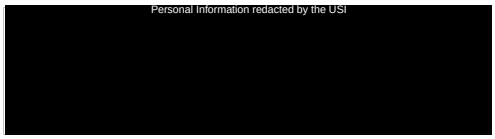
181. I recall this episode all the more as within 15 minutes of the end of the meeting, I received a telephone call from Mr Haynes who advised me that he agreed with me entirely. I remember this call as Mr Haynes was even more exercised by Mr O'Donoghue being present in a room with the cancer tracker and two clinical nurse specialists, Mrs Kate O'Neill and Mrs Leanne McCourt, in the midst of a potentially lethal global pandemic while the remaining members linked in remotely. I was bemused by Mr Haynes requesting my advice as to how to deal with him. I advised him to raise the issue with him privately. I have been even more bemused to read Mrs Corrigan's evidence that she spoke to Mr Haynes about the manner in which I spoke to Mr O'Donoghue [TRA-07279]. She did not know whether he did anything about it. Given the content of his call to me in respect of Mr O'Donoghue's conduct, I suspect he did not do anything about it.

182. In his evidence at TRA-08583 Mr John O'Donoghue said the following:

"As I said earlier today, I mean I've seen some of the letters he dictated whilst on-call and they were four-pages long of no paragraphs, just continuous narrative. I think if you tried to do that kind of long letters, I don't know how many hundred come in a week, it's impossible. I don't think of any benefit because nobody can read those letters. They're just too long, too unfocused."

183. I am not aware of any examples of any such letters being provided by Mr O'Donoghue or the Trust to the Inquiry. I do not accept that I ever dictated such letters which were four pages of continuous narrative without any paragraphs, resulting from triage of referrals.

184. I hope that this addendum statement will be of further assistance to the Inquiry. I am happy to provide any further clarifications required.



Signed

Dated: 28 March 2024