National Prostate Cancer Audit State of the Nation Report 2025

Outlier Communications

Outlier Communications

Introduction to the NPCA Outlier Process

The National Prostate Cancer Audit (NPCA) publishes risk-adjusted performance indicators of the quality of care received by men diagnosed with prostate cancer.

Using funnel plots to compare individual provider results with the national average, we can identify 'potential negative outliers' whose performance is outside normal limits (further from the national average than would usually occur by chance alone).

An estimate for a performance indicator more than three standard deviations from the national average is deemed to be an 'alarm'. Trusts/ health boards in the current report cycle (State of the Nation 2025) were considered potential outlier 'alarm' Trusts according to the NPCA Outlier Policy 2025. The outlier approach was adapted from the '*NCAPOP Outlier Guidance: Identification and management of outliers*'[1].

The potential outlier 'alarms' relate to three adjusted treatment-related outcomes:

***Performance indicator 4**: Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older, presented at the level of the sMDT).*

***Performance indicator 6**: Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

***Performance indicator 7:** Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

An estimate for a performance indicator more than two but below three standard deviations from the national average for two consecutive years is deemed to be an 'alert'. The condition that an estimate should be within the defined range for two consecutive years before it is considered an 'alert' was added to reduce the chance that a trust/health board is erroneously identified as a potential outlier.

The potential outlier 'alerts' relate to two adjusted treatment-related outcomes:

***Performance indicator 6**: Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy*

***Performance indicator 7**: Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) within 2 years of radical prostate radiotherapy*

Following notification of potential 'alert' and 'alarm' outlier status, each trust was given the opportunity to review their individual data and check this against the NPCA data. The provider was then invited to respond by letter to the NPCA team, about the possible underlying causes, and any relevant quality improvement interventions adopted or planned.

The CQC was notified as per the NPCA Outlier Policy 2025.

This document publishes the trust responses following this process, to support learnings from hospitals who are embarking upon an improvement journey.

Professor Noel Clarke, Urological Clinical Lead representing the British Association of Urological Surgeons

Dr Alison Tree, Oncological Clinical Lead representing the British Uro-oncology Group

[1] HQIP-NCAPOP-Outlier-Guidance_21022024.pdf

Responses from Trusts to the Potential 'outlier' alarm 'case to answer' during the NPCA Outlier Policy[2]

Each Trust was contacted by means of a letter to the Clinical Lead. The letter contained an aggregate table explaining the distribution of certain patient characteristics of the patients of interest from their trust compared to national demographics. Trusts were also provided, on request, with a password protected spreadsheet which contained patient level data to support the review.

The following trusts were contacted in relation to the following specific performance indicators. Their final outlier status is also indicated, where "not confirmed" means the review process highlighted inaccuracies in the data held by the NPCA, so the provider is found not to be an outlier, and "confirmed" means the provider's outlier status was confirmed following the review process.

sMDTs

Performance indicator 4*:* Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older, presented at the level of the sMDT)

For men with newly diagnosed hormone-sensitive metastatic disease who underwent systemic treatment intensification between 1 January 2022 and 31 December 2022.

- Wirral University Teaching Hospital NHS Foundation Trust (Page 5) – not confirmed
- Royal Marsden NHS Foundation Trust (Page 6) – not confirmed
- Leeds Teaching Hospitals NHS Trust (Page 7) – not confirmed
- Liverpool University Hospitals NHS Foundation Trust (Page 10) – not confirmed
- Northern Care Alliance NHS Foundation Trust (Page 13) – not confirmed
- University Hospitals Birmingham NHS Foundation Trust (Page 15) – not confirmed

Surgical centres

Performance indicator 6*:* Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).

For men who underwent a radical prostatectomy between 1 September 2021 and 31 August 2022.

- Wirral University Teaching Hospital NHS Foundation Trust (Page 16) – confirmed
- Bradford Teaching Hospitals NHS Foundation Trust (Page 19) – confirmed

Radiotherapy centres

Performance indicator 7: Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).

For men who underwent radical prostate radiotherapy between 1 September 2021 and 31 August 2022.

- University Hospitals of Derby and Burton NHS Foundation Trust (Page 23) – confirmed

[2] NPCA Outlier Policy 2025 - National Cancer Audit Collaborating Centre

- Gloucestershire Hospitals NHS Foundation Trust (Page 24) – not confirmed
- University Hospitals Dorset NHS Foundation Trust (Page 27) – not confirmed

The responses from individual outlier trusts in relation to their potential outlier ‘alarm’ status are as follows:

Response from Wirral University Teaching Hospital NHS Foundation Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

Dear NPCA colleagues,

At The Clatterbridge Cancer Centre, we deliver a centralised oncology services to a network of seven acute trusts across the region. I can confirm that we are fully compliant with the Systemic Anti-Cancer Therapy (SACT) submission requirements, and all SACT treatments (including hormone therapies) have been submitted in a timely manner.

Following the identification of one of our network trusts as a potential outlier, we conducted validation of our SACT data. We identified seven patients that belonged to our Trust from the list provided by NPCA (using the local ID), out of which all patients were not outliers as they did receive treatment with Apalutamide/ Triptorelin within 12 months (we provided details of these cases to the NPCA and acute hospital teams).

We are unsure why the treatment records are not evident in the NPCA data flow and will liaise with our Northwest Data Liaison Manager to confirm whether there are any outstanding issues related to the transition.

Regards,

Dr. Helen Wong

Quality Manager (Audit & Statistics)

Data send to: ccf-tr.ccoaudit@nhs.net

The Clatterbridge Cancer Centre NHS Foundation Trust

Response from Royal Marsden NHS Foundation Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

The ROYAL MARSDEN
NHS Foundation Trust

The Royal Marsden
Fulham Road
London SW3 6JJ
Tel: 020 7352 8171
Royalmarsden.nhs.uk

National Prostate Cancer Audit
National Cancer Audit Collaborating Centre
The Royal College of Surgeons
38-43 Lincoln's Inn Fields
London
WC21 3PE

Dear NPCA Project Team,

Re : Potential Outlier Alarm Notification

Thank you to the NPCA for highlighting this important issue. We have reviewed our data internally and have identified some data issues which we are now working on. An internal audit of our data indicates that we are prescribing additional therapy for M1 patients in line with national standards. Therefore, it has been confirmed that our Trust is not an outlier for this performance indicator.

Yours sincerely,

Professor Nicholas van As
Chief Medical Officer

Response from Leeds Teaching Hospital NHS Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

Dear Alison Tree, Noel Clarke and the NPCA audit team,

We write in response to your letter identifying Leeds Teaching Hospital NHS Trust (LTHT) as a potential outlier in relation to the proportion of men under 75 years old AND 75 years and over with metastatic disease receiving systemic treatment intensification therapy (patients diagnosed in 2022).

For context, the advanced prostate cancer service in Leeds is delivered by four consultant medical oncologists, who have site specialisation in the management of urological malignancies, with a practice supported by clinical nurse specialists and a pharmacy prescriber.

In response to your letter we have (1) requested and reviewed the shared NCPA data, (2) undertaken a snap shot audit of patients with metastatic prostate cancer discussed in our Prostate MDT in the first three months of 2022, (3) retrieved and analysed data around SACT cycle 1 for patients under our care for metastatic hormone sensitive prostate cancer in 2022 and (4) escalated to our Lead Clinician and the Leeds Teaching Hospitals NHS Trust Cancer Team.

1. Does the trust consider the NPCA data to be accurate in comparison to your hospital records?

No.

These data are inaccurate both in terms of the patient group identified as having metastatic prostate cancer and the number of patients receiving SACT.

<u>Inaccuracies and issues with the NPCA data</u>

The NPCA data has identified 59 men aged <75 years and 65 men aged >75 years with newly diagnosed metastatic prostate cancer in this time period (124 men total). The audit states that 20.6% and 11.3% of these men received SACT, respectively. This would suggest that just 19 (12 + 7) men received treatment intensification in Leeds during 2022.

We have had three weeks to review this data and our own records.

It has been challenging to identify some of the patients included in the NPCA.

We are unable to identify 28 men from information provided by NPCA.

NPCA identifies 124 men diagnosed with metastatic prostate cancer in 2022; our local clinical system (PPM) finds 108. There is poor consistency between these data. Only 58 of 108 are included in NPCA data.

<u>We have identified the following flaws to the data:</u>

Response from Leeds Teaching Hospital NHS Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

- Of identifiable patients, a number of these have not been seen, diagnosed or treated with SACT in Leeds (n= 18)
- The cohort includes patients treated for localised prostate cancer (n=4; 3 radical radiotherapy, 1 brachytherapy)
- For men >75, none of the NCPA SACT data is accurate. All patients recorded as receiving SACT were treated elsewhere or unidentifiable (n = 7); none of the patients in this cohort given SACT in Leeds were recorded (n=10).

Review of LTHT data

Within this short timeframe we are limited in our ability to complete a full re-audit to identify our patient cohort and identify the proportion of those men that received treatment intensification. A formal audit has been initiated but in the time available we have established the following:

1. A simple Chemocare search of patients with a diagnosis of metastatic hormone sensitive prostate cancer receiving cycle one of SACT in 2022 identifies 86 treated patients: Docetaxel (n= 35), Enzalutamide (n=20), Abiraterone (n=1), and Apalutamide (n=30).

2. We have performed a snapshot audit using data from our MDT from January to March 2022. Please see attached document.

2. Subject to the data being accurate, are there justifiable reasons for the variation that mean the trust should not be considered an outlier for this performance indicator?

The data are not accurate.

3. Have quality improvement measures been put in place in order to correct potential problems in the future?

We have found that the data provided by the NPCA team is not a true reflection of practice at LTHT. We do feel that there is an opportunity in LTHT to look at a system we could introduce to record this patient cohort going forward, for quality and audit purposes. This can then be submitted to the database on which the NPCA draws its dataset for review. We are in discussion about the best way forward to implement a local database, in order to identify any issues locally and provide robust data for submission nationally for the NPCA in the future.

We would hope for support and resources from the NPCA to work collaboratively in accurately reviewing the 2022 data and more importantly, to move towards more robust quality assurance processes in future to prevent further issues and ensure patient confidence.

Response from Leeds Teaching Hospital NHS Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

Summary and Conclusion:

We have significant concerns regarding the missing data and discrepancy between patients identified by the audit and our actual patient population.

Other national data, though covering all prostate cancer indications for SACT, does not support the very low levels of SACT recorded in the NCPA. National Disease Registration Service data shows that more patients with prostate cancer diagnosis were treated with SACT in West Yorkshire and Harrogate (in which Leeds is a large centre) 2013-22 than on average across England (9.3% compared to 8.5%)[3].

LTHT was not an outlier in NHS England review of Case-Mix adjusted 30 day mortality after SACT for prostate cancer in England 2018-19. That data showed we treated 117 patients (case mix adjusted 30 day mortality 9.5).

We trust that the NPCA data for our trust will not be published in its current form. This would have a significant detrimental impact on the reputation of the Leeds Cancer Centre. Additionally, this would cause high anxiety amongst patients treated in our service, as well as undermining their confidence in the care that we and LTHT provides.

Yours sincerely,

Mr Conor Devlin, Consultant Urologist, LTHT

Dr Helen Dearden, Dr Satinder Jagdev, Dr Christy Ralph and Dr Naveen Vasudev

Consultant Medical Oncologists, LTHT

[3] https://nhsd-ndrs.shinyapps.io/cancer_treatments/ accessed 18 July 2025

Response from Liverpool University Hospital NHS Foundation Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

Dear Prof. Clarke and Dr. Tree,

We would like to thank you for the recent notification regarding our potential alarm outlier status for men being commenced on systemic anti-cancer treatment in 2022, as part of the National Prostate Cancer Audit (NPCA). As per your recommendation we requested the trust's patient-level data and conducted an in-depth review of each patients records.

Having had the opportunity to review the data, we conclude that the data is inaccurate in comparison to our hospital records and that our performance is in line with national averages. As such we believe that we are not an outlier for this performance indicator. Given that there is no significant variation, we do not believe quality improvement measures are necessary. Furthermore, we request that you do not publish our results in the report, data tables / dashboards, or include them in control charts (funnel plots) as per your NATCAN outlier policy.

Please see below a summary of the data for both the over 75 and under 75 cohorts. The excel spreadsheet with individual breakdown of data can be provided on request.

Over 75 cohort

	NPCA data (n)	LUHFT data (n)
Metastatic	75	71
Non-metastatic	0	4
No SACT	67	55
Received SACT	8	16
% of M1 receiving SACT	10.70%	22.50%
We note that 13.4% is the cut off at which this trust would be deemed an outlier		
Breakdown of those not receiving SACT		
	LUHFT data (n)	%
Diagnosis NOT in 2022	2	2.8
No identifier	5	7
Identifier not recognised	5	7

Response from Liverpool University Hospital NHS Foundation Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

Limited notes	3	4.2
Deemed unfit	22	31
Against national guidance	1	1.4
No documented reason	17	23.9
Total	55	

Under 75 cohort

	NPCA data (n)	LUHFT data (n)
Metastatic	82	80
Non-metastatic	0	2
No SACT	52	26
Received SACT	30	54
% of M1 receiving SACT	36.60%	67.50%

We note that 48.9% is the cut off at which this trust would be deemed an outlier, and our performance of 67.5% is above the national average.

Breakdown of those not receiving SACT

	LUHFT data (n)	%
No identifier	2	2.5
Identifier not recognised	8	10
Does not live in area	1	1.25
Limited notes	4	5
Deemed unfit	10	12.5
Declined SACT	1	1.25
Total	26	

Response from Liverpool University Hospital NHS Foundation Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

There were several themes coming from our data analysis that are summarised thus:

- When NPCA stated SACT was started within 12 months this was always correct although there were some minor discrepancies with the exact date the patient was started on SACT, usually with the start date being 1-2 months shorter than NPCA had stated.
- There were a significant number of cases, especially in the under 75 cohort, where NPCA had a patient as not starting SACT, but this was incorrect.
- A small proportion of patients in both groups were not metastatic and so should be excluded from analysis for this performance indicator.
- There were a significant number of patients in each group where either a local identifier was not provided, the local identifier was not recognised or there were very limited data due to issues in sharing data between trusts which meant we were unable to corroborate data accuracy. **In these patients, the NPCA data was deemed accurate for inclusion in the final analysis.** We believe that there are likely to be similar discrepancies between NPCA data and our data in this group and therefore our figures are likely to reflect an underestimate of the true figure.
- For the reasons outlined above, we believe that the number of patients commenced on SACT declared on our own data analysis is therefore a conservative estimate and likely underestimates the true number.

We thank NPCA for the opportunity to check this data and would welcome working with NPCA do improve data accuracy and quality for future years.

Kind regards,

Benjamin Starmer
Consultant urologist and departmental audit lead
Liverpool University Hospitals NHS Foundation Trust.

Response from Northern Care Alliance NHS Foundation Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

Christie Hospital NHS
NHS Foundation Trust

Telephone: 0161 446 3364

Email: noel.clarke@nca.nhs.uk

28th August 2025

Re: NCA Outlier Status NPCA 2025 SoTN Report

Dear Marina

Further to your letter regarding the NCA's "outlier" status I have been in discussion with Alex Hoyle, clinical lead for urology at NCA, and Sotonye Tolofari, both Consultant Urological Surgeons. It seems a little strange answering my own letter (!) but be reassured, I do so on their behalf because of the relatively unusual circumstances of the NCA / Salford Royal SMDT and the inter-relationship with The Christie when it comes to SACT prescribing for advanced prostate cancer patients.

As we have discussed in the NPCA executive meetings there are some notable "SACT outliers" which, on critical examination have been proven to have been designated in this way because the SACT-based prescribing data for the SMDT's serving those institutions has been fundamentally flawed. This is exemplified by the data for The Royal Marsden Hospital, which featured as a big under-prescriber initially. Further interrogation was made on the basis that "The Marsden", as one of the largest prostate cancer treatment centres in the UK, would be an unlikely outlier and this did prove to be the case. The Christie is another large SACT prescriber and it is the largest prostate cancer treatment centre in the UK: its under-performance in SACT proscribing seems similarly doubtful. The Greater Manchester cancer network which ramifies throughout that conurbation is also unusual in that virtually all the SACT prescribing comes from Christie-based clinicians working in a networked manner in peripheral clinics in hospitals like the ones incorporated in the NCA trust.

Salford Royal has been assimilated into an over-arching trust called the Northern Care Alliance (NCA), comprising Salford Royals and the 3 hospitals serving Bury, Oldham and Rochdale. Cases from Bury and Rochdale are discussed at the Salford Royal SMDT, which also looks after Bolton and Wigan (a cumulative population close to 1.5 million), whilst the Oldham-based patients have their cases discussed at the prostate cancer SMDT based at The Christie. Decisions regarding future treatment using SACT for the Salford/NCA SMDT are documented at the weekly NCA SMDT but treatment is usually prescribed at the peripheral hospitals by visiting Christie doctors. It is likely therefore that the documentation for patients is not being recorded properly, much in the way that there was a problem at The Royal Marsden.

It should be possible to obtain SACT prescription data for Greater Manchester as any SACT prescription has to be approved centrally in Manchester before funding can be granted. I will look into this but this process will take a few weeks and the result will fall beyond the deadline date for production of the SoTN Report by the NPCA. In light of this I would be grateful if you

Response from Northern Care Alliance NHS Foundation Trust

Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

would consider removing the NCA "dot" from the funnel plot displayed in the forthcoming SotN report.

In answer to your direct questions:

1. Does the trust consider the NPCA data to be accurate in comparison to your hospital records?

It is highly likely that the NPCA data on SACT prescribing at the NCA is inaccurate relative to the "actual" numbers receiving SACT

2. Subject to the data being accurate, are there justifiable reasons for the variation that mean the trust should not be considered an outlier for this performance indicator?

The numbers of patients and shortfall in SACT prescribing suggested in your figures do not seem plausible given the population size of patients with advanced prostate cancer seen and treated within the NCA.

3. Have quality improvement measures been put in place in order to correct potential problems in the future?

The intention of conducting a full audit on this topic, which will be the focus of the NCA team in the near future, will hopefully address the question of whether or not there is a shortfall in SACT prescribing, and if there is, to correct it.

Yours Sincerely

Noel W. Clarke MBBS, FRCS(Eng), ChM, FRCS(Urol)

Consultant Urological Surgeon

Professor of Urological Oncology

The Christie and Salford Royal Hospitals

Manchester UK

Response from University Hospitals Birmingham Hospital NHS Foundation Trust
Performance indicator 4: *Proportion of men with newly diagnosed hormone-sensitive metastatic disease receiving systemic treatment intensification within 12 months of diagnosis (under 75 years old and 75 years and older)*

Response from Wirral University Teaching Hospital NHS Foundation Trust

Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

Thank you for your correspondence and for sharing the patient dataset related to the outlier alert concerning 2-year genitourinary complications requiring procedural or surgical intervention following radical prostatectomy at Wirral University Hospitals NHS Trust.

We have thoroughly reviewed the patient cohort and would like to provide the following detailed response and clarification:

1. **Patient Numbers and Data Review**

Your dataset identified 90 patients from Wirral Hospitals who underwent radical prostatectomy during the reporting period (1 September 2021 – 31 August 2022). However, our internal records indicate that a total of 135 patients were operated on by two surgeons during this period.

We have therefore reviewed all 135 patients, including both the original 90 and the additional 45 not listed in the NPCA dataset.

2. **Summary of Complications**

- Of the 90 patients in your dataset:
  - **20 patients** had at least one recorded complication.
  - **7 patients** had a second recorded complication.
  - **1 patient** had a third recorded event.
- Among the additional 45 patients:
  - **9 patients** had secondary interventions.

This results in 29 patients with at least one recorded event among the total 135 patients.

3. **Clinical Relevance of Events**

Upon detailed review:

- **6 of the 29 events** were not related to surgical complications or did not require significant genitourinary intervention. These included:
  - 1 case of recatheterisation for hematuria,
  - 2 interventional radiology drain insertions for lymphoceles,
  - 1 wound infection managed with antibiotics,
  - 1 circumcision for phimosis,
  - 1 TURBT for an incidental bladder tumour.

This leaves **23 (17%)** patients who underwent procedures directly related to post-prostatectomy urinary complications.

4. **Breakdown of Relevant Complications**

- **Urinary Leaks (2 patients, 1.4%):**

- One had prolonged catheterisation post-difficult surgery
- The second patient was re-catheterised for an anastomotic leak and then subsequently, after catheter removal, developed bladder neck stenosis due to Hem-o-lok clip migration.

- **Clip Migration with Bladder Neck Stenosis (4 patients, 2.8%):**
  - There were four patients who developed voiding symptoms over the two-year period and, on investigation, were found to have Hem-o-lok clip migration. They were managed with cystoscopy, dilatation, and/or BNI. All are currently stable.
- **Urethral Strictures (3 patients, 2.2%):**
  - Subtypes: meatal stenosis, submeatal stricture, and bulbar stricture.
- **Diagnostic Cystoscopies (10 patients, 7.4%):**
  - 1 for incontinence (AUS referral)
  - 1 rigid cystoscopy at patient request
  - 8 flexible cystoscopies (various indications – hematuria, split stream)

5. **Reflections and Actions**

- **Urinary Leak Rate (2 patients, 1.4%):**
  - Falls within reported leak rates in literature(1–6%). One of the leaks in hindsight could have been anticipated due to a very difficult operation.
  - **Action**: Planning to introduce routine cystograms prior to catheter removal in complex cases.
- **Clip Migration (4 patients, 2.8%):**
  - Higher than expected.
  - **Action**: Reviewing surgical technique and clip type; considering reduced use of Hem-o-lok clips or alternative options.
- **Stricture Rate (2.2%):**
  - Within expected range.
  - **Action**: Assessing the potential impact of catheter type and reviewing intraoperative catheter protocols.
- **Cystoscopy Usage:**
  - Approx. 7.4 % underwent flexible cystoscopy, occasionally for uncertain indications.
  - **Action**: Cystoscopies to be performed or reviewed by the primary operating surgeon to reduce unnecessary investigations.

6. **Conclusion**

Response from Wirral University Teaching Hospital NHS Foundation Trust
Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*
We believe the complication rates observed fall largely within expected national ranges. The slightly higher rate of clip-related complications is being actively addressed. We are committed to continuous audit and quality improvement, and plan to resurrect our own local database, as it would allow us to identify potential issues and help take early remedial actions. We do appreciate the opportunity to review and reflect on our outcomes. Please let us know if any further clarification or data is required

Response from Bradford Teaching Hospitals NHS Foundation Trust

Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

Dear Professor Clarke & Dr Tree

National Prostate Cancer Audit (NPCA)

Thank you for your letter dated 25th June 2025 sent to Mr Molokwu (Consultant Urological Surgeon) regarding the potential outlying performance of Bradford Teaching Hospitals NHS Foundation Trust with respect to the following performance indicator:

Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within two years of radical prostatectomy (presented at the level of the surgical centre). For men who underwent a radical prostatectomy between 1 st September 2021 and 31st August 2022.

We appreciate the feedback that we receive from NPCA as it provides an opportunity to assess our practise and compare with our peers nationally. These are helpful in focussing our attention on areas of concern to improve our practise and provide improved care for our patients.

At the outset we would like to clarify that locally recorded data shows we operated on 158 patients during this period, higher than those reported in your letter (136), which would bring the percentage down to 15.1%. We appreciate this would still trigger an outlier status. We have assessed 29 patients whom we have identified as having urinary complications as defined by NPCA. These have been listed in the table included at the end of this letter.

Our findings are as follows:

Over a period of two years post-robotic prostatectomy ('RALP') with or without pelvic lymph-node dissection ('PLND'), 24 patients overall underwent a flexible cystoscopy for a variety of reasons.

Haematuria investigations were the commonest indication in nine patients, of these: one was found to have a bladder transitional cell carcinoma ('TCC'), one further patient had a 1cm vesical calculus, the remaining seven flexible cystoscopies were unremarkable. LUTS of varying degrees post-surgery were reported by 15 patients.

On evaluation, two patients were noted to have an anastomotic stricture, which was subsequently dilated under general anaesthetic. Another had a Hemolock clip migration into the anastomosis. Urethral strictures (two) and a meatal stenosis were further findings observed.

No abnormality was noted in the remaining nine patients.

Two patients had early catheter issues, one had a blockage which necessitated a change and the second reported dislodgment of the catheter which was replaced easily.

We had two patients develop a urinary leak post-RALP; both these patients had required a bladder neck repair during the RALP itself. These resolved with drainage of the urinoma and catheterisation until healing was confirmed on cystography.

Response from Bradford Teaching Hospitals NHS Foundation Trust

Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

One patient had urodynamics for severe stress urinary incontinence and subsequently underwent placement of an artificial urinary sphincter ('AUS'), which has helped resolve the incontinence.

One patient unfortunately developed a recto-urethral fistula, presenting almost two weeks postoperatively with diarrhoea and sepsis. He was managed by placement of a suprapubic catheter ('SPC') and a sigmoid colostomy. He has since had a successful recto-urethral fistula repair at Sheffield and the colostomy has been reversed. That robotic prostatectomy was deemed straightforward by the surgeon without any additional complicating factors. The blood was 80cc and the total operating time for his RALP and PLND (Gleason 4+4 disease) was two hours.

We have noted that in our cohort of patients there is a substantially higher proportion of locally advanced disease (54%) compared to the national average of 37%. These are technically more challenging with wider excisions and a higher likelihood of bladder neck repairs. We do a twolayered repair with 'V-lock' in preference to non-braided sutures. In addition, the Bradford cohort presents a significantly lower proportion of low risk patients (4%) than the national average (9%).

As a team, we have noted that a high percentage of patients are undergoing flexible cystoscopies post-RALP. Investigations for haematuria sometimes require this and in two patients, treatable causes were identified. We have noted bladder neck and urethral/meatal strictures in five patients. Nine flexible cystoscopies were clear and were likely performed to reassure patients. We have recently changed our approach to using uroflowmetry, rather than invasive cystoscopy, as a first line to investigate these patients in acknowledgement that our threshold for undertaking a flexible cystoscopy was possibly too low.

In summary, we feel that after excluding our flexible cystoscopies for haematuria (seven) and a further nine for mild LUTS where no findings were noted, we had 13 patients who required intervention for urinary issues. We feel the bladder TCC and vesical calculus should be excluded from the analysis as these are unrelated. We would therefore conclude that 11 patients with positive findings truly necessitated interventions that should be attributed to the RALPs (11/158 = 6.9%).

Of these, two patients had early catheter issues which were resolved with straightforward replacement. Percutaneous urinoma drainage and catheterisation resolved the situation for two further patients. Surgical endoscopic intervention was required in five patients with bladder neck/urethral and meatal dilatation (four patients), and Hemolock clip removal (one patient). Serious complications necessitating open surgery were required for only two patients; the placement of AUS in one patient and multiple surgical interventions required to resolve a rectourethral fistula in another.

We are hopeful that our analysis will address the concerns raised. Please let us know if any further information is required.

Response from Bradford Teaching Hospitals NHS Foundation Trust

Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

Kind regards,

John Bolton MD FRCS

Acting Chief Medical Officer &

Consultant Urological Surgeon

On behalf of:

R Chahal, Consultant Urological Surgeon

C Gkikas, Consultant Urological Surgeon

C Molokwu, Consultant Urological Surgeon

R Singh, Consultant Urological Surgeon

R Guest, Senior General Manager

P Munjuluri, Consultant Obstetrician and Gynaecologist

N Rushton, Patient Safety Manager

L Tomlin, Head of Quality Improvement and Clinical Outcomes

Table

Intervention for urinary symptoms/ complications	**No. of Patients**
Flexible cystoscopy NAD	9
Flexible cystoscopy for haematuria clear	7
Flexible cystoscopy for haematuria: Bladder TCC	1
Flexible cystoscopy for haematuria: Vesical calculus	1
Meatal dilatation	1
Bladder neck dilatation	2
Urethral dilatation	1
Catheter changes (dislodged and blockage)	2
Clip removal	1
AUS	1

Response from Bradford Teaching Hospitals NHS Foundation Trust	
Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*	
SPC & Colostomy for recto-urethral fistula	1
US guided drainage of urinoma	2
	29

Response from University Hospitals of Derby and Burton NHS Foundation Trust
Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Response from Gloucestershire Hospitals NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Gloucestershire Oncology Centre
Cheltenham General Hospital
Sandford Road
Cheltenham
GL53 7AN
29th July 2025

Dear Dr Tree, Mr Clarke and the NPCA team,

We write in response to your email of 24th June 2025 addressed to our Urology MDT lead concerning our centre's results for the following metric in the National Prostate Cancer Audit:

Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (GI complication) up to 2 years following radical prostate radiotherapy (patients treated 1st September 2021 – 31st August 2022.)

You kindly sent us partially anonymised individual patient data allowing us to investigate this finding in detail, which we did through our uro-oncology peer review framework.

In response to your questions:

1. **Does the trust consider the NPCA data to be accurate in comparison to your hospital records?**

Our records for this period suggest we treated 274 men with radical prostate radiotherapy. This is higher than the 206 cases reported in the NPCA. We include in this total one man who received ultra-hypofractionated treatment as part of the PACE trial and several additional cases where variation in planning system (ARIA) course codes might have influenced how their treatment course was represented in the national RTDS. We have not included those who received 20 fraction treatments in the context of low volume metastatic prostate cancer.

We found 20 cases of proven radiation toxicity after 'a procedure of the large bowel' (which we interpreted as diagnostic endoscopic examination) in the 2 years following radical radiotherapy. We were able to exclude from the list of cases you sent to us several where other causes of altered bowel habit were diagnosed, in the apparent absence of radiation toxicity. Several men appeared to have had *asymptomatic* referrals to bowel cancer screen services after positive qFit testing and as a result we did not feel these men could be defined as having a grade 2 radiation toxicity.

Overall, our findings appeared to bring us much closer to the national average than previously suggested:

Response from Gloucestershire Hospitals NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

DATA OVERVIEW 29 July 2025: Gloucestershire Hospitals NHS Foundation Trust
Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy.

	Gloucestershire Hospitals	England
Number of patients who had radical prostate radiotherapy between 1 September 2021 and 31 August 2022	274	13,773
Percentage patients having a procedure of the large bowel and a diagnosis indicating radiation toxicity within 2 years	7%	8.1%

2. **Subject to the data being accurate, are there justifiable reasons for the variation that mean the trust should not be considered an outlier for this performance indicator?**

Yes. We reflected on our case load at this time and the huge challenges to our normal system of working due to the COVID-19 pandemic. We treated far fewer patients in this year than our average. Many were assessed remotely where they would normally have been assessed face to face. We wondered if more men with pre-existing undiagnosed bowel issues might have been treated because of this.

3. **Have quality improvement measures been put in place in order to correct potential problems in the future?**

Yes. We now have a robust uro-oncology peer review process and in the last year have adjusted our prostate radiotherapy planning process to fall in line with regional ODN guidance and the protocols of the PIVOTAL and PACE trials. We recruited to both of these trials after successfully completing the necessary RTQA.

Please let us know if you would like more information from our centre supporting our findings.

Thank you for involving us in the findings of the NPCA.

Yours sincerely,

Response from Gloucestershire Hospitals NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Warren Grant, Consultant Clinical Oncologist

On behalf of the Urology MDT at Gloucestershire Hospitals NHS Foundation Trust

Response from University Hospitals Dorset NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

NHS
University Hospitals Dorset
NHS Foundation Trust

Poole Hospital
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Poole
Dorset
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Tel: 01202 665511
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Dear NPCA team,

On behalf of the team at UHD, please kindly review our response to the notification of potential outlier status within the NPCA regarding performance indicator 7.

Review of local database
On receipt of the notification of potential outlier status, we requested the database kept by the NPCA and cross-referenced this with our local record of patients treated within the reference timescale. The information held by the NPCA was incomplete and we were able to update and verify that the number of patients treated was greater than that recorded by the national audit. We also reviewed the patients who were highlighted as meeting performance indicator 7 and found that a number of patients were designated in error. This was largely due to pre-existing plans for surveillance endoscopies for other pathologies in otherwise asymptomatic patients.

Likely underlying causes
Since liaising with the NPCA, our centre is no longer regarded as an outlier. Despite this, our rate of patients affected within performance indicator 7 was above the national average of 8.1%. As such we believe that there may be a number of reasons why our result is as it is. Our practice locally at this time increased the number of patients undergoing pelvic nodal irradiation and as such, our GI toxicity rate was likely to increase following the increased use. Furthermore, our previous dose and margins were greater with a primary dose of 60Gy with a 5mm margin to the prostate (+/- extra prostatic extension) and 52Gy with a 10mm margin to the prostate and included seminal vesicles (+/- extra-prostatic extension).

Remediation
In 2023, our local radiotherapy protocol was updated so that our target margins had reduced and we believe this will have a significant impact on the rates of GI toxicity to follow. Our high dose remains 60Gy but with a reduced margin of 3mm. Our secondary dose is reduced to 47Gy with a tighter margin of 6mm. As such, the overall volume has reduced in size and therefore less rectum and bowels will be included within the treatment field. Since the introduction of the PEARLS trial locally in 2024/2025, we have also tightened our OAR tolerances to reflect the constraints within the PEARLS/PACE trials. Again, this will have an overall positive impact on our GI toxicity rates moving forward. We continue to use daily on-set imaging which again will help to reduce the dose being administered to the rectum and bowels.

Response from University Hospitals Dorset NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Conclusion
Our local review of the data suggests that we are within 2 standard deviations of the national mean. As a centre, we will always strive to do the best for our patients to ensure the best Oncological outcome and survivorship. We have taken steps to improve our radiotherapy technique by reducing margins and secondary doses and this will inevitably have a positive impact on our GI toxicity rates. We will remain vigilant and engaged in any response from the NPCA.

Best wishes,

Dr. Matthew Roberts
Consultant Clinical Oncologist
University Hospitals Dorset

Responses from Trusts to the Potential 'outlier' alert 'case to answer' during the NPCA Outlier Policy[4]

Each Trust was contacted by means of a letter to the Clinical Lead. The letter contained an aggregate table explaining the distribution of certain patient characteristics of the patients of interest from their trust compared to national demographics. Trusts were also provided, on request, with a password protected spreadsheet which contained patient level data to support the review.

The following trusts were contacted in relation to the following specific performance indicators. Their final outlier status is also indicated.

Surgical centres

Performance indicator 6*:* Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).

For men who underwent a radical prostatectomy between 1 September 2021 and 31 August 2022.

- East and North Hertfordshire NHS Trust (Page 30) – confirmed

Radiotherapy centres

Performance indicator 7: Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).

For men who underwent radical prostate radiotherapy between 1 September 2021 and 31 August 2022.

- University Hospitals of North Midlands NHS Trust (Page 33) – confirmed
- East Suffolk and North Essex NHS Foundation Trust (Page 40) – not confirmed

The responses from individual outlier trusts in relation to their potential outlier 'alert' status are as follows:

[4] NPCA Outlier Policy 2025 - National Cancer Audit Collaborating Centre

Response from East and North Hertfordshire NHS Trust

Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

Dear Team

Many thanks for the opportunity to reply to this latest outlier data.

(GU toxicity 11% ct 16% previously.)

We did a deep dive into this same issue in 2024 and discovered a strong and direct link between the development of bulbar urethral structures relating to 2 issues

Catheters left for longer than 10 -14 days post RALP coupled with too large a catheter at 18F

Compared to one of our surgeons who left a 16F catheter for maximum 8 days who had a much lower than National average stricture rate

Very useful learning information for other units if a suggestion for a switch to larger catheters or delays in TWOCs occur

This latest PROM was too early to see a change as only we introduced the 7 days 16F rule in 2024.

It will take until 2026/7 before we see a reasonable reduction in GU toxicity although we have already seen a reduction form 16-11% in the NPCA data.

Please see original deep dive sent in to NPCA in 2024 below:

Dear Team,

Thank you for the opportunity to respond to the GU toxicity outlier notification. As the 6th highest volume centre in the NCPA, we are very keen to resolve this.

In a bid to understand the potential reasons for being an outlier, as a department of 13 Urologists we have presented and debated the possible causes of this. We have undertaken a full interrogation of the NPCA data and our own prospectively updated RALP dataset with in-house analysis performed independently from the RALP surgeons and presented to the department on 14/2/24 at our monthly audit meeting.

The NPCA have identified 29/177 (16.4%) patients with a GU toxicity intervention recorded on HES. This is compared to the National average of 7%.

Firstly, I agree that the NPCA data is close to accurate. From our own prospective database, we actually performed 200 RALPs at the Trust between 1/9/19 and 31/8/20 meaning our audit / coding team missed 23 cases.

When we have looked at the full 200 RALPs, 31/200 (15.5%) had a GU toxicity intervention according to the HES codes used by NPCA as per Appendix 3 of the Methodology Supplement of the State of the Nation Report. I understand, this is still an outlier even if we included all procedures performed. None of the 200 patients had received prior or subsequent radiotherapy. Only one of these GU interventions was

Response from East and North Hertfordshire NHS Trust

Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

performed outside our Trust and we have managed to obtain the data on that as well. We feel, therefore, that we have analysed this dataset comprehensively.

When we have looked at the GU intervention cases in more detail, we have identified that there are some patients with a planned intervention and some unplanned. We do feel there is a difference between planned and emergency GU toxicity codes.

The breakdown of the 29/177 patients

Planned

Seven out of 29 including 2 planned stent removals, and 5 planned elective outpatient flexible cystoscopies, all of which were normal.

Unplanned

Excluding the 7 cases above, only 22/29 patients had an actual true GU toxicity. This would give an overall GU toxicity intervention percentage across all 177 cases of 12.4%. Of these, 15/22 had a true bulbar-urethral stricture requiring dilation and 4/22 had a meatal stenosis requiring dilation. This is a 10.7% (19/177) stricture rate.

The remaining cases were made up of 2/22 needing recatheterising temporarily and 1/22 needing a stent insertion for poorly draining dilated hydronephrosis post RALP.

There were NO anastomotic strictures or AUS insertions in the whole 200 cohort.

Individual surgeon analysis

We decided to separate the GU intervention codes per surgeon to see if we could identify where the issue could be solved.

During this time period there were 3 surgeons performing RALP. Using the NPCA data from 177 operations,

Surgeon 1 performed 41 cases with GU toxicity incidence 4.88% (2 patients)

Surgeon 2 performed 112 cases with GU toxicity incidence 16.96% (19 patients)

Surgeon 3 performed 24 cases with GU toxicity incidence 33.3% (8 patients)

If we exclude the elective GU codes such as pre-existing stent removal or normal flexible cystoscopies as mentioned above, then the individual surgeon GU toxicity percentages per cases performed change:

Surgeon 1 GU toxicity incidence 4.88% (2 GU toxicity patients)

Response from East and North Hertfordshire NHS Trust

Performance indicator 6: *Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).*

Surgeon 2 GU toxicity incidence 11.61% (13 GU toxicity patients)

Surgeon 3 GU toxicity incidence 29.17% (7GU toxicity patients)

Clearly Surgeon 1 was below the national average in this group and we have discovered that the catheter size and average length of catheterisation time is most likely the contributing factor.

If we look at surgeon differences regarding catheter size used and length of time to TWOC it is outlined below:

Surgeon 1 - 16Fr catheter median 8 days of catheterisation

Surgeon 2 -18Fr catheter median 13 days of catheterisation

Surgeon 3 -18Fr catheter median 13 days of catheterisation

We believe that the NPCA has identified a problem that we were not aware of and so are grateful to the NPCA team and their work in improving National patient outcomes.

Our plan going forward is to see if we can achieve the Surgeon 1 results by all surgeons switching to a size 16Fr catheter and reducing average length of catheterisation to 7-8 days. We believe that Surgeon 2 and 3 will achieve improved non outlying results by the next audit.

Mr Jim M Adshead

MA MD FRCS(Urol)

Response from University Hospitals of North Midlands NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

29/02/2024

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ST4 6QG
Tel: 01782 715444

Secretary: 01782 672569
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Email: oncology.faxes@nhs.net

Department of Oncology

To NPCA Team

Thank you for your email correspondence, notifying us at the University Hospitals of North Midlands NHS Trust, Stoke-on-Trent, of our potential outlier status. The 2-year gastrointestinal complications following radical radiotherapy indicator, for 219 men undergoing radical radiotherapy for prostate cancer between the 1st of September 2019 and the 31st of August 2020, at our centre, show that we are an outlier. We have reviewed the data you shared with us, and this is our response.

In England, 10% of patients undergoing radiotherapy experienced at least one gastrointestinal complication requiring a procedural / surgical intervention within 2 years after radical radiotherapy, with radiotherapy centres ranging from 3-17%. Our result is 17.3%.

We have been cognisant of the fact that our Cancer Centre's GI toxicity rate was higher than the national average, even before the National Prostate Cancer Audit 2023 was published.

See figure 1. In autumn 2022, we had a multidisciplinary team meeting with our clinical oncologists, medical physicists, and radiotherapy planning department for a deeper dive into why our patients are experiencing more GI side effects and to put some countermeasures in place to mitigate against this. Previous NPCA reports showed that we were still within three standard deviations of the mean.

Figure 1

Response from University Hospitals of North Midlands NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Publication Date	Year of Treatment	N	% of 60Gy / 20#	UHNM Toxicity	National Average	Lowest in the WM region
2018	2015	143	0.0%	9%	10%	5%
2019	2016	174	32.5%	12%	10%	5%
2020	2017	202	72.3%	12%	11%	8%
2021	2018	77	85.5%	20%	11%	3%
2022	2019	198	85.7%	14%	10%	5%

Before November 2022, we checked that planned doses to the bladder and the rectum agreed, with predicted doses using an in-house programme, to predict bladder and rectum DVH parameters. If rectal doses were outside tolerance, patients would be re-planned, provided there was no geometrical or anatomical reason for exceeding the predicted dose, for example prostatic hip.

An internal audit to going back to 2014, showed that bladder and rectal doses was consistent over that period.

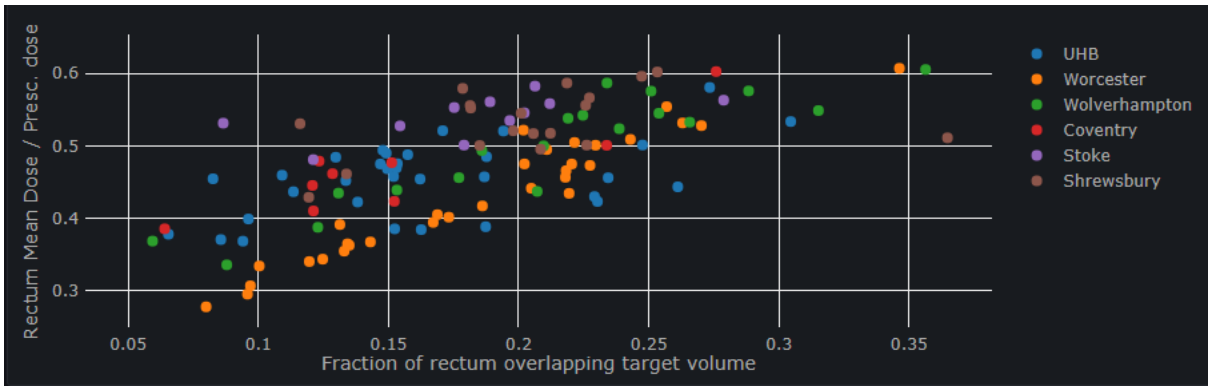
Within our network we have 6 cancer centres. Birmingham (UHB). Coventry, Wolverhampton, Stoke, Shrewsbury and Worcester. Another small audit of 60Gy/20# prostate patients, by the West Midlands Operational Delivery Network carried out over the summer 2022 showed:

1. Our PTV coverage was like other centres within the region.
2. Our high dose rectum stats were comparable to other centres.
3. Our bladder V50Gy was comparable to other centres.
4. But our intermediate dose rectum stats (V30Gy and V40Gy) were higher than some other centres.

In autumn 2022 results of a West Midlands regional prostate cancer audit, show that across the region we were getting higher rectal doses. Everyone was using the CHiPP trial dose limits data, which encourages centres to constrain the higher doses. It appeared that the lower rectal doses were not consistent across the region, as the lower CHiPP dose constraints can be achieved without much focus on meeting the target. It was clear that the mean dose to the rectum should be lower

for patients with less overlap of the PTV and rectum and this was observed in some centres but was not the case at UHNM. (Figure 2).

Figure 2



The equation in figure 3, was used to predict mean rectal dose based on overlap with PTV. This is not only patient specific but also scan specific is a bigger rectal volume will decrease the expected mean dose. We agreed that whether the link between toxicity and V30Gy is real or not, we should be aiming to reduce intermediate dose to the rectum as other centres have demonstrated that it's possible to do this without compromising PTV coverage.

Figure 3

$$\frac{D_{mean}}{D_{Px}} = A + B\left(1 - exp\left(\frac{CV_{ovr}}{V_{OAR}}\right)\right)$$

Powis, R., Bird, A., Brennan, M., Hinks, S., Newman, H., Reed, K., Sage, J. and Webster, G. (2017). Clinical implementation of a knowledge based planning tool for prostate VMAT, *Radiation Oncology*, 12(1):81.

In the NPCA 2021 report, we couldn't understand why our toxicity jumped to 20% but we also see that the number of patients was only 77, which is more than half the number for other years. (Range 143-202). We feel that result is more exaggerated but was still a concern for us. Given the consistency in our planning we were not convinced that it had a dosimetry explanation, but it was still a good idea to reduce the rectal doses as low as possible. (Figure 6)

Response from University Hospitals of North Midlands NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Post November 2022, we have implemented was method to control the mean rectal dose and to continue with our internal programme to ensure consistency of higher doses. We hope that this intervention will show in future NPCA audits that our GI toxicity comes down dramatically.

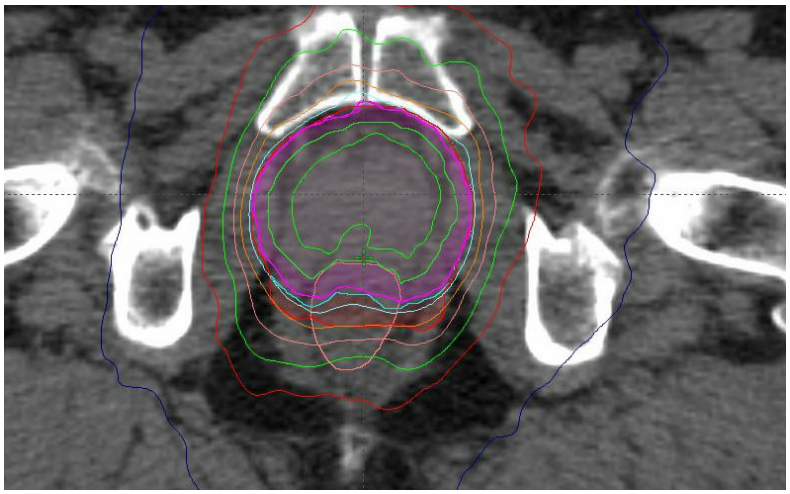


Figure 4 Pre mean rectal dose predictor.

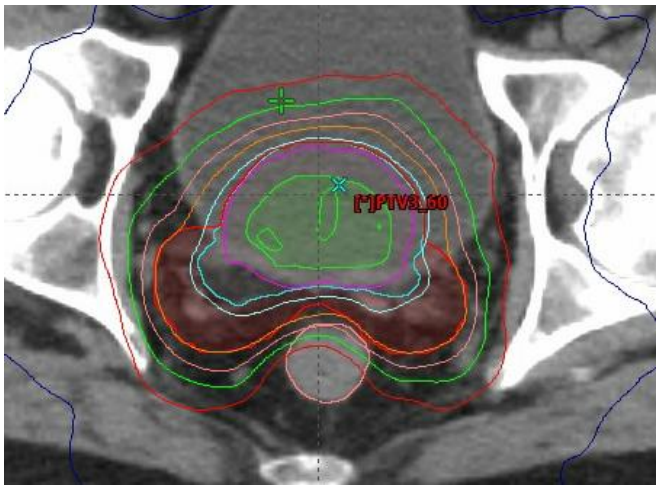


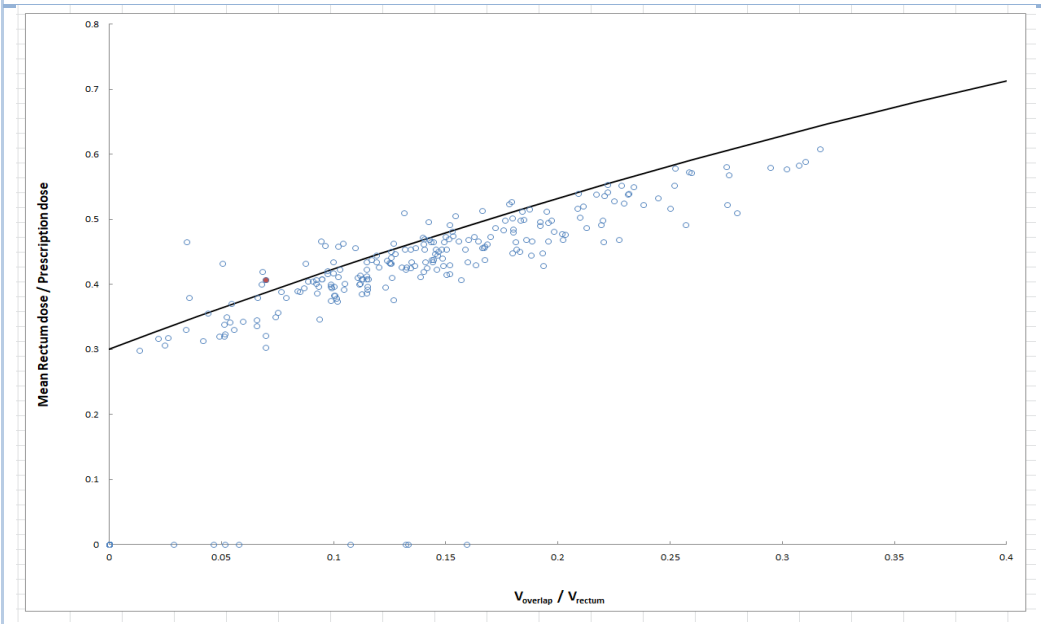
Figure 5 Post mean rectum dose predictor.

Figure 4 and 5 illustrates how we can sculpt off the dose from the rectum with Rapid Arc.

Figure 6

Response from University Hospitals of North Midlands NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*



This month we have collected mean rectum dose data from 925 patients starting from April 2016 (figure 7). We didn't have enough time to collect data for every patient in this period but from looking at the data we think we can assume that our planning technique is consistent between 2016 and 2022. In 2016 we switched over from 74Gy/37# to 60Gy/20#; to allow us to compare like with like we've scaled the 74Gy/37# mean rectum doses to what they would have been if they were planned as 60Gy/20# - these patients are represented by the orange data points. The horizontal blue dashed lines represent 2 standard deviations of the mean for the 2016 data and the blue data points represent the mean for each year. The vertical dashed line represents the point at which we switched over to using the mean rectum dose predictor (MRDP). The key points are:

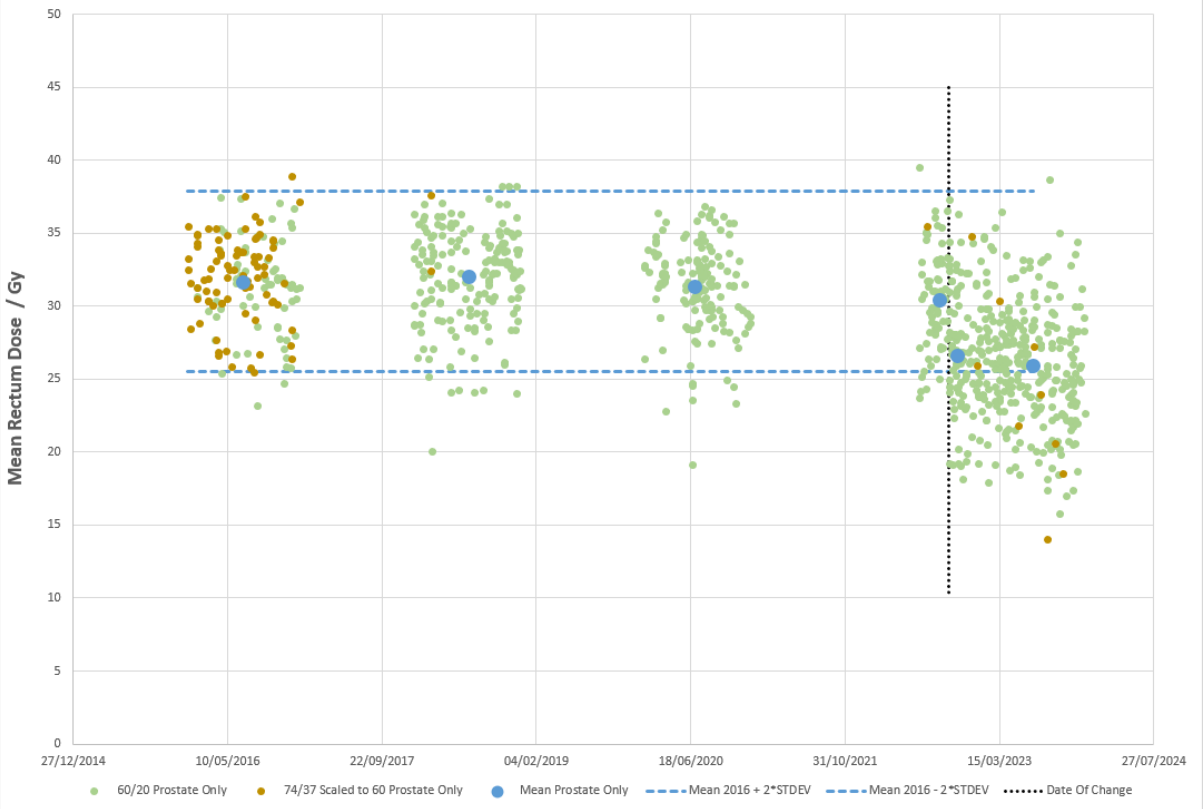
- The mean rectum dose and interpatient variation has remained consistent between 2016 and the point at which we introduced the MRDP.
- Use of the MRDP has resulted in the population mean rectum dose reducing from approximately 31Gy to 26Gy.
- The mean rectum dose is consistent between 74Gy/37# and 60Gy/20# (when scaled for the change in prescription dose)

From the data, we can conclude that there have been no step changes or gradual drift in our mean rectum dose so it would be hard to attribute the increase in GI toxicity with unintended changes in the rectal dose. I do not think it will be possible to investigate the link further until we know which patients have reported GI toxicity so we could see if these patients had a higher-than-

Response from University Hospitals of North Midlands NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

average rectum dose. Is it possible for you to unblind the 219 patients, so that we can continue with our exploration?



In addition to the work above, we introduced a rectal spacer service in October 2020 at UHNM. NICE guidance IPG590, from 2017 states that Biodegradable Spacer insertion could be used to reduce rectal toxicity during radiotherapy for prostate cancer. There was safety and efficacy data and on the back of the Innovation Technology Payment (ITP) programme to get the service up and running, we have used the hydrogel in more than 150 men, mostly with intermediate risk prostate cancer. We have been prospectively auditing our data using EPIC-CP Tool, Expanded prostate cancer index composite for clinical practice and we have an audit ongoing in these patients. We are hopeful that this will also show a downward late toxcity GI and GU trend in future audits.

Other positive things within our department is the Halycon linacs which deliver faster treatments with less chance of internal organ movement, the use of MVision, AI autocontouring to bring about more contouring consistencies bewteen CTVs and OARs, more stable consultant workforce with less reliance on agency doctors and more focus on peer review for standardisation, quality control, education and training and protocol adherence.

Response from University Hospitals of North Midlands NHS Foundation Trust
Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*
We believe that we have been a response department in tackling these issues. We have learnt from others and adopted and implemented changes and our commitment to learning and improving together is strong. All the changes that we have made in the last 2-3 years will not be reflecting in your current data but this is indeed a watch metric for us. If you believe that a go, look, learn approach to an external center would benefit us, we would be happy to comply. Equally, we would welcome a external audit team to come and visit us and provide suggestions for improvement. We look forward to your acknowledgement of this reply as well as any advice on moving forward. Thank you also for the excellent data and all the work that goes on to produce this document. Yours thankfully, Dr Rajanee Bhana MBBCh, MRCP, FRCR, PGcert, SCE and ESMO (Medical Oncology 2022) Consultant Clinical Oncologist Clinical Director for Oncology, Haematology, Palliative Care, Allery and Immunology and Medical Physics University Hospitals of North Midlands NHS TRUST, Cancer Centre, Stoke on Trent, ST4 6GQ Office: 01782 672595 Mobile: 07720 705 591 rajanee.bhana@uhnm.nhs.uk

Response from East Suffolk and North Essex NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Dr Liz Sherwin,

Clinical Director

Oncology and Haematology

East Suffolk and North Essex NHSFT

Ipswich Hospital

Heath Road

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IP4 5PD

Dr Alison Tree and Mr Noel Clarke

Oncological and Urological Clinical Leads

National Prostate Cancer Audit

29th July 2025

Dear Dr Tree and Mr Clarke,

National Prostate Cancer Audit (NPCA) Potential Outlier Notification

Thank you for your letter dated 24.06.25 to Mr Sam Datta notifying us that the East Suffolk and North Essex NHS Foundation Trust (ESNEFT) is a potential 'alert' outlier for the following Performance Indicator:

Proportion of patients receiving a procedure of the large bowel and diagnosis indicating radiation toxicity (GI complication) up to 2 years following radical prostate radiotherapy

We understand that the ESNEFT data demonstrates that the trust is >2SDs from the national average for two consecutive years with a result of 12.2% for patients commencing radical radiotherapy to the prostate in the 2 years from 1st September 2020.

Thank you for providing us with the patient-level data items for the 2 years this notification relates to. ESNEFT has two radiotherapy departments, one based on the Colchester Hospital site and the other on the Ipswich Hospital site. Separate teams of Clinical Oncologists, Therapeutic Radiographers and Medical Physicists staff each site and consequently operational practices in relation to the planning and delivery of radiotherapy do differ for some tumour sites.

The patient level data has been separated based on where the patient received their radiotherapy.

Response from East Suffolk and North Essex NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

Table 1 summarises the Colchester and Ipswich data. More events relate to patients receiving their radiotherapy in Colchester and the number of events is greater than 2SDs from the national average. The number of events relating to patients receiving their radiotherapy in Ipswich is in line with the national average.

Table 1

Publication Date	Year of Treatment	Colchester		Ipswich		National Result
		Number of Events	Toxicity	Number of Events	Toxicity	
2024	2020	31	20.1%	13	8.5%	10%
2025	2021	19	12.8%	12	8.0%	8.1%

A review of the completeness and accuracy of the data has commenced. Patient records along with endoscopy results and other investigations have been reviewed for each patient. Table 2 shows how many patients have had confirmation of radiation induced toxicity following endoscopy. A cohort of patients were found to have alternative bowel conditions that either pre-existed their radiotherapy treatment or were not found to be associated with their treatment such as polyps. No information is available for a further cohort of patients either because there is no record relating to endoscopy or because the patients are under the care of another hospital trust.

Table 2

Site	Publication Date	Year of Treatment	Reported Events	Confirmed Radiation Events	No Information	Other Causes
Colchester	2024	2020	31	22	7	2
	2025	2021	19	14	3	2
Ipswich	2024	2020	13	8	-	5
	2025	2021	12	6	1	5

Even though the number of confirmed radiation events is lower than those reported, the data still indicates higher rates of GI toxicity in Colchester patients in comparison to Ipswich.

A deep dive of those patients with confirmed toxicity is being undertaken focusing on:

Response from East Suffolk and North Essex NHS Foundation Trust

Performance indicator 7: *Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).*

- Radiotherapy treatment plan quality and adherence to protocolised margins and dose constraints
- Radiotherapy treatment plan delivery including daily CBCT image guidance and position of bowel and rectum in relation to high dose volumes during daily treatment

Whilst it has not yet been possible to complete a full dosimetric analysis of all treatment plans and daily dose delivery, our preliminary findings are:

- Toxicity events were associated with patients receiving prostate only radiotherapy and prostate and pelvic node radiotherapy (PPN)
- Prescribed doses were consistent with the clinical protocols
- Target volume delineation and CTV to PTV margins were consistent with the clinical protocols
    - CTV to PTV margins defined in the clinical protocols differ between Colchester and Ipswich. It is acknowledged that this difference leads a larger volume of rectum within the high dose volume for the Colchester treatment plans
- Rectal contours were defined for all patients. In Colchester the bowel was only contoured for patients receiving PPN treatment
- Rectal and bowel dose constraints defined in the clinical protocols were in line with nationally accepted dose constraints.
    - As rectal dose constraints are based on relative volumes and not absolute, it is acknowledged that the volume of the rectum in the planning CT will determine whether a plan meets dose constraints.
- All Colchester plans met all mandatory rectal dose constraints.
- Four Ipswich plans did not meet some mandatory dose constraints for the rectum, these patients have confirmed radiation proctitis.
    - The prescribing clinical oncologist is responsible for reviewing all treatment plans and dose distributions and determining whether to compromise PTV coverage to meet constraints
- One Colchester PPN plan did not meet some mandatory dose constraints for bowel, this patient has confirmed radiation proctitis.
    - Further analysis will be needed to determine whether bowel constraints would have been met for prostate only patients
- Differences in the imaging protocols for daily CBCT image guidance between Colchester and Ipswich mean that larger volumes of rectum and bowel are accepted within the treatment volumes in Colchester than in Ipswich. Whilst we have not had the opportunity to complete a full dosimetric analysis of the treated volumes and organ at risk doses,

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initial offline review demonstrates that the volume of rectum included within the treatment volume is consistently higher than planned for the Colchester patients.

Our findings indicate that the consistently higher levels of GI toxicity in patients receiving radiotherapy to the prostate in Colchester are most likely due to the protocol for CBCT image guidance. The protocol allows a higher volume of rectum and bowel within the treatment volumes than indicated within the planning CT. Consequently the doses to the rectum and bowel are likely to be higher than indicated in the dose statistics for the treatment plan.

Our immediate action is to review and implement the necessary changes to CBCT image guidance and daily localisation together with the acceptable daily variation in patient positioning and internal anatomy

Our review of the individual patients and data has indicated that a number of other areas where action is required that may lead to a reduction GI toxicity. The clinical oncologists will lead a multi-disciplinary team reviewing the image guidance along with the following crosssite:

- Dose prescription
- Bowel preparation and determination of acceptable volumes for treatment planning
- The impact of the introduction of auto-segmentation. MVision was implemented on both hospital sites in March 2024 and has resulted in consistent voluming of normal tissues and organs at risk. In addition it has enabled the monitoring of bowel dose constraints for prostate only patients in Colchester
- CTV to PTV margins
- Decision making process regarding patients continuing to treatment when mandatory dose constraints are not met in the treatment plan

We acknowledge that changes to be implemented as a result of the multi-disciplinary teams considerations will not come into effect until the 2025/26 data collection and that toxicity events for patients receiving radiotherapy to the prostate at Colchester Hospital are likely to remain higher than the national average for a further 3 data collection periods.

Please let us know whether there is any further information that you require from us at this time.

Your sincerely

Dr Liz Sherwin

Clinical Director

Oncology and Haematology

ESNEFT