Southern Health and Social Care Trust

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SOUTHERN HEALTH & SOCIAL CARE TRUST

UROLOGY LOOKBACK REVIEW

Activity & Outcomes Report (Cohort 1)

9 August 2023

CONTENTS

1.0 INTRODUCTION

1.1 PURPOSE

The purpose of a Lookback Review is to ensure patients have received / are receiving the care and treatment they required and if not, remedy care where possible.

The purpose of this report is to outline the activity undertaken as part of the Southern Health and Social Care Trust Urology Lookback Review and describe the outcomes for Cohort 1 of this process.

1.2 BACKGROUND AND CONTEXT

In June 2020, the Trust became aware of a potential issue regarding patients under the care of Mr Aidan O'Brien, Consultant Urologist. On investigation, it appeared that a number of patients who required surgery to remove renal stenting might not have been added to an inpatient / day case waiting list as expected.

This was considered a serious concern because these patients were at risk of not receiving the necessary treatment and potentially suffering serious side effects as a consequence. Based on the clinical risk identified the Southern Trust deemed it necessary to undertake further investigations to determine the outcome for the patients identified, to establish if other patients under Mr O'Brien's care were similarly affected and to consider the implications for other patients and the wider service.

A subsequent administrative review undertaken by the Service Manager, and shared with a senior Trust Consultant Urologist, led to the identification of further potential issues in other elements of Mr O'Brien's work. Namely: delays or absence of reports and/or investigations; lack of / poor communication; incorrect treatment; and un-actioned outcomes following cancer multidisciplinary team meetings including for example, onward referrals and planned reviews.

In considering the outcomes of the audit, the Southern Trust determined that, due to the nature of the findings a Lookback Review would be appropriate.

1.3 WHAT IS A LOOKBACK REVIEW?

A Lookback Review Process is implemented where "…*a number of people have been exposed/potentially exposed to a specific hazard in order to identify if any of those exposed have been harmed and to identify the necessary steps to ameliorate the harm*

e.g. repeat diagnostic test/ investigation/ referral to relevant clinical service, change treatment pathway, etc".[1]

[1] Department of Health, 2021 *Policy for Implementing a Lookback Review Process* doh-pol-implem-lookback-review.pdf (health-ni.gov.uk)

A Lookback Review is a formal process underpinned by a regional Department of Health Policy and supporting guidance[2] and normally consists of four stages:

- *Stage 1*: Immediate action and preliminary investigation and risk assessment to scope the extent, nature and complexity of the incident/ concern/issue;
- *Stage 2*: Identifying and tracing service users at risk;
- *Stage 3*: Service User Recall;
- *Stage 4*: Closing, Evaluating and Reporting on the Lookback Review Process.

Lookback Review exercises are by nature high volume, high-complexity and as described above they involve multiple stages which can lead to logistical challenges and cumulative delays. For this reason, there must be a methodical, systematic approach to undertaking the exercise with clear lines of management and accountability to ensure it is delivered effectively.

As previously referenced, the primary objective of a Lookback Review is to remedy care for patients when required, and where possible. However, it also provides an opportunity to elicit learning in order to take action and prevent the situation from reoccurring in the same or a different speciality.

[2] Department of Health, 2021 *Regional Guidance for Implementing a Lookback Review Process.* doh-reg-guide-lookback-reveiw.pdf (health-ni.gov.uk)

1.4 METHODOLOGY FOR THE SOUTHERN TRUST UROLOGY LOOKBACK REVIEW

Using the Department of Health's, *Regional Guidance for Implementing a Lookback Review Process* as a framework the Southern Trust Urology Lookback Review, was carried out in four stages as defined and described in further below:

SOUTHERN TRUST UROLOGY LOOKBACK REVIEW – COHORT 1		
STAGE: 1	**IMMEDIATE ACTION** and **PRELIMINARY INVESTIGATION** and **RISK ASSESSMENT** to scope the extent, nature and complexity of the incident/ concern/issue, to confirm the scope and number of patients in the Lookback Review (Cohort 1).	
STAGE: 2	The Patient **REVIEW** including 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).	**Stages 2 – 4 ran concurrently for patients in Cohort 1**
STAGE: 3	The **RECALL** of patients, for whom there was concern from stage 2, to a Lookback Clinic. This included face-to-face or telephone communication with patients to complete a clinical assessment and a change to treatment plans as required.	
STAGE: 4	**CLOSURE** 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; b) Production of a Cohort 1 Outcomes and Activity Report; c) Dissemination of a Cohort 1 Outcomes and Activity Report, including next steps, and closure of the Cohort 1 Lookback Review Exercise.	

2.0 ACTIVITY & OUTCOMES

2.1 STAGE 1: IMMEDIATE ACTION / RISK ASSESSMENT

The Regional Lookback Review guidance indicated that the first stage of a Lookback Review process is to take immediate action, including a risk assessment in terms of the presenting issue and establish the cohort of patients to be reviewed as a part of the Lookback exercise.

As referenced, concerns about this situation initially came about when the Trust became aware that patients under Mr O'Brien, who required a surgical procedure,

appeared not to have been added to the waiting list for this procedure. This presented a concern that there might have been patients missed and may not have received the required treatment and care.

There was sufficient concern that an audit was undertaken by the Service Manager which led to the identification of further issues with Mr O'Brien's work including potential issues with prescribing practices and onward referral, etc.

A formal risk assessment of the situation was undertaken using the Regional Risk Matrix (HSCB, 2016)[3]. The risk that patients may not have received the correct care was graded as "extreme". This was calculated as follows:

Likelihood - **5** (Almost Certain) **x** Consequence - **4** (Major) **= 20** (Extreme).

On this basis, the Trust considered that patients would need to be recalled to establish if their care was appropriate. This was essentially a Lookback Review situation.

As per the Regional Lookback Review guidance, when a situation is determined to require a Lookback, it is necessary to establish the cohort of patients who may been exposed to harm.

Therefore, in July 2020, the Trust embarked on a process of identifying patients that may require a review and **Recall** with regard to the care they received. As the purpose of a Lookback Review is to remedy care for patients when required and where possible, the timeframe of **1 January 2019 to 30 June 2020** was selected as a starting point.

June 2020 was selected as the end date for this Cohort of patients because this is when Mr O'Brien retired from the Trust.

The reason **January 2019** was selected as the starting point was because clinical advice indicated that a patient who had a renal stent in place should have that stent removed within 18 months (i.e. 18 months prior to June 2020).

To identify the total number of patients in this cohort, the Trust gathered details of the Mr O'Brien's patients from the following sources. Reports were extracted from a number of hospital systems for the review time period of **January 2019** to **June 2020** and cross-referenced to remove duplicate entries. The following systems were interrogated and a composite database developed to record all **2112** patients in the Lookback Review:

- Patient Administration System (PAS);
- Cancer Patient Pathway System (CaPPS);
- Northern Ireland Electronic Care Record (NIECR);
- Theatre Management System (TMS);
- Radiology Information System (SECTRA).

[3] Health & Social Care Board (2016) *Procedure for the Reporting and Follow up of Serious Adverse Incidents*. Appendix 16

A summary of the information is tabled below:

Urology Patients Under Mr O'Brien - January 2019 – June 2020			
Category	**Numbers**		**Rolling Total**
	Added	**Minus**	
1. Emergency Urology Patients (TMS)	160		160
2. Theatre Elective (TMS)	352		512
3. Oncology Review Backlog (PAS)	236		748
4. Pathology Results (NIECR)	168		916
5. Radiology Results (NIECR and checked on SECTRA)	1536		2452
6. Urology MDM (CaPPS)	271		2723
SUB-TOTAL			**2723**
Duplicate Patients - patients in more than one of the groups above		377	2346
New patients initially coded to AOB but not seen by him – seen by different consultant (PAS)		234	2112
FINAL NUMBER IN COHORT 1			**2112**

These 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 **2112 patients** being included in the first cohort of patients for the Lookback Review.

A high-level summary of the outcomes for this group of patients is included as **Appendix 1**.

Demographic Data

The demographic detail of the patients in the first cohort of the Lookback Review at the commencement of the process (i.e. 1 July 2021 when the Review Stage formally commenced).

Gender:

- Male – 1539 (73%);
- Female – 573 (27%).

Age:

- The mean age 69 years (including patients' age at death i.e. if a patient had deceased before the lookback process had completed, the patients age at their time of death was used in the analysis).
- Range from 3 months to 98 years.

Status:

- Living patients – 1797 (85%)
- Deceased patients – 315 (15%

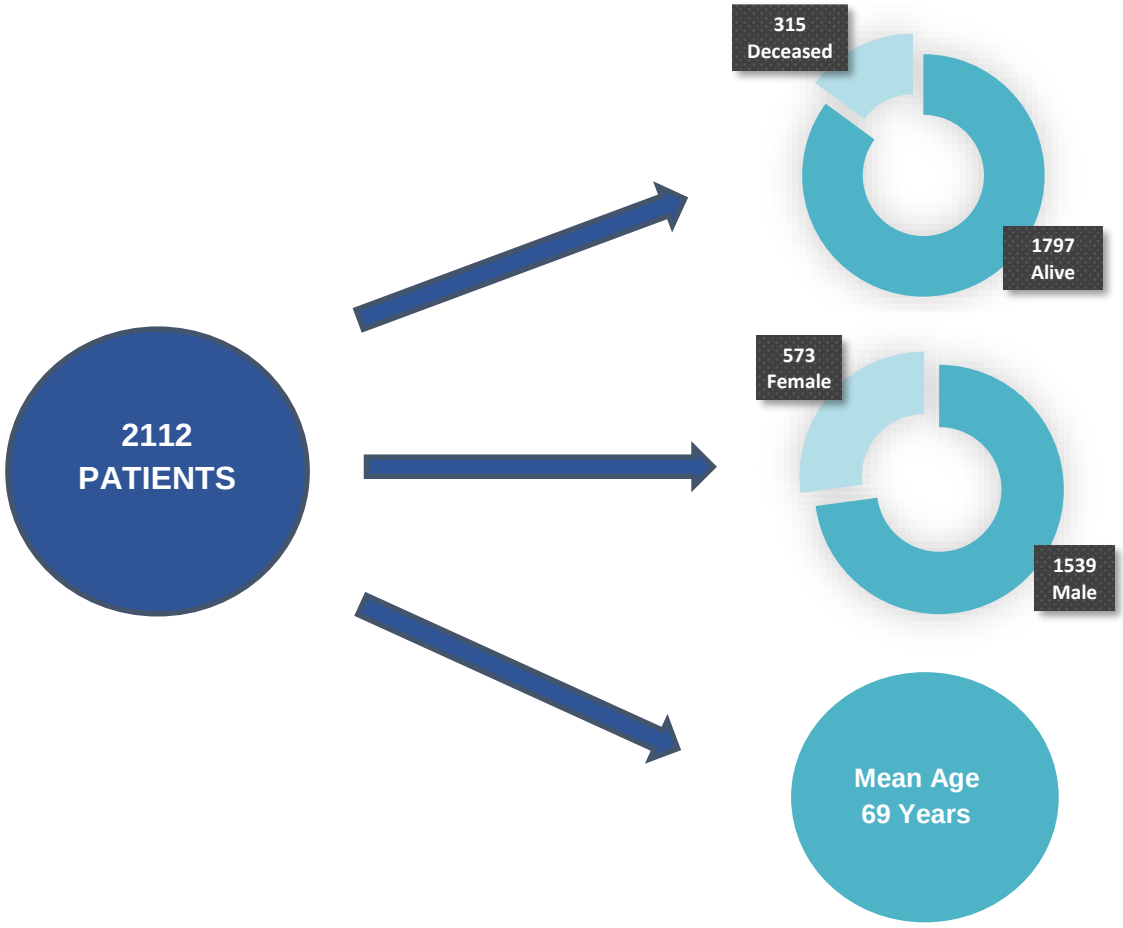


***Chart 1**: Summary of demographic make-up of Urology Lookback Review Cohort 1*

Clinical Conditions

Of these **2112** patients identified, **560** 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.

The remaining **1552** patients had a non-cancer condition.

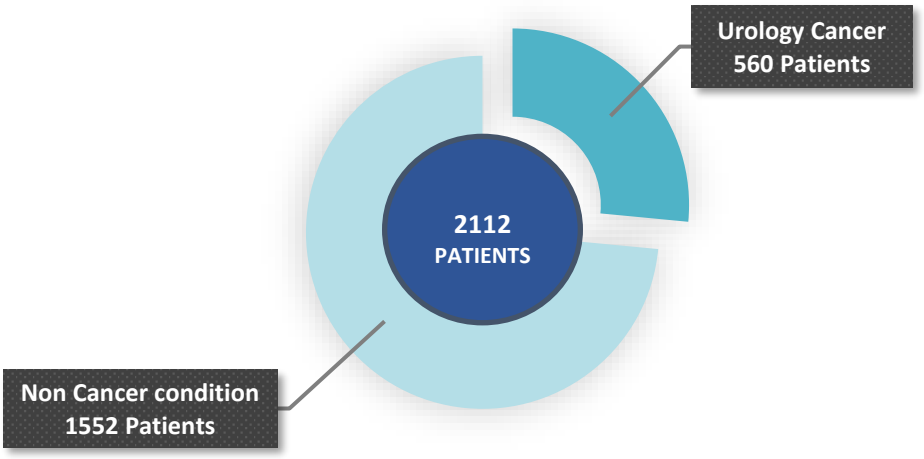


***Chart 2**: Cancer versus non-cancer conditions*

The actual urological conditions, both cancer and non-cancer related, associated with patients within this cohort includes the following:

Cancer

- Prostate
- Bladder
- Kidney
- Penile/ Testicular

Non-Cancer

- Lower Urinary Tract Symptoms (LUTS)
- Urinary Tract Infections
- Renal Stones
- Haematuria
- Bladder conditions including Detrusor Over/ Under Activity, Urinary Retention, Bladder Flow Obstruction & Incontinence
- Prostate conditions including Benign Prostatic Disease / Enlarged & Obstructive Prostates
- Catheterisation including intermittent and suprapubic/ urethral.

2.2 STAGE 2 – REVIEW

Within the Trust's Urology Lookback Exercise, the purpose of the **REVIEW** stage was to identify which of the **2112** patients required a Lookback / **Recall** appointment.

A Patient Review Form was developed to capture information for the review stage of the Lookback. The Patient Review Form was used to capture the clinical aspects of this review. A copy of this form is included as **Appendix 2**. The review stage, including the completion of the Patient Review Forms, commenced in July 2021.

To complete the Patient Review Form process, all patients in Cohort 1 had either a face-to-face or telephone review undertaken by one of the Consultant Urologists in the Southern Trust, or their case notes were reviewed virtually by an external urologist using the Northern Ireland Electronic Care Record (NIECR). A number of factors were considered when determining if the patient required face to face or telephone review i.e. need to physically assess the patient, mobility and accessibility of the patient.

When populated by the consultant with patient specific information, the Patient Review Form was triaged to assist with the decision on whether or not a patient would progress to the **Recall** stage of the process. This triage was essentially a "sorting" process to establish if there were concerns or issues with the care received by patients and if these necessitated the patient being recalled and seen in an outpatient setting by a senior urologist from the Trust.

All Patient Review Forms were reviewed and triaged into one of three categories i.e.:

1. No clinical concerns	No clinical issues / concerns identified in Patient Review Form.
2. Concerns but not clinical in nature	Issues / concerns identified in Patient Review Form, which **did not** have a clinical impact on the patient.
3. Clinical concerns	Issues / concerns identified in the Patient Review Form, which **could** have a clinical impact on the patient.

Determinations Following Triage of Patient Review Forms

The result of this triage exercise for the **2112** patients highlighted the following:

TRIAGE RESULT		ACTION
1. No concerns with care received	1696 Patients (80.3%)	Closed to the Lookback Review**
2. Concerns but not clinical in nature	176 Patients (8.3%)	Further review in Lookback / Recall Clinic
3. Clinical Concerns	240 Patients (11.4%)	Further review in Lookback / Recall Clinic

Patients triaged into Category 1, received a letter from the Trust advising their care had been reviewed and no concerns were identified. For the purpose of the Lookback Review process, these patients were subsequently closed on the Urology Lookback database.

Of the **1696 patients in Category 1, **111** patients were being actively treated for cancer at the time. Whilst there were no concerns identified with the treatment and care of these patients were receiving, a decision was taken by the team that all active cancer patients would receive a face-to-face appointment in a clinic setting to ensure they continued on the correct patient pathway.

It was determined that patients triaged into Categories 2 and 3, required further assessment therefore were progressed to the **Recall** stage of the Lookback. These patients were advised as such and a Lookback appointment was made with a Southern Trust Consultant Urologist.

In summary, 527 patients from the Review stage progressed to a Lookback clinic at the **Recall** stage of the process.

Summary of Patients Progressing to the Recall Stage of Lookback	
Determined Category	**Number of Patients**
Patients determined as ‘clinical concerns’	240
Patients determined as ‘concerns but not clinical in nature’	176
Cancer patients with ‘no concerns’	111
Total Number of Patients Recalled	**527**

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 were required to the patient's clinical pathway.

The **Recall** stage of the Lookback process commenced in July 2021 and was managed alongside the review phase. Patients were recalled according to their clinical need.

RECALL

The Urology Lookback Review **Recall** appointments took place with a Trust Consultant Urologist either face-to-face in an outpatient setting or virtually via video or telephone. Following the patient's appointment, the consultant dictated an outcomes letter, which was shared with the patient and their GP.

In order to ascertain the outcomes of the **Recall** aspect of the Lookback Review, senior nurses in the Lookback team scrutinised the clinic letter, which was generated by the consultant after each appointment. This was to establish if Mr O'Brien had placed the patient on the correct management plan or if a change was required to the clinical management plan and if so, what this change was.

For the purpose of this exercise, "Change" was considered to be: "*The ceasing and / or amending of the clinical management plan put in place by Mr O'Brien".*

The outcome of the senior nurses' analysis are described below.

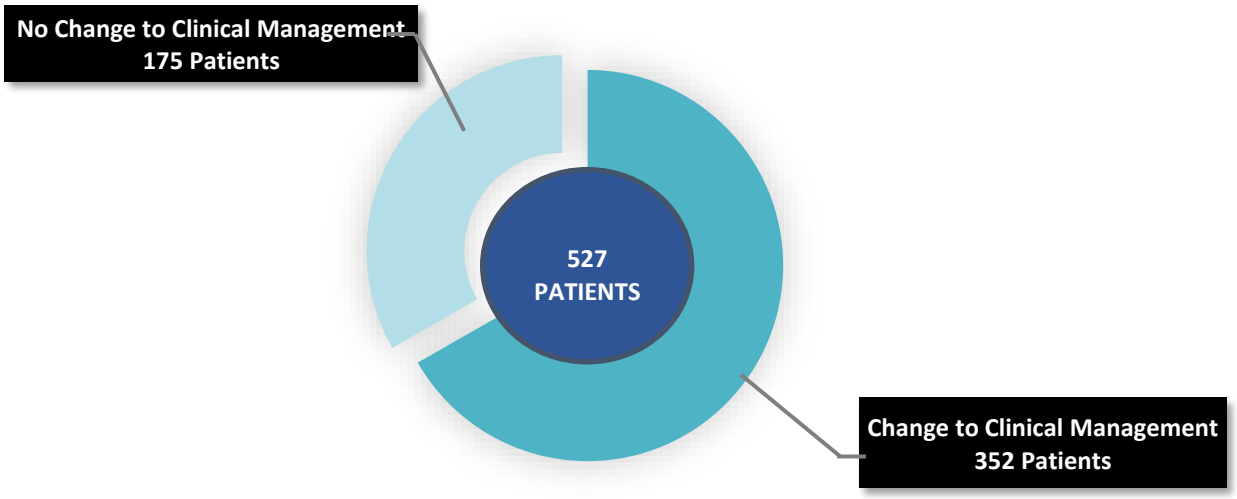


Chart 3: *Breakdown of "change" versus "no change" in clinical management plan following* ***Recall*** *appointment*

Of the **527** Lookback **Recall** appointments completed:

- **352** of patients (67%) required at least one change to their clinical management plan. **92** patients out of this **352** (26%), were Urological Cancer patients; and

- A total of **175** (33%) of the **527** patients who attended a Lookback **Recall** appointment did have a change to their clinical management plan however they did receive information regarding the Lookback Review as well as advice and reassurance as required.

Further detail of this is provided in **Sections 2.3.1 and 2.3.2** below**.**

2.3.1 Changes to Clinical Management Plan

The analysis undertaken by the senior nurses relating to changes in management plan was grouped into 4 categories:

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.

Each of these categories had a number of subcategories. The categories and sub-categories are detailed in **Appendix 3**.

The chart below details the changes to the clinical management plan for the **352** patients who required a change to their clinical management plan.

To note, some patients required more than one change therefore the total number of patients in each category below is greater than **352** i.e. the number of patients who had an appointment.

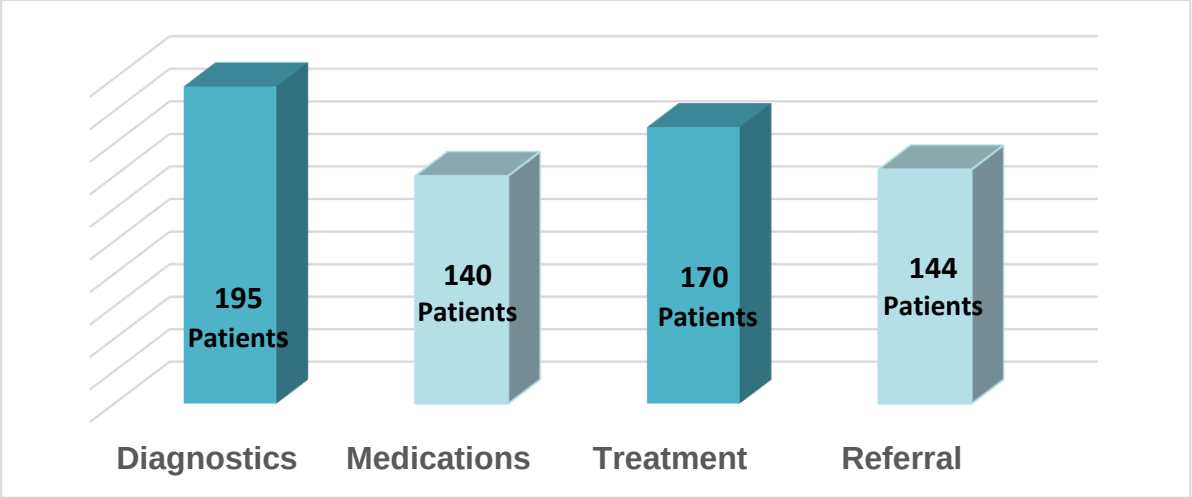
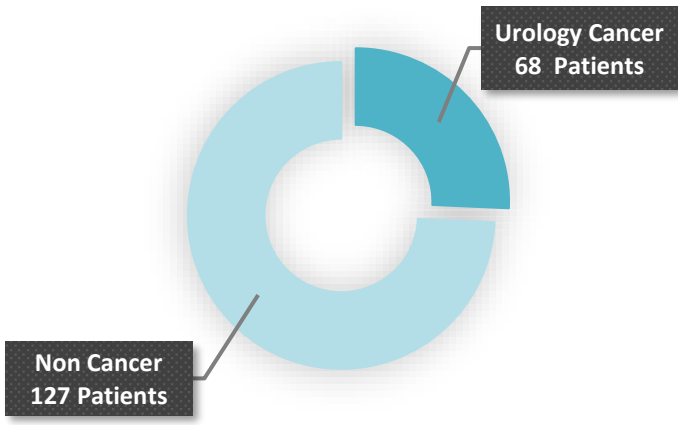


Chart 4: *Patients with a Change in Clinical Management N=352*

Diagnostics

The most prevalent change was found in the category of diagnostics. A total of **195** patients required a diagnostic action. The cancer / non-cancer split of these patients was:



Of these **195** patients, the "change" was as follows:

Breakdown of Required Diagnostic Changes	No. of Patients	%
➢ Repeat diagnostic tests e.g. CT or MRI scanning	87	45%
➢ New / additional diagnostic tests e.g. Scanning or urodynamics	68	35%
➢ Place on blood testing surveillance (PSA monitoring all prostate cancer disease) [4]	40	20%

[4] *This change in clinical pathway coincided with the discontinuation hormone medication i.e. Bicalutamide (detailed below in "medication") and moving the patient to an appropriate surveillance pathway.*

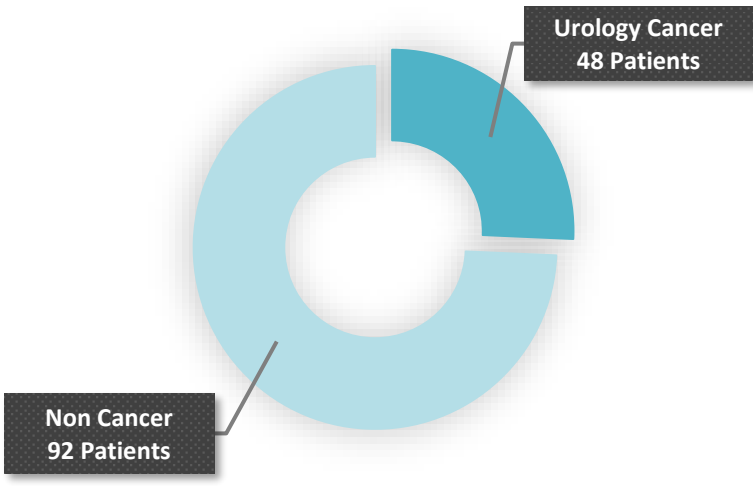
Of the **127** patients with non-cancerous urological conditions, **26** patients had renal stone disease treated with or without ureteric stenting (21%). For these patients, the diagnostic analysis identified the need to request either new or repeated investigations to assess renal stone disease or confirm the presence of ureteric stents.

The Lookback Team considered the renal stone disease findings to be significant given the potential effect on patients with untreated stone disease and ureteric stents.

The subsequent action taken following diagnostics for these patients is reflected in the "*treatment*" section on page 16.

Medication

A change in medication was required for **140** patients seen at Lookback **Recall** clinic. The cancer / non-cancer split of these patients was:



For the **48** patients with cancer, the medication issue focused entirely on prescribing Bicalutamide medication (hormone therapy) that was not in line with recognised standard clinical practice. This is specific to male patients with a diagnosis of prostate cancer. Issues with Bicalutamide prescribing were two-fold:

i. The unlicensed prescribing of low dose Bicalutamide 50mg, as a monotherapy when the patient's clinical pathway should have been surveillance (**23** patients); and

ii. Prolonged prescribing of Bicalutamide either before, or instead of, referral to Oncology, as would have been standard treatment and practice (**25** patients).

All **48** patients required the prescribing of Bicalutamide to be stopped.

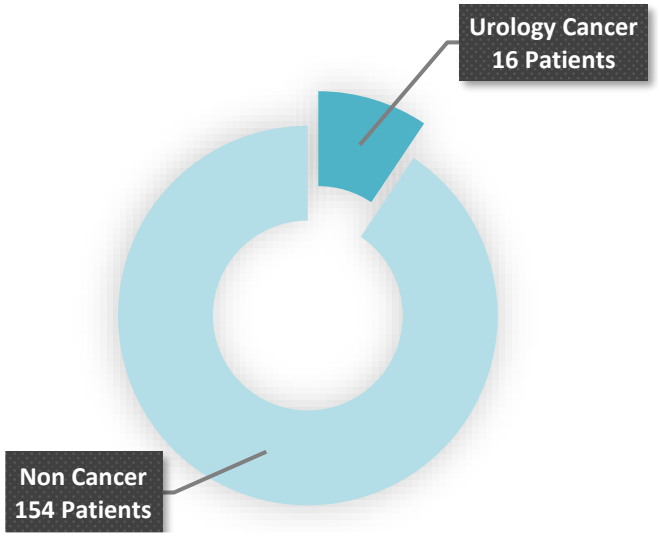
In addition to the medication being stopped **19** of these patients were discussed at MDM for treatment planning and were referred to Oncology. The remaining **29** patients were placed on a surveillance pathway with regular checking of their PSA.

For the **93** patients with a non-cancerous urological condition the following medication changes were required:

Breakdown of Medication Changes Required	No. of Patients	%
➢ Antibiotics stopped (these had been prescribed indefinitely or had continued as a result of patient not being reviewed)	19	20%
➢ Other medication stopped (as it was determined to not be of benefit to the patient)	18	19%
➢ New medication commenced	50	54%
➢ Current medication doses increased	6	7%

Treatment

In relation to "change in treatment" category, a total of **170** patients either had a procedure which was not clinically indicated, or were on a waiting list for a procedure which, when reviewed, was not required. The cancer / non-cancer split of these **170** patients is:



Breakdown of Treatment Changes Required	No. of Patients	Cancer	Non-Cancer
Had a procedure which was not clinically indicated	47	5	42
On a waiting list for a procedure which when reviewed was not required	123	11	112

Procedure Performed Not Clinically Indicated

Of the **47** patients who had a procedure that was not clinically indicated, **5** patients had a Cancer and **42** patients had a non-cancerous urological condition.

An example of the procedures, which were considered not required, include:

- Transurethral Resection of Prostate (TURP)
- Ureteroscopy/ Urethrotomy
- Hydrodistension/ Bladder Distension
- Testicular/ Scrotal Exploration
- Epididymectomy
- Cystoplasty/ Pyeloplasty
- Other procedures such as penile implants, upsizing of catheter & self-catheterisation, intravesical Botox treatment and Urodynamics

Waiting List Adjustment

There were **123** patients who were on a waiting list for a procedure who, following the Lookback **Recall** Clinic did not require that procedure.

The following changes to the waiting lists took place:

Changes to Waiting List	No. of Patients	%
Removed from the Waiting List – other follow up required	66	54%
Removed – assessed and deemed suitable to manage with simple lifestyle changes	10	8%
Suspended from the Waiting List with trial of lifestyle changes (noted the need for surgical intervention was highly unlikely)	21	21%
Removed from one waiting list and added to another waiting list for a different procedure.	26	17%

It should be noted that patients were not adversely impacted by changes to waiting lists i.e. if removed from one waiting list and added to another waiting list for a different procedure they were backdated so effectively they waited the same amount of time.

A total of **76** patients were either removed from the waiting list (**66** patients), or suspended from the waiting list (**10** patients). The chart below demonstrates the procedure sites for which they had been listed for surgery:

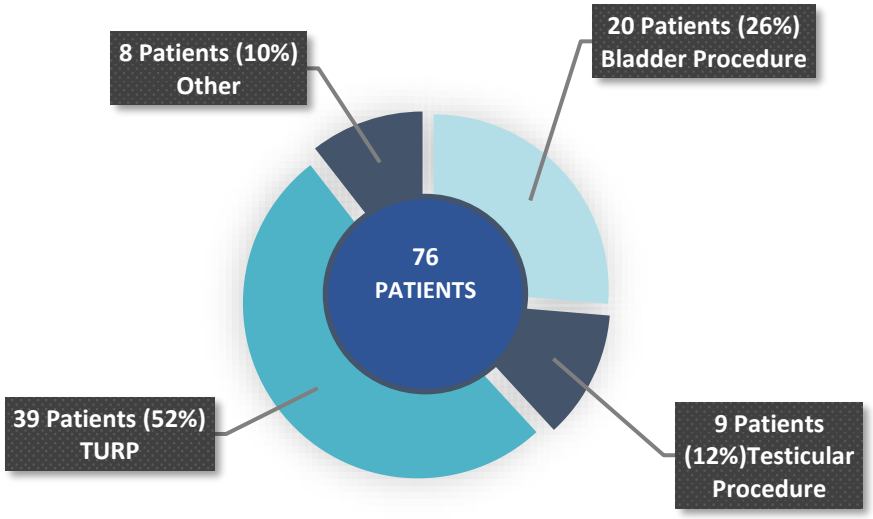


Chart 5: Patient Removed from Waiting List

**Category of "other" includes Penile Procedures, complex procedures of Mitrofanoff, Ileal Conduit and Urinary Diversion and Revision of Nephrectomy Wound.*

Prostate related procedures were greater in number with **39** patients requiring a change in the management plan decided upon by Mr O'Brien. The following findings were noted as the reason for change of pathway:

- First line treatment including lifestyle changes and medications to manage symptoms had not been offered;
- Diagnostics performed did not support the need for TURP;
- Diagnostics had not been performed/were missing from records;
- Alternative options were available but not offered to the patient;
- Co-morbidities made the patient high risk for surgery, which was known prior to adding to the waiting list for a TURP procedure; and
- Patient age - either too young or too old for the associated risks and potential side effects.

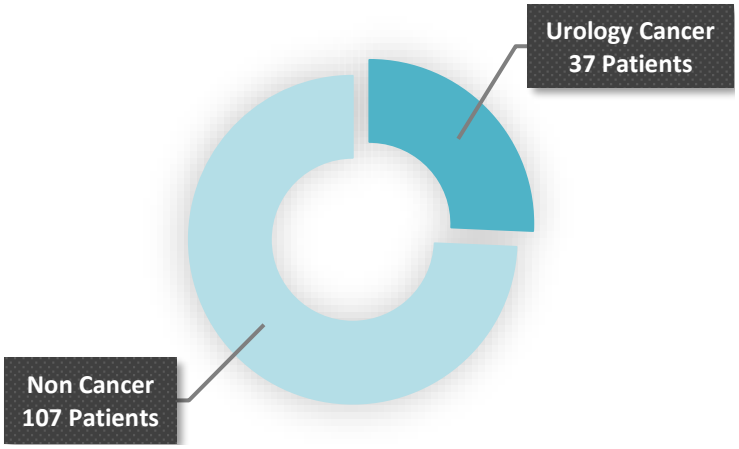
As detailed in "*diagnostics*" section on page 15, **26** patients, with renal stone disease treated with or without ureteric stenting, required further treatment following diagnostic follow up. The treatment changes for these patients include the following:

- Requiring either stone treatment surgery or had an ureteric stent identified as still being in situ which required either removal or replacement;
- Onward referral to the Stone Treatment Centre for lifestyle advice and placed onto surveillance;
- Annual surveillance; and
- Discharged to their GP with advice on fluid intake, dietary considerations and symptoms of recurrence of stone formation;

As a benign disease, given the potential effect on patients with untreated stone disease and encrusted ureteric stents, this condition needs to be specifically included in any extension of the current Lookback Review.

Referral

Change required in relation to "Referral" was noted for **144** patients. The cancer / non-cancer spit of these patients is:



Of the 37 patients with a urological cancer, the following referrals were actioned:

Changes to Referral Required for Patients with Urological Cancer	No. of Patients	No. of Referrals
➢ Referred to the Lower Urinary Tract Symptoms (LUTS) Clinic for assessment and management of symptoms associated with cancer diagnosis	16	16
➢ Referred to Cancer Nurse Specialists	6	7
➢ Referred to Oncology/Specialist Urology Unit to commence Cancer Treatment	6	7
➢ Required discussion at the Urology Multidisciplinary Team Meeting (MDT) for treatment plan recommendation	5	6
➢ Referred to another speciality	4	4
Total Number of patients / referrals	**37**	**40**

This applies to 37 patients however, 40 referrals were made in total as 3 patients had 2 referrals each.

Of the **107** patients with a non-cancerous Urological Condition requiring referral actions, the following referrals were actioned:

Changes to Referral for Patients with Non-Urological Cancer	No. of Patients
➢ Referred to the Lower Urinary Tract Symptoms (LUTS) Clinic for assessment and management of urinary symptoms	52
➢ Referred to Specialist Urology Units or Practitioner	20
➢ Referred to another Speciality for example Gynaecology	14
➢ Referred to another Trust Urologist with a speciality / MDT in specific Urological conditions for example renal stone disease	10
➢ Referred to others e.g., physio, Continence Nurses	11
Total Number of patients	**107**

Reflecting the findings in "*diagnostics"* in relation to patients with renal stone disease, with or without the use of ureteric stents (i.e. non-urological cancer patients), of the **107** patients requiring referral action, **13** patients had a diagnosis of stone disease and required onward referral for treatment.

2.3.2 No Change to Clinical Management Plan

A total of **175** patients (33% of patients) who had a Lookback appointment did not have any change in their clinical management plan.

All of these patients were informed about the Lookback Review and were provided with the detail of the specific issues identified with the treatment they received while under the care of Mr O'Brien.

Where patients had deceased during the period since the commencement of the review, their Next of Kin were informed of the findings in writing. In addition, they were offered the opportunity to meet with a Senior Urology Consultant to discuss the issues and have an opportunity to have questions addressed.

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 or their next of kin have received a final written communication from the Lookback Team detailing the outcomes of their review.

Where there were concerns with a patient's care and their case was subject of deeper analysis to establish learning opportunities for the Trust, these patients, or next of kin for deceased patients, have been provided with correspondence detailing the learning identified.

At the time of publishing this report, **2029** individual cases have been closed on the Lookback database. The Lookback cannot be closed for an outstanding 83 patients. This is because the patients are deceased and despite extensive efforts the Lookback Team were unable to identify the next of kin details for these patients. Consequently, the Trust has not been able to write and advise these relatives of the outcomes of the Lookback with regard to their family member.

The protracted time interval between the commencement of the Lookback Review and the publication of this report is recognised, however it has been necessary to ensure robust completion of the following actions:

- Identifying the patients to be reviewed and ensure a robust database of all patients affected;
- The subsequent large volume of patients identified to be reviewed and progress through each stage of the Lookback process;
- The limited clinical resource available to undertake the different elements of the Lookback Review methodology;
- Arranging **Recall** clinic appointments with the one consultant available to undertake this work; and
- Completing a report for each patient to be shared with them/their next of kin detailing the outcome of their Review i.e. any findings/shortcomings with their care.

As previously referenced, patients were managed through this process according to clinical priority.

At a patient level, all of the urology patients in the Lookback Review received individual letters to advise of the outcome of the review as soon as possible after their review was complete. Nevertheless, the length of time to complete the full Lookback Review for all 2112 patients has been prolonged and it is recognised that a timelier conclusion of the process would be preferable for any further cohorts.

3.0 NEXT STEPS

3.1 Extension of the Urology Lookback Review

This report provides high-level outcome data for people who were under the care of Mr O'Brien's from January 2019 until June 2020. As a result of the findings from Cohort 1, it is recognised that a further cohort of individuals (Cohort 2) will need to be further analysed and reviewed.

In identifying this group of patients the Trust determined that they are patient groups where there would be a greater opportunity to change their clinical management pathway for a more positive outcome. This includes patients with Urological Cancer and patients who were diagnosed with renal stones, who were treated with or without ureteric stents and any patient who continues to have an "open" episode of care and has yet to be discharged or their care taken over by another Trust urologist.

In addition, a concern has been raised that Mr O'Brien may have seen and treated patients privately in his own home. Due to the ongoing difficulties in gaining access to Mr O'Brien's private patients, it is the intention of Southern Trust to include in Cohort 2 any private patients, who wish to have a review. Patients who fall into this category will be invited to come forward and make contact with the Trust directly.

In summary, the Urology Lookback Review will be extended to a second cohort of patients to include:

1. Patients diagnosed with a Urological Cancer diagnosed from 1 April 2010 (this is when Cancer MDM's became functional in Southern Trust) *who have not already been seen by another 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 (this is when the Northern Ireland Electronic Care Record (NIECR) was implemented and utilised in conjunction with paper-based case notes); and 31st December 2018 who have not already been seen by another consultant and who are currently alive;

3. Any patient who continues to have an "open" episode of care who have not already been seen by another consultant and who are currently alive; and

4. Any patient who was seen and treated privately by Mr O'Brien and wishes to be included in this Cohort.

The Trust expects that when this second cohort of patients have progressed through the Trust's Lookback Review, all of Mr O'Brien's patients, for whom there may have been a requirement to change or adjust their ongoing clinical management plan, will have been reviewed. Therefore, there is no expectation that review of a third cohort will be required. However, this situation will be kept under review.

Appendix 1: Summary of Activity & Outcomes of Cohort 1

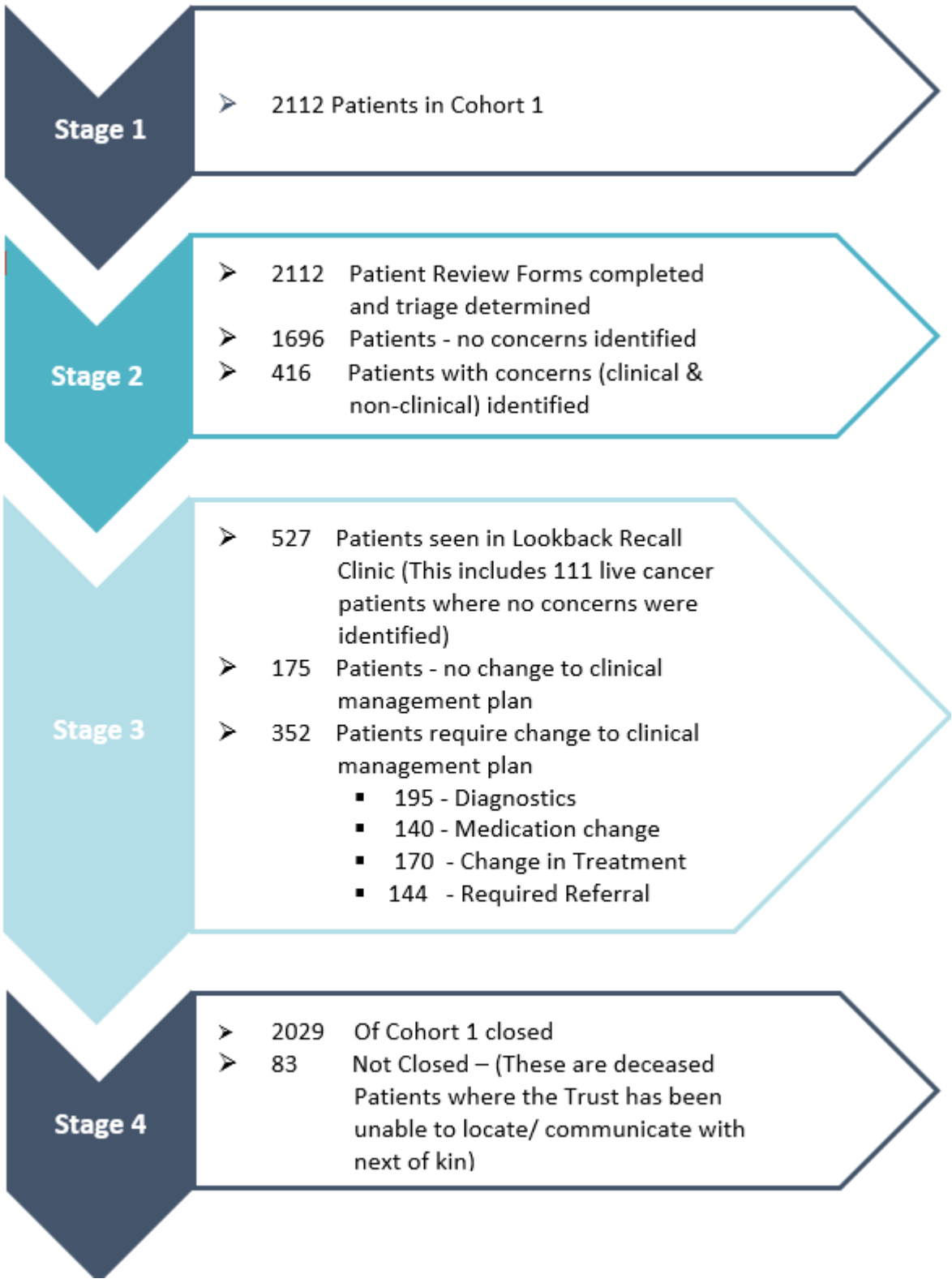


Chart 6: Hi-Level Lookback Review Summary for Cohort 1

Appendix 2: Patient Review Form Template

UROLOGY LOOKBACK REVIEW
PATIENT REVIEW FORM

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 / Unable to Determine**
- **The "Details" section is for free text if more information is required to supplement the Yes / No / Unable to Determine 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)	

Clinical Details

Patient Clinical Summary	

Regarding the patients current care

	Question	Yes / No / Unable to Determine (UTB)	Details
1	**Is the present diagnosis / diagnoses reasonable?** ('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?)*		

2	**Are the current medications prescribed appropriate?** *('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)*		
3	**Is a secure clinical management plan currently in place?** *('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)*		
4	**If there is not a secure clinical management plan in place please document immediate actions required to be taken**		

Regarding the Patient's Historical Care.

No.	Question	Y / N / Unable to Determine	Details
5	**Were appropriate and complete investigations carried out for all relevant conditions?** *('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?)*		
6	**Were the medications prescribed appropriate?** *('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?)*		
7	**Was the diagnosis / diagnoses reasonable?**		

	('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?		
8	**Was the clinical management approach taken reasonable?** *('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.)*		
9	**Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc?)** *('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 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)*		
10	**On balance - was the patient's care:** **Optimal** **Suboptimal** **Unable to Determined**		

Clinical Professional Reviewing Care

Name	
Title	
Date of Casenote Review **(DD/MM/YYYY)**	

Appendix 3: Change of Management Plan - Categories and Subcategories