

# SOUTHERN HEALTH & SOCIAL CARE TRUST UROLOGY LOOKBACK REVIEW

## Activity and Outcomes Report for Cohort 2

(Including Summary of Activity and Outcomes for  
Cohort 1 and Cohort 2)

9 July 2024

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## SECTION 1: INTRODUCTION

In July 2021 a Lookback Review of urology patients under the care of Mr Aidan O'Brien, Consultant Urologist, commenced. The patients who were the subject of this review were those under the care of Mr O'Brien from January 2019 until June 2020. The activity and outcomes relating to these patients (Cohort 1) was published in August 2023 and can be accessed via this link <https://Southerntrust.hscni.net/news/urologylookbackreview>.

Based on the learning from Cohort 1, it was recognised that a further cohort of patients (Cohort 2) should be reviewed so that the Trust could ensure that all of Mr O'Brien's patients are receiving / have received the care and treatment they require(d) and, if not, and where possible, to provide a review with a consultant urologist and new treatment plan as required.

This document provides information regarding the activity and outcomes for Cohort 2.

It also provides a summary of the Urology Lookback Review process in totality and the activity and outcomes for Cohort 1 and Cohort 2 together.

### 1.1 DESCRIPTION OF COHORT 2

In identifying patients for this extension to the Lookback Review, the Trust used a risk stratification to determine the clinical conditions from Cohort 1 that required intervention. These were patients with a Urological Cancer diagnosis; and patients who were diagnosed with Renal Stone Disease and were treated with or without ureteric stents. As the purpose of a Lookback Review is to ensure patients have received / are receiving the care and treatment they require(d) and, if not, to remedy care where possible, the Trust focused its attention on patients who were alive at the time of commencing this phase of the Review.

In addition, the Trust included any living patient who continued to have an "open" episode of care under Mr O'Brien and had not had their care taken over by another Trust Consultant Urologist at the time of Mr O'Brien's retirement.

Furthermore, concern had been raised that Mr O'Brien saw and treated patients privately in his own home. Specifically targeted media communication invited such private patients to come forward for review within this cohort.

In summary therefore, Cohort 2 of the Urology Lookback Review includes:

1. Patients diagnosed with a Urological Cancer (prostate, penile, bladder and kidney tumour groups) diagnosed from 1 April 2010 to 31 December 2018<sup>1</sup>, who have not been seen by another urology consultant and who are currently alive;
2. Patients with Renal Stone Disease, which may or may not have been treated with Ureteric Stenting, between 1 April 2013 and 31 December 2018<sup>2</sup>, who have not been seen by another urology consultant and who are currently alive;
3. Any patient who continues to have an “open” episode of care who has not already been seen by another consultant at the time of Mr O’Brien’s retirement and who is currently alive;
4. Any patient who was seen and treated privately by Mr O’Brien and who wished to be included in this Cohort. It should be noted that, despite Trust efforts via the media to call private patients, none came forward.

Therefore, this means that upon completion of Cohort 2 of the Lookback Review, there will be no further living patients who were under the care of Mr O’Brien who will require review.

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<sup>1</sup> 1 April 2010 is when Cancer MDM’s became functional in Southern Trust, prior to this date there was no formal process for joint discussion of urological cancer and therefore no consistent approach to shared treatment planning.

<sup>2</sup> 1 April 2013 is when the Northern Ireland Electronic Care Record (NIECR) was implemented and utilised in conjunction with paper-based case notes.

## 1.2 LOOKBACK REVIEW METHODOLOGY FOR COHORT 2

The Trust used the Department of Health's, *Regional Guidance for Implementing a Lookback Review Process*, as a framework for the Urology Lookback Review and adopted the same methodological approach as it did for Cohort 1. The detail of the four stages is defined and described below.

SOUTHERN TRUST UROLOGY LOOKBACK REVIEW – COHORT 2	
Stage: 1	<b>IMMEDIATE ACTION</b> to scope the extent, nature, and complexity of the incident/ concern/issue, <b>to identify the patients in the Lookback Review (Cohort 2).</b>
Stage: 2	The Patient <b>REVIEW</b> included the completion of Patient Review Forms to establish if there were concerns / no concerns to decide which patients should progress to a Lookback Clinic (Recall of patients).
Stage: 3	The <b>RECALL</b> of patients, for whom there was concern from Stage 2 review. This was a hybrid clinic utilising a combination of virtual and face-to-face consultation i.e. the Consultant Urologist conducted the appointment via video link whilst the patient was in a Trust Outpatient clinic room with a Clinical Nurse Specialist present. At this appointment clinical assessment and a change to treatment plan was discussed and completed as required.
Stage: 4	<b>CLOSURE</b> <ul style="list-style-type: none"> <li>a) Closing individual cases on the database - Each Patient reviewed at Stage 2 and Stage 3 received a letter to confirm the outcome of the review of their case;</li> <li>b) Production of a Cohort 2 Outcomes and Activity Report;</li> <li>c) Dissemination of a Cohort 2 Outcomes and Activity Report, and closure of the Cohort 2 Lookback Review.</li> </ul>

Stages 2 – 4 ran concurrently for patients in Cohort 2

## SECTION 2: LOOK BACK REVIEW COHORT 2 ACTIVITY AND OUTCOMES

### 2.1 STAGE 1: IDENTIFICATION OF PATIENTS

There is no single hospital system capable of producing a composite list to identify the patients with urological cancer, renal stone disease and other conditions with an open episode under Mr O'Brien during the period 1 April 2010 to 31 December 2018. Therefore, reports were extracted from a number of hospital systems for this time period and cross-referenced to remove duplicate entries. The following systems were interrogated, and a composite database developed to record all patients identified to be included in the Lookback Review:

- Patient Administration System (PAS)
- Cancer Patient Pathway System (CaPPS)
- Urology MDM Records
- BHSCT Laboratory Report

The reason 1 April 2010 was identified as the starting point for review of patients diagnosed with a Urological Cancer was that this is when Urology Cancer Multi-Disciplinary Meetings (MDMs) became functional in the Southern Trust. Prior to this date, there was no formal multidisciplinary forum for discussion of Urological cancer patients.

The reason 1 April 2013 was identified as the starting point for the review of patients with Renal Stone Disease was that this is when the Northern Ireland Electronic Care Record (NIECR) was implemented and utilised in conjunction with paper-based case notes.

In all cases, 31 December 2018 was the end date as this merges with the start date of Cohort 1.

When the patient numbers within each system were captured, the lists were validated to confirm the total number of patients who remained under Mr O'Brien and had not been transferred to a different consultant. This resulted in more than 190 patients being identified from which a small number<sup>3</sup> of patients were removed as they advised they did not want to be included in the Lookback Review process. This resulted in **190** patients being included in Cohort 2 of the Lookback Review.

A summary of these patients and the source of their identification is described in table 1 below.

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<sup>3</sup> The actual number is not specified as this could result in patients being identified.

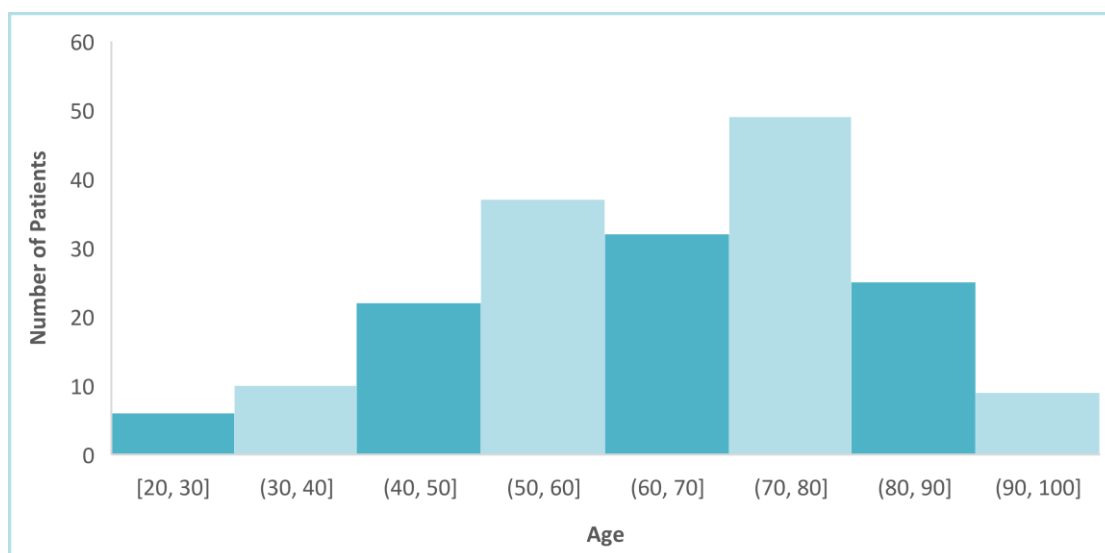
**Table 1:** Summary of number of patients for Cohort 2

Urology Patients Under Mr O'Brien – 1 April 2010 – 31 December 2018					
Source		Renal Stone Disease	Urology Cancer	Other Open Cases	Total
1.	PAS	80	0	0	80
2.	CaPPS Report	N/A	56	0	56
3.	Urology MDM	N/A	29	0	29
4.	BHSCT Laboratory Extract	N/A	4	0	4
5.	Open & Not Previously Included in Cohort 1	15	6	0	21
<b>Patients</b>		<b>95</b>	<b>95</b>	<b>0</b>	<b>190</b>

To identify private patients for Cohort 2 the Trust issued a media statement in August 2023 asking private patients to contact the Trust. As no private patients contacted the Trust, a further press release was issued in February 2024. Again, no private patients came forward.

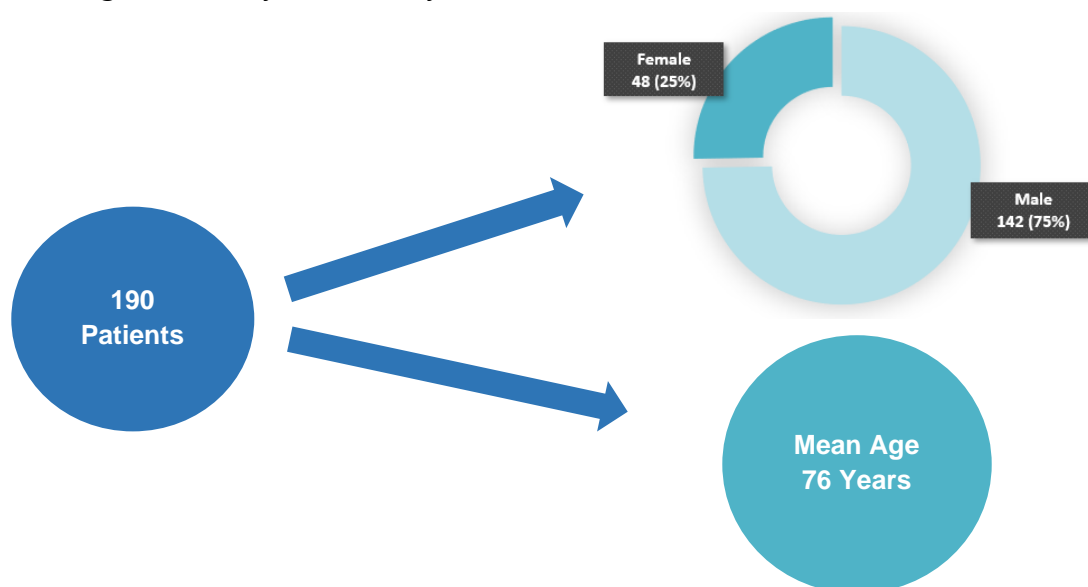
### 2.1.1 Demographic Data

Below is the demographic detail of the patients in Cohort 2 of the Lookback Review at the commencement of this phase of the Lookback Review process.



**Chart 1.** Histogram of Age Distribution for Patients in Cohort 2 (Data Date: 10<sup>th</sup> May 2023)

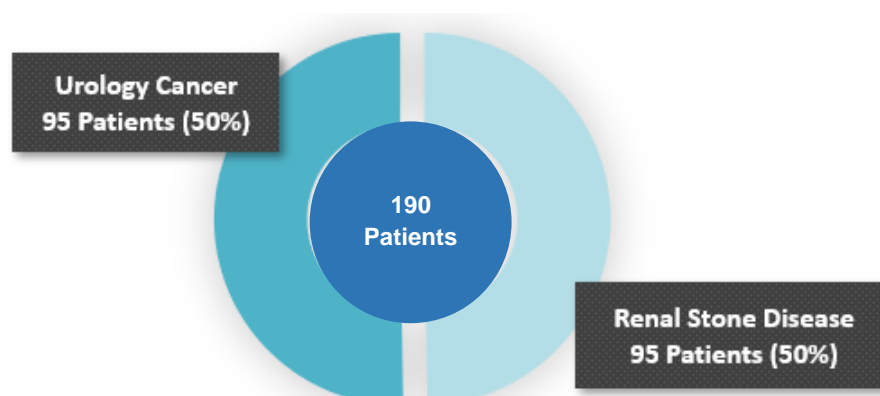
- Gender** ➤ Male – 142 (75%)  
➤ Female – 48 (25%)
- Age:** ➤ Mean 76 years (inc. patients' age at death).  
➤ Range from 29 years to 99 years



*Chart 2: Summary of Demographic of Urology Lookback Review Cohort 2*

### 2.1.2 Clinical Conditions

Of these **190** patients, **95** patients had either an active urological cancer diagnosis or, had been treated for a urological cancer in the past and remained under review with Mr O'Brien. **95** patients had been treated for Renal Stone Disease.



*Chart 3: Breakdown of clinical conditions*

## 2.2 STAGE 2 – REVIEW

Within the Trust's Urology Lookback Review, the purpose of the **REVIEW** stage was to identify which patients required a Lookback / recall appointment.

There were **190 patients** in Cohort 2 who progressed to the Review Stage of the Lookback Review process.

**Table 2:** Urology Patients Under Mr O'Brien – 1 April 2010– 31 December 2018

Category	Number of Patients
Urology Cancer	95
Renal Stone Disease	95
Private Patients	0
Other Open Cases	0
<b>Total for Cohort 2</b>	<b>190</b>

In the review stage of the process, a Patient Review Form was adapted from the version used in Cohort 1 to capture the clinical aspects of the Lookback Review. A copy of this form is included as **Appendix 1**. The review stage, including the completion of the Patient Review Forms, commenced in September 2023.

To complete the Patient Review Form all patient case notes were reviewed by an Independent Consultant Urologist. Review was completed virtually using the Northern Ireland Electronic Care Record (NIECR) and in conjunction with scanned copies of the paper medical records held for the patients.

Upon completion of the Patient Review Form the consultant made the decision on whether there was a clinical requirement for a patient to progress to the **Recall** Stage of the process. This categorisation was essentially a method to establish if there were concerns or issues with the care received by patients, and, if these necessitated the patient being recalled and seen by a consultant urologist.

**Table 3:** All Patient Review Forms were reviewed and categorised into one of three categories.

1.	<b>No Concerns Identified</b>	No clinical issues / concerns identified in Patient Review Form.
2.	<b>Concerns Identified - Not Clinical in Nature</b>	Issues / concerns identified in Patient Review Form, which <b>did not</b> have a clinical impact on the patient.
3.	<b>Clinical Concerns Identified</b>	Issues / concerns identified in Patient Review Form, which <b>could</b> have a clinical impact on the patient.

### 2.2.1 Categorisation of Patient Review Forms

The categorisation of the Patient Review Forms for the **190** patients is highlighted in Table 4 below:

**Table 4:** Categorisation of Patient Review Forms

Category		Urology Cancer Patients	Renal Stone Disease Patients	Total
1	<b>No Concerns Identified</b>	44 (46%)	70 (74%)	<b>114</b>
2	<b>Concerns Identified - Not Clinical in Nature</b>	29 (31%)	25 (26%)	<b>54</b>
3.	<b>Clinical Concerns Identified</b>	22 (23%)	0	<b>22</b>

The concerns found in categories 2 and 3 as part of the **Review process** pertained to:

- *Diagnostics*
  - diagnostics tests requested and not followed up;
  - incorrect tests requested; and
  - diagnostics not requested.
- *Medication*
  - incorrect medication type;
  - incorrect dose of medication; or
  - medication not being prescribed as required.
- *Treatment*
  - patients not being added to the waiting list for their required procedure; or
  - having a procedure which is not clinically required.

- *Communication* this was the largest category where:
  - there was either missing or no clinical correspondence completed; or
  - no evidence of communication with the patient or family including;
  - no evidence of informed consent.
- *Referral*
  - this category was primarily delayed referrals to cancer Multidisciplinary Meeting (MDM), or
  - delayed/lack of completing actions from the cancer MDM.

In terms of action taken following the categorisation of the Patient Review Forms; the **114** patients for whom no concern was identified (i.e., in Category 1) received a letter from the Trust advising their care had been reviewed as part of the Lookback Review process and that no concerns were identified with the treatment they had received. These patients were subsequently closed on the Lookback Review database.

The **54** patients in Category 2 received a letter from the Trust advising their care had been reviewed, that concerns had been identified in the review which were not clinical in nature. Each patient received a short description providing specific detail of the issue. These patients were subsequently closed on the Lookback database.

The **22** patients in Category 3 were progressed to the **Recall** stage of the Lookback Review. All these patients were in the urology cancer group. They were offered an appointment with the Independent Consultant Urologist who reviewed their case. During this appointment full disclosure of the review of their care was provided. The detail pertaining to the **Recall** appointments Stage is described in section 2.3 below.

## 2.3 STAGE 3 – RECALL / LOOKBACK REVIEW CLINICS

The purpose of the **Recall** element of the Urology Lookback Review is to establish if a patient's diagnosis and treatment is correct and, if not, what amendments are required to the patient's clinical pathway. In Cohort 2, **22** patients, all of whom were in the Urology Cancer category, required a recall appointment. No patients in the renal stone disease group required a recall appointment.

The Recall Stage of the Lookback process commenced in December 2023.

### 2.3.1 Recall Appointment

The Urology Lookback Review recall appointments were provided using a hybrid model for outpatient consultations. The Independent Consultant Urologist conducted the appointment via video whilst the patient attended the Outpatient clinic on Trust premises. The patient was accompanied and supported by a Cancer Specialist Nurse who remained in the clinic room

throughout. In addition, a member of the Trust Patient Liaison Team was available in the department to meet and greet the patient and provide further support as required.

During the Outpatient consultation, the Consultant Urologist determined if the patient was on the correct management plan or if a change to the clinical management plan was required. He also explained, in depth, what his findings were in terms of the sub-optimal care that the patient had received from Mr O'Brien and apologised for that sub-optimal care on behalf of the Trust. The consultant subsequently dictated an outcome letter detailing issues found and any required amendments to the patients' treatment. This was shared with the patient and their GP.

For this Review "Change" was defined as: *"The ceasing and / or amending of the clinical management plan put in place by Mr O'Brien."*

There were **22** Lookback Recall appointments offered to patients with a Cancer Diagnosis:

- **6** patients were either unable to attend the clinic on any dates offered or declined a recall appointment. All these patients received the outcome of the review of their care in writing.
- **16** patients attended their Recall appointment.

Out of the **22** patients (including the 16 patients who attended recall in person) where a clinical concern was identified with their care, a small number<sup>4</sup> required a change to their clinical management plan. The remainder required no change to their clinical management plan.

### **2.3.2 Change to Clinical Management Plan - Medication**

A change in medication was required and implemented for a small number of patients<sup>4</sup> who had a cancer diagnosis and who required a change to their management plan. For these patients, the medication issue focused entirely on the prescribing of bicalutamide medication (hormone therapy) which was not in line with recognised standard clinical practice. Bicalutamide medication is specific to male patients with a diagnosis of prostate cancer. The issue with Bicalutamide prescribing was the unlicensed prescribing of low dose bicalutamide 50mg, as a monotherapy when the patient's clinical pathway should have been one of surveillance. This required the prescribing of the bicalutamide to be stopped.

### **2.3.3 No Change to Clinical Management Plan Required**

The majority of the **22** patients who were offered a Lookback Review Recall appointment did not require any change in their clinical management plan. That said, there were issues with

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<sup>4</sup> As before - the actual number is not specified as this could result in patients being identified.

bicalutamide prescribing for **12** of these patients, however, the treatment had already come to an end by the time the Lookback Review had been undertaken, hence there was no requirement for a change in management plan at the time of their recall appointment.

## **2.4 STAGE 4 – CLOSURE**

Stage 4 of the Regional Lookback Review Guidance focuses on Closing, Evaluating, and Reporting on the Lookback process.

The Lookback of each individual patient's case is considered to be complete and closed when they have received a final written communication from the Lookback Team detailing the outcomes of their review.

At the time of publishing this report all **190** patients in Cohort 2 have been closed to the Lookback Review.

## SECTION 3: SUMMARY OF ACTIVITY AND OUTCOMES FOR COHORT 1 AND COHORT 2 COMBINED

This section (and **Appendix 2**) provides a brief, high-level summary of the combined activity and outcomes for Cohort 1 and Cohort 2.

### 3.1 SUMMARY DEMOGRAPHICS

There were **2302** patients in total in the Urology Lookback Review. The breakdown of the combined demographic composition of the Cohort 1 patients and Cohort 2 patients are summarised in Table 6 below.

**Table 6:** Summary of number of patients included in the Urology Lookback Review

Cohort 1 & 2 Total = 2302	Average Age	Age Range	Males	Females
Cohort 1 - 2112 Patients	69	<1 year - 98 years	73%	27%
Cohort 2 - 190 Patients	76	29 years - 99 years	75%	25%

### 3.2 SUMMARY OF REVIEW STAGE

The categorisation of the Cohort 1 patients and Cohort 2 patients, including the total of both Cohorts following the completion of the Patient Review Form process of the Lookback are highlighted below:

**Table 7:** Summary of determinations following categorisation of Patient Review Forms

Category		Cohort 1	Cohort 2	Cohorts 1 & 2 Combined
1.	No Concerns Identified	1696	114	1810 (79%)
2.	Concerns Identified - Not Clinical in Nature	176	54	230 (10%)
3.	Clinical Concerns Identified	240	22	262 (11%)
Total Patients		2112	190	<b>2302 (100%)</b>

There were **492** patients across both cohorts for whom there were concerns (clinical and non-clinical) with the care they received. This equates to 21% of cohorts 1 & 2 combined. The nature of these concerns were consistent and pertained to:

- **Diagnostics**      Diagnostics tests requested and not followed up; incorrect tests requested; and diagnostics not requested.
- **Medication**      Incorrect medication type; incorrect dose of medication; or medication not being prescribed as required.
- **Treatment**      Patients not being added to the waiting list for their required procedure; or alternatively having a procedure which was not clinically required.
- **Communication**      This was the largest category where there was either missing or no clinical correspondence or where there was no evidence of communication with the patient or family including no evidence of informed consent.
- **Referral**      This category was primarily delayed referrals to MDM or delayed/lack of completing actions from the cancer MDMs.

### 3.3 SUMMARY OF RECALL STAGE

A total of **549** patients from Cohort 1 and Cohort 2 combined were offered a recall appointment, with **543** attending either an in person or virtual appointment (**6** patients were either unable to attend the clinic on any dates offered or declined a recall appointment).

**Table 8:** *Summary of Patients Progressing to the Recall Stage of Lookback*

Recall Cohort 1	Recall Cohort 2	Recall Cohorts 1 & 2 Combined
527	22	<b>549</b>

Of these **549** patients who were offered a recall appointment, **353 (64%)** had at least one change in their clinical management plan as a result. The changes in management plan are divided into 4 groups i.e.,

- 1. Diagnostics** – this includes the requesting of new or repeat diagnostic examinations, blood tests;
- 2. Medication** - this includes the stopping, increasing or decreasing of dosage of current medication or the starting of new medication;
- 3. Treatment** - this includes providing new treatment or the adding of a patient to a surgical waiting list, or the removal or suspension of a patient from an existing surgical waiting list;
- 4. Referral** - this includes referral to Oncology, Multidisciplinary Meeting (MDM), a specialist Urology Unit or Specialist Urology/ Cancer Nurses or to another Specialist Team outside of Urology.

In Table 9 below the number and categories of changes required for 353 patients\* is quantified.

**Table 9:** *Summary of changes required to treatment plans for Cohort 1 and 2 combined.*

Changes Made...	Occurrences
Diagnostic Related Changes	195
Changes to Medication	141
Changes to Treatment	170
Onward Referral	144
<b>Total number of changes made for 353 patients*</b>	<b>650</b>

\*To note; the number of occurrences of change (650) is greater than the number of patients (353) because some patients required more than one change to their Clinical Management Plan.

## SECTION 4: CONCLUSION

This report reflects the specific activity and outcomes for Cohort 2 of the Urology Lookback Review into the care of patients under Mr O'Brien, Consultant Urologist in the Southern Health, and Social Care Trust. For ease of reference, it also includes a summary of the activity and outcomes for Cohorts 1 and 2 combined in **Appendix 2**.

The Trust is confident that, within Cohort 1 and Cohort 2, it has identified all of Mr O'Brien's NHS patients, who are currently alive, for whom there may have been a requirement to review, change or adjust their ongoing clinical management plan.

Therefore, the Southern Trust has now completed the Lookback Review of all patients under the care of Mr O'Brien.

In the future, should any patient, including any private patient, come forward to raise concerns about the care provided by Mr O'Brien, the Trust will undertake a review of their care in line with the Lookback Review methodology.

## Appendix 1: Patient Review Form

### UROLOGY LOOKBACKPATIENT CASENOTE REVIEW FORM

(Updated June 2023)

This form is to be used to review the care of the patient identified below as part of the Urology Lookback Review.

- Each question **must** be completed using a response from the “drop down” options i.e. Yes / No / NA
- The “Details” section is for free text if more information is required to supplement the Yes / No / NA answer
- The reviewer’s details and date must be recorded in the final section.

Please refer to the User Guide to ensure the correct format of saving and upload is followed on completion of this review form.

#### Patient Details

Name	
H&C Number	
Date of Birth (DD/MM/YYYY)	
Gender	

#### Patient Status

NHS/Private Patient	<input type="checkbox"/> NHS <input type="checkbox"/> Private Patient
Patients Records assessed to complete PRF	<input type="checkbox"/> NIECR <input type="checkbox"/> Paper Record  Is all Information available  Brief Note of Information not available

Clinical Details

Original Diagnosis	
Patient Clinical Summary	

## Regarding the Patients Current Care

Question		Yes / No / NA	Details
1	<b>Is the present diagnosis / diagnoses reasonable?</b> <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	<b>Are the current medications prescribed appropriate?</b> <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	<b>Is a secure clinical management plan currently in place?</b> <i>(‘Secure Clinical Management Plan’ to consider if the current patient treatment pathway is optimal and in line with current best evidence-based practice and guidance)</i>		
4	<b>If there is not a secure clinical management plan in place please document immediate actions required to be taken</b>		

## Regarding the Patient's Historical Care.

No.	Question	Y / N	Details
5	<b>Were appropriate and complete investigations carried out for all relevant conditions?</b> <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>		
6	<b>Were the medications prescribed appropriate?</b> <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>		
7 a	<b>At the time of Review did the patient require a urological procedure?</b>		
b	<b>If Yes – were they added to a waiting list</b>		
8	<b>Was the diagnosis / diagnoses reasonable?</b> <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 confirm diagnosis / diagnoses?)</i>		
9	<b>Was the clinical management approach taken reasonable?</b> <i>(‘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)</i>		

	<i>and guidance available at that time.)</i>		
<b>10 a</b>	<b>Did the Patient have a Urological Procedure?</b>		
<b>If Yes</b>			
<b>b</b>	<b>Is there Documentation of consent?</b>		
<b>c</b>	<b>Is there evidence that the risks and benefits associated with the procedure were discussed?</b>		
<b>d</b>	<b>Is there evidence that procedure information/leaflets were provided to the patient?</b>		
<b>e</b>	<b>Was the Consent form fully completed?</b>		
<b>f</b>	<b>Was input sought from other disciplines and evidenced as part of pre-operative planning &amp; Consent?</b>		
<b>g</b>	<b>Was the Consent form completed prior to the day/time of surgery?</b>		
	<b>If Not</b>		
<b>h</b>	<b>What was omitted?</b>		
<b>11</b>	<b>Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc)</b> <i>(‘Unreasonable Delays’ to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence-based practice</i>		

	<i>and guidance available at that time. The Southern 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)</i>		
12	<b>On balance - was the patient's care <u>Not</u> Sub-optimal, Sub-optimal</b>		

	<b>If Sub-Optimal - Reason?</b>  <b>Diagnostics</b>  <b>Medications</b>  <b>Treatment</b>  <b>Communication</b>  <b>Referral</b>  <b>Record Keeping</b>  <b>Did this result in harm to the patient?</b>  <b>Was there a change in Diagnosis</b>	
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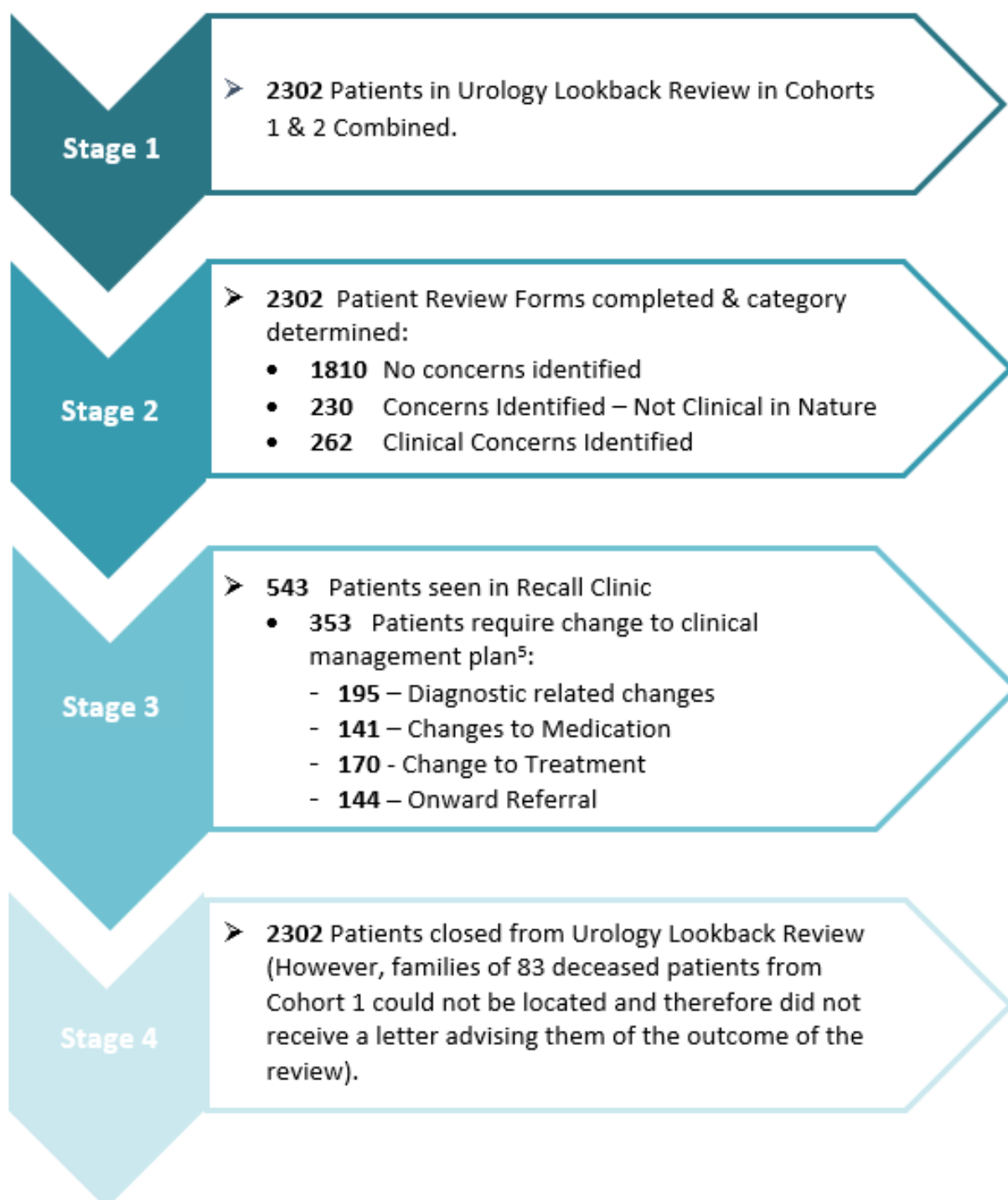
## SAI

Does this meet the threshold for an SAI?	
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## Completed By:

<b>Name</b>	
<b>Title</b>	
<b>Date (DD/MM/YYYY)</b>	

## Appendix 2: Summary of Activity and Outcomes – Cohort 1 and Cohort 2 Combined



<sup>5</sup> To note; the number of occurrences of change (650) is greater than the number of patients (353) because some patients required more than one change to their Clinical Management