

(SCRR) of your care. We have included a leaflet to explain this process in further detail.

The external independent Consultant has determined that the treatment plan you were given in 2009 was potentially not appropriate. This treatment plan will be reviewed in the SCRR. Once this is complete we will write to you to inform you of the outcome.

I want to assure you that your current care is completely safe and appropriate. You had a telephone consultation with Mr Haynes, Urology Consultant in April 2021. As discussed with you, your initial diagnosis in 2009 you potentially should have been offered radiotherapy in conjunction with the medication. It was noted in 2020 your PSA level (prostate specific antigen blood test which indicates possible prostate cancer or progression of cancer) was rising above the normal range and the medication was no longer controlling this. Mr Haynes advised this medication should be stopped and a CT scan of your chest, abdomen and pelvis and a bone scan be completed. These were completed and reported as normal. Whilst your PSA returned to within normal limits, I note Mr Haynes discussed the option of radiotherapy with you and completed a referral to the Oncology Team in Belfast. You completed your radiotherapy in October this year. The Oncology Team will be reviewing you annually for the next 5 years with checks of your PSA every 3 months

We hope your review with Mr Haynes and subsequent reviews in Belfast has provided you some assurance. I do fully appreciate that up until you received this letter this may have been a worrying time. The leaflet included with this letter outlines the support services available to you. Dedicated Trust Liaison Officers who are trained professional staff are available for any queries, concerns or questions you may have. This is a strictly confidential service for the purposes of this review process.

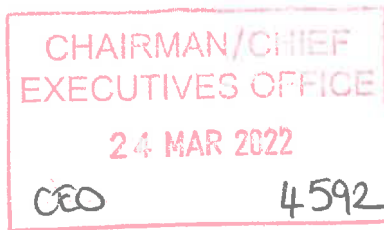
I apologise it has taken some time to complete. This was due to the volume of patients involved and wanting to assure ourselves that every patient record was

reviewed fully. Finally you have the right to expect the very best care and treatment every time you use our services, for this expectation not being met I apologise.

Yours Sincerely

Shane Devlin

CHIEF EXECUTIVE



Patient 38

Personal Information redacted
by the USI

21 March 2022

Christine A Smith QC
Chair to the Urology Services Enquiry
1 Bradford Court
Belfast

Dear Ms Smith

I refer to your correspondence of 10 March regarding the enquiry into my treatment while a patient of the Southern Trust's Urology Department.

I wish to inform you of inaccuracies in a letter to me from the Chief Executive of the Southern Trust dated 31 December 2021.

In this letter (page 2) the Chief Executive wrote:

"Mr Haynes discussed the option of radiotherapy with you and completed a referral to the Oncology Team in Belfast. You completed your radiotherapy in October this year."

This is inaccurate. While the option of radiotherapy was discussed, this was not the treatment option that I chose. Due to the potential side effects given my age and other long-term conditions, I opted for an injection therapy and did not receive radiotherapy treatment.

While I am very happy with Mr Haynes' care and treatment, I am concerned that such inaccurate information was included in a letter to me.

I was and remain very confident in Mr O'Brien's treatment and care over many years and consider that he acted in my best interests given my age and co-morbidities. Mr O'Brien undertook regular reviews and, over the most recent period of treatment, contacted me and my designated next of kin by telephone on a number of occasions in the period prior to his retirement to discuss my condition and made agreed adjustments to my treatment.

I cannot specifically recall Mr O'Brien discussing radiotherapy but other options were discussed, and we agreed the least invasive options in respect of optimising benefit. He referred me for Renal review so I am also currently under the excellent care of the Renal service at Daisy Hill Hospital.

I believe Mr O'Brien provided me with information, advice and treatment taking into account my age, co-morbidities and in the interests of my quality of life – which has been relatively good thanks to Mr O'Brien's care.

Yours sincerely,

Patient 38



✓ cc Chief Executive, Southern H&SC Trust

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I want to assure you that your current care is completely safe and appropriate. You had a telephone consultation with Mr Haynes, Urology Consultant in April 2021. As discussed with you, your initial diagnosis in 2009 you potentially should have been offered radiotherapy in conjunction with the medication. It was noted in 2020 your PSA level (prostate specific antigen blood test which indicates possible prostate cancer or progression of cancer) was rising above the normal range and the medication was no longer controlling this. Mr Haynes advised this medication should be stopped and a CT scan of your chest, abdomen and pelvis and a bone scan be completed. These were completed and reported as normal. Whilst your PSA returned to within normal limits, I note Mr Haynes discussed the option of radiotherapy with you and completed a referral to the Oncology Team in Belfast. You completed your radiotherapy in October this year. The Oncology Team will be reviewing you annually for the next 5 years with checks of your PSA every 3 months

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Audit Title: Audit of Prescribing of anti-androgen medicine 'Bicalutamide'

Directorate: Acute Services ☒ Children & Young People ☐ Older Persons & Primary Care ☐
Mental Health & Disability ☐ Corporate request ☐

Division:

Auditor's name: Mr Mark Haynes

Audit Supervisor's Name : Not Applicable

Contact details: mark.haynes@shsc.nhs.uk (email)

Is this a: National audit ☐ Regional audit ☐ Trust audit ☒ International audit ☐

Proposed audit commencement date 27th October 2020

Proposed audit completion date .../.../....

Audit Aims

To ensure that the anti-androgen medicine 'Bicalutamide' has been prescribed as licensed and in line with NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Audit Objectives

- To ensure that where Bicalutamide is prescribed only where indicated and as per licensed usage
- To ensure that where Bicalutamide is prescribed this is prescribed in the correct therapeutic dosages
- To ensure that patients prescribed Bicalutamide is appropriately reviewed as part of the patients ongoing care
- To ensure that any deviations from prescribing guidance is based on sound evidence based clinical rationale

Audit Standards

The following audit standards obtained from NICE guideline [NG131] Prostate cancer: diagnosis and management
Published date: 09 May 2019.

Audit Criteria	Target	Exceptions	Source of Evidence
Bicalutamide prescribed as per indicated conditions in NICE NG131	100%	Clinical rationale for deviation from guidance	NICE guideline NG131 Prostate Cancer: Diagnosis and Management
Therapeutic doses of anti-androgen monotherapy with bicalutamide are prescribed at recommended dose (150 mg).	100%	Discussions with patient / Clinical rationale	NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Audit Methodology

The following audit methodology will be followed:

- HSCB to provide information on primary care prescriptions of the medication Bicalutamide
- Southern Health and Social Care Trust patients to be identified and a consultant led review of prescribing to take place to identify prescribing of Bicalutamide that is outside of that prescribed in NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Rationale for the audit (please tick all that apply)

Topic is included in the Directorate's clinical audit work-plan

☐ Compliance with standards & guidelines



National Healthcare Quality Improvement Partnership (HQIP) audit	<input type="checkbox"/>	Regional RQIA/GAIN audit	<input type="checkbox"/>
Other national / international audit	<input type="checkbox"/>	Trust based audit topic important to team/division	<input checked="" type="checkbox"/>
Clinical risk	<input checked="" type="checkbox"/>	Recommendation from national / regional report	<input type="checkbox"/>
Serious Adverse Incident or Adverse Incident review	<input checked="" type="checkbox"/>	Clinician / personal interest	<input type="checkbox"/>
Incident reporting	<input type="checkbox"/>	Educational audit	<input type="checkbox"/>
Other – please specify			
Level 1	<input type="checkbox"/>	Level 2	<input checked="" type="checkbox"/>
		Level 3	<input type="checkbox"/>
		Level 4	<input type="checkbox"/>
Has this audit been approved based on the priority level?		Yes	<input checked="" type="checkbox"/>
		No	<input type="checkbox"/>
Level 1 - Approval required by Associate Medical Director or Clinical Director or Directorate Governance Forum Level 2 - Approval required by Associate Medical Director or Clinical Director or Directorate Governance Forum Level 3 – Approval required by Supervising Consultant Level 4 – Approval required by Supervising Consultant Please be advised that the audit cannot proceed without approval as above.			
Please Note: The Information Team have advised they will not release data to the requestor unless the clinical audit has been approved as above. The clinical audit team will also advise contact with Information Governance for any advice required.			
The clinical audit team can be contacted via:			
Email:	Personal Information redacted by the USI		
Tel:			
Raymond Haffey	Personal Information redacted by the USI	Mary Markey	Personal Information redacted by the USI
Terri Harte		Roisin Feely	
Sandra McLoughlin		Philip Sullivan	
<i>In submitting this audit registration form, I agree to share the audit findings, recommendations and audit summary template with: the Audit Supervisor, appropriate Divisional/Directorate Committee and the Trust's Clinical audit team</i>			
Please submit your audit registration form to:		Personal Information redacted by the USI	

Priority levels for clinical audit

Level	Audit type - projects identified through	
Level 1 audits, "external must dos" (where the service is applicable to SHSCT)	<ul style="list-style-type: none"> National audits (NHS England Quality Accounts List (HQIP), including the National Confidential Enquiry into Patient Outcomes and Deaths (NCEPOD) / Other Confidential Inquires 	1
Level 2 audits, other national audits and 'internal must dos'	<ul style="list-style-type: none"> National audits not contained within the HQIP list, or other clinical audits arising from: Clinical risk Serious untoward incident / internal reviews National Institute of Clinical Excellence Standards & Guidelines Complaints Re-audit Regional audits initiated by RQIA / GAIN 	2
Level 3 audits, 'divisional priorities'	<ul style="list-style-type: none"> Local topics important to the division 	3
Level 4 audits	<ul style="list-style-type: none"> Clinician / personal interest Educational audits 	4

Data Notes

Data relates to March to August 2020.

There are 1,265 unique patients identified in the data.

There are 3 patients who cross LCG areas as they have changed practice in this time period. I have highlighted these in the data.

LCG	PatientHcn	DrugName	No. of prescription items	Quantity (count of tablets)
Belfast	Personal Information redacted by the USI	Bicalutamide 50mg tablets	2	56
Belfast		Bicalutamide 50mg tablets	6	168
Belfast		Bicalutamide 50mg tablets	1	21
Belfast		Bicalutamide 50mg tablets	3	168
Belfast		Bicalutamide 150mg tablets	1	84
Belfast		Bicalutamide 50mg tablets	1	42
Belfast		Bicalutamide 50mg tablets	5	140
Belfast		Bicalutamide 50mg tablets	4	112
Belfast		Bicalutamide 50mg tablets	1	28
Belfast		Bicalutamide 50mg tablets	5	140
Belfast		Bicalutamide 50mg tablets	1	21
Belfast		Bicalutamide 150mg tablets	4	112
Belfast		Bicalutamide 150mg tablets	1	56
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Belfast		Bicalutamide 150mg tablets	3	168
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Belfast		Bicalutamide 150mg tablets	6	168
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Belfast		Bicalutamide 150mg tablets	2	112
Belfast		Bicalutamide 50mg tablets	2	168
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Belfast	Personal Information redacted by the USI	Bicalutamide 50mg tablets	6	168
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Northern		Bicalutamide 150mg tablets	3	168
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Northern		Bicalutamide 50mg tablets	2	112
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Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	28
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Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	21

Northern	Personal Information redacted by the USI	Bicalutamide 150mg tablets	2	84
Northern		Bicalutamide 50mg tablets	4	224
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	1	84
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 150mg tablets	3	84
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	5	140
Northern		Bicalutamide 50mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	56
Northern		Casodex 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	3	168
Northern		Casodex 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	10
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 50mg tablets	4	112
Northern		Bicalutamide 150mg tablets	3	84
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	1	56
Northern		Casodex 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	4	112
Northern		Bicalutamide 50mg tablets	4	112
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 150mg tablets	2	112

Northern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	1	84
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 150mg tablets	5	140
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 150mg tablets	5	196
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	84
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 150mg tablets	1	84
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 150mg tablets	3	180
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	3	84
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	1	112
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	2	224
Northern		Bicalutamide 150mg tablets	2	84
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	5	140

Northern	Personal Information redacted by the USI	Bicalutamide 150mg tablets	5	140
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	5	150
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	5	168
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 150mg tablets	4	112
Northern		Bicalutamide 150mg tablets	6	168
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 150mg tablets	2	88
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	3	91
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 150mg tablets	3	66
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	5	140
Northern		Bicalutamide 50mg tablets	3	112
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	84
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 150mg tablets	3	168

Northern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 150mg tablets	1	28
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	14
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 150mg tablets	1	84
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	4	112
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	7	161
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 150mg tablets	1	28
Northern		Bicalutamide 150mg tablets	4	112
Northern		Bicalutamide 150mg tablets	3	84
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	4	168
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	4	112
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 150mg tablets	3	84
Northern		Bicalutamide 50mg tablets	2	56
Northern		Bicalutamide 50mg tablets	2	168
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	2	168
Northern		Bicalutamide 150mg tablets	4	112
Northern		Bicalutamide 50mg tablets	2	168
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	4	112
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	2	56

Northern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	3	84
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	3	84
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 50mg tablets	8	224
Northern		Bicalutamide 50mg tablets	1	28
Northern		Casodex 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 150mg tablets	5	140
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 150mg tablets	5	252
Northern		Bicalutamide 50mg tablets	4	224
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 50mg tablets	1	14
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	3	119
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 150mg tablets	2	84
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 50mg tablets	4	120
Northern		Bicalutamide 50mg tablets	4	175
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 150mg tablets	1	84
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	2	112

Northern	Personal Information redacted by the USI	Bicalutamide 150mg tablets	1	84
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 50mg tablets	2	84
Northern		Bicalutamide 150mg tablets	1	28
Northern		Bicalutamide 50mg tablets	3	140
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	6	168
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	5	140
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	5	280
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	30
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	2	84
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	1	28
Northern		Bicalutamide 50mg tablets	1	42
Northern		Bicalutamide 150mg tablets	2	56
Northern		Bicalutamide 50mg tablets	3	77
Northern		Bicalutamide 150mg tablets	3	168
Northern		Bicalutamide 50mg tablets	5	147
Northern		Bicalutamide 50mg tablets	4	112
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 150mg tablets	1	28
Northern		Bicalutamide 150mg tablets	1	56
Northern		Bicalutamide 50mg tablets	2	56
Northern		Bicalutamide 50mg tablets	4	112
Northern		Bicalutamide 50mg tablets	3	168
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 50mg tablets	2	112
Northern		Bicalutamide 50mg tablets	5	140
Northern		Bicalutamide 50mg tablets	1	56
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	2	112
Northern		Bicalutamide 150mg tablets	5	140
Northern		Casodex 150mg tablets	5	140
Northern		Bicalutamide 50mg tablets	1	21
Northern		Bicalutamide 150mg tablets	6	168
Northern		Bicalutamide 150mg tablets	1	84
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 50mg tablets	4	112

South Eastern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	6	168
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	0
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	4	156
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	7
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 150mg tablets	4	112
South Eastern		Bicalutamide 150mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	5	115
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	2	168
South Eastern		Bicalutamide 50mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	168
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	140
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 150mg tablets	5	129
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 150mg tablets	2	84
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	5	140

South Eastern	Personal Information redacted by the USI	Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	84
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	1	140
South Eastern		Bicalutamide 150mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	4	140
South Eastern		Bicalutamide 50mg tablets	6	168
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	112
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 150mg tablets	6	168
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	168
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	2	84
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 150mg tablets	1	28
South Eastern		Bicalutamide 150mg tablets	3	84
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	3	126
South Eastern		Bicalutamide 50mg tablets	3	84
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	84
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 150mg tablets	5	140

South Eastern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	3	84
South Eastern		Bicalutamide 50mg tablets	3	84
South Eastern		Bicalutamide 50mg tablets	2	224
South Eastern		Bicalutamide 150mg tablets	1	28
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	180
South Eastern		Bicalutamide 150mg tablets	6	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	168
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 150mg tablets	3	84
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 150mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 150mg tablets	6	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	168
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 150mg tablets	1	84
South Eastern		Bicalutamide 150mg tablets	3	180
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	6	168
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	5	196
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 150mg tablets	3	84
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	5	140

South Eastern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	6	168
South Eastern		Bicalutamide 150mg tablets	1	84
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 150mg tablets	2	56
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 150mg tablets	1	60
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 150mg tablets	6	168
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	2	168
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	2	21
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	6	168
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	4	112
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	56
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	1	28
South Eastern		Bicalutamide 150mg tablets	5	140
South Eastern		Bicalutamide 150mg tablets	4	224
South Eastern		Bicalutamide 150mg tablets	1	28
South Eastern		Bicalutamide 50mg tablets	1	90
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 150mg tablets	2	112

South Eastern	Personal Information redacted by the USI	Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 150mg tablets	2	56
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 50mg tablets	1	56
South Eastern		Bicalutamide 50mg tablets	6	147
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 150mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 150mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	2	42
South Eastern		Bicalutamide 150mg tablets	4	112
South Eastern		Bicalutamide 50mg tablets	5	140
South Eastern		Bicalutamide 150mg tablets	2	112
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 150mg tablets	6	168
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 150mg tablets	4	224
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	2	168
South Eastern		Bicalutamide 150mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 150mg tablets	3	84
South Eastern		Bicalutamide 150mg tablets	1	56
South Eastern		Bicalutamide 150mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	3	168
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	21
South Eastern		Bicalutamide 50mg tablets	1	28
South Eastern		Bicalutamide 50mg tablets	2	56
South Eastern		Bicalutamide 50mg tablets	1	56
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	5	168

Southern	Personal Information redacted by the USI	Bicalutamide 150mg tablets	1	56
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 150mg tablets	3	84
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	2	33
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	7	172
Southern		Bicalutamide 50mg tablets	2	56
Southern		Bicalutamide 150mg tablets	3	84
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 150mg tablets	6	168
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 150mg tablets	2	56
Southern		Bicalutamide 50mg tablets	1	56
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	2	84
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 50mg tablets	1	5
Southern		Bicalutamide 150mg tablets	3	70
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	6	168
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	1	56
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 150mg tablets	4	87
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 150mg tablets	1	28
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 150mg tablets	1	84
Southern		Bicalutamide 150mg tablets	1	28
Southern		Bicalutamide 150mg tablets	1	56
Southern		Bicalutamide 50mg tablets	3	98
Southern		Bicalutamide 50mg tablets	3	168

Southern	Personal Information redacted by the USI	Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	4	168
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 150mg tablets	1	28
Southern		Bicalutamide 150mg tablets	4	168
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	2	56
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 150mg tablets	2	56
Southern		Bicalutamide 150mg tablets	1	56
Southern		Bicalutamide 50mg tablets	2	56
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 50mg tablets	1	10
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	1	84
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	5	168
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 50mg tablets	1	21
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 150mg tablets	6	168
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	4	224
Southern		Bicalutamide 150mg tablets	1	56
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 150mg tablets	3	168

Southern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	2	504
Southern		Bicalutamide 50mg tablets	1	14
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 150mg tablets	6	168
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	2	56
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	1	56
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 150mg tablets	1	56
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	125
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 50mg tablets	1	56
Southern		Bicalutamide 150mg tablets	1	84
Southern		Bicalutamide 50mg tablets	1	56
Southern		Bicalutamide 50mg tablets	4	154
Southern		Bicalutamide 50mg tablets	3	180
Southern		Bicalutamide 50mg tablets	3	77
Southern		Bicalutamide 50mg tablets	7	196
Southern		Bicalutamide 50mg tablets	1	56
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	3	168
Southern		Casodex 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 150mg tablets	1	56
Southern		Casodex 50mg tablets	1	28
Southern		Bicalutamide 150mg tablets	1	28

Southern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 50mg tablets	2	56
Southern		Bicalutamide 150mg tablets	1	56
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	1	21
Southern		Bicalutamide 50mg tablets	5	420
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	2	84
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	1	10
Southern		Bicalutamide 50mg tablets	1	56
Southern		Bicalutamide 50mg tablets	5	133
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	3	84
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	2	56
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	3	84
Southern		Bicalutamide 50mg tablets	2	56
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	1	21
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	1	84
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 150mg tablets	3	84
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 150mg tablets	3	140
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	35
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 150mg tablets	1	28

Southern	Personal Information redacted by the USI	Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	3	84
Southern		Bicalutamide 50mg tablets	5	140
Southern		Bicalutamide 150mg tablets	2	56
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 50mg tablets	1	21
Southern		Bicalutamide 150mg tablets	4	112
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 150mg tablets	5	140
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 50mg tablets	3	168
Southern		Bicalutamide 50mg tablets	4	112
Southern		Bicalutamide 150mg tablets	3	140
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 50mg tablets	6	168
Southern		Bicalutamide 50mg tablets	2	56
Southern		Bicalutamide 150mg tablets	2	120
Southern		Bicalutamide 150mg tablets	3	168
Southern		Bicalutamide 150mg tablets	1	28
Southern		Bicalutamide 50mg tablets	3	84
Southern		Bicalutamide 150mg tablets	2	56
Southern		Bicalutamide 50mg tablets	2	112
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 150mg tablets	2	112
Southern		Bicalutamide 50mg tablets	1	28
Southern		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 50mg tablets	2	112
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	3	168
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	30
Western		Casodex 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 150mg tablets	2	112
Western		Bicalutamide 150mg tablets	3	84
Western		Bicalutamide 50mg tablets	2	168
Western		Bicalutamide 50mg tablets	2	56
Western		Casodex 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 150mg tablets	3	84

Western	Personal Information redacted by the USI	Bicalutamide 50mg tablets	5	280
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 150mg tablets	3	84
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	21
Western		Casodex 150mg tablets	4	112
Western		Bicalutamide 50mg tablets	3	66
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 50mg tablets	4	112
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	5	140
Western		Casodex 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	3	168
Western		Bicalutamide 150mg tablets	2	112
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	2	112
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 50mg tablets	4	112
Western		Casodex 50mg tablets	1	28
Western		Casodex 50mg tablets	4	112
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	3	84
Western		Bicalutamide 150mg tablets	1	14
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 150mg tablets	6	168
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	4	112
Western		Bicalutamide 50mg tablets	3	252
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	6	168
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	4	70
Western		Bicalutamide 50mg tablets	6	168

Western	Personal Information redacted by the USI	Bicalutamide 150mg tablets	1	84
Western		Bicalutamide 150mg tablets	1	84
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	4	112
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	1	14
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	1	56
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 150mg tablets	3	84
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 150mg tablets	3	168
Western		Bicalutamide 50mg tablets	1	7
Western		Bicalutamide 150mg tablets	3	168
Western		Bicalutamide 150mg tablets	4	140
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 50mg tablets	1	84
Western		Bicalutamide 150mg tablets	3	168
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	4	112
Western		Bicalutamide 150mg tablets	3	140
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 150mg tablets	6	168
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	3	84
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 150mg tablets	2	112
Western		Bicalutamide 50mg tablets	3	84
Western		Bicalutamide 150mg tablets	1	84
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	3	168
Western		Bicalutamide 50mg tablets	3	84

Western	Personal Information redacted by the USI	Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 150mg tablets	1	56
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 150mg tablets	2	112
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 50mg tablets	4	105
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	4	224
Western		Bicalutamide 50mg tablets	4	112
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	6	168
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	2	35
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	4	112
Western		Bicalutamide 150mg tablets	1	84
Western		Bicalutamide 50mg tablets	1	56
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 150mg tablets	5	140
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	6	161
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 150mg tablets	3	84
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28

Western	Personal Information redacted by the USI	Casodex 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 150mg tablets	3	84
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 150mg tablets	4	224
Western		Bicalutamide 50mg tablets	2	84
Western		Casodex 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	3	84
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 50mg tablets	3	168
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 150mg tablets	1	84
Western		Bicalutamide 50mg tablets	4	112
Western		Bicalutamide 50mg tablets	6	168
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 50mg tablets	2	112
Western		Bicalutamide 150mg tablets	2	112
Western		Bicalutamide 150mg tablets	2	112
Western		Bicalutamide 50mg tablets	5	140
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 150mg tablets	1	28
Western		Bicalutamide 50mg tablets	1	28
Western		Bicalutamide 50mg tablets	4	112
Western		Bicalutamide 50mg tablets	1	21
Western		Bicalutamide 50mg tablets	1	56
Western		Bicalutamide 150mg tablets	2	56
Western		Bicalutamide 150mg tablets	4	112
Western		Bicalutamide 50mg tablets	2	56
Western		Bicalutamide 150mg tablets	1	100

UROLOGY PATIENT REVIEW FORM

Patient Details

Appointment Details

Presenting Condition	
Summary of Appointment	

While under Mr O'Briens care please answer the following to the best of your knowledge

Question	Y/N	Details
Where appropriate investigations carried out?		
Was the prescribed treatment appropriate at the time / is it appropriate now?		
Was the diagnosis secure?		
Was the clinical management approach taken reasonable?		
Was there unexplained delays with any aspect of care (reviews, prescribing, diagnostics etc)		
Did the patient suffer harm as a result?		

Clinical Professional Reviewing Care

Name	
Title	
Date of Appointment	

Montgomery, Ruth

From: Wallace, Stephen
Sent: 27 January 2021 20:55
To: O'Neill, Michael (DoH) [Personal Information redacted by the USI]; paul.cavanagh [Personal Information redacted by the USI]
Cc: OKane, Maria; Haynes, Mark; Corrigan, Martina; McClements, Melanie; Carroll, Ronan; Gormley, Damian
Subject: Urology Patient Review Form
Attachments: Proforma for patient lists.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Michael / Paul,

Please find attached a proforma developed by the Trust taking into account the 6 questions identified to be asked regarding the care provided by Mr O'Brien from patients undergoing review who were previously under his care. The purpose of this form is to standardise the format and information collected as a supplementary note to the patient clinical record.

Grateful if you can provide any comments, we intend to commence using this form from Monday.

Thanks
Stephen

Stephen Wallace
Interim Assistant Director of Clinical and Social Care Governance
Mob: [Personal Information redacted by the USI]

Montgomery, Ruth

From: O'Neill, Michael (DoH) [Personal Information redacted by the USI]
Sent: 27 January 2021 22:19
To: Wallace, Stephen; paul.cavanagh [Personal Information redacted by the USI]
Cc: OKane, Maria; Haynes, Mark; Corrigan, Martina; McClements, Melanie; Carroll, Ronan; Bovill, AnneMarie; Gormley, Damian; Johnston, Jackie (DoH)
Subject: RE: Urology Patient Review Form
Attachments: Proforma for patient lists.docx

Stephen – thanks for this. [Irrelevant information redacted by the USI]

He will likely have views on the extent of info available to him and colleagues following the BHSCT recalls. Clinical colleagues in BHSCT may have lessons learned from the process too.

Will return to you with DOH comments asap.

M.

Michael O'Neill

General Healthcare Policy | Department of Health

Contact: [Personal Information redacted by the USI] | **Tel:** [Personal Information redacted by the USI] | **DD:** [Personal Information redacted by the USI]

From: Wallace, Stephen [Personal Information redacted by the USI]
Sent: 27 January 2021 20:55
To: O'Neill, Michael (DoH) [Personal Information redacted by the USI]; paul.cavanagh [Personal Information redacted by the USI]
Cc: OKane, Maria [Personal Information redacted by the USI]; Haynes, Mark [Personal Information redacted by the USI];
 Corrigan, Martina [Personal Information redacted by the USI]; McClements, Melanie [Personal Information redacted by the USI];
 [Personal Information redacted by the USI]; Carroll, Ronan [Personal Information redacted by the USI];
 Gormley, Damian [Personal Information redacted by the USI] >
Subject: Urology Patient Review Form

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Grateful if you can provide any comments, we intend to commence using this form from Monday.

Thanks
 Stephen

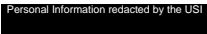
Stephen Wallace
 Interim Assistant Director of Clinical and Social Care Governance
Mob: [Personal Information redacted by the USI]

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Southern Health & Social Care Trust IT Department 

Montgomery, Ruth

From: Wallace, Stephen
Sent: 27 January 2021 20:55
To: O'Neill, Michael (DoH) [Personal Information redacted by the USI]; paul.cavanagh [Personal Information redacted by the USI]
Cc: OKane, Maria; Haynes, Mark; Corrigan, Martina; McClements, Melanie; Carroll, Ronan; Gormley, Damian
Subject: Urology Patient Review Form
Attachments: Proforma for patient lists.docx

Michael / Paul,

Please find attached a proforma developed by the Trust taking into account the 6 questions identified to be asked regarding the care provided by Mr O'Brien from patients undergoing review who were previously under his care. The purpose of this form is to standardise the format and information collected as a supplementary note to the patient clinical record.

Grateful if you can provide any comments, we intend to commence using this form from Monday.

Thanks
Stephen

Stephen Wallace
Interim Assistant Director of Clinical and Social Care Governance
Mob: [Personal Information redacted by the USI]



UROLOGY PATIENT REVIEW FORM

Patient Details

Appointment Details

Presenting Condition	
Summary of Appointment	

While under Mr O'Briens care please answer the following to the best of your knowledge

Question	Y/N	Details
Where appropriate investigations carried out?		
Was the prescribed treatment appropriate at the time / is it appropriate now?		
Was the diagnosis secure?		
Was the clinical management approach taken reasonable?		
Was there unexplained delays with any aspect of care (reviews, prescribing, diagnostics etc)		
Did the patient suffer harm as a result?		

Clinical Professional Reviewing Care

Name	
Title	
Date of Appointment	

Montgomery, Ruth

From: Wallace, Stephen
Sent: 09 February 2021 15:12
To: O'Neill, Michael (DoH) Personal information redacted by the USI
Subject: Form
Attachments: UROLOGY PATIENT REVIEW FORM v3.docx



UROLOGY PATIENT REVIEW FORM

This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Appointment Details

Regarding the patients current care

While under Mr O'Briens care please answer the following to the best of your knowledge



approach taken reasonable?		
Was there unexplained delays with any aspect of care (reviews, prescribing, diagnostics etc)		
Do you have reason to believe the problem lead to harm?		

Clinical Professional Reviewing Care

Name	
Title	
Date of Appointment	

Montgomery, Ruth

From: Wallace, Stephen
Sent: 11 February 2021 09:08
To: paul.cavanagh [Personal Information redacted by the USI] O'Neill, Michael (DoH) [Personal Information redacted by the USI]
Cc: OKane, Maria; Corrigan, Martina; Haynes, Mark; Gormley, Damian
Subject: Urology Patient Review Form
Attachments: UROLOGY PATIENT REVIEW FORM v5.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Michael /Paul,

Please find final version of the patient review form following local specialty / DLS and external subject matter expert input. We intend to pilot this on a sample of cases to assess effectiveness.

Michael, as discussed grateful if you are able to confirm if Lourda from a DoH perspective this is acceptable. Our intention is to commence using this as soon as confirmation is received.

Thanks
Stephen

UROLOGY PATIENT REVIEW FORM

This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Appointment Details

Regarding the patients current care

Based on the information available at the time, please answer the following to the best of your knowledge. If a determination cannot be made please give reasons why.



the time?		
Was the clinical management approach taken reasonable?		
Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc)		
On balance, did the patient suffer any harm or detriment as a result?		

Clinical Professional Reviewing Care

Name	
Title	
Date of Appointment	

Montgomery, Ruth

From: Paul Cavanagh [Personal Information redacted by the USI]
Sent: 01 March 2021 10:11
To: OKane, Maria; Wallace, Stephen
Cc: Caroline Cullen; Michael O'Neill [Personal Information redacted by the USI]
Subject: FW: Urology Patient Review Form
Attachments: UROLOGY PATIENT REVIEW FORM v5_LG_28.02.21.docx

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

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Maria, Stephen

Comments from DoH. Assuming you accept Lourda's comments, I think you can proceed to deploy the form.

Paul

From: O'Neill, Michael (DoH) [Personal Information redacted by the USI]
Sent: 01 March 2021 10:07
To: Paul Cavanagh
Cc: Bovill, AnneMarie; Caroline Cullen
Subject: RE: Urology Patient Review Form
Importance: High

Paul,

Comments from Lourda re the form outlined below and attached. Apologies for the delay.

- Good idea to pilot the form;
- Form is clearly operational in nature, but from DOH point of view, the Trust will want to be reassured that form users are on a similar page in terms of definitions of terms like 'appropriate', 'reasonable', 'secure clinical management plan';
- May be more than one diagnosis; and
- 'Available at the time' – need to be clear this is when the recall is undertaken rather than at clinic with AOB.

Michael O'Neill

General Healthcare Policy | Department of Health

Contact: [Personal Information redacted by the USI] | **Tel:** [Personal Information redacted by the USI] | **DD:** [Personal Information redacted by the USI]

From: Paul Cavanagh [Personal Information redacted by the USI]
Sent: 26 February 2021 09:39
To: O'Neill, Michael (DoH) [Personal Information redacted by the USI]
Cc: Bovill, AnneMarie [Personal Information redacted by the USI]; Caroline Cullen [Personal Information redacted by the USI]
Subject: RE: Urology Patient Review Form

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Michael

Has Lourda come back to you on this? We need to sign off today to allow Prof Sethia to get on with his work.

Also, I presume you are not expecting an update this week and we will ensure this is provide for UAG next week.

Paul

From: O'Neill, Michael (DoH) [Personal Information redacted by the USI]
Sent: 23 February 2021 14:36
To: Paul Cavanagh
Cc: Bovill, AnneMarie
Subject: RE: Urology Patient Review Form

Paul,

Stephen had sent me this to consider too, I know he is keen to confirm and get going with Dr Sethia – however I am keen to get a DCMO view on it and Lourda hasn't had the chance to clear or comment.

She is back to back for rest of evening, lots of media demand around CV19 presently.

Michael O'Neill

General Healthcare Policy | Department of Health

Contact: [Personal Information redacted by the USI] | **Tel:** [Personal Information redacted by the USI] | **DD:** [Personal Information redacted by the USI]

From: Paul Cavanagh [Personal Information redacted by the USI]
Sent: 23 February 2021 13:26
To: O'Neill, Michael (DoH) [Personal Information redacted by the USI]
Subject: FW: Urology Patient Review Form

"This email is covered by the disclaimer found at the end of the message."

Michael

See attached a patient review form which has been agreed by the coordinating group last week. For noting from your perspective but happy to take any comments if you wish.

Thanks

Paul

From: Wallace, Stephen [Personal Information redacted by the USI]
Sent: 22 February 2021 09:40
To: Paul Cavanagh
Cc: OKane, Maria; Melanie McClements (SHSCT); Corrigan, Martina
Subject: Urology Patient Review Form

Hi Paul,

Grateful if you can let us know if we can progress with using the attached form as discussed at the HSCB meeting last week.

If you want to discuss give me a call anytime on Personal Information redacted by the USI.

Thanks
Stephen

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Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

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UROLOGY PATIENT REVIEW FORM

reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Appointment Details

Comment [GL3]: As above- is this a summary of the planned review/recall appointment?
Are you content to leave to free text only?

Regarding the patients current care

Question	Y/N	Details
Is the present diagnosis reasonable?		
Are the current medications prescribed appropriate?		
Is a secure clinical management plan currently in place?		

Comment [GL4]: Could be more than one diagnosis, neurology recall found % os pts had more than one diagnosis. Need to define what is meant by 'reasonable'?

Comment [GL5]: Need to define what mean by 'appropriate' in this context.

Comment [GL6]: Need to define what mean to 'secure clinical management plan' in this context.

Based on the information available at the time, please answer the following to the best of your knowledge. If a determination cannot be made please give reasons why.

Comment [GL7]: What does 'at the time' mean here?

Question	Y / N / Unable to Determine	Details
Were appropriate and complete investigations carried out?		
Were the medications prescribed reasonable?		
Was the diagnosis reasonable at		

Comment [GL8]: Need to define 'appropriate', also need to take account of possibility of more than one diagnosis

Comment [GL9]: Need to take account of possibility of more than one diagnosis, and that there potentially is likely to be an investigative and diagnostic pathway relevant to each diagnosis

the time?		
Was the clinical management approach taken reasonable?		
Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc)		
On balance, did the patient suffer any harm or detriment as a result?		

Comment [GL11]: See above comments

Comment [GL12]: Need to define what 'unreasonable delays' means in this context. Is 'delay' the only parameter of interest?

Clinical Professional Reviewing Care

Name	
Title	
Date of Appointment	

Montgomery, Ruth

From: Wallace, Stephen
Sent: 03 March 2021 22:16
To: Paul Cavanagh; OKane, Maria
Cc: Caroline Cullen; Michael O'Neill Personal Information redacted by the USI
Subject: RE: Urology Patient Review Form
Attachments: UROLOGY PATIENT REVIEW FORM v6.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you Paul,

Please find attached an updated form based on the comments supplied

Regards
Stephen

From: Paul Cavanagh Personal Information redacted by the USI
Sent: 01 March 2021 10:11
To: OKane, Maria; Wallace, Stephen
Cc: Caroline Cullen; Michael O'Neill Personal Information redacted by the USI
Subject: FW: Urology Patient Review Form
Importance: High

"This email is covered by the disclaimer found at the end of the message."

Maria, Stephen

Comments from DoH. Assuming you accept Lourda's comments, I think you can proceed to deploy the form.

Paul

From: O'Neill, Michael (DoH) Personal Information redacted by the USI
Sent: 01 March 2021 10:07
To: Paul Cavanagh
Cc: Bovill, AnneMarie; Caroline Cullen
Subject: RE: Urology Patient Review Form
Importance: High

Paul,

Comments from Lourda re the form outlined below and attached. Apologies for the delay.

- Good idea to pilot the form;
- Form is clearly operational in nature, but from DOH point of view, the Trust will want to be reassured that form users are on a similar page in terms of definitions of terms like 'appropriate', 'reasonable', 'secure clinical management plan';
- May be more than one diagnosis; and
- 'Available at the time' – need to be clear this is when the recall is undertaken rather than at clinic with AOB.

Michael O'Neill

General Healthcare Policy | Department of Health

Contact: [Redacted] | Tel: [Redacted] | DD: [Redacted]

From: Paul Cavanagh [Redacted]
Sent: 26 February 2021 09:39
To: O'Neill, Michael (DoH) [Redacted]
Cc: Bovill, AnneMarie [Redacted]; Caroline Cullen [Redacted]
Subject: RE: Urology Patient Review Form

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Also, I presume you are not expecting an update this week and we will ensure this is provide for UAG next week.

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Cc: Bovill, AnneMarie
Subject: RE: Urology Patient Review Form

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General Healthcare Policy | Department of Health

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Sent: 23 February 2021 13:26
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Subject: FW: Urology Patient Review Form

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Subject: Urology Patient Review Form

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Thanks
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UROLOGY PATIENT REVIEW FORM

This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	
H&C Number	
Date of Birth	

Appointment Patient Details

Presenting Condition(s)	
Summary of Appointment Patient Summary	

Comment [GL1]: Does this information relate to the review appointment? Is the review appointment as part of a recall or is it any of the review appointments that pt's may have been called to/had already? If it's any of the review appointments that pt's may have been called to/had already – now sure previous review apts have been captured?

Comment [GL2]: Will the pts have a presenting condition – are they not likely to have one or more diagnoses, based on their previous care and treatment from the Consultant?

Comment [GL3]: As above- is this a summary of the planned review/recall appointment?
Are you content to leave to free text only?

Regarding the patients current care

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / <u>diagnoses</u> reasonable? (<i>'Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?</i>)		
2	Are the current medications prescribed appropriate? (<i>'Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?</i>)		
3	Is a secure clinical management plan currently in place? (<i>'Secure Clinical Management Plan' to consider if the current</i>		

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Comment [GL4]: Could be more than one diagnosis, neurology recall found % os pts had more than one diagnosis. Need to define what is meant by 'reasonable'?

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Comment [GL5]: Need to define what mean by 'appropriate' in this context.

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Comment [GL6]: Need to define what mean to 'secure clinical management plan' in this context.

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	<i>patient treatment pathway is optimal and in line with current best evidence based practice and guidance).</i>		
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

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Based on the information available at the time of previous reviews, please answer the following to the best of your knowledge. If a determination cannot be made please give reasons why.

Comment [GL7]: What does 'at the time' mean here?

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? <i>('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)</i>		
5	Were the medications prescribed reasonable/appropriate? <i>('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)</i>		
6	Was/Were the diagnosis / diagnoses reasonable? at the time? <i>('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to</i>		

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Comment [GL8]: Need to define 'appropriate', also need to take account of possibility of more than one diagnosis

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Formatted: Justified

Comment [GL9]: Need to take account of possibility of more than one diagnosis, and that there potentially is likely to be an investigative and diagnostic pathway relevant to each diagnosis

Comment [GL10]: Need to define what 'at the time' means/relates to

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Formatted: Justified

	<u>confirm diagnosis / diagnoses?)</u>		
7	Was the clinical management approach taken reasonable? <u>(‘Reasonable’ to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)</u>		<p>Comment [GL11]: See above comments</p> <p>Formatted: Font: Italic</p> <p>Formatted: Justified</p> <p>Formatted: Font: Not Bold, Italic</p> <p>Formatted: Font: Not Bold, Italic</p>
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) <u>(‘Unreasonable Delays’ to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)</u>		<p>Comment [GL12]: Need to define what ‘unreasonable delays’ means in this context. Is ‘delay’ the only parameter of interest?</p> <p>Formatted: Justified</p>
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9) ?		<p>Comment [GL13]: Is this ‘as a result’ of delay? If relates to ‘delay’ only, are you content this is sufficient?</p>

Clinical Professional Reviewing Care

Name	
Title	
Date of Appointment	

Quality Care - for you, with you

20th February 2022

Ref: MOK/ec

Via email

Irrelevant information redacted by the USI

Professor Timothy Rockall FRCS
Chair of the Invited Review Mechanism
Professional and Clinical Standards
The Royal College of Surgeons of England
35-43 Lincoln's Inn Fields
London

Dear Professor Rockall,

RE: ROYAL COLLEGE OF SURGEONS INVITED REVIEW SERVICE

I am writing in regards to the invited review commissioned from the Royal College of Surgeons by the Southern Health and Social Care Trust, Northern Ireland in 2021 relating to urology services.

As you may be aware, the Trust is currently undertaking a lookback exercise regarding urology patients that were under the care of a particular consultant urologist over an 18-month period to identify any potential patient safety issues. The Royal College invited review outcome will assist in guiding the relevant bodies decide if an extended period of lookback will be required.

We are currently awaiting the Royal College report on this matter. To date we have been unable to obtain a target date for the report to be shared with the Trust therefore I would be grateful if you could advise when we should expect to receive draft copies of the report. As you will be aware we are keen to plan for all eventualities, I would therefore be grateful

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Tel:

Personal Information redacted by the USI

Email:

Personal Information redacted by the USI

if you could provide details of when this report may be available and if any interim findings are of relevance to patient or service safety.

I look forward to hearing from you.

Yours sincerely

Personal Information redacted by the USI

Dr Maria O’Kane
Medical Director

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Tel:

Personal Information redacted by the USI

Email:

Personal Information redacted by the USI



Dr Maria O'Kane
Medical Director
Southern Health & Social Care Trust

SENT BY E-MAIL ONLY

24 February 2022

PRIVATE AND CONFIDENTIAL

Dear Dr O'Kane,

Thank you for your letter dated 20 February 2022 further to the invited clinical record review of 100 urological surgical records that commenced in June 2021. As the review involved the assessment of a substantial number of records (100 clinical records) and there were initial delays/issues in accessing the Trust's systems, the review team were not able to complete their initial review of the clinical records until late 2021.

We are working to complete the invited review report, which is currently being drafted, as soon as possible. Prior to issuing the final report to the Trust, the report will need to be quality assured by relevant members of the Invited Review Oversight Group and approved by the review team before it can be issued to the Trust. We estimate that the final invited clinical record review report will be ready later in April 2022.

The review team's full conclusions on the circumstances of the review and any recommendations made to address its terms of reference, will be contained in the final invited review report. These views will be based on consideration of the 100 clinical records provided to the review team by the Trust.

Please note that Romina Trinidad, Invited Review Programme Manager, has been in communication with Martina Corrigan (Assistant Director for Public Inquiry and Trust Liaison), in December 2021 and January 2022, regarding the delay in producing the RCS England review report for Southern Trust.

I hope the above information is useful and thank you for your patience. Should you have any further questions please contact Romina Trinidad by email - Personal Information redacted by the USI or by telephone - Personal Information redacted by the USI

Yours sincerely,

Personal Information redacted by the USI

Professor Timothy Rockall FRCS
Chair of the Invited Review Mechanism

The Royal College of Surgeons of England
38-43 Lincoln's Inn Fields
London WC2A 3PE

Personal Information redacted by the USI
Personal Information redacted by the USI
W: www.rcseng.ac.uk

Registered Charity No. 212808

Wallace, Stephen

From: Wallace, Stephen
Sent: 28 January 2022 14:03
To: OKane, Maria; Gormley, Damian
Subject: Fw: RQIA Review of SCRR Process

Just to mention re below - I spoke to Shane who agreed that we should commence the process of sharing the SCRR with the SME's for completion

Thanks
Stephen

From: Wallace, Stephen
Sent: 27 January 2022 12:14
To: Wright, Elaine (Personal Information redacted by the USI)
Subject: FW: RQIA Review of SCRR Process

Apologies Elaine, could you also ask Shanes views re below please

Thanks
Stephen

From: Wallace, Stephen
Sent: 26 January 2022 22:18
To: Devlin, Shane (Personal Information redacted by the USI)
Cc: OKane, Maria; Gormley, Damian
Subject: RE: RQIA Review of SCRR Process

Hi Shane,

Further to below I spoke to Maria briefly re this tonight and she feels that if we are unable to get confirmation from the DoH re RQIA involvement to QA our processes it may be best to proceed in its absence with the SCRR process. Can you confirm if you are happy with this approach?

Thanks
Stephen

From: Wallace, Stephen
Sent: 26 January 2022 13:27
To: Devlin, Shane (Personal Information redacted by the USI)
Cc: OKane, Maria; Gormley, Damian
Subject: FW: RQIA Review of SCRR Process

Hi Shane,

We never received a response from the DoH re below obtaining RQIA assurance on the SCRR processes. We are in a position to progress this process however would appreciate your view on the next steps, should we approach DoH again prior to taking moving forward?

Thanks
Stephen

From: Wallace, Stephen
Sent: 30 November 2021 11:46
To: 'jim.wilkinson' Personal Information redacted by the USI; 'Robbie.Davis' Personal Information redacted by the USI
Cc: OKane, Maria; Devlin, Shane (Personal Information redacted by the USI)
Subject: RE: RQIA Review of SCRR Process

Jim / Robbie, grateful if you can advise re below, we are keep to progress this.

Thanks
Stephen

From: Wallace, Stephen
Sent: 25 November 2021 14:02
To: 'jim.wilkinson' Personal Information redacted by the USI; 'Robbie.Davis' Personal Information redacted by the USI
Subject: RQIA Review of SCRR Process

Hi Jim / Robbie,

Just checking on actions from the previous UAG meeting Monday, 1st November this year. Shane mentioned that he would like RQIA to quality assure our approach to conducting urology structured clinical record reviews. The minutes read that Shane was to contact the perm secretary re this however I think that Jim agreed that this would be taken forward as an action automatically from the meeting. Can you confirm if Shane is required to contact the Permanent Secretary regarding this separately or if this has been progressed internally by DoH?

Apologies if I picked this up incorrectly.

Best regards
Stephen

Stephen Wallace

Assistant Director Systems Assurance
Craigavon Area Hospital
Portadown

Personal Information redacted by the USI

PROPOSAL FOR STRUCTURED CLINICAL RECORD REVIEW

DRAFT V1 - 17th February 2021

Background

1. On the 23rd November 2021 the Minister for Health gave direction for the initiation of a Public Inquiry regarding the Clinical Practice of Mr Aidan O'Brien, Consultant Urologist.
2. Although yet to be developed, the terms of reference for Public Inquiry will consider Mr O'Brien's practice across all of his clinical activity. This will likely include reviews involving individual patient cases where a potential adverse outcome was identified.
3. While ensuring that the work of the Public Inquiry is not disrupted or delayed, in the interests of maintaining patient safety it remains incumbent on the Trust to ensure that where potential patient safety incidents are identified, a proportionate patient safety review should take place to inform learning and develop safer systems in a timely manner.
4. Remaining cognisant of regional parameters and requirements for the identification, review and learning from Adverse and Serious Adverse Incidents (SAI) as set out in the HSCB *Procedure for the Reporting and Follow up of Serious Adverse Incidents (November 2016)* the Trust has sought to provide an alternative, proportionate and robust review structure that can be utilised to review SAI's in a timely manner.
5. Any patient safety review process will function and report within the existing clinical governance arrangements for the Trust and as such be subject to quality assurance processes and an appropriate level of scrutiny.

Title of Review Structure

6. The Trust is mindful that any proposed alternative review structure should be demarcated clearly as different to the SAI process. It is therefore important that for clarity for service users, staff and the public that the title should articulate this clearly.

Proposal 1 – The name of the review mechanism will be titled STRUCTURED CLINICAL RECORD REVIEW (SCRR)

Underpinning Review Methodology

7. To ensure confidence in the SCRR process an adoption of a robust and validated method will be required. To this end, the Trust has spoken to the Royal College of Physicians with a view to adapting the underpinning principles and methodology found in the Structured Judgement Review (SJR) Process.
8. The Royal College of Physicians SJR combines clinical-judgement based review methods with a standard format. The format requires reviewers to make safety and

quality judgements over phases of care, to make explicit written comments about care for each phase, and to score care for each phase.

9. As an outcome of the SJR the result is a short but rich set of information about each case in a form that can also be aggregated to produce knowledge about clinical services and systems of care.
10. The objective of the SJR method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about the hospital systems where care goes well, and to identify points where there may be gaps, problems or difficulty in the care process.
11. In order to answer these questions, there is a need to look at: the whole range of care provided to an individual; holistic care approaches and the nuances of case management and the outcomes of interventions.
12. The Trust proposes developing an adapted form from the base Royal College of Physicians SJR template and seeking Royal College of Surgeons agreement. The Trust envisages that the tool will be developed in two sections to consider both inpatient and outpatient care provided.

Proposal 2 – The underpinning methodology will be based on the Royal College of Physicians Structured Judgement Review tool

Identification of Cases for Structured Clinical Record Reviews

13. The inclusion criteria and thresholds for cases in the SCRR process will remain in keeping with those set out in the HSCB *Procedure for the Reporting and Follow up of Serious Adverse Incidents (November 2016)* with particular reference to section 4.2 of the document which outlines the following specific criteria:
 - Serious injury to, or the unexpected/unexplained death of a service user
 - Unexpected serious risk to a service user and/or staff member and/or member of the public
 - Unexpected or significant threat to provide service and/or maintain business continuity
14. Where appropriate the Trust will continue to screen adverse incidents, complaints and returns from patient record reviews for consideration of inclusion in the SCRR process.

Proposal 3 – The Trust will maintain the same screening criteria, thresholds and processes for SCRR as is currently in place for SAIs

Conducting Structured Clinical Record Reviews

15. The Trust recognises the requirement to conduct SCRR in a timely manner to identify and action learning and system changes as appropriate. In this regard the Trust

proposes engaging the services of an independent Consultant Urologist via the Royal College of Surgeons to conduct the SCRR process who has training, knowledge and experience in applying Structured Judgement Review methodology.

16. To support the process for conducting the SCRR the Trust clinical governance teams will source and share records electronically and support the development of 'timelines' that will support the reviewer in their task completing the SCRR.

Proposal 4 – The Trust will seek to engage an Independent Consultant Urologist Subject Matter Expert to conduct SCRR's and ensure that appropriate clinical governance support is available to facilitate each review

Engaging Patients and Families in Structured Clinical Record Reviews

17. The Trust places paramount importance on the need to fully involve patients and families are engagement in the SCRR process. The Trust recognises that the communication of the SCRR process to patients and families is crucial in terms of setting expectations of outcomes and how this will relate to the work of the Public Inquiry.
18. To support this work the Trust has appointed a dedicated Urology Service User Liaison Officer to communicate and support patients and families who are part of the SCRR process.
19. The outline proposed family engagement strategy is as follows:
 - a. Once the requirement for an SCRR is identified, the patient or family is notified via phone-call and then follow up letter informing of the decision to conduct a SCRR. Communication will include details of what the review process is, what the expected outcomes will be and how this process links to the Public Inquiry. The communication will also contain the contact details of the Service User Liaison Officer who can offer individual patient and family support.
 - b. The review will be conducted by the independent Consultant Urologist and the judgement and outcomes recorded.
 - c. The Service User Liaison Officer will share the report's findings with the patient and family for their review and comment.
 - d. The Service User Liaison Officer will return feedback to the Consultant Urologist from the family if received.
 - e. A final copy of the SCRR will be shared with the family and arrange any required further follow-up or discussions required with the Trust Urology service.

Proposal 5 – The Trust will utilise the Service User Liaison Model to engage patients and families with set milestones as outlined

Timescales for Completion of Structured Clinical Record Reviews

20. Although to be formally agreed it is expected that each SCRR should be completed within 8 weeks in line with the regional timescales for Level 1 Significant Event Audits..

Proposal 6 – The timescale for completion of each SCRR should be a maximum of 8 weeks

Initiating Learning and Change from the SRCC

21. The Trust will incorporate the learning and findings from SCRR's into existing clinical governance streams. This includes ensuring that:
- a. Where actionable outcomes are identified, these are taken forward to improve services
 - b. learning for regional bodies is shared via HSCB
 - c. assurance on action closure is provided to the UAG
 - d. Where a SRCC identifies the requirement for a more in-depth review, this is flagged for consideration at the Trust and HSCB weekly meeting.

Proposal 7 – The process of learning and change from SRCC will be embedded in Trust clinical governance structures and appropriate escalations for learning and if required further review is considered

UNAFI

PROPOSAL FOR STRUCTURED CLINICAL RECORD REVIEW

DRAFT ~~V1~~ V2 - 17th-29th February-November 2021

Background

1. On the 23rd November 2021 the Minister for Health gave direction for the initiation of a Public Inquiry regarding the Clinical Practice of Mr Aidan O'Brien, Consultant Urologist.
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 - b. The ~~SCRR review~~ will be conducted by the independent Consultant Urologist and the judgement and outcomes recorded.
 - c. The ~~Service User Liaison Officer~~ Trust will share the report's findings with the patient and family for their review and comment.
 - d. The ~~Service User Liaison Officer~~ Trust will return feedback to the independent Consultant Urologist from the family if received.
 - e. A final copy of the SCRR will be shared with the family if they request this
 - f. ~~The Trust Urology service will~~ arrange any ~~required~~ further follow-up or discussions required. ~~with the Trust Urology service.~~

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Proposal 7 – The process of learning and change from SRCC-SCRR will be embedded in Trust clinical governance structures and appropriate escalations for learning and if required further review is considered

PROPOSAL FOR STRUCTURED CLINICAL RECORD REVIEW

Updated 4th March 2022

Background

1. On the 24th November 2020 the Minister for Health gave direction for the initiation of a Public Inquiry regarding Southern Health and Social Care Trust Urology Services.
2. While ensuring that the work of the Public Inquiry is not disrupted or delayed, in the interests of maintaining patient safety it remains incumbent on the Trust to ensure that where potential patient safety incidents are identified, a proportionate patient safety review should take place to inform learning and develop safer systems in a timely manner.
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 - b. The SCRR will be conducted by the independent Consultant Urologist and the judgement and outcomes recorded.
 - c. The Trust will share the report's findings with the patient and family for their review and comment.
 - d. The Trust will return feedback to the independent Consultant Urologist from the family if received.
 - e. A final copy of the SCRR will be shared with the family if they request this
 - f. The Trust Urology service will arrange any further follow-up or discussions required.

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Timescales for Completion of Structured Clinical Record Reviews

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Proposal 7 – The process of learning and change from SCRR will be embedded in Trust clinical governance structures and appropriate escalations for learning and if required further review is considered

Timeline for Progression of SCRR Process

1. Informing Patients and Commencing Reviews

Action	Start Date	Completion Date	Who	Details	Supporting Documents
Identification of Subject Matter Experts	NA	NA	MDO	8 Subject Matter Experts identified via BAUS to conduct structured clinical record reviews	
Patients informed of SCRR process	25 th October 2021	5 th November 2021	Liaison Team	Patients contacted via telephone to advise of intention to conduct SCRR review – ongoing liaison support to be offered	 Draft Script for SCRR Communications.docx
Follow up letter to patients informing of SCRR process	25 th October 2021	5 th November 2021	Acute Governance Team / Urology Lookback lead	Patients posted letter and leaflet advising of the process	 Draft Letter_Review of Urology Care.docx 
Communication with Mr O'Brien regarding SCRR Process	25 th October 2021	25 th October 2021	MDO	Letter to be issued to Mr O'Brien via solicitor advising of the process being conducted via SCRR	Communication to be created
Records Shared with SCRR Subject Matter Experts	25 th October 2021	5 th November 2021	Acute Governance Team / Urology Lookback lead	Records electronically shared with SME's to conduct SCRR reviews	

2. Quality Assurance and Themed Report

Action	Start Date	Completion Date	Who	Details	Supporting Documents
SCRRs returned to Trust	10 th November 2021	20 th December 2021	SMEs	SCRR information to be returned to Trust by SME's to Acute Governance Team / Urology Lookback lead	
SCRR Quality Assurance	??	??	?? BAUS	BAUS Considering mechanisms for this	
SCRR Themed Report	??	??	BAUS	Upon completion and return of Quality Assured SCRR's themed report to be provided by BAUS lead with input from pattern recognition support	
Themed Report returned to Trust	??	??	BAUS	Themed report returned to Trust	

3. Communication of SCRR outcomes

Action	Start Date	Completion Date	Who	Details	Supporting Documents
Letter to Patient communicating SCRR outcomes	??	??	Acute Governance Team / Urology Lookback lead	Letters to be issued to patients regarding outcomes	Communication to be created
Letter to Mr O'Brien containing themed report	??	??	MDO	Letter containing themed report to be shared with Mr O'Brien	

Urology Telephone Call

1. Hello my name is XXXXXX; I'm a liaison officer from the Southern Health and Social Care Trust. How are you? Is now a good time to talk?
2. The reason I am contacting you today is to talk to you about your care within the Urology service within the Southern Health and Social Care Trust
3. Firstly, before I go any further, I want to assure you that your current treatment plan is correct for you and there are no concerns about your current care
4. However, we would like to review the care that you received in the past to ensure it was correct and of an appropriate standard. As a result of this, the Southern Trust is completing a lookback review of the care you received from the Consultant Urologist Mr Aidan O'Brien. What this means is an independent Consultant Surgeon will assess the care delivered by the retired Consultant Urologist. They will examine the care you received at the time to see if your care was acceptable. *(Check for understanding)* is that ok?
5. Once the review is complete, the Trust will be in contact with you to let you know the outcome. The review will provide you with a summary of the standard of urology care you received.
6. You may be aware that the Minister for Health has commissioned a public inquiry regarding Southern Trust Urology services. As part of this your details will be shared with the Public Inquiry panel as part of this look back review.
7. Let me tell you a little about my role: I am here to ensure you are supported during this time and to pass on any concerns or questions you may have to the clinical team
8. I'm going to send you some further information about this in the post. If you have any worries, concerns or questions you can contact me. Have you got a pen I'll give you my number? Do you have someone else you prefer me to discuss this with or you ok with me discussing with you? ***(If patient requests to be reviewed face to face or telephone, liaison officer will advise they will pass details on to clinical team to contact)***
9. I will also be sending you a letter over the next few days, with details of support available to you and what the process will look like. There will be an information leaflet which will explain more about the process we are undertaking and provide contact details for getting in touch.
10. Is it ok for me to contact you on the telephone or would you prefer email or letter?
11. Thank you so much for your time. Please do not hesitate to contact me if you need anything.

Quality Care - for you, with you

XX XXXXXXXXXX 2021

Healthcare Ref: _____

Private & Confidential

<Name>

<Address>

Dear <title> <name>

RE: Review of Urology Care relating to the Practice of a Southern Health and Social Care Trust Consultant

The Southern Health and Social Care Trust has become aware that a Consultant Urologist previously employed by our organisation may have delivered care that did not meet with the standards we would expect and, as a Trust, we are committed to being open when events such as this occur.

As a precaution, we will be reviewing patients where we have identified potential deficits in the level of treatment and care. I want to assure you that your current treatment plan is correct and there are no concerns about your current ongoing care. As a result the Southern Trust has commissioned an independent review of the care you received. What this means is an independent Consultant Surgeon will assess the care delivered to you. They will review your patient records to understand if the level of your previous treatment and care was of an appropriate standard.

As I'm sure you will understand, this review of the care provided will unfortunately be a considerable process, however we want to assure you that we will strive to provide you with an update as soon as possible. Once the review is complete, the Trust will be in contact with you to let you know the outcome. The review will provide you with a summary of the standard of urology care you received.

You may be aware that the Minister for Health has commissioned a public inquiry regarding Southern Trust Urology services. As part of this your details will be shared with the Public Inquiry panel as part of this look back review, the Public Inquiry panel may contact you directly regarding your experience.

I am aware this information may be upsetting to you however we wanted to ensure you are fully aware of all information regarding your care and that you are kept fully up to date about the review process. Please also find enclosed a leaflet which will explain about the review process in more detail.

We will update you in writing after your care has been reviewed to advise of the outcome, but in the meantime, if you have any worries, concerns or queries please do not hesitate to contact the dedicated Trust Liaison Officer who has contacted you recently, contact details for this service are also included in the enclosed leaflet.

The liaison service is strictly confidential and operated by trained professional staff that can support you. Details of the support services provided can be found on the back of the enclosed factsheet, and it would be helpful to have your letter to hand when you call the helpline, as you will be asked for your unique reference number printed at the top.

You have a right to expect the very best care every time you use our services. However, if things do go wrong, it is the role of the Trust and our staff to learn from any failings, so that we can provide answers to families and patients and improve our care now and in the future.

Yours Sincerely,

Support:

We appreciate that this may be a worrying time for you and your family and want to support you through this process.

Liaison Officer, Fiona Sloan is available to offer support for patients and families involved in the structured clinical review.

Tel: Personal Information redacted by the USI Monday-Friday 9am to 5pm

Email: Personal Information redacted by the USI

The **Patient Client Council** offers independent, confidential advice and support to people who have a concern about a health and social care service. This may include help with writing letters, making telephone calls or supporting you at meetings, or if you are unhappy with recommendations / outcomes of the reviews.

Tel: 08009170222 or via Email: complaints.pcc@hscni.net

You have the right to contact the **Northern Ireland Public Services Ombudsman NIPSO** at the end of the review process. NIPSO impartially and independently investigates complaints about health and social care.

Tel: 0800 343424 or via Email: nipso@nipso.org.uk

HSC Southern Health
and Social Care Trust

Quality Care - for you, with you

Structured Clinical Record Review

Urology

**Information for service
users, family members
and carers.**



Working together



Excellence



Openness & Honesty



Compassion

Overview:

You may be aware of the Health Minister's announcement on 24 November 2020 to establish a Statutory Public Inquiry into the work of a single urology consultant who was based in Craigavon Area Hospital.

This Statutory Public Inquiry will begin in winter 2021-2022.

As a patient of Urology services, this leaflet has been designed to explain the review process and outline what this will mean for you in relation to your care.

As previously explained to you by the Trust Urology team, some aspects of the care provided to you may have fallen short of the level we would expect to see.

We would like to assure you however, that following your recent appointment, your treatment plan has been reviewed and reassessed for your needs to ensure you receive the appropriate care going forward.

Statutory Public Inquiry:

The purpose of the inquiry process is to review individual patient cases and identify if there were any concerns in the care that was provided. If there are any potential issues discovered, the Trust will ensure that there is learning from these events to address any specific issues identified and prevent future recurrence.

Health Minister Robin Swann has appointed Christine Smith QC to Chair the Public Inquiry, which will be supported by a wholly independent expert team.

Structured Clinical Record Review:

The Southern Trust has commissioned a team of experts to assess your care through a process known as a Structured Clinical Record Review.

This review will be conducted by an independent Consultant Urologist who will examine the care you received, and determine if it was appropriate, or if there were any issues that would require addressing.

The outcome of the review will be shared with you by the Trust Service User Liaison Officer when available, and you will have an opportunity to discuss it and to make any comments on the findings which will then be fed back to the Consultant Urologist prior to the report being finalised.

If the independent review determines it necessary, you may receive a clinical follow up with a consultant urologist.

The findings of your Structured Clinical Record Review will be given to the Public Inquiry team as part of the Statutory

Learning and Change:

If there are actionable outcomes identified by the structured clinical record reviews, the Trust is committed to ensuring that learning from the findings, and any change required, will be taken forward to improve services.

The Trust has appointed a dedicated Service User Liaison officer who will be your point of contact throughout this process. You can find their contact details on the reverse of this leaflet.



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Wallace, Stephen

From: Wallace, Stephen
Sent: 16 December 2021 14:21
To: paul.rajjayabun Personal Information redacted by the USI
Cc: Gormley, Damian
Subject: Southern Trust Structured Clinical Record Reviews

Dear Mr Rajjayabun,

We are grateful to you for agreeing to participate in the Southern Health and Social Care Trust work to conduct Urology Structured Clinical Record Reviews (SCRR). The SCRR process is designed to allow the Southern Trust to ensure that our clinical governance process - designed to address concerns in an individual's practice - is reasonable and accurate and identify if there are any areas where patient safety can be improved.

Whilst a Public Inquiry has been established by the Northern Ireland health minister to examine Southern Trust Urology services, this work is separately commissioned by Trust for our internal use. As such, the work is indemnified by the Trust, and we will also pay you directly for your work. Normally this type of review would be conducted internally within the Trust but due to extreme pressures on capacity the Trust has commissioned this externally.

The cases have been identified by the incumbent urologists at SHSCT with the support of Professor Krishna Sethia. Your role will be to check whether or not there are real concerns and, ultimately, to understand any underlying themes. To be consistent, we require these to be completed using the bespoke Structured Judgement Review proforma that is underpinned using Structured Judgement Review methodology.

As in introduction, Dr Damian Gormley, Deputy Medical Director for Quality and Safety would welcome the opportunity to speak with you either via phone call or zoom meeting to provide an introduction and answer any questions you may have. We would be grateful if you would let us know if you would have 30 minutes available to take a brief call to discuss this.

Our intention is to commence sharing the records in early January 2022.

Thank you again for your support for this work

With best regards
Stephen

Stephen Wallace

Assistant Director Systems Assurance
Craigavon Area Hospital
Portadown

Personal Information redacted by the USI

Quality Care - for you, with you

13th December 2021

Via Email [paul.rajjayabun](mailto:paul.rajjayabun@shsc.nhs.uk)

Personal Information redacted
by the USI

Mr Paul Rajjayabun
Consultant Urological Surgeon

Dear Paul,

RE: UROLOGY SERIOUS ADVERSE INCIDENT REVIEWS

Thank you for agreeing to participate in the Structured Clinical Record Review (SCRR) process relating to Urology services within the Southern Health and Social Care Trust, specifically related to a number of cases attributed to a surgeon.

I am writing to confirm that the Southern Health and Social Care Trust will provide indemnity for you with regards to this engagement in relation to any civil claims arising out of your professional or clinical review of this matter, subject always to your acting at all relevant times in good faith and with reasonable care and skill within the normal limits of reasonable professional and clinical competence.

Best regards,

Personal Information redacted by the USI

Dr Maria O'Kane
Medical Director

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

SECTION C: USER ACCEPTANCE FORM

I understand it is my responsibility to work within the Trust's guidelines and procedures.

I understand a breach of Trust Policies may result in the termination of access by the Southern Health and Social Care Trust and may lead to disciplinary procedures by my employer.

I agree to only use Trust information and data for the purpose of the agreed business which includes but is not limited to information, knowledge or data however disclosed including copies which are of intellectual, technical, scientific, financial or commercial which are not in the public domain.

I understand that my use of Trust facilities and systems will be logged and may be monitored and that any information I create may be subject to disclosure under Freedom of Information legislation.

Upon completion of the appointment, I shall make no further use of the Trust's information /data. I will return all information /data in my possession, which will include all originals and any subsequent copies of the information /data held.

This agreement will come into effect on (date) 8/11/21

Non-Trust Staff member to complete	SHSCT Staff to complete
Signature <small>Personal Information redacted by the USI</small>	Signature <small>Personal Information redacted by the USI</small>
Print Name PAUL RAJJAYABUN	Print Name Melanie McClements
Job title CONSULTANT UROLOGICAL SURGEON	Job title Director of Acute Services
Date 8/11/21	Date 09/11/2021

NB. Signed forms should be retained by the Trust Signatory or appropriate SHSCT Manager and a copy given to the non-Trust staff member.

Any queries should be directed to the Information Governance Team, Bannvale Site, Ferndale House, Gilford.

Tel – Personal Information redacted by the USI

Email – Personal Information redacted by the USI

Confidentiality

During the course of your time with the SHSCT, non-Trust staff may have access to confidential information. Confidential information includes all information relating to the business of the Trust and its patients/clients and employees.

This information must not be disclosed to any other person unless in pursuit of your duties as detailed within a data access agreement or contract between SHSCT and your employer. Under the DPA, it is an offence to obtain or disclose personal data belonging to SHSCT, without its prior consent. This includes the unauthorised accessing of personal data from SHSCT electronic systems or manual files and/or the supply of personal data to a third party, outside of the agreed contractual terms.

You may also have access to and be entrusted with information in respect of the services, business and financing of the SHSCT and its dealings, transactions and affairs, all of which is confidential.

All notes and memoranda or any intellectual property or confidential information concerning the business of the SHSCT which shall be acquired, received or made during the course of your appointment with the SHSCT shall be the property of the SHSCT and shall be surrendered by you to someone duly authorized by the Trust, at the termination of your appointment or at the request of the SHSCT at any time during the course of your appointment. This information will be retained (as per the Trust's Retention and Disposal schedule) for the appropriate period thereafter.



Confidentiality Agreement for Non-Trust Staff

SECTION A: GENERAL DETAILS

Name of Non-Trust Staff Member:

MR PAUL RAJJAYABUN

Company Name, Address & Phone number:

Personal Information redacted by the USI

Personal Information
redacted by the USI

SHSCT Contact

Contact Number

Service/Department:

Duration of Appointment

SECTION B: Agreement Details**Data Protection**

The Data Protection Act 2018 ('DPA') and the General Data Protection Regulation (GDPR) regulates the use of all personal information held within electronic and paper records, relating to living individuals (patients, service users, staff and the wider public). Within this agreement the term 'personal data' includes sensitive personal data and the term 'processing' refers to the accessing, handling, storing, transfer or disposal of personal data belonging to the Southern Health and Social Care Trust ('SHSCT').

The SHSCT adheres to the six data protection principles within the GDPR which provide a framework for the processing of personal and sensitive personal data. In general terms, the principles state personal information must be:

- Fairly and lawfully processed
- Processed for one or more specified purposes
- Adequate, relevant and not excessive
- Kept accurate and up to date (when necessary)
- Kept only for as long as is necessary
- Processed in a manner that ensures appropriate security

Policy, procedures and legislation

The SHSCT processes large volumes of personal data and requires non-Trust Staff to adhere to Trust policies and procedures when processing any personal data belonging to the SHSCT.

The SHSCT requires all non-Trust staff to use the information technology and communications facilities sensibly, professionally and lawfully; and abide by corporate policy and procedures in respect of the use of IT and communications equipment. The Trust monitors the use of ICT systems for this purpose.

Non-Trust staff should be aware that contravention of policies and/or the legislation from which the policies are derived (DPA/GDPR and the Computer Misuse Act 1990) may lead to disciplinary action by your employer and possible prosecution.

Data Sharing Agreement

This Agreement is made on the 8 day of November 2021

BETWEEN

THE Southern Health & Social Care Trust, (hereinafter referred to as "the SHSCT")

Of 68 LURGAN ROAD, PORTADOWN, COUNTY ARMAGH, BT63 5QQ

of the one part

AND

MR PAUL RAJJAYABUN

Of

Personal Information redacted by the USI

of the other part

The SHSCT is the provider of Health and Social Care services for the population of Northern Ireland in the Southern Trust Area. In the course of providing those services, the SHSCT may on occasion require to engage services from third party Associates/Consultants at times when additional specialist support would be of benefit to the SHSCT in conducting its functions.

The purpose of this Agreement ("the Agreement") is to ensure the lawful processing of Personal Data passing between the SHSCT and the Associate during the course of providing such support. This Agreement sets out the framework for the sharing of Personal Data between the parties as Controllers. It defines the principles and procedures that the parties shall adhere to and the responsibilities the parties owe to each other. This Agreement will benefit the SHSCT and the patients and service users it represents by allowing timely sharing of Personal Data and by providing the SHSCT and Data Subjects with clarity about how Personal Data will be processed and securely transferred between the SHSCT and Associate/Consultant. The parties recognise that the SHSCT will regularly disclose Personal Data to the Associate/Consultant and that, on occasion, the Associate/Consultant will disclose Personal Data to the SHSCT.

For the purpose of this Agreement, the Southern Health and Social Care Trust is described as 'the SHSCT' and associate instructed is described as 'Associate' and collectively they are referred to as 'the parties'.

The terms of this Agreement shall apply as appropriate to all occasions in which the SHSCT has provided Instructions to an Associate for the provision of services including Instructions provided prior to the date stated at the start of this Agreement.

- A. The SHSCT agrees to share Personal Data with the Associate on the terms set out in this Agreement. If the Associate shares Personal Data with the SHSCT, it will also be shared on the terms set out in this Agreement.
- B. The Associate agrees to use the Personal Data within the European Economic Area "the EEA" (which comprises the countries in the European Union and Iceland, Liechtenstein and Norway) and on the terms set out in this Agreement.

- C. This is a free standing Agreement and does not incorporate any commercial business terms established by the parties under separate commercial Agreements.

AGREED TERMS

1. INTERPRETATION

1.1 The following definitions and rules of interpretation apply in this Agreement:

Agreed Purposes: In connection with Services sought by the SHSCT: (i) the provision of specialist support and services; (ii) engagement with other HSC bodies and third parties on behalf of the SHSCT.

Controller, Data Subject, Personal Data, processing (and related expressions including process, processed or processes shall be construed accordingly) and Appropriate technical and organisational measures: have the meanings given to them in the Data Protection Legislation in force at the time.

Data Protection Legislation: means all applicable data protection and privacy legislation in force from time to time in Northern Ireland including the UK General Data Protection Regulation ("UK GDPR") ((EU) 2016/679), the Data Protection Act 2018 or any successor legislation and any other European Union legislation relating to personal data.

Health and Social Care Bodies means as defined in the Health and Social Care (Reform) Act (Northern Ireland) 2009, as amended.

Instructions means the instructions, requests for work to be done (and all accompanying materials), this Agreement and any other applicable terms and conditions, whether written or oral, given by the SHSCT to the Associate for the purposes of the supply of services by the Associate.

Personal Data Breach: a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to the Shared Personal Data.

Permitted Recipients: (i) The parties to this Agreement; (ii) the employees, servants or agents of each party; (iii) any third parties engaged to perform obligations in connection with this Agreement; and (iv) any third party to whom it is necessary to allow access to the Shared Personal Data (as defined in clause 3 of this Agreement) for one or more of the Agreed Purposes as set out in this Agreement.

Sensitive Personal Data: has the meaning given in the Data Protection Legislation in force at the time and in particular has the same meaning as "special categories of personal data" in Article 9 of the UK GDPR and for the purposes of this Agreement Criminal Offence Data (as defined in the Data Protection Act 2018) is to be treated in the same way as special categories of personal data.

Services/Support means the particular service or support required, whether contentious or non-contentious, in respect of which the Associate is instructed to supply services to the SHSCT.

Shared Personal Data: means the Personal Data and Sensitive Personal Data to be shared between the parties under this Agreement.

Data Subject Request: meaning a request made by or on behalf of a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.

Term: This Agreement shall commence on the date stated at the start of this Agreement and shall continue indefinitely thereafter.

1.2 The schedule forms part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the schedule.

1.3 Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.

1.4 References in this Agreement to statutory provisions shall (where the context so admits and unless otherwise expressly provided) be construed as references to those provisions as respectively amended, consolidated, extended or re-enacted (as the context requires) and to any orders, regulations, instruments or other subordinate legislation made under the relevant statutes.

1.5 Any words following the terms “including”, “include” “in particular” or “for example” or any similar phrase shall be construed as illustrative and shall not limit the generality of the related general words.

1.6 In the case of any ambiguity between any provision contained in the body of this Agreement and any provision contained in the schedule, the provision in the body of this Agreement shall take precedence.

1.7 Any reference to writing or written includes email.

1.8 Unless otherwise required the reference to one gender shall include a reference to the other gender.

1.9 In the event of any inconsistency between this Agreement and any other terms and conditions between the parties, the terms of the Agreement shall prevail.

2. COMPLIANCE WITH NATIONAL DATA PROTECTION LAWS

2.1 The Associate must ensure compliance with Data Protection Legislation at all times during the Term of this Agreement. Any material breach of the Data Protection Legislation by the Associate shall, if not remedied with 30 days of written notice from the SHSCT, allow the SHSCT to terminate the Associates Instruction for the provision of services to the SHSCT.

3. SHARED PERSONAL DATA

3.1 The following types of Personal Data may be shared between the parties during the Term of this Agreement for any of the Agreed Purposes:

- 3.1.1 personal details (including contact and location details);
- 3.1.2 family details;
- 3.1.3 lifestyle and social circumstances;
- 3.1.4 financial details;
- 3.1.5 education, training and employment details;
- 3.1.6 information relating to the matter in which the SHSCT is seeking support, services or representation;
- 3.1.7 Any other Personal Data which is relevant and necessary to be shared for the Agreed Purposes.

3.2 The following types of Sensitive Personal Data may be shared between the parties during the Term of this Agreement for any of the Agreed Purposes:

- 3.2.1 racial or ethnic origin;
- 3.2.2 political opinions;
- 3.2.3 religious or philosophical beliefs;
- 3.2.4 trade union membership;
- 3.2.5 data concerning a natural person's physical or mental health or condition;
- 3.2.6 data concerning a natural person's sex life or sexual orientation;
- 3.2.7 genetic or biometric data used to uniquely identify a natural person;
- 3.2.8 the commission or alleged commission of any offence; and
- 3.2.9 any proceedings for any offence committed or alleged to have been committed, the disposal of such proceedings or the sentence of any court in such proceedings.

3.3 Requirements for Third Party (Individual)

The Trust expects all individual third parties, to agree and ensure the following:

- 3.3.1 Have previously completed data protection/information governance training and/or participate in data protection training provided by the Trust (if required).
- 3.3.2 Confidentiality will endure after the individual has completed their interaction with the Trust and will remain in place, indefinitely.
- 3.3.3 All information generated by the individual (via the Trust's manual/electronic systems), remains the property of the Trust and may be disclosed or used by the Trust, where the disclosure is deemed legitimate.
- 3.3.4 The individual must not take copies, remove or retain any electronic/manual information, unless specifically agreed by the Trust.
- 3.3.5 The individual will notify the Trust immediately if there is a data breach or they witness any incident or concern, during their time in the Trust.
- 3.3.6 Any transfer of information (manually or electronically) and the method of

- transfer must be approved by senior staff within the Trust (section 2).
- 3.3.7 Where there is agreement to transfer or retain information, it must be kept secure and in line with Trust policies.
 - 3.3.8 All ICT equipment and devices belonging to the Trust must be returned directly to the appropriate Trust manager and it is the third party's responsibility to arrange and ensure the equipment/devices are safely returned.
 - 3.3.9 All ICT equipment and devices belonging to the Trust must be returned directly to the appropriate Trust manager and it is the third party's responsibility to arrange and ensure the equipment/devices are safely returned.
 - 3.3.10 The organisation must be registered with the Information Commissioner's Office and provide assurance that there is no legal issue, potential concern or obstruction, to undertaking the proposed work within the Trust.
 - 3.3.11 Third party organisations must ensure their staff have an understanding of data protection responsibilities (either through training or policies) and these can be evidenced, if required.

4. PARTICULAR OBLIGATIONS RELATING TO DATA SHARING

The Associate agrees to:

- 4.1 ensure that all necessary notices and consents are in place to enable the lawful transfer of the Shared Personal Data to any of the Permitted Recipients for any of the Agreed Purposes;
- 4.2 give full information to the SHSCT regarding any Data Subject whose Personal Data may be processed under this Agreement of the nature of such processing. This includes giving notice that, where processing of the Shared Personal Data is no longer necessary for the Agreed Purposes, on the termination of their Instruction for a particular Service to the SHSCT, Personal Data relating to them may be retained by, or as the case might be may be transferred to, one or more of the Permitted Recipients;
- 4.3 process the Shared Personal Data only for the Agreed Purposes;
- 4.4 not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients or otherwise as required by law;
- 4.5 ensure that any disclosure of the Shared Personal Data to any Permitted Recipients is in compliance with Data Protection Legislation;
- 4.6 ensure that Appropriate technical and organisational measures are adopted by them to ensure safekeeping against unauthorised or unlawful processing of the Shared Personal Data and against accidental loss, or destruction of, or damage to, the Shared Personal Data, including taking all such measures as may be required to comply with Article 32 of the GDPR and without prejudice to any other obligation in this clause 4.6 comply with the reasonable instructions of the SHSCT in that regard;
- 4.7 not transfer any Shared Personal Data outside the EEA unless the Associate:

- 4.7.1 complies with the provisions of Article 26 of the UK GDPR (in the event the third party is a joint controller); and
- 4.7.2 ensures that:
- (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 of the UK GDPR; or
 - (ii) there are appropriate safeguards in place pursuant to Article 46 of the UK GDPR; or
 - (iii) one of the derogations for specific situations in Article 49 of the UK GDPR applies to the transfer.

4.8 The following policies must be complied with, before the third party commences with the Trust or accesses Trust information / systems:

- (i) Data Protection and Confidentiality policy
- (ii) ICT – Server, desktop and portable security policy
- (iii) Mobile Telephone and Devices Policy
- (iv) Social Media Policy

For access to particular service areas/premises or Trust information systems, the following additional policies or procedures must be reviewed:

Policy/Procedure name	Applicable area

5. ASSISTANCE TO THE SHSCT

The Associate shall assist the SHSCT in complying with all applicable requirements of the Data Protection Legislation. In particular the Associate shall:

- 5.1 consult with the SHSCT about any notices given to Data Subjects in relation to the Shared Personal Data;
- 5.2 promptly inform the SHSCT about the receipt of any Data Subject Request;
- 5.3 provide the SHSCT with reasonable assistance in complying with any Data Subject Request;
- 5.4 not disclose or release any Shared Personal Data in response to a Data Subject Request without first consulting the SHSCT wherever possible;
- 5.5 assist the SHSCT, at the costs of the Associate, in responding to any request from a Data Subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security breach notifications, data privacy impact assessments and consultations with supervisory authorities or regulators;

- 5.6 notify the SHSCT without undue delay upon becoming aware of any breach of the Data Protection Legislation;
- 5.7 shall either securely and permanently delete or securely return Shared Personal Data and copies thereof to the SHSCT who provided the copies of the Shared Personal Data, where processing of the Shared Personal Data is no longer necessary for the Agreed Purposes, or on termination of Instruction in a provision of Service to the SHSCT, unless otherwise agreed between the parties or unless required by law or professional obligation to retain the Shared Personal Data, in which case it shall be retained no longer than is necessary for such purpose(s) and only that Shared Personal Data which is necessary shall be processed for such purpose(s).
- 5.8 use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from Personal Data transfers;
- 5.9 maintain complete and accurate records and information to demonstrate its compliance with this clause;
- 5.10 notify the SHSCT of any Personal Data Breach without undue delay (but in any event no later than 24 hours after becoming aware of the Personal Data Breach) and thereafter provide the SHSCT with such details as they reasonably require.

6. Freedom of Information Act 2000

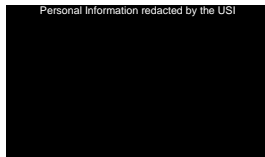
The Freedom of Information Act (FOIA) applies to all of the Trust's activities/functions and will include the information generated or collected from the activities and functions. The third party shall accept and support the Trust's obligations under the FOIA by ensuring all relevant records are retained. The Trust may have to disclose information about an organisation or individual, in response to a request under the FOIA, but will (where appropriate) inform the third party ahead of the disclosure.

The FOIA does permit some exemptions to the release of information and if the Trust decides that an exemption is applicable, it will withhold the information but will not inform the third party.

7. INDEMNITY

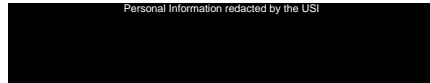
The Associate will carry their own professional indemnity insurance. The Associate shall indemnify the SHSCT against all liabilities, costs, expenses, damages and losses (including but not limited to any direct, indirect or consequential losses, loss of funding, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the SHSCT arising out of or in connection with breach of the Data Protection Legislation by the Associate, provided that the SHSCT gives to the Associate prompt notice of such claim, full information about the circumstances giving rise to it, reasonable assistance in dealing with the claim and sole authority to manage defend and/or settle it.

SIGNED



MR PAUL RAJJAYABUN MD FRCS UROL, CONSULTANT UROLOGICAL SURGEON
Associate (INSERT NAME OF ASSOCIATE / CONSULTANT)

SIGNED



~~SHSCT Chief Executive~~/SHSCT Director

For and on behalf of the Southern Health & Social Care Trust

SCHEDULE**1 Subject-matter of processing:**

Personal Data related to the provision of services/support to the SHSCT

2 Duration of the processing:

For as long as is necessary for the Agreed Purposes or until termination of Instruction for Services by the SHSCT unless otherwise as may be agreed between the parties or unless required by law or professional obligation to retain the Shared Personal Data, in which case it shall be retained no longer than is necessary for such purpose(s) and only that Shared Personal Data which is necessary shall be processed for such purpose(s).

3 Nature and purpose of the processing:

The nature of the processing means any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means) etc.

The purpose is as defined in the Agreed Purposes.

4 Type of Data:**Personal Data may include:**

Personal details (including contact and location details)

Family details

Lifestyle and social circumstances

Financial details

Education training and employment details

Information relating to the matter in which the SHSCT is seeking services or representation

Any other Personal Data which is relevant and necessary to be shared for the Agreed Purposes.

Sensitive Personal Data may include:

Racial or ethnic origin;

Political opinions;

Religious or philosophical beliefs;

Trade union membership;

Data concerning a natural person's physical or mental health or condition;

Data concerning a natural person's sex life or sexual orientation;

Genetic or biometric data used to uniquely identify a natural person;

The commission or alleged commission of any offence; and

Any proceedings for any offence committed or alleged to have been committed, the disposal of such proceedings or the sentence of any court in such proceedings.

5 Categories of Data Subjects:

SHSCT or other Health and Social Care Body former or current staff; actual or prospective patients/service users; family, carers, and next of kin of Data Subject; members of the public; plaintiff; claimant; defendant; respondent; debtor; solicitors; counsel; pupils; witnesses; experts; professional advisers; staff of Northern Ireland Courts and Tribunals Service, PSNI, Ombudsman, regulatory or investigatory bodies, legal aid, CRU, costs drawer, public registers such as land registry or registrar of deeds, external auditors, Embassies, Consulates, Schools, Northern Ireland Prison Service, Labour Relations Agency, Tracing and Service Agents, UKBA, insurance companies; anyone related to or ancillary to actual or potential proceedings and/or legal advices or services sought or given or to the Agreed Purposes.

6 Processing Instructions

All Personal Data will be dealt with confidentially and with appropriate security measures in place to prevent unauthorised or unlawful processing, accidental loss, destruction or damage.

General Medical Council

Paul Hosie RAJJAYABUN

GMC reference no: Personal Information

Results of search on: 11 Nov 2021 at 14:17 GMT

The details shown are valid at the date and time of the search only.



Registered with a licence to practise



This doctor is not on the GP Register



This doctor is on the Specialist Register

Urology from 24 Nov 2008

This doctor is a trainer recognised by the GMC.

This doctor is subject to revalidation

Designated body	Worcestershire Acute Hospitals NHS Trust
Responsible officer	Christine Blanshard

Primary medical qualification	MB ChB 1994 University of Birmingham
Provisional registration date	04 Jul 1994
Full registration date	02 Aug 1995
Gender	Male

Further information

This doctor may work at any grade in the NHS including consultant. Doctors working in general practice in the UK health service are required to be on the General Practitioner Register. Please refer to the relevant NHS performers lists regulations.

Annual retention fee due date: 02 Aug 2022

Trainer info

This doctor is recognised by the GMC in one or more of the following roles.

- Named clinical supervisors
- Named educational supervisors
- Lead coordinators of undergraduate training at each local provider
- Doctors responsible for overseeing students' educational progress for each medical school

Doctor's history

Registration and licensing history (since 20 October 2005)

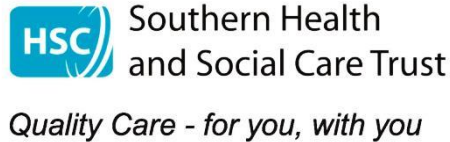
From *****	To *****	Status *****
16 Nov 2009	Present	Registered with a licence to practise
20 Oct 2005	16 Nov 2009	Registered

Please note:

All doctors who were registered before 20 October 2005 have their registration 'From' date set to 20 October 2005.

This is the date when the register went online.

If you need to know whether the doctor was registered before 20 October 2005 please [contact us](#).



ROLE DESCRIPTION

JOB TITLE	Independent Consultant Urology Subject Matter Expert
REPORTS TO PROFESSIONALLY	Dr Maria O’Kane, Medical Director
TIME COMMITMENT	Sessional Work on an ongoing basis

ROLE SUMMARY

To support an ongoing review. The Southern Health and Social Care Trust requires an independent Consultant Urologist to undertake Structured Clinical Record Reviews (SCRR) of a selection of patients who received urology care within the Southern Health and Social Care Trust.


ROLE DUTIES

1. To conduct SCRR’s that are based on Structured Judgement Review methodology that will review the urology care provided from the patients’ commencement of care through to discharge from the service.
2. In conducting the SCRR, review the Trust clinical records systems both electronic databases and electronic scanned copies of patient records to complete the judgement process.
3. To raise with the Trust Medical Director immediately if any concerns are identified that may give rise to any immediate patient safety concerns.

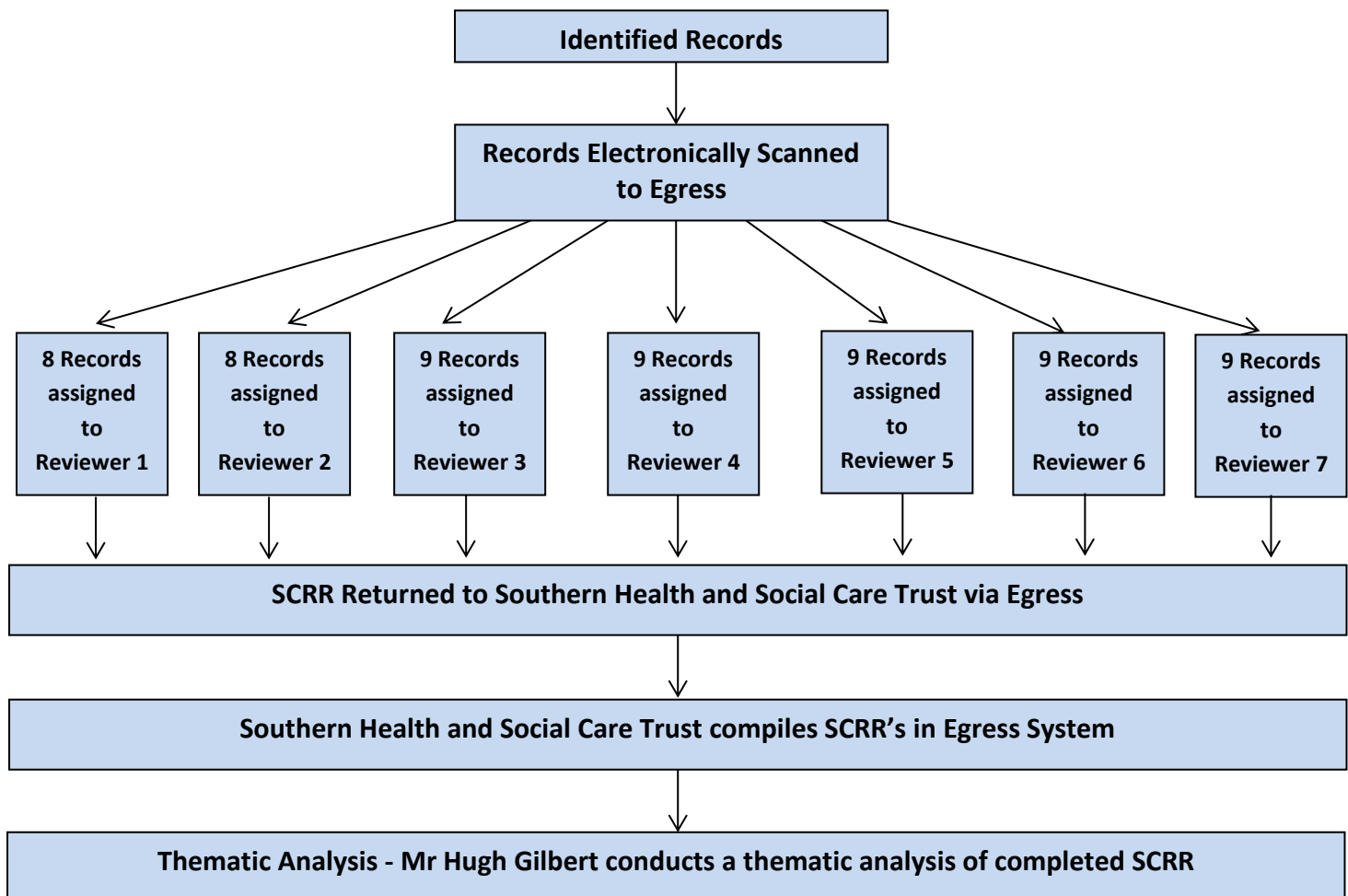
Structured Clinical Record Review Engagement

16th August 2021

1. Overview

Aim	<p>To conduct Structured Clinical Record Reviews (SCRR) using Structured Judgement Review methodology on 61 urology patients where potential sub-optimal care has been identified.</p> <p>A team of reviewers will make safety and quality judgements over phases of care, making explicit written comments and score about each.</p>
Review Team	Seven Consultant Urologists who are independent to the Southern Health and Social Care Trust have been identified via the British Association of Urological Surgeons (BAUS) to conduct the SCRR's
Method	<p>Judgement from each review conducted will be populated into a structured clinical record review form (attached)</p> <p> Structured Clinical Record Review Form.</p>
Access to Records	<p>Patient records will be scanned and electronically hosted on the Trust secure 'Egress' record management system. Reviewers will be granted access to view these files remotely for the purposes of the SCRR.</p> <p>An individual SCRR form will be completed for each patient and returned to the Southern Health and Social Care Trust via Egress.</p>
Indemnity	The Southern Health and Social Care Trust will indemnify the reviewers regarding any civil claims arising out of their clinical review of these matters, subject to this being conducted within the normal limits of reasonable clinical competence.
Payment for Services	<p>Payment for services will be on a per hour basis, value of £Commer cially Sensitiv. Costs to be invoiced to stephen.wallace Personal Information redacted by the USI</p>
Thematic Analysis	On completion Mr Hugh Gilbert will provide a thematic analysis report on the completed SCRR's for the Southern Health and Social Care Trust.

2. Process Flow



3. Proposed Timeline for Delivery

Stage	Identified Date for Delivery
Records Identified	Complete
Records Scanned to Egress*	16 th August 2021
Records Assigned to Reviewer	16 th August 2021
SCRR's returned to Trust	17 th September 2021
SCRRs issued for thematic Outcomes	5 th October 2021

**Patient files will be provided to reviewers in groups as they become available*

Structured Clinical Record Review title(SCRR)

Section 1

*This section should be completed as soon as is possible following identification of the incident
If it is deemed appropriate to complete Section 2, it should be completed within 8 Weeks (56 days)*

Patient identification number:		Gender:	
Date of birth (dd/mm/yyyy)		Age:	
Date of Incident		Date Incident Reported:	
Datix Incident Number			
Date of death (if relevant)			
Location of death (if relevant)			
Was the patient identified as being within the last 12 months of life?			
Cause of death (if known)			
Primary diagnosis, including ICD-10 code (if known)			
Co-morbidities			
Healthcare teams involved in the patient's care at the time of incident			
Patient summary (can be completed by the clinical team)			
Concerns from family members or carers about the patient's care (please outline concerns, or state if there were no concerns)			
Concerns from staff about the patient's care (please outline concerns, or state if there were no concerns)			

Time taken to complete Section 1 of this form (minutes):

Date of completion:

Name of person completing Section 1:

Job title of person completing Section 1

Care Review Tool for Urology

Section 2

Please state the information sources used for the review, including the names of the electronic systems accessed:

2.1. Phase of care: Triage (where relevant)

- Was triage conducted in a timely manner?
- Was the triage outcome assigned an appropriate level of priority given the information available at the time?

Please record your explicit judgements about the triage process and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.2. Phase of care: Initial assessment or review (where relevant)

- Were the investigations, prescribing, diagnosis and clinical management approach and communications with patient, primary care and MDT teams appropriate?
- Were diagnostic tests or investigations requested in a timely manner and with sufficient clinical information to allow appropriate onward prioritisation?

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.3. Phase of care: Review of Diagnostics (where relevant)

- Were diagnostic tests or investigations reviewed in a timely manner with appropriate further actions taken?
- Were any required actions adequately communicated to patient / primary care / MDT teams?
- Please list medication if known and relevant, and comment on medication monitoring where appropriate

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.4. Phase of care: Ongoing Outpatient Care (where relevant)

- Were ongoing reviews scheduled at appropriate intervals?
- Were referrals made to other teams / professionals appropriately and in a timely manner?
- Where any further required tests / investigations requested and performed in line with good current practice?
- Please list medication if known and relevant, and comment on medication monitoring where appropriate

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.5. Phase of care: Admission and Initial Management (approximately the first 24 hours) (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

Care Review Tool for Urology

2.6. Phase of care: Ongoing Inpatient Care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

Care Review Tool for Urology

2.7. Phase of care: Care during a procedure (excluding IV cannulation) (where relevant)
Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.8. Phase of care: Perioperative care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.9. Phase of care: Discharge plan of care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

2.10. Other area of care (please specify)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.11. Overall care

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.

Areas identified where learning could occur, including areas of good practice, should be included in addition to any potential areas of further investigation.

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

2.12. If care was below an acceptable standard, did it lead to harm?

If yes, please provide details and state an action plan

Care Review Tool for Urology

2.13. If the patient died is it considered more likely than not to have resulted from problems in care delivery or service provision?
If yes, please provide details and state an action plan (consider whether a serious incident investigation is required).

2.14. If a family member, carer, or staff raised concerns, please outline any feedback provided and state who was responsible for providing this feedback. Please state further action required. If no feedback was provided, please consider how the outcome of this review should be fed back to the relevant people, considering the duty of candour principle.

2.15. Were the patient records adequate for the purpose of the review?

Yes ☐

No ☐

Please outline any difficulties in accessing appropriate information:

Time taken to complete Section 2 of this form (minutes):

Date of completion:

Name of person completing Section 2:

Job title of person completing Section 2:

Assessment of problems in healthcare for Urology patients

In this section, the reviewer is asked to comment on whether one or more specific types of problem(s) were identified and, if so, to indicate whether any led to harm. Please circle correct response.

Problem types

<p>1. Problem in assessment, investigation or diagnosis</p>	<p>Yes No</p>
<p>Did the problem lead to harm?</p>	<p>No Uncertain Yes</p>
<p>In which phase(s) did the problem occur?</p>	<p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>
<p>2. Problem with medication / IV fluids / electrolytes / oxygen</p>	<p>Yes No</p>
<p>Did the problem lead to harm?</p>	<p>No Uncertain Yes</p>
<p>In which phase(s) did the problem occur?</p>	<p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>

Care Review Tool for Urology

<p>3. Problem related to treatment and management plan</p> <p>Did the problem lead to harm?</p> <p>In which phase(s) did the problem occur?</p>	<p>Yes No</p> <p>No Uncertain Yes</p> <p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>
<p>4. Problem related to operation / invasive procedure <i>(other than infection control)</i></p> <p>Did the problem lead to harm?</p> <p>In which phase(s) did the problem occur?</p>	<p>Yes No</p> <p>No Uncertain Yes</p> <p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>
<p>5. Problem with infection management</p> <p>Did the problem lead to harm?</p> <p>In which phase(s) did the problem occur?</p>	<p>Yes No</p> <p>No Uncertain Yes</p> <p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation)</p>

Care Review Tool for Urology

	Perioperative care Discharge plan of care Other area of care
6. Problem in clinical monitoring (including failure to plan, to undertake, or to recognise and respond to changes) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
7. Problem in resuscitation following a cardiac or respiratory arrest (including cardiopulmonary resuscitation (CPR)) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
8. Problem of any other type not fitting the categories above (including patient records and documentation, informed consent, communication with patients and carers and organisational issues) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care


Care Review Tool for Urology

	Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
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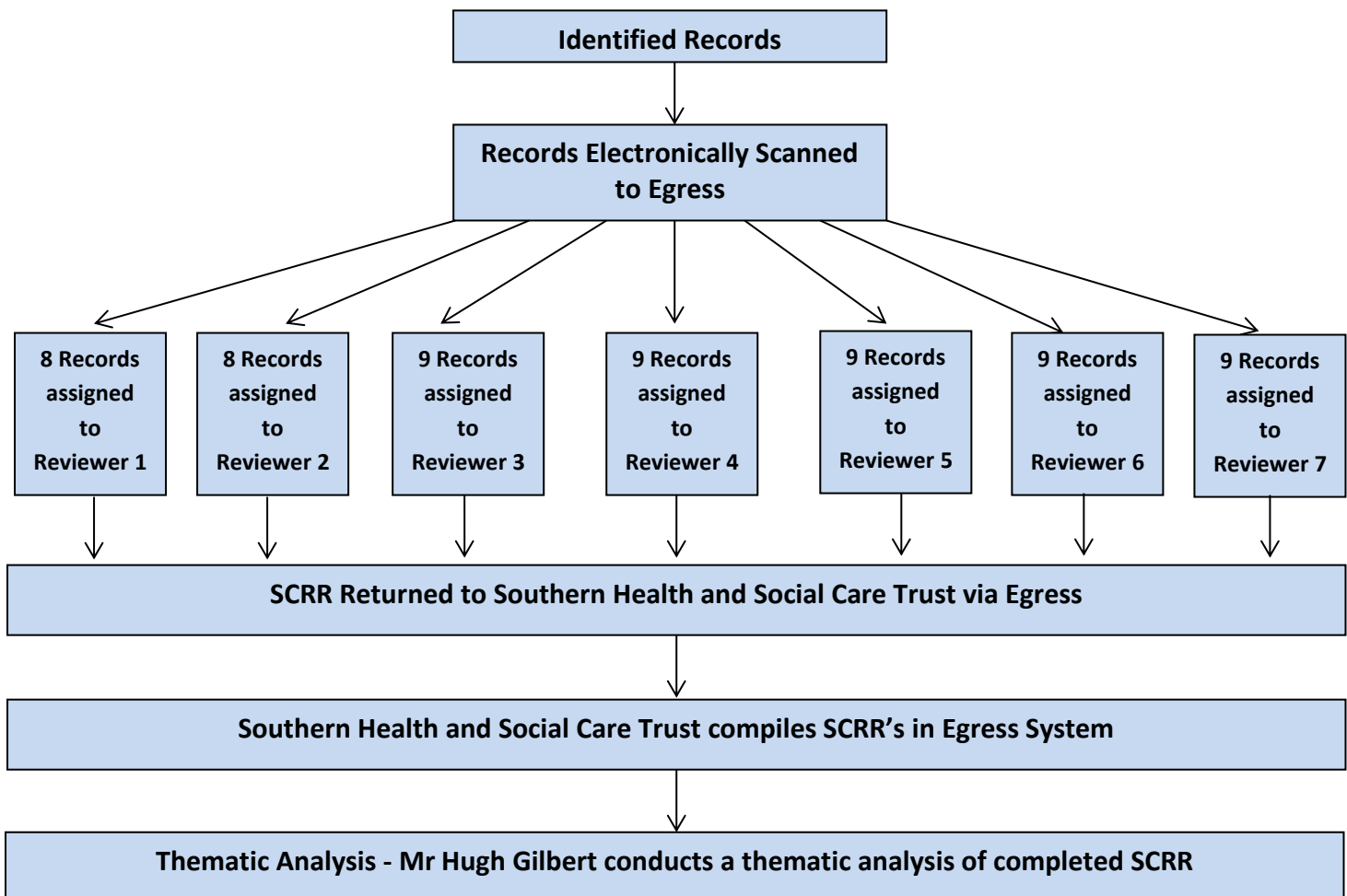
Structured Clinical Record Review Engagement

7th March 2022

1. Overview

Aim	<p>To conduct Structured Clinical Record Reviews (SCRR) using Structured Judgement Review methodology on urology patients where potential sub-optimal care has been identified.</p> <p>A team of reviewers will make safety and quality judgements over phases of care, making explicit written comments and score about each.</p>
Review Team	<p>Seven Consultant Urologists who are independent to the Southern Health and Social Care Trust have been identified via the British Association of Urological Surgeons (BAUS) to conduct the SCRR's</p>
Method	<p>Judgement from each review conducted will be populated into a structured clinical record review form (attached)</p> <p> Structured Clinical Record Review Form.</p>
Access to Records	<p>Patient records will be scanned and electronically hosted on the Trust secure 'Egress' record management system. Reviewers will be granted access to view these files remotely for the purposes of the SCRR.</p> <p>An individual SCRR form will be completed for each patient and returned to the Southern Health and Social Care Trust via Egress.</p>
Indemnity	<p>The Southern Health and Social Care Trust will indemnify the reviewers regarding any civil claims arising out of their clinical review of these matters, subject to this being conducted within the normal limits of reasonable clinical competence.</p>
Payment for Services	<p>Payment for services will be on a per hour basis, value of £ <small>Commercially Sensitive</small> Costs to be invoiced to stephen.wallace <small>Personal Information redacted by the USI</small></p>
Thematic Analysis	<p>On completion Mr Hugh Gilbert will provide a thematic analysis report on the completed SCRR's for the Southern Health and Social Care Trust.</p>

2. Process Flow



3. Proposed Timeline for Delivery

Stage	Identified Date for Delivery
Records Identified	Complete
Records Scanned to Egress*	16 th August 2021
Records Assigned to Reviewer	16 th August 2021
SCRR's returned to Trust	17 th September 2021
SCRRs issued for thematic Outcomes	5 th October 2021

**Patient files will be provided to reviewers in groups as they become available*

Structured Clinical Record Review title(SCRR)

Section 1

*This section should be completed as soon as is possible following identification of the incident
If it is deemed appropriate to complete Section 2, it should be completed within 8 Weeks (56 days)*

Patient identification number:		Gender:	
Date of birth (dd/mm/yyyy)		Age:	
Date of Incident		Date Incident Reported:	
Datix Incident Number			
Date of death (if relevant)			
Location of death (if relevant)			
Was the patient identified as being within the last 12 months of life?			
Cause of death (if known)			
Primary diagnosis, including ICD-10 code (if known)			
Co-morbidities			
Healthcare teams involved in the patient's care at the time of incident			
Patient summary (can be completed by the clinical team)			
Concerns from family members or carers about the patient's care (please outline concerns, or state if there were no concerns)			
Concerns from staff about the patient's care (please outline concerns, or state if there were no concerns)			

Time taken to complete Section 1 of this form (minutes):

Date of completion:

Name of person completing Section 1:

Job title of person completing Section 1

Care Review Tool for Urology

Section 2

Please state the information sources used for the review, including the names of the electronic systems accessed:

2.1. Phase of care: Triage (where relevant)

- Was triage conducted in a timely manner?
- Was the triage outcome assigned an appropriate level of priority given the information available at the time?

Please record your explicit judgements about the triage process and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.2. Phase of care: Initial assessment or review (where relevant)

- Were the investigations, prescribing, diagnosis and clinical management approach and communications with patient, primary care and MDT teams appropriate?
- Were diagnostic tests or investigations requested in a timely manner and with sufficient clinical information to allow appropriate onward prioritisation?

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.3. Phase of care: Review of Diagnostics (where relevant)

- Were diagnostic tests or investigations reviewed in a timely manner with appropriate further actions taken?
- Were any required actions adequately communicated to patient / primary care / MDT teams?
- Please list medication if known and relevant, and comment on medication monitoring where appropriate

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.4. Phase of care: Ongoing Outpatient Care (where relevant)

- Were ongoing reviews scheduled at appropriate intervals?
- Were referrals made to other teams / professionals appropriately and in a timely manner?
- Where any further required tests / investigations requested and performed in line with good current practice?
- Please list medication if known and relevant, and comment on medication monitoring where appropriate

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.5. Phase of care: Admission and Initial Management (approximately the first 24 hours) (where relevant)
Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

Care Review Tool for Urology

2.6. Phase of care: Ongoing Inpatient Care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

Care Review Tool for Urology

2.7. Phase of care: Care during a procedure (excluding IV cannulation) (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.8. Phase of care: Perioperative care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.9. Phase of care: Discharge plan of care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

2.10. Other area of care (please specify)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.11. Overall care

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.

Areas identified where learning could occur, including areas of good practice, should be included in addition to any potential areas of further investigation.

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

2.12. If care was below an acceptable standard, did it lead to harm?

If yes, please provide details and state an action plan

Care Review Tool for Urology

2.13. If the patient died is it considered more likely than not to have resulted from problems in care delivery or service provision?
If yes, please provide details and state an action plan (consider whether a serious incident investigation is required).

2.14. If a family member, carer, or staff raised concerns, please outline any feedback provided and state who was responsible for providing this feedback. Please state further action required. If no feedback was provided, please consider how the outcome of this review should be fed back to the relevant people, considering the duty of candour principle.

2.15. Were the patient records adequate for the purpose of the review?

Yes ☐

No ☐

Please outline any difficulties in accessing appropriate information:

Time taken to complete Section 2 of this form (minutes):

Date of completion:

Name of person completing Section 2:

Job title of person completing Section 2:

Assessment of problems in healthcare for Urology patients

In this section, the reviewer is asked to comment on whether one or more specific types of problem(s) were identified and, if so, to indicate whether any led to harm. Please circle correct response.

Problem types

<p>1. Problem in assessment, investigation or diagnosis</p>	<p>Yes No</p>
<p>Did the problem lead to harm?</p>	<p>No Uncertain Yes</p>
<p>In which phase(s) did the problem occur?</p>	<p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>
<p>2. Problem with medication / IV fluids / electrolytes / oxygen</p>	<p>Yes No</p>
<p>Did the problem lead to harm?</p>	<p>No Uncertain Yes</p>
<p>In which phase(s) did the problem occur?</p>	<p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>

Care Review Tool for Urology

<p>3. Problem related to treatment and management plan</p> <p>Did the problem lead to harm?</p> <p>In which phase(s) did the problem occur?</p>	<p>Yes No</p> <p>No Uncertain Yes</p> <p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>
<p>4. Problem related to operation / invasive procedure <i>(other than infection control)</i></p> <p>Did the problem lead to harm?</p> <p>In which phase(s) did the problem occur?</p>	<p>Yes No</p> <p>No Uncertain Yes</p> <p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>
<p>5. Problem with infection management</p> <p>Did the problem lead to harm?</p> <p>In which phase(s) did the problem occur?</p>	<p>Yes No</p> <p>No Uncertain Yes</p> <p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation)</p>

Care Review Tool for Urology

	Perioperative care Discharge plan of care Other area of care
6. Problem in clinical monitoring (including failure to plan, to undertake, or to recognise and respond to changes) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
7. Problem in resuscitation following a cardiac or respiratory arrest (including cardiopulmonary resuscitation (CPR)) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
8. Problem of any other type not fitting the categories above (including patient records and documentation, informed consent, communication with patients and carers and organisational issues) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care

Care Review Tool for Urology

	Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
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Royal College
of Physicians

National Mortality Case
Record Review Programme

WIT-10786

Frequently asked questions 2019

In partnership with



Commissioned by HQIP and funded by NHS Improvement



Sections

1. The Structured Judgement Review (SJR) methodology.....	3
2. The mortality review process.....	7
3. The National Mortality Case Record Review (NMCRR) Programme	10
References	12

Foreword

This document is a non-exhaustive list of frequently asked questions about the National Mortality Case Record Review (NMCRR) Programme and the Structured Judgement Review (SJR) methodology. Various sources have been used to compile this list, including information from pilot sites. This document is to be used as an aid to support the training of reviewers. It will be subject to amendments as we gain further experience and gather more feedback during the course of the NMCRR Programme.

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1. The Structured Judgement Review (SJR) methodology

1.1 Is this methodology validated and reliable?

This method has been shown to be valid¹ and is used extensively in several healthcare systems in England. Case study reviews from our pilot sites and the work done in Yorkshire and Humber show that consensus agreement can occur more than 95% of the time.

1.2 Why is this method being used rather than other methodologies eg PRISM2?

The methodology has many aspects in common with other retrospective methodologies used for case note reviews. This method has been used extensively in England and validated on a large cohort of cases. It was chosen to be the standardised mortality review tool by NHS Improvement.

1.3 Why do we need both scores and judgement comments?

This is covered in some detail in the Royal College of Physicians' (RCP's) guide for reviewers.² The data provide different forms of information that can be used for individual cases and for groups of cases. Contrasting judgement comments and care scores can also assist reviewers in their decision making in each phase of care.

1.4 How much of the scoring is subjective and how much is objective?

Many decisions in healthcare have both subjective and objective elements in the final formulation and, of course, these decisions vary from case to case and between situations. These processes also apply to SJR.

1.5 Could there be a large variation in subjectivity in the judgement: ie doves and hawks?

This can be so, but work on training cases suggests that this variation is not as great as one might expect and, of course, it has always been present with mortality reviews, whatever the method used. Quality assurance of the reviews via the governance process should help to identify cases where additional training is required.

1.6 Do the five care scores represent a nominal or an ordinal scale?

The scores do not represent a scale. They are a convenient way of indicating what the phase of care judgement is, so it is useful both as a shorthand (ie 'This is a 5', meaning excellent) and when clustering phase of care scores together. Searching for cases with a score of (say) 3 is somewhat easier than searching for and displaying cases of 'adequate care'.

1.7 Is there a matrix available to judge what is 'good' and what is 'not so good' care?

No. Experience shows that in all but the poorest care, the judgement on the range of care is much more subtle. And even when care is poor, there is often some good 'rescue' work. Therefore, explicit judgements about care form the basis of the reviews, rather than using a criterion-based approach.

1.8 How do I make a judgement on a colleague's work?

The training sessions cover the principles of SJR and should facilitate this process. This is also a governance question and local processes should be in place to support this.

1.9 Do the issues/comments carry different weightings when giving a phase score?

Yes, they do, but not as 'mini scores', because the weight of a particular component of a phase of care may carry most importance in making a decision. If everything else is adequate and one item is poor, this could bring the care score down. The reverse could happen if one element of the care was excellent.

1.10 Do we name the care giver (eg the doctor/nurse) when writing the judgement comment?

No. Care givers' names are not used in the review, although role titles can be used where it is thought to be relevant.

1.11 How long, on average, does it take for a review to be completed?

This mainly depends on the details of the case. SJR and other structured methods such as PRISM2 require the reviewer to give attention to the detail of the case throughout the care episode, so by definition some of these reviews can take a significant amount of time: up to, and sometimes even over, 1 hour.

1.12 If the care received by a patient prior to their arrival at hospital is relevant, should I record that in the review? If so, should it be in the admission phase?

Yes but this is background information and it should not form part of the material on which a judgement is made, since the review process only looks at the care that is provided within the hospital.

1.13 What should we record as 'procedures'? Should cannula insertions be recorded?

The reviewer needs to make a judgement here. Where procedures carry some risk (and some cannulations do so), then these should be included as procedures.

1.14 Should do not attempt cardiopulmonary resuscitation decisions be recorded in the end-of-life (EOL) phase even if they are completed in the first 24 hours?

Activities and care that occur within the first 24 hours should be recorded there, even if these are decisions that refer to EOL care. They should be referred to again in the EOL section, with the 'hindsight' on whether this was appropriate at the early stage of care.

1.15 Should a surgical procedure be recorded in the 'care during a procedure' phase or in the perioperative phase?

Preferably, surgical procedures should be recorded in the perioperative phase. However, they can be recorded anywhere in the case review as long as they are recorded at least once and care scores are given appropriately.

1.16 Should surgical procedures that are performed within the first 24 hours be recorded in the 'initial first 24-hour phase of care'?

Preferably, surgical procedures should be recorded in the perioperative phase. However, they can be recorded anywhere in the case review as long as they are recorded at least once and care scores are given appropriately.

1.17 What is the inter-rater variability in terms of scoring?

There are no inter-rater comparisons available from SJR training or recent practice. Initial inter-rater comparisons from the supporting research were similar to other assessments; that is, agreement of about 60–70% between two reviewers separately examining the same set of case notes.

1.18 Why is there variability in scores during training?

Variability during training is to be expected because of known inter-rater variability between reviewers and because the training session is the first time that many people have used this new methodology.

1.19 Can nurses review a surgical procedure?

Just as with the whole spectrum of professional reviewers, specialist nurses with the appropriate skills can contribute to a surgical case review.

1.20 How do we accommodate reviewers' specialist skillsets or reviews that require specialist information? Can we review what is not within our speciality?

In general, reviewers will work within their broad areas of expertise or they will occasionally undertake a joint review. Where specialist information is required, colleague support should be arranged through local processes.

1.21 Is it a problem when a reviewer's specialist knowledge guides their focus when they are doing reviews?

Reviewers will often draw on specialist knowledge when they undertake reviews. However reviewers will recognise that many of the quality issues that they find are about the organisation and delivery of care and are thus generic.

1.22 Can trainees be reviewers?

Doctors who are in the later stages of training often make very perceptive reviewers. After their review training, trainees would work within the governance process, as would all other reviewers.

1.23 Can we use SJR for reviews other than where there has been a death?

Yes. SJR is a quality and safety review process and it works well for cases where there has not been a death. This is, of course, outside of the framework of the NMCRR Programme.

1.24 Can this review method be used on near-miss/random samples as part of quality improvement work?

Yes, the SJR method works well in these circumstances, as it provides rich information for themed reviews.

2. The mortality review process

2.1 How do we select the cases for review?

Each trust will publish an account of the rationale for choosing case notes for review, but a minimum list has been described by NHS Improvement and the Clinical Quality Commission (CQC) in *National guidance on learning from deaths*.³

2.2 Who can train to be a reviewer?

Usually reviewers are consultants, senior trainees or senior nursing staff but in principle anyone can train to be a reviewer as long as the quality of their reviews is good and consistent and they have the appropriate clinical skills to assess the appropriateness of the care provision.

2.3 Can the second review be done by a team?

Yes, provided all the members of the review team have also reviewed the notes. Good governance processes suggest there should be a lead reviewer who takes responsibility for the review team's decisions.

2.4 Why is there an issue with consultants reviewing their own cases?

The issues are around the need to ensure review objectivity. The 2017 NHS guidance *National guidance on learning from deaths*, Section 20,³ sets out the expectations for objectivity.

2.5 How does SJR fit into our governance processes?

All mortality review processes need to be part of the hospital governance process. The strengthening of good governance processes following the implementation of SJR has provided extra support for reviews and reviewers.

2.6 What happens if we identify a problem in care?

The duty of candour and National Framework legislation⁴ apply to this process and each trust should have a system in place to act on any problems in care that are identified.

2.7 How do we avoid duplication of reviews with mortality and morbidity reviews and/or other national audits?

Correlation rather than duplication is required here. Mortality and governance committees should be able to provide guidance.

2.8 How do we integrate this process with serious untoward incidents investigations and root cause analysis?

For this to happen, the NMCRR Programme needs to be firmly embedded in the hospital governance programme.

2.9 How does this process correlate with coroners' cases?

There is currently no evidence for this with any review programme, although some research evidence may be available in the future.

2.10 On average, what proportion of cases at first review end up with an overall phase score of 1 or 2 and need escalating?

This proportion varies greatly between the types of cases and selection methods, but one might expect around 5–10% of cases to go to second review.

2.11 Should we review elective palliative radiological interventions?

It would be wise to review such cases if there is a concern that the intervention may have played a part in the death of a patient.

2.12 Can we review paediatric deaths?

While the SJR method can be applied to the review of child deaths, the NMCRR Programme is concerned with the deaths of adults (aged 18 years and over) who die in acute hospitals. There may be instances where children aged 16–17 years die in an acute hospital, for example in the intensive care unit, but special processes will be in place in the hospital to manage reviews under these circumstances.

2.13 Does the NMCRR Programme advocate review of all deaths?

There is no suggestion from the NMCRR Programme that all deaths require review. However, local processes may differ. There is also much clearer national guidance³ on which cases should be included in the review process..

2.14 Within how many days should a review be done?

There is no set time frame for reviews to be done, although it is likely that the hospital will have developed a policy on this. It makes sense to try to get the reviews done without delay because there is always a chance that an unexpected issue might be found that will require disclosure. This is better done sooner rather than later. Delay is a governance issue and it is explicitly addressed in the *National guidance on learning from deaths*.³

2.15 How do I conduct a timely review when there are delays in getting the case notes?

This problem is faced by many reviewers, who will need the support of the hospital governance process to recognise the requirement to improve the timeliness of access to case notes.

2.16 I am a busy consultant, how do I find time to do reviews?

We understand that this is a frequent and a difficult problem however there is a statutory requirement to undertake reviews. This is being addressed in different ways across the country including the use of a more structured approach to undertaking reviews and managing the information from those reviews.

2.17 As a trust, how do we assess our cohort of reviewers?

This is the role of the hospital's governance process. Continuous quality improvement assessment approaches assess the quality and appropriateness of the reviews in the hospital programme. This can be done, for example, by exploring the quality of qualitative data that are being provided and matching judgements against the scores that are given.

2.18 Are the review forms disclosable to families/carers if they make a complaint?

Yes, just as all of the other patient records are available.

3. The National Mortality Case Record Review (NMCRR) Programme

3.1 The NMCRR Programme is only being implemented in England and Scotland, what is happening to other parts of the UK?

The current contract covers England and Scotland, so if sites from other parts of the UK wish to participate they should contact the Healthcare Quality Improvement Partnership (HQIP).

3.2 Which sites were involved in the pilot phase of the NMCRR Programme?

The sites involved in the pilot phase were: NHS Highland (Scotland), University Hospitals of South Manchester NHS Foundation Trust, Harrogate and District NHS Foundation Trust, York Teaching Hospital NHS Foundation Trust, St George's University Hospitals NHS Foundation Trust and West of England Academic Health Science Network (including Bristol, Bath and Swindon).

3.3 What are the implications for the NMCRR Programme after it becomes part of the wider mortality framework?

The NMCRR was commissioned as an independent programme from the mortality framework and it will continue to be so for its lifetime.

3.4 Where can we find the NMCRR Programme support materials?

All resources, including the e-learning, can be accessed via the RCP mortality programme webpage which can be found at: <https://www.rcplondon.ac.uk/mortality>.

3.5 How will I know I am accessing the most up-to-date NMCRR Programme support materials?

All resources are continually reviewed to ensure they remain up-to-date. The latest versions of all NMCRR Programme support materials are available via the RCP mortality programme webpage.⁵

3.6 Who can be a Tier 1 trainer?

Tier 1 trainers can be recruited from clinical and non-clinical backgrounds but they must have educational and training competencies. Usually, Tier 1 trainers come from senior educationalist, consultant staff or senior allied health disciplines, including nursing and physiotherapy.

3.7 We have a different methodology in my trust, does this matter?

The Framework³ specifies that, where needed, the SJR method should be used for case record review but it is not completely mandatory and some flexibility exists. The CQC and NHS Improvement³ would need to be reassured that the system in place in your trust is validated and reproducible.

3.8 Will anything else happen to the information we input? Will it be reported nationally?

Individual hospitals will only be able to see and analyse their own information. However, the RCP and the Yorkshire and Humber Improvement Academy will have access to all anonymised information nationally. The NMCRR Programme will report this anonymised information nationally; for example, on the identification of themes such as good practice and learning points as per the 2018 NMCRR Annual Report.^{ref} This information will not take the form of league tables.

3.9 How will the NMCRR Programme ensure that the quality of reviews in hospitals is maintained?

The NMCRR will not be responsible for ensuring the quality of trust reviews but it will have a role in assessing the quality of training provision by Tier 1 trainers. The core project team have developed a quality assurance strategy, which will be deployed when the Tier 1 trainers become fully engaged in the implementation and roll out of the programme.

3.10 What will happen to the NMCRR Programme at the end of the 3-year contract?

The decision whether or not to renew the contract will be taken during Year 2. As the SJR process has become part of the wider Department of Health mortality structure, it is likely that SJR will continue as a lead mortality review process even if the contract is renewed.

3.11 What is the current situation with DATIX and the platform?

The online platform is now available via: .

We strongly advise all users to undertake training provided by DATIX UK prior to using the platform to understand the benefits and make full use of the system.

3.12 How much will the DATIX platform cost my trust?

The platform is free for hospitals/trusts to use, and training is provided by DATIX UK. Hospitals/trusts that do not currently use DATIX systems will still be able to use the mortality platform. We strongly advise all users to undertake training prior to using the platform to understand the benefits and make full use of the system.

3.13 Why can't we input the date and time for patients' admissions and deaths on the DATIX platform?

Entering these data would make the patient more likely to be identified. The platform only allows for the input of non-identifiable data.

3.14 How will the DATIX platform help us to understand our mortality reviews?

Clinicians input their mortality reviews onto the platform and, as the numbers of reviews build, the platform makes it possible to perform thematic analyses to identify areas of concern and also good practice. It is possible to analyse data from days or specific wards, so that mortality can be better understood locally. The training package provided by DATIX UK provides guidance on undertaking analysis of the reviews performed.

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Royal College
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National Mortality Case
Record Review Programme

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Using the Structured Judgement Review method

A guide for reviewers

2019

In partnership with



Commissioned by HQIP and funded by NHS Improvement



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Structured Judgement Review

1 Background to the method and its strengths

In order to provide the benefits to patient care which are commensurate with the effort put into case note review, review methods need to be standardised, yet not rigid, and usable across services, teams and specialties.

Structured Judgement Review blends traditional, clinical-judgement based, review methods with a standard format. This approach requires reviewers to make safety and quality judgements over phases of care, to make explicit written comments about care for each phase, and to score care for each phase.¹ The result is a relatively short but rich set of information about each case in a form that can also be aggregated to produce knowledge about clinical services and systems of care.

The object of the review method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about the hospital systems where care goes well, and to identify points where there may be gaps, problems or difficulty in the care process. In order to ask these questions there is a need to look at:

the whole range of care provided to an individual; holistic care approaches; the nuances of case management and the outcomes of interventions.

Structured judgement case note review can be used for a wide range of hospital - based safety and quality reviews, across services and specialties, and not only for those cases where people die in hospital. For example, it has been used to assess care for people who have had a cardiac arrest in hospital and to review safety and quality of care prior to and during non-elective admission to intensive care settings. It has also been used to review care for people admitted at different times of the week.

An important feature of the method is that the quality and safety of care is judged and recorded whatever the outcome of the case and that good care is judged and recorded in the same detail as that care which has been judged problematic. Evidence shows that most care is of good or excellent quality and that there is much to be learned from the evaluation of high quality care.

2 How the Structured Judgement Review process works

2.1 Who does what and when?

There are two stages to the review process. The first stage is mainly the domain of what might be called 'front line' reviewers, who are trained in the method and who undertake reviews as part of the hospital mortality review programme. There is evidence of a wide range of approaches being taken to case and reviewer choice, including cases selected through the governance process or within their own services or directorates; reviews sometimes taking the form of morbidity and mortality (M&M) reviews and sometimes as a team looking at the care of groups of cases. This is where the bulk of

the reviewing is done and most of the reviews are completed at this point. A second stage review is recommended where care problems have been identified by a first- stage reviewer and an overall care score of 1 or 2 has been used to rate care as very poor or poor, or where harms have been identified. This second stage review is usually undertaken within the hospital governance process, using a variety of approaches which sometimes includes a repeat 'validation' Structured Judgement Review by a second reviewer.

Hospital governance processes in England will be further enhanced from 2019 onwards through the introduction of a hospital Medical Examiner [ME] function. Evidence from the ME pilot projects indicate that an ME may suggest

that an SJR is undertaken through the governance process where a case may indicate some cause for concern but which does not require referral to the Coronial system.

2.2 Phases of care – the ‘structure’ part of the method

The phase of care structure provides a generalised framework for the review and also allows for comparisons among groups of cases at different stages of care. The principal phase descriptors are shown in Box 1. However the use of the phase structure depends much on the type of care and service being reviewed – not all phase of care headings will be used for

any particular case. Thus the procedure-based review sections may only be required in a limited number of medical cases (e.g. a lumbar puncture, a chest drain or non-invasive ventilation) but are likely to be used in most surgical cases. It is up to the reviewer to judge which phase of care forms are appropriate in a particular case.

Box 1 Phase of care headings

- Admission and initial care – first 24 hours
- Ongoing care
- Care during a procedure
- Perioperative / procedure care
- End-of-life care (or discharge care*)
- Assessment of care overall

*Note that discharge care is included because this method is just as applicable for the review of care for people who do not die during an admission.

2.3 Explicit judgement comments – the core of the method

The purpose of the reviews is to provide information from which teams or the organisation can ask ‘why’ questions and to support quality improvement. Explicit judgement commentaries serve two main purposes. First, they allow the reviewer to concisely describe how and why they assess the safety and quality of care provided. Second, they provide commentary in a way that other health professionals can readily understand if they subsequently look at the completed review.

When asked to write comments on the quality and safety of care, clinical staff often tend to write a resume of the notes or make an implicit critique of care. This is not helpful when others try to understand the reviewer’s real meaning. So the

central part of the review process comprises short, written, explicit judgement statements about the perceived safety and quality of care provided in each care phase.

This review guide does not include a glossary of explicit terms that reviewers might choose from, since this approach would inevitably be constraining or would fail to cover all eventualities in the complexities of clinical practice. Instead, reviewers are asked to use their own words in a way that explicitly states their assessment of an aspect of care and gives a short justification for why they have made the assessment.

Explicit statements use judgement words and phrases such as ‘good’ or ‘unsatisfactory’ or ‘failure’ or ‘best practice’.

Box 2 Examples of phase of care structured judgement comments

- Continued omission to provide oxygen and respiratory support – poor care.
- Team still failed to discuss potential diagnosis with patient – unsatisfactory.
- Referral to the intensive treatment unit (ITU) was too late.
- There was some evidence of good management by overnight team, with prompt review and intervention.
- Although the patient was discussed with a consultant once and an SpR once, for 4 days they were only seen by junior doctors. This is completely unsatisfactory.
- Very good care – rapid triage and identification of diabetic ketoacidosis with appropriate treatment.

These judgement words are included in short statements that provide an explicit reason why a judgement is made – e.g. ‘unsatisfactory because etc’ and, for example, ‘Resuscitation and ceiling of treatment decisions made far too late in course of admission – poor care’. The purpose here is not to write long sentences but to encapsulate the clinical process in a few explicit statements.

Box 2 contains some examples.

Judgement comments should be made on anything the reviewer thinks important for a particular case. Among other things this will include the appropriateness of management plans and subsequent implementation together with the extent to which, and how, care meets good practice. In some cases there may be care in a phase that has both good and poor aspects. Both should be commented on.

Commentary on holistic care is just as important as that on technical care, particularly where complex ceiling of treatment and end-of-life care discussions might be held. Judgements should be made on how the teams have managed end-of-life decision making and to what extent patients and their relatives have been involved. Thus, for example, a judgement comment might be couched as ‘end-of-life care met recommended practice, good ceiling of treatment discussion

with patient and family’. Similar approaches and levels of detail are required when care is thought not to have gone well, or where aspects of care are judged only just acceptable. Then words such as ‘unsatisfactory care’, ‘poor practice’ or ‘doesn’t meet good practice standards’ might be necessary.

Sometimes it is not possible to get a clear view from the records about why clinical decisions have been made, or there appears to be a lack of decision making or guidance. Here, judgement words such as ‘delay’, ‘poor planning’, ‘lack of leadership’ etc may be used. Where this lack of clarity is due to the level of documentation, comments such as ‘inadequate record keeping’ may apply.

Overall phase of care comments are intended to bring a focus to the review by asking for an explicit, clear judgement on what the reviewer thinks of the whole care episode, taking all aspects into consideration. It is not necessary to repeat all of what has been commented on before, though sometimes it is useful to repeat some key messages – that is a reviewer choice. Again, though, it is important to make clear and explicit what the overall judgement is and why. Examples are given in Box 3.

Box 3 Examples of overall care structured judgement comments

- Overall, a fundamental failure to recognise the severity of this patient's respiratory failure.
- Good multidisciplinary team involvement.
- On the whole, good documentation of clinical findings, investigation results, management plan and discussion with other teams.
- Poor practice not to be aware of the do not attempt resuscitation (DNAR) status of patient, especially when it has been discussed with the family, clearly documented when first put in place and reviewed later on.

Cause of death information should if possible form part of the review framework. If, on review, the certified cause of death causes the reviewer some concern, this should be explicitly stated, since there may be a clinical governance question involved.

So, the overall message about review language is that it should be explicit and clear, in order that you, the reviewer, feel you have made the points clearly and that others who read the review will be able to understand what you have said and why.

2.4 Giving phase of care scores**Box 4 Phase of care scores**

1. Very poor care
2. Poor care
3. Adequate care
4. Good care
5. Excellent care

Care scores are recorded after the judgement comments have been written and the score is in itself the result of a judgement by the reviewer. Only one score is given per phase of care: it is not necessary to score each judgement statement.

Scores range from Excellent (Score 5) to Very Poor ([Score 1]) – see Box 4 – and are given for each phase of care commented on and for care overall.

These scores have a number of uses. For the individual reviewer, scores assist in coming to a rounded judgement on the phase of care, particularly when there may be a mix of good and unsatisfactory care within a phase. The reviewer must judge what their overall decision is about

the care provided for each phase and for care overall. Scoring makes this very explicit.

Overall care scores are particularly important in the review process. A score of 1 or 2 is given when the reviewer decides that care has been very poor or poor. Research evidence suggests this might happen in upwards of 10% of cases in some circumstances, less in others. A score at this level should trigger a second stage review through the hospital clinical governance process (see section 2.1 above).

The full data collection tool is available from the Royal College of Physicians (RCP) website: www.rcplondon.ac.uk/mortality

2.5 Judging whether problems in care have caused harm

Problems in care take many forms and may have a range of impacts, some of which are potential rather than actual. Some of these events cause harms, but many do not.

The first-stage reviewer has an important role here in assisting the hospital to identify both actual and potential threats to patient safety.

The assessment of problems makes two important contributions. First, it is of importance in clarifying the issues within individual reviews. Second, the information aggregated within the hospital across reviews may pick up more fundamental care process issues that require attention.

Reviewers are asked three questions in relation to problems identified in care. These are in the format of:-

A) Were there one or more problems in care during this admission – Yes or No

B) If so, in which area(s) of the care process and care phases did this/these occur?

C) And for each of these problems, did any cause harm?

There is a free text box for a description of the problem. The data collection format is outlined further in Appendix 1.

2.6 Judging the quality of recording in the case notes

Case note review of course depends critically on the content and the legibility of the records. Safety of care also depends to some extent on good record keeping. Therefore, as part of the

overall care assessment, the reviewer is also asked to record their judgement on the quality and legibility of the records, again using a score of 1-5.

3 The review in practice

Case note review takes up expensive clinical resource so that time spent on establishing the purpose and desired outcome of the review is important. Case selection is increasingly being seen as a hospital policy issue and many organisations are now formalising review governance and management.

In some hospitals the majority of mortality reviews take place in an 'M&M' context and so cases are often already being considered to be potentially problematic cases. Structured Judgement Review has been found to be of value in providing a reproducible process for these M&Ms.

However the challenge for hospitals has often been the gathering together of the material from these M&M reviews so that it can be used to examine care processes beyond the individual case. For preference, data from M&M cases should be entered into the hospital reviews database. Aggregated information is more powerful in the longer term than is the data from individual cases.

Another approach to case selection is to evaluate care for all or some patients who come to a particular service, or to explore the care for the majority of people who die in hospital over a particular time period in particular services. For

example, all elective surgery deaths or cases of Acute Kidney Injury might require review.

For many situations, given the constraints on reviewer availability and the need to produce usable information from the reviews, the principle of 'less done better is more' applies.

In some situations a simple time-based longitudinal sample of around 40 - 50 cases will produce a rich source of quantitative and qualitative information on what goes right and what is not working properly. Timely review, rather than review after a delay, provides better information.

Time spent on the analysis and information presentation outweighs the benefit of adding a

few more cases to the sample. The textual information allows for themes to be developed and that then allows a focus for the next improvement steps. Such an approach also has the benefit of being able to learn from, and celebrate, the cases where care has gone well.

An e-learning guide to undertaking the analysis of the quantitative and qualitative data provided by Structured Judgement Review is available through the Royal College of Physicians Mortality Review Programme [website](#).

Appendix 1 – Assessment of problems in healthcare

In this section, the reviewer is asked to comment on whether one or more specific types of problem(s) were identified and, if so, to indicate whether any led to harm.

Were there any problems with the care of the patient? (Please tick)

No ☐ (please stop here) Yes ☐ (please continue below)

If you did identify problems, please identify which problem type(s) from the selection below and indicate whether it led to any harm. Please tick all that relate to the case.

Problem types

1. **Problem in assessment, investigation or diagnosis** (*including assessment of pressure ulcer risk, venous thromboembolism (VTE) risk, history of falls*): Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐
2. **Problem with medication / IV fluids / electrolytes / oxygen** (*other than anaesthetic*): Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐
3. **Problem related to treatment and management plan** (*including prevention of pressure ulcers, falls, VTE*): Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐
4. **Problem with infection control**: Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐
5. **Problem related to operation/invasive procedure** (*other than infection control*): Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐
6. **Problem in clinical monitoring** (*including failure to plan, to undertake, or to recognise and respond to changes*): Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐
7. **Problem in resuscitation following a cardiac or respiratory arrest** (*including cardiopulmonary resuscitation (CPR)*): Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐
8. **Problem of any other type not fitting the categories above**: Yes ☐
Did the problem lead to harm? No ☐ Uncertain ☐ Yes ☐

Adapted from Hogan H, Zipfel R, Neuberger J, Hutchings A, Darzi A, Black N. Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis. *BMJ* 2015;351:h3239. DOI: 10.1136/bmj.h3239²

Editorial note

This document has been adapted with permission from: Hutchinson A, McCooe M, Ryland E. *A guide to safety, quality and mortality review using the structured judgement case note review method*. Bradford: The Yorkshire and the Humber Improvement Academy, 2015. (Copyright The Yorkshire and the Humber Improvement Academy.)

The case note review methods discussed in this guide were primarily developed in a research study published as: Hutchinson A, Coster JE, Cooper KL, McIntosh A, Walters SJ, Bath PA *et al*. Comparison of case note review methods for evaluating quality and safety in health care. *Health Technol Assess* 2010;14(10):1–165.

All clinical examples and structured judgement comments in this document are taken from hypothetical scenarios.


References

1. Hutchinson A, Coster JE, Cooper KL, Pearson M, McIntosh A, Bath PA. A structured judgement method to enhance mortality case note review: development and evaluation. *BMJ Quality and Safety* 2013;22:1032–1040. DOI: 10.1136/bmjqs-2013-001839 [Accessed July 2017].
2. Hogan H, Zipfel R, Neuberger J, Hutchings A, Darzi A, Black N. Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis. *BMJ* 2015;351:h3239. DOI: 10.1136/bmj.h3239 [Accessed July 2017].
3. Royal College of Physicians. *Using the Structured Judgement Review method – a clinical governance guide to mortality case record reviews*. London: RCP, 2016.

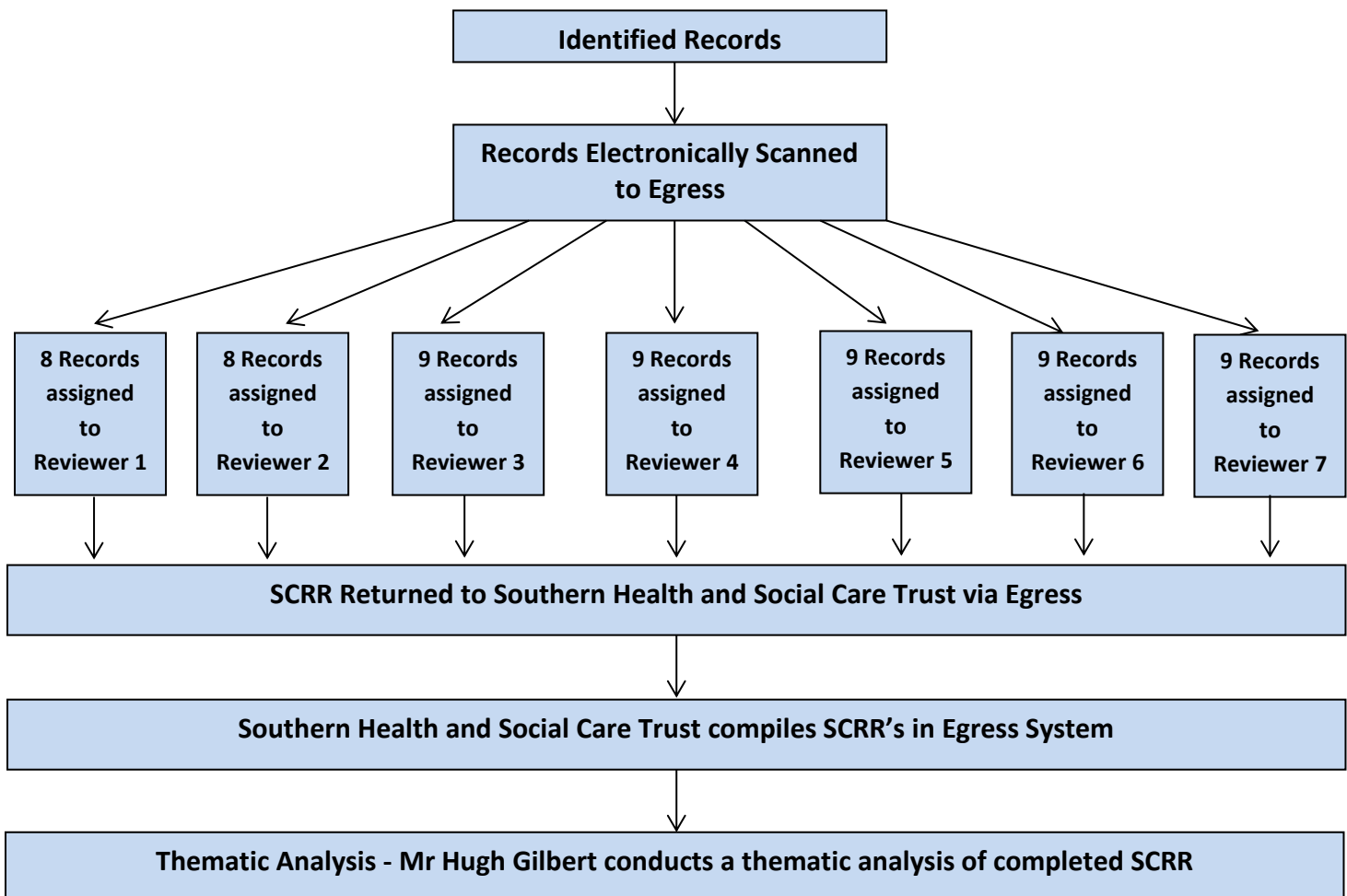
Structured Clinical Record Review Engagement

16th August 2021

1. Overview

Aim	<p>To conduct Structured Clinical Record Reviews (SCRR) using Structured Judgement Review methodology on 61 urology patients where potential sub-optimal care has been identified.</p> <p>A team of reviewers will make safety and quality judgements over phases of care, making explicit written comments and score about each.</p>
Review Team	<p>Seven Consultant Urologists who are independent to the Southern Health and Social Care Trust have been identified via the British Association of Urological Surgeons (BAUS) to conduct the SCRR's</p>
Method	<p>Judgement from each review conducted will be populated into a structured clinical record review form (attached)</p> <div style="text-align: center;">  Structured Clinical Record Review Form. </div>
Access to Records	<p>Patient records will be scanned and electronically hosted on the Trust secure 'Egress' record management system. Reviewers will be granted access to view these files remotely for the purposes of the SCRR.</p> <p>An individual SCRR form will be completed for each patient and returned to the Southern Health and Social Care Trust via Egress.</p>
Indemnity	<p>The Southern Health and Social Care Trust will indemnify the reviewers regarding any civil claims arising out of their clinical review of these matters, subject to this being conducted within the normal limits of reasonable clinical competence.</p>
Payment for Services	<p>Payment for services will be on a per hour basis, value of £ Commer cially Sensitiv. Costs to be invoiced to stephen.wallace Personal Information redacted by the USI</p>
Thematic Analysis	<p>On completion Mr Hugh Gilbert will provide a thematic analysis report on the completed SCRR's for the Southern Health and Social Care Trust.</p>

2. Process Flow



3. Proposed Timeline for Delivery

Stage	Identified Date for Delivery
Records Identified	Complete
Records Scanned to Egress*	16 th August 2021
Records Assigned to Reviewer	16 th August 2021
SCRR's returned to Trust	17 th September 2021
SCRRs issued for thematic Outcomes	5 th October 2021

**Patient files will be provided to reviewers in groups as they become available*

Structured Clinical Record Review title(SCRR)

Section 1

*This section should be completed as soon as is possible following identification of the incident
If it is deemed appropriate to complete Section 2, it should be completed within 8 Weeks (56 days)*

Patient identification number:		Gender:	
Date of birth (dd/mm/yyyy)		Age:	
Date of Incident		Date Incident Reported:	
Datix Incident Number			
Date of death (if relevant)			
Location of death (if relevant)			
Was the patient identified as being within the last 12 months of life?			
Cause of death (if known)			
Primary diagnosis, including ICD-10 code (if known)			
Co-morbidities			
Healthcare teams involved in the patient's care at the time of incident			
Patient summary (can be completed by the clinical team)			
Concerns from family members or carers about the patient's care (please outline concerns, or state if there were no concerns)			
Concerns from staff about the patient's care (please outline concerns, or state if there were no concerns)			

Time taken to complete Section 1 of this form (minutes):

Date of completion:

Name of person completing Section 1:

Job title of person completing Section 1

Care Review Tool for Urology

Section 2

Please state the information sources used for the review, including the names of the electronic systems accessed:

2.1. Phase of care: Triage (where relevant)

- Was triage conducted in a timely manner?
- Was the triage outcome assigned an appropriate level of priority given the information available at the time?

Please record your explicit judgements about the triage process and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.2. Phase of care: Initial assessment or review (where relevant)

- Were the investigations, prescribing, diagnosis and clinical management approach and communications with patient, primary care and MDT teams appropriate?
- Were diagnostic tests or investigations requested in a timely manner and with sufficient clinical information to allow appropriate onward prioritisation?

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.3. Phase of care: Review of Diagnostics (where relevant)

- Were diagnostic tests or investigations reviewed in a timely manner with appropriate further actions taken?
- Were any required actions adequately communicated to patient / primary care / MDT teams?
- Please list medication if known and relevant, and comment on medication monitoring where appropriate

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.4. Phase of care: Ongoing Outpatient Care (where relevant)

- Were ongoing reviews scheduled at appropriate intervals?
- Were referrals made to other teams / professionals appropriately and in a timely manner?
- Where any further required tests / investigations requested and performed in line with good current practice?
- Please list medication if known and relevant, and comment on medication monitoring where appropriate

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.5. Phase of care: Admission and Initial Management (approximately the first 24 hours) (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

Care Review Tool for Urology

2.6. Phase of care: Ongoing Inpatient Care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

Care Review Tool for Urology

2.7. Phase of care: Care during a procedure (excluding IV cannulation) (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.8. Phase of care: Perioperative care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.9. Phase of care: Discharge plan of care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

2.10. Other area of care (please specify)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.
Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

Care Review Tool for Urology

2.11. Overall care

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.

Areas identified where learning could occur, including areas of good practice, should be included in addition to any potential areas of further investigation.

Please also include any other information that you think is important or relevant.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☐

2.12. If care was below an acceptable standard, did it lead to harm?

If yes, please provide details and state an action plan

Care Review Tool for Urology

2.13. If the patient died is it considered more likely than not to have resulted from problems in care delivery or service provision?
If yes, please provide details and state an action plan (consider whether a serious incident investigation is required).

2.14. If a family member, carer, or staff raised concerns, please outline any feedback provided and state who was responsible for providing this feedback. Please state further action required. If no feedback was provided, please consider how the outcome of this review should be fed back to the relevant people, considering the duty of candour principle.

2.15. Were the patient records adequate for the purpose of the review?

Yes ☐

No ☐

Please outline any difficulties in accessing appropriate information:

Time taken to complete Section 2 of this form (minutes):

Date of completion:

Name of person completing Section 2:

Job title of person completing Section 2:

Assessment of problems in healthcare for Urology patients

In this section, the reviewer is asked to comment on whether one or more specific types of problem(s) were identified and, if so, to indicate whether any led to harm. Please circle correct response.

Problem types

<p>1. Problem in assessment, investigation or diagnosis</p>	<p>Yes No</p>
<p>Did the problem lead to harm?</p>	<p>No Uncertain Yes</p>
<p>In which phase(s) did the problem occur?</p>	<p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>
<p>2. Problem with medication / IV fluids / electrolytes / oxygen</p>	<p>Yes No</p>
<p>Did the problem lead to harm?</p>	<p>No Uncertain Yes</p>
<p>In which phase(s) did the problem occur?</p>	<p>Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care</p>

Care Review Tool for Urology

3. Problem related to treatment and management plan	Yes	No
	Did the problem lead to harm?	No Uncertain Yes
	In which phase(s) did the problem occur?	Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
4. Problem related to operation / invasive procedure (other than infection control)	Yes	No
	Did the problem lead to harm?	No Uncertain Yes
	In which phase(s) did the problem occur?	Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
5. Problem with infection management	Yes	No
	Did the problem lead to harm?	No Uncertain Yes
	In which phase(s) did the problem occur?	Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation)

Care Review Tool for Urology

	Perioperative care Discharge plan of care Other area of care
6. Problem in clinical monitoring (including failure to plan, to undertake, or to recognise and respond to changes) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
7. Problem in resuscitation following a cardiac or respiratory arrest (including cardiopulmonary resuscitation (CPR)) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
8. Problem of any other type not fitting the categories above (including patient records and documentation, informed consent, communication with patients and carers and organisational issues) Did the problem lead to harm? In which phase(s) did the problem occur?	Yes No No Uncertain Yes Triage Initial assessment or review Review of Diagnostics Ongoing Outpatient Care

Care Review Tool for Urology

	Admission and Initial Management Ongoing Inpatient Care Care during a procedure (excluding IV cannulation) Perioperative care Discharge plan of care Other area of care
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**Patients under the care of Mr O'Brien and currently in process of being reviewed
30 September 2021**

	Patient Group	Number of Patients in Group	Reviewed to date	Reviewed by	Remaining to be reviewed	Reviewed by	Provisional date	Quality Assured	Comment
Administrative Review Only	<i>Elective Cohort</i>	<i>352 Patients</i>	<i>352 (Administrative Review)</i>	<i>M Corrigan</i>	<i>352</i>	<i>Needs Clinical Review</i>	<i>N/A</i>	<i>No</i>	<i>All are part of the 2309 patients required reviewed between Jan 2019 – Jun 2020. Review to date only considered administrative processes</i>
	<i>Emergency Patients (Stents)</i>	<i>160 Patients</i>	<i>160 (Administrative Review)</i>	<i>M Corrigan</i>	<i>160</i>	<i>Needs Clinical Review</i>	<i>N/A</i>	<i>No</i>	<i>All are part of the 2309 patients requiring reviewed between Jan 2019 – Jun 2020 Review to date only considered administrative processes</i>
	Radiology Results	1025 Patients	1025	Professor Sethia	276 (second opinion)	Professor Sethia	July 2021	No	Update from last report: No change
	Pathology Results	150 Patients	150 (Result Review)	M Haynes/D Mitchell	0	N/A	N/A	Yes	Update from last report: No change
	Oncology Reviews (IS)	236 Patients	200 (Face to Face ISP)	P Keane	36	M Haynes	October 2021	No	Update from last report: 53 (M Haynes & M Corrigan currently reviewing all patients returned to Trust from this exercise)
	Post MDM Patients	187 Patients	187 (SME Record Review)	Prof Sethia	52 (need second opinion)	M Haynes	July 2021	No	Update from last report: No Change

	Patient Group	Number of Patients in Group	Reviewed to date	Reviewed by	Remaining to be reviewed	Reviewed by	Provisional date	Quality Assured	Comment
	Review Backlog	511 Patients	209 (Virtual Clinics)	M Haynes	302	M Haynes	March 2022	No	Update from last report: No Change
	Information Line	159 Patients	13(reviewed at clinic)	M Haynes	146	M Haynes/ Prof Sethia	Dec 2021	No	Update from last report: 1 patient
	Patients prescribed Bicalutamide	933 Patients	747 (Record Review, 26 Face to Face Reviews)	M Haynes	186	M Haynes	March 2022	No	Update from last report: No change
	Patients on Inpatient Waiting List for TURP	143 patients	0	TBA	143	Clinical Team	Dec 2021	No	Update from last report: No change
	Total	3856	3043		1653				

- Please note that one patient can be included in a number of the groups listed above



Our Ref: 845

2 March 2022

Dr Maria O'Kane
Medical Director
SHSCT

Email only: Personal Information redacted by the USI

Dear Dr O'Kane

Urology Structured Clinical Record Review Process

Thank you for your letter of the 20 February and the detail provided about the work undertaken so far by the Trust in relation to the Urology Structured Clinical Record Review Process. I note also the specific request you are making of RQIA.

We have considered this and agree that providing external independent assurance of your approach in respect of these cases would be an appropriate task for us to undertake.

I have requested that our Director of Hospital Services, Independent Health Care, Audit and Reviews, Mrs Emer Hopkins take forward this piece of work with the support of our Clinical Lead for Medicine, Dr Leanne Morgan, and other members of our review programme as required. Emer will be in touch over the next few days and it is likely she will ask for a meeting with your team, to discuss the scope, your approach to the record review and how it fits in the overall context of the Urology Inquiry. She can also discuss possible methodologies and timescales and have a first sight of the SCRR tools you have produced.

In the meantime, we will develop a methodology for this work and prepare confidential information request for relevant documents under Article 41 of The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003. This means that these documents can be prepared in good time for consideration by any panel/team we may appoint to assist us with our review and in advance of meeting with appropriate members of the Trust team undertaking this work if required.

RQIA, 7th Floor
Victoria House
15-27 Gloucester Street
Belfast BT1 4LS

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
Twitter @RQIANews

INVESTORS IN PEOPLE
We invest in people Silver

Assurance, Challenge and Improvement in Health and Social Care



If you would wish to discuss any of this further, please do not hesitate to contact Emer Hopkins at Personal Information redacted by the USI.

Yours sincerely

Personal Information redacted by the USI

Briege Donaghy
Chief Executive

cc Emer Hopkins, Director of Hospital Services, Independent Health Care, Audit and Reviews, RQIA
Andrew Dawson, Director of Quality Safety and Improvement, DoH
Dr Leanne Morgan, Clinical Lead, RQIA

Quality Care - for you, with you

20th February 2022

Ref: MOK/ec

Via email

Personal Information redacted by the USI

Briege Donaghy
Chief Executive
Regulation and Quality Improvement Agency
9th Floor BT Tower
Belfast

Dear Briege,

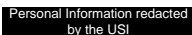
RE: UROLOGY STRUCTURED CLINICAL RECORD REVIEW PROCESS

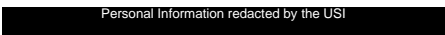
As you will be aware, the Southern Trust is conducting a lookback exercise regarding our Urology services. The purpose of the lookback exercise is to review patients who were under the care of an individual consultant no longer employed by the Trust.

Following the completion of an initial nine Serious Adverse Incident (SAI) reviews in 2021 and as advised by the Department of Health, the SAI process will not be used to review subsequent potential issues in care identified as a result of the lookback process. However remaining cognisant of regional parameters and requirements for the identification, review and learning from Adverse and Serious Adverse Incidents (SAI) as set out in the HSCB *Procedure for the Reporting and Follow up of Serious Adverse Incidents (November 2016,)* the Trust has sought to provide an alternative, proportionate and robust review structure that can be utilised to review these incidents in a timely manner.

As a result of this the Trust has developed a '*Structured Clinical Record Review*' (SCRR) process founded on Structured Judgement Review methodology as developed by the

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Tel:  Personal Information redacted by the USI

Email:  Personal Information redacted by the USI

Royal College of Physicians. The SCRR process has been designed to allow the Southern Trust to identify if there is any learning or areas where patient safety can be improved.

I understand the Department of Health Sponsor Branch has made contact with you regarding support to the Trust through conducting a review relating to the SCRR process. Specifically we are asking for RQIA to undertake the following please:

- A review of the choice of SJR methodology to underpin the SCRR process
- A review of the SCRR process in relation to its effectiveness in identifying learning

In terms of output from this, it would be useful to have a statement to assure the Urology Assurance Group on the effectiveness of the SCRR process please. If in the event that the SCRR process is not found to be satisfactory, I would be grateful if you could recommend an alternative approach please.

I look forward to hearing from you.

Yours sincerely

Personal Information redacted by the USI

Dr Maria O’Kane
Medical Director

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Tel:

Personal Information redacted by the USI

Email:

Personal Information redacted by the USI

Wallace, Stephen

From: Philip Higgs [Personal Information redacted by the USI]
Sent: 26 November 2021 10:00
To: Wallace, Stephen
Cc: OKane, Maria
Subject: RE: Southern Health and Social Care Trust - Northern Ireland

This message was sent from outside of the Southern Trust. Please do not click links or open attachments unless you recognise the source of this email and know the content is safe.

Dear Stephen,

I have discussed this internally and we are not currently in the position to provide or support quality assurance for an investigation or report that is outside of the College invited review framework. In any request for assistance in a surgical matter that falls outside of the usual IRM process, we would usually liaise between the enquirer and the relevant surgical specialty association; however our involvement would usually not go further than facilitating that contact and any individuals identified to assist would not be working as a formal College representative.

I am aware from communication with both yourself and Hugh that you are already in contact with BAUS. It is most likely that any urology expert group would be identified by and comprised of BAUS membership in any respect.

Of course, the College remains available to provide advice and assistance to the Trust in relation to the invited review mechanism.

Kind regards,

Phil

Philip Higgs
Head of Invited Reviews

Royal College of Surgeons of England
38-43 Lincoln's Inn Fields
London WC2A 3PE

T: [Personal Information redacted by the USI]
E: [Personal Information redacted by the USI]
W: www.rcseng.ac.uk

From: Wallace, Stephen [Personal Information redacted by the USI]
Sent: 25 November 2021 14:03
To: Philip Higgs [Personal Information redacted by the USI]
Cc: OKane, Maria [Personal Information redacted by the USI]
Subject: RE: Southern Health and Social Care Trust - Northern Ireland

Hi Phil,

Just checking if you have had a chance to consider the below.

Thanks
Stephen

From: Wallace, Stephen
Sent: 23 November 2021 08:57

To: 'Philip Higgs'
Cc: OKane, Maria
Subject: Southern Health and Social Care Trust - Northern Ireland

Dear Phil,

Thank you for speaking on Friday past.

Just by way of background to our request for RCS support. As you know the RCS IRM is currently undertaking a review of urology cases that relate to an individual surgeon was previously employed by the Southern Trust. These case relate to care provided during the 2015 calendar year.

In conjunction with this we are undertaking a review of more recent care provided by the consultant. As a result of our local review we have identified cases that we feel the level of care may not have been of the standards we would expect. To review these patients we asked the RCS to request via BAUS external experts to facilitate this. Mr Hugh Gilbert has kindly helped us identify urology consultant experts who are willing to support us in this work. Each patient will be reviewed using a modified SJR methodology to understand the aspects of the care which may have differed from what would be expected.

We would like the RCS to discuss if a Quality Assurance process could be supported around a sample of these cases. We are open to suggestions of how this may be facilitated however discussions with Mr Gilbert suggested that a urology expert group review of the SJR findings which assigns a judgement of the outcome, potentially using the NCEPOD framework may be a suitable vehicle. The assurance exercise would be for 77 cases.

We would be grateful if it would be possible to discuss the potential of this with you and if possible Mr Gilbert at the earliest time of your convenience.

Best regards
Stephen

Stephen Wallace

Assistant Director Systems Assurance
Craigavon Area Hospital
Portadown

Personal Information redacted by
the USI

Disclaimer

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Wallace, Stephen

From: Wallace, Stephen
Sent: 09 February 2022 09:40
To: 'Robbie.Davis' <[Personal Information redacted by the USI]>
Cc: Gormley, Damian; OKane, Maria; Devlin, Shane
<[Personal Information redacted by the USI]>
Subject: FW: RQIA Review of SCRR Process

Hi Robbie,

We were hoping that RQIA could perform the following:

- A review of the choice of SJR methodology to underpin the SCRR process
- A review of the SCRR process in relation to its effectiveness in identifying learning

In terms of time commitment I am unsure however would likely involve some online virtual engagements and documentation sharing. In terms of output it would be useful to have a statement to assure the UAG on the process. Regarding deadlines initially we had hoped that this could be conducted in December prior to the commencement of the SCRR process. From January we have currently progressed with the first 20 SCRR's so we would be keen to have a finalised piece of work to present to UAG as soon as possible.

If in the event that the SCRR process was not found to be satisfactory by RQIA then suggesting of an alternative method would be useful.

Thanks
Stephen

From: Davis, Robbie <[Personal Information redacted by the USI]>
Sent: 07 February 2022 17:50
To: Wallace, Stephen <[Personal Information redacted by the USI]>
Subject: RE: RQIA Review of SCRR Process

Stephen,

If you can provide a little more detail about the potential ask (level of work, time commitment, deadlines, etc) we can pick up with RQIA

Thanks,

Robbie

From: Wallace, Stephen <[Personal Information redacted by the USI]>
Sent: 04 February 2022 10:53
To: Davis, Robbie <[Personal Information redacted by the USI]>
Subject: FW: RQIA Review of SCRR Process

Apologies Robbie,

Just following up on this in advance of the UAG, is there an update

Thanks
Stephen

From: Wallace, Stephen

Sent: 30 November 2021 11:46

To: [jim.wilkinson](#) Personal Information redacted by the USI; 'Robbie.Davis' Personal Information redacted by the USI <Personal Information redacted by the USI>
Cc: OKane, Maria <Personal Information redacted by the USI>; Devlin, Shane (Personal Information redacted by the USI)
<Personal Information redacted by the USI>

Subject: RE: RQIA Review of SCRR Process

Jim / Robbie, grateful if you can advise re below, we are keep to progress this.

Thanks
Stephen

From: Wallace, Stephen

Sent: 25 November 2021 14:02

To: 'jim.wilkinson' Personal Information redacted by the USI; 'Robbie.Davis' Personal Information redacted by the USI

Subject: RQIA Review of SCRR Process

Hi Jim / Robbie,

Just checking on actions from the previous UAG meeting Monday, 1st November this year. Shane mentioned that he would like RQIA to quality assure our approach to conducting urology structured clinical record reviews. The minutes read that Shane was to contact the perm secretary re this however I think that Jim agreed that this would be taken forward as an action automatically from the meeting. Can you confirm if Shane is required to contact the Permanent Secretary regarding this separately or if this has been progressed internally by DoH?

Apologies if I picked this up incorrectly.

Best regards
Stephen

Stephen Wallace

Assistant Director Systems Assurance
Craigavon Area Hospital
Portadown

Personal Information redacted by the USI

Wallace, Stephen

From: GILBERT, Hugh (GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST)
 <Personal Information redacted by the USI >
Sent: 15 March 2022 11:26
To: Wallace, Stephen
Subject: Re: SHSCT - Subject Matter Experts

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Dear Seephen

I realised I haven't directly responded to you; apologies. I am on this and will be in touch on Friday at the latest.

KR, Hugh

From: Wallace, Stephen <Personal Information redacted by the USI >
Sent: 09 March 2022 16:44
To: GILBERT, Hugh (GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST) <Personal Information redacted by the USI >
Cc: Gormley, Damian <Personal Information redacted by the USI >
Subject: SHSCT - Subject Matter Experts

Hi Hugh,

Just touching base re the subject matter experts we have contacted. To date we have contacted 12 with 4 of these moving through to support this work (table below). Ideally to finish the first round we would wish to have 6 experts in total. We really appreciate the work you have put in to get these however we would be very grateful if you were able to put us in touch with 2 more to fulfil our quota.

Thank you for your help to date

Best regards
 Stephen

p.s. We have tried to get in contact with Mr Pal since we issued records however have not received a response – I think he is a colleague of yours in Bristol. Would you know of a secretary contact number where we could reach him?

Edward Tudor	Withdrawn
Nick Burns-Cox	Withdrawn
Raj Pal	Completed undertaking reviews currently
DV Chadwick	Completed – No Response to subsequent emails
David Thomas	Completed undertaking reviews currently
Raj Persad	No response
Tim Porter	No response
Faith McMeekin	Completed – No Response to subsequent emails
Paul Rajjayabun	Completed undertaking reviews currently

Amr Hawary	Completed Ready to Undertake Reviews
Jon McFarlane	Contacted
Adel Makar	No response

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