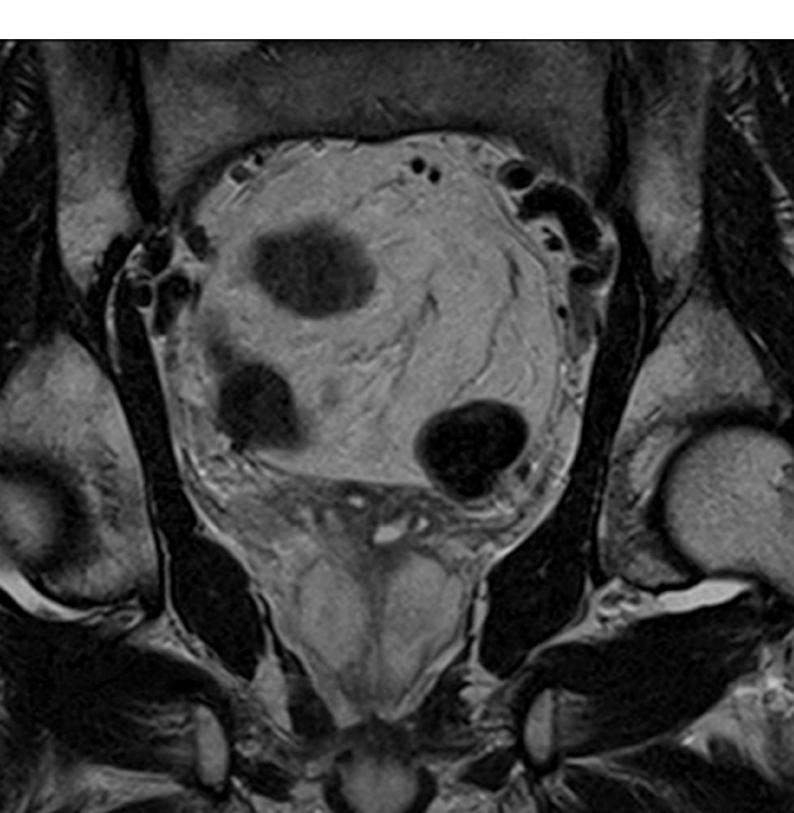




National Prostate Cancer Audit State of the Nation report 2023

Outlier Communications



National Prostate Cancer Audit

NPCA State of the Nation report 2023 Outlier Communications



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The British Uro-oncology Group (BUG) was formed in 2004 to meet the needs of clinical and medical oncologists specialising in the field of urology. As the only dedicated professional association for uro-oncologists, its overriding aim is to provide a networking and support forum for discussion and exchange of research and policy ideas. Registered Charity no: 1116828



This work uses data that has been provided by patients and collected by the NHS as part of their care and support. For patients diagnosed in England, the data is collated, maintained and quality assured by the National Disease Registration Service (NDRS), which is part of NHS England. Access to the data was facilitated by the NHS England Data Access Request Service.



NHS Wales is implementing a new cancer informatics system. As a result, the quality and completeness of data from Wales is likely to have been impacted due to implementation of this new system across multiple NHS organisations (Health Boards), which has resulted in data being supplied by both old and new systems.

Additionally, and reflecting the uncertainty of data quality, the data submitted to the audit may not have undergone routine clinical validation prior to submission to the Wales Cancer Network (WCN), Public Health Wales

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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 <u>funnel plots</u> to compare individual hospital 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 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 twice in a row before it is considered an 'alert' was added to reduce the chance that a Trust / Health Board is erroneously identified as a potential outlier. There are no 'alert' Trusts in the current report cycle (State of the Nation 2023) as an outlier process was not carried out in the previous year (Annual Report 2022).

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 2023) were considered potential outlier 'alarm' Trusts according to the NPCA Outlier Policy 2023. The outlier approach was adapted from the 'NCAPOP Outlier Guidance: Identification and management of outliers'¹.

The potential outlier 'alarms' relate to two adjusted treatment-related outcomes.

Performance indicator 5: 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 6: 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).

Following notification of outlier status each trust was given the opportunity to review their individual data and check this against the NPCA data gathered from their hospital. The trust was then invited to respond by letter to the NPCA executive, about the possible underlying causes, and any relevant improvements interventions adopted/ or planned.

The CQC was not notified as part of this year's audit process.

From 2024, the NPCA team will provide teams with a hospital identifier linked to data gathered from their hospital to reduce the burden for staff carrying out patient level case reviews as part of the outlier process.

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 03012024.pdf

Responses from Trusts to the 'Potential' outlier alarm 'case to answer' during the NPCA Outlier Policy²

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 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:

Surgical centres

Performance indicator 5: 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 2019 and 31 August 2020.

- East and North Hertfordshire NHS Trust (page 5)
- Bradford Teaching Hospitals NHS Foundation Trust (page <u>7</u>)

Radiotherapy centres

Performance indicator 6: 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 2019 and 31 August 2020.

- University Hospitals of North Midlands NHS Trust (page <u>9</u>)
- Sheffield Teaching Hospitals NHS Foundation Trust (page <u>15</u>)

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

² https://www.npca.org.uk/wp-content/uploads/2024/01/NPCA-Outlier-Policy-2023 FINAL 050124.pdf

Response from East and North Hertfordshire NHS Trust

Performance indicator 5: 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 NPCA 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, we agree that the NPCA data is almost 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 didn't upload 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 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 catheter related stricture requiring dilation and 4/22 had a catheter related 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 177 or 200 cohort.

Response from East and North Hertfordshire NHS Trust

Performance indicator 5: 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).

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)

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 better than 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 Surgeons 2 and 3 will achieve improved non outlying results by the next audit

We look forward to the NPCA response and very happy to share the detailed HES analysis of the 29/177 if needed .

Mr Jim M Adshead

MA MD FRCS(Urol)

Response from Bradford Teaching Hospitals NHS Foundation Trust

Performance indicator 5: 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 Sir/Madam

Thank you for your email dated the 12th of January 2024 regarding the potential outlying performance of BTHFT with respect to the following performance indicator:

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 2019 and 31 August 2020.

I have assessed the 25 patients who have been listed in the attached Excel spreadsheet. My findings are as follows:

Over a period of 2 years post Robotic prostatectomy (with or without pelvic lymph-node dissection) 20 patients overall underwent a flexible cystoscopy for a variety of reasons.

LUTS post RALP was the commonest reason in 10 patients. Of these, 5 patients complained of a poor flow. On evaluation one patient was noted to have an anastomotic stricture which was subsequently dilated under GA and another had a hemolock clip which had migrated into the anastomosis. No abnormality was noted in the remaining 3 patients. Three patient had storage urinary symptoms, none of these had an abnormality noted at flexible cystoscopy. Two further patients had severe storage symptoms post salvage radiotherapy and were noted to have post radiotherapy changes. Five patients had an episode of haematuria which necessitated assessment along with upper tract imaging.

One patient had an early episode of urinary retention post TWOC and was noted to have a patent anastomosis at flexible cystoscopy. A short period of catheterisation resolved the issue. Another patient complained of excessive spraying and possibly had an unnecessary flexible cystoscopy for reassurance.

Three patients had flexible cystoscopy and urodynamics as part of assessment for urinary incontinence. None of these have undergone any surgical treatment as pelvic floor exercises have helped reduce the level of incontinence to 1-2 pads per day.

Four patients had cystograms to assess the anastomosis post bladder neck repair to ensure full healing prior to removal of catheter. No intervention has subsequently been necessary.

1 patient had a colonoscopy and no urological intervention or assessment has been undertaken for this patient.

Response from Bradford Teaching Hospitals NHS Foundation Trust

Performance indicator 5: 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).

In summary, of the 25 patients, flexible cystoscopy was performed in 20 patients of which only 2 patients had a subsequent operative procedures, one for dilatation of a stricture and the second for removal of a migrated clip. Four further patients had cystograms to assess healing of the anastomosis.

Please let us know if any further information is required.

Performance indicator 6: 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).

Date: 29/02/2024

Cancer Centre
Royal Stoke University Hospital
Newcastle Road
Stoke-On-Trent
ST4 6QG
Tel: 01782 715444

Secretary: 01782 672569

Fax: 0844 272 8462

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 Table 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.

Table 1

Publication	Year of		% of	UHNM		Lowest in the
Date	Treatment	N	60Gy / 20#	Toxicity	National Average	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%

Performance indicator 6: 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).

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 1).

Figure 1



The equation in figure 2, 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.

Performance indicator 6: 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).

Figure 2

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

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 5)

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.

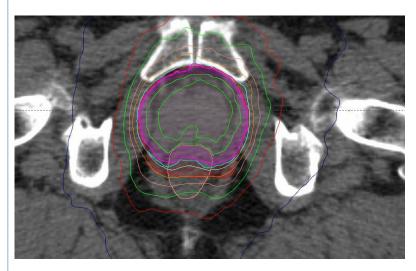


Figure 3 Pre mean rectal dose predictor.

Performance indicator 6: 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).

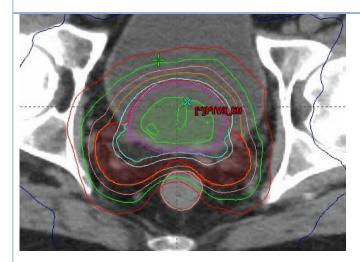
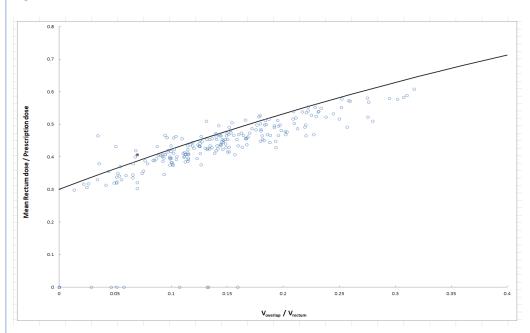


Figure 4 Post mean rectum dose predictor.

Figure 3 and 4 illustrates how we can sculpt off the dose from the rectum with Rapid Arc.

Figure 5



This month we have collected mean rectum dose data from 925 patients starting from April 2016 (figure 6). 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

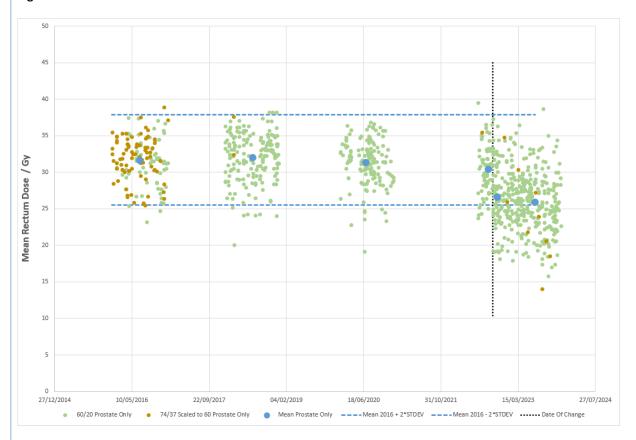
Performance indicator 6: Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).

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

Figure 6



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

Performance indicator 6: 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).

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.

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

[contact details removed]

Response from Sheffield Teaching Hospitals NHS Foundation Trust

Performance indicator 6: 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).



Sheffield Teaching Hospitals

NHS Foundation Trust

Clinical Effectiveness Unit Sheffield Teaching Hospitals NHSFT 21 Claremont Crescent SHEFFIELD S10 2TA

Tel: 0114 2713858 janet.brain@nhs.net

Noel Clarke & Ajay Aggarwal Urological and Oncological Clinical Leads National Prostate Cancer Audit The Royal College of Surgeons of England 38-43 Lincoln's Inn Fields London WC2A 3PE

29 February 2024

Private and Confidential

Dear Mr Clarke and Dr Aggarwal

Re: NPCA Potential Outlier Notification

Thank you for your letter to Mr Aiden Noon of 22 January 2024 informing of the information recorded in relation to radical radiotherapy which set our Trust outside the expected 'alarm' limits for the national mean rate for genitourinary (GU) complications. Upon review of the data, I can see this should have said gastrointestinal (GI) complications (17.1% compared with the England average of 10%) and hence this response relates to GI rather than GU complications.

A local review of the completeness and accuracy of the aggregate data has not yet been possible, due to operational pressures in the Trust at this time. However, the clinical team have provided the following response by way of explanation.

The adjusted percentage of men receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity within two years after radical radiotherapy (GI complication) for STH remains above the National figure by 7%. This data applies to patients having undergone radiotherapy in 2018/19. A previous deep dive was carried out in 2020 (relating to men treated in 2016) of the 55 patients who reported toxicity. On closer analysis, 17 of these patients had an alternative bowel condition or pathology identified after their radiotherapy. These alternative pathologies could also explain bowel symptoms post radiotherapy. Patients who have preexisting GI issues cannot be excluded from the NPCA so would still be included in the data. Additionally, the type of radical radiotherapy given and the access to modern equipment and techniques at Sheffield Teaching Hospitals NHSFT would possibly have more impact on the GI complications.

We have implemented changes since then to improve practice and specifically reduced bowel and rectal radiation doses that is unlikely to reflect an improvement in results (of reducing the proportion of GI complications) until data for patients having undergone radiotherapy from 2021 onwards are made available.

The changes that have been implemented since 2019 include:

- Switching to VMAT technique radiotherapy treatment for all patients so the dose distribution is more conformal
- MRI fusion planning which allows more accurate delineation of the prostate
- Margin for the treated high dose radiation volume is reduced (CHIIP trial margins)
- Daily CBCT image guidance is done for radiotherapy treatment
- A cohort of patients have a Space OAR to reduce rectal radiation dose
- Appropriate reduction in number of patients receiving pelvic lymph node radiotherapy

The on-going national data collection for 2022/23 should hopefully demonstrate further improvements.

I hope this is acceptable, but please let me know if anything further is required at this stage.

Yours sincerely

J. Brain

Janet Brain Senior Manager, Clinical Effectiveness Unit Sheffield Teaching Hospitals NHS Foundation Trust

Additional information

Sheffield Teaching Hospitals NHS Foundation Trust is currently undertaking a comprehensive review of the completeness and accuracy of the aggregate data. The NPCA Team will publish the findings from this as an addendum to the document later in 2024.