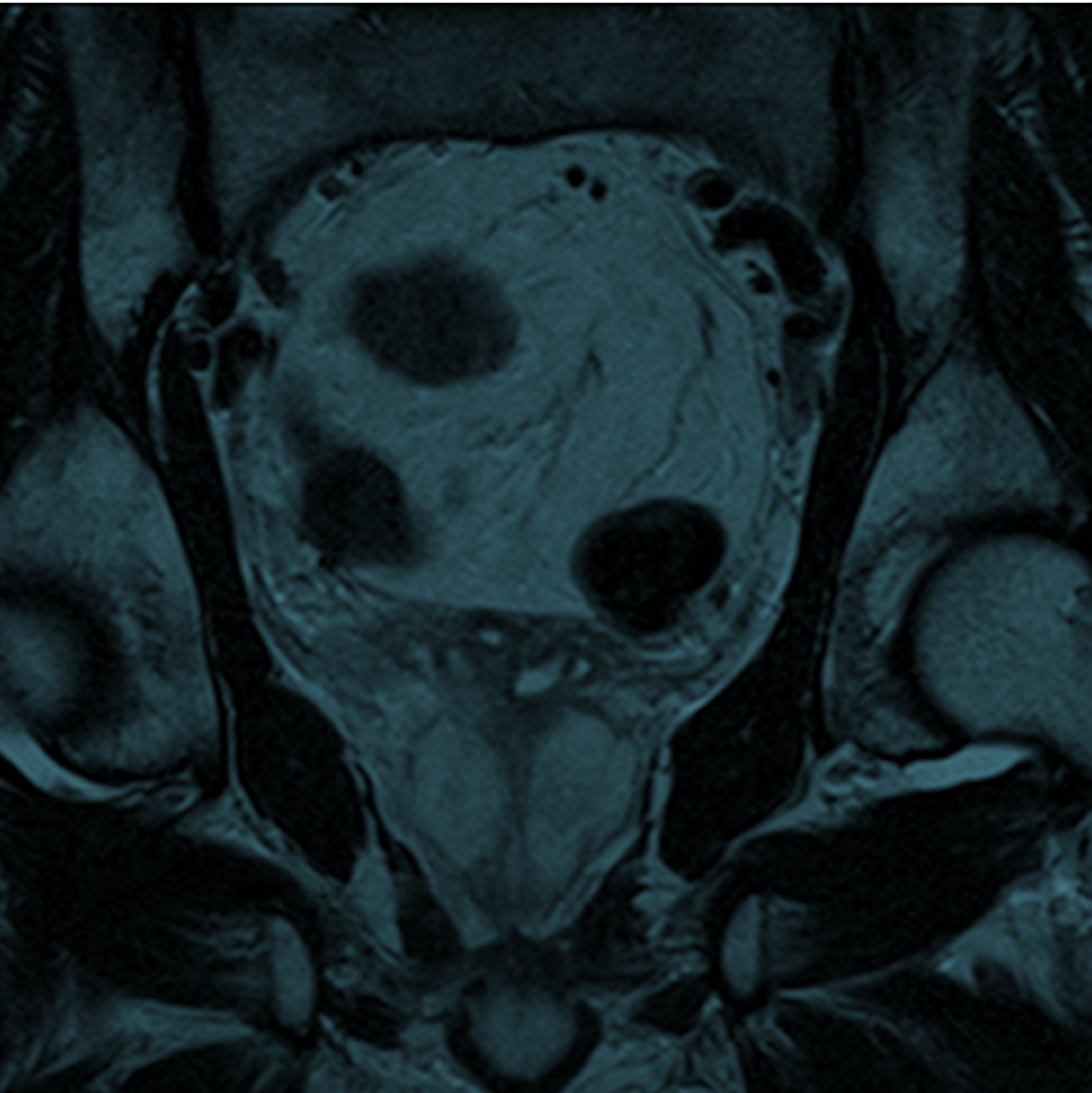
NPCA
National Prostate Cancer Audit

Annual Report 2019

Results of the NPCA Prospective Audit in England and Wales for men diagnosed from 1 April 2017 to 31 March 2018 (published January 2020).



National Prostate Cancer Audit

Sixth Year Annual Report – Results of the NPCA Prospective Audit in England and Wales for men diagnosed 1 April 2017 – March 2018

London: The Royal College of Surgeons of England, 2020.

Registered Charity No: 212808

The Royal College of Surgeons of England (RCS) is an independent professional body committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care. As part of this it supports Audit and the evaluation of clinical effectiveness for surgery.

The NPCA is based at the The Clinical Effectiveness Unit (CEU). The CEU is an academic collaboration between The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine, and undertakes national clinical audits and research. Since its inception in 1998, the CEU has become a national centre of expertise in methods, organisation, and logistics of large-scale studies of the quality of surgical care. The CEU managed the publication of the NPCA Annual Report, 2019.

In partnership with:

The British Association of Urological Surgeons (BAUS) was founded in 1945 and exists to promote the highest standards of practice in urology, for the benefit of patients, by fostering education, research and clinical excellence. BAUS is a registered charity and qualified medical practitioners practising in the field of urological surgery are eligible to apply for membership. It is intended that this website will be a resource for urologists, their patients, other members of the healthcare team and the wider public.

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.

National Cancer Registration and Analysis Service (NCRAS), Public Health England collects patient-level data from all NHS acute providers and from a range of national data feeds. Data sources are collated using a single data processing system ('Encore') and the management structure is delivered through eight regional offices across England.

The NCRAS is the data collection partner for the NPCA.

Commissioned by:

The Healthcare Quality Improvement Partnership (HQIP) is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the National Clinical Audit Programme, comprising more than 30 clinical audits that cover care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual audits, also funded by the Health Department of the Scottish Government, DHSSPS Northern Ireland and the Channel Islands.

Published January 2020 by the National Prostate Cancer Audit

The Royal College of Surgeons of England
35–43 Lincoln's Inn Fields
London
WC2A 3PE

T 020 7869 6601
E npca@rcseng.ac.uk
www.npca.org.uk

Designed @ www.superbirdcreative.co.uk

Copyright © 2020 Healthcare Quality Improvement Partnership (HQIP)

Contents

Acronym list

Androgen Deprivation Therapy (ADT)

British Association of Urological Surgeons (BAUS)

British Uro-Oncology Group (BUG)

Cancer Network Information System Cymru (CaNISC)

Cancer Outcomes and Services Dataset (COSD)

Clinical Effectiveness Unit (CEU)

Clinical Nurse Specialist (CNS)

Clinical Outcomes Programme (COP)

Clinical Reference Group (CRG)

Expanded Prostate Cancer Index Composite 26-item (EPIC-26)

External Beam Radiation Therapy (EBRT)

Gastrointestinal (GI)

General Practitioner (GP)

Genitourinary (GU)

Healthcare Quality Improvement Partnership (HQIP)

Hospital Episode Statistics (HES)

Intensity Modulated Radiation Therapy (IMRT)

International Classification of Disease (ICD)

Kilovoltage Imaging (KV imaging)

Magnetic Resonance Imaging (MRI)

Minimum Data Set (MDS)

Multi-Disciplinary Team (MDT)

National Cancer Patient Experience Survey (NCPES)

National Cancer Registration and Analysis Service (NCRAS)

National Clinical Audit and Patient Outcomes Programme (NCAPOP)

National Clinical Audit Benchmarking (NCAB)

National Health Service (NHS)

National Institute for Health and Care Excellence (NICE)

National Prostate Cancer Audit (NPCA)

National Radiotherapy Data Set (RTDS)

Office for National Statistics (ONS)

Office of Population Censuses and Surveys (OPCS)

Patient Episode Database for Wales (PEDW)

Patient-Reported Experience Measure (PREM)

Patient-Reported Outcome Measure (PROM)

Prostate Specific Antigen (PSA)

Public Health England (PHE)

Radical Prostatectomy (RP)

Royal College of Surgeons (RCS)

The Index of Multiple Deprivation (IMD)

Tumour, Nodes, Metastases (TNM)

Wales Cancer Network (WCN)

Welsh Cancer Intelligence and Surveillance Unit (WCISU)

Acknowledgements

The National Prostate Cancer Audit (NPCA) is commissioned by the Healthcare Quality Improvement Partnership (HQIP)[1] and funded by NHS England and the Welsh Government as part of the National Clinical Audit and Patient Outcomes Programme. The audit is a collaboration between the Clinical Effectiveness Unit (CEU) at the Royal College of Surgeons of England (RCS), the British Association of Urological Surgeons (BAUS) and the British Uro-oncology Group (BUG).

The Project Team would like to thank all urologists, uro-oncologists and their clinical and non-clinical teams at NHS Trusts in England and Health Boards in Wales who collected and submitted data for the audit. Your support is key to enabling the NPCA to evaluate the care that men receive following a diagnosis of prostate cancer in England and Wales and whether this care reflects recommended guidelines and quality standards. For the first time, the NPCA compares NHS Providers in England identifying any potential outlying performance related to both short and medium-term treatment outcomes following radical treatment. A report summarising the key results will be published in a patient friendly format in Spring 2020.

We are grateful to the NPCA data collection partners including the National Cancer Registration and Analysis Service (NCRAS), Public Health England (PHE)[2] and the Wales Cancer Network, Public Health Wales for supporting NPCA data submissions from Trusts and Health Boards and for supplying data for this report.

We would like to thank BAUS and BUG for their continued professional guidance and for raising awareness amongst urological and uro-oncological colleagues.

This report was prepared by members of the NPCA Project Team:

Clinical Effectiveness Unit, The Royal College of Surgeons of England and LSHTM

Matthew Parry, NPCA Clinical Research Fellow

Julie Nossiter, NPCA Audit Lead

Thomas Cowling, NPCA Data Analyst

Ajay Aggarwal, Clinical Audit Coordinator (Oncology)

Paul Cathcart, Clinical Audit Coordinator (Urology)

Jan van der Meulen, NPCA Chair and Methodological Lead

Arun Sujenthiran, NPCA Clinical Research Fellow

Brendan Berry, Academic Clinical Fellow

The British Association of Urological Surgeons

Noel Clarke, NPCA Urological Clinical Lead

The British Uro-Oncology Group

Heather Payne, NPCA Oncological Clinical Lead

With support from:

The National Cancer Registration and Analysis Service (NCRAS), Public Health England (PHE)

Natasha Wood, NCRAS Audit Manager

Eleanor Fitzgerald, Cancer Intelligence Analyst

Saffron Norkett, Cancer Intelligence Analyst

Jem Rashbass, Director for National Disease Registration

NCRAS Data Liaison and Registration teams

Wales Cancer Networks, Public Health Wales (PHW)

Julia Thomas, Wales Information Specialist
Hywel Morgan, Wales Cancer Network Lead

[1] The NPCA is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing, and National Voices. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual projects, other devolved administrations and crown dependencies https://www.hqip.org.uk/national-programmes/

[2] Data for the NPCA in England is based on patient-level information collected by the NHS, as part of the care and support of cancer patients. The data is collated, maintained and quality assured by the National Cancer Registration and Analysis Service, which is part of Public Health England.

With review by:

The NPCA Clinical Reference Group:

Roger Kockelbergh (Chair), Consultant Urological Surgeon, Urology Expert Advisory Group, NCRAS, PHE

Stephen Allen, Patient representative, Tackle Prostate Cancer

Pauline Bagnall, Uro-oncology nurse specialist, British Association of Urological nurses (BAUN)

Victoria Coupland, Principal Cancer Intelligence Analyst, NCRAS, PHE

Adam Glaser, Clinical Associate Professor, UK Cancer Survival Initiative

Luke Hounsome, Analytical Programme Manager, NCRAS, PHE

Michael Kirby, Visiting Professor, Royal College of General Practitioners (RGCP)

Gokul KandaSwamy, Consultant Urological and Robotic Surgeon, BAUS (Wales)

John McGrath, Consultant Urological Surgeon, NHS England's Specialised Cancer CRG

Krishna Narahari, Consultant Urological Surgeon, BAUS Oncology

Raj Persad, Consultant Urological Surgeon and Andrologist, BAUS

Janet Rimmer, Senior Implementation Lead, NHS Cancer Screening Programmes

Simon Russell, Consultant Oncologist, BUG

Vijay Sangar, Consultant Urological Surgeon, Chair of of NHS England Specialist Cancer Surgery CRG

Karen Stalbow, Head of Policy, Knowledge & Impact, Prostate Cancer UK

Members of the NPCA Project Team

NPCA Project Board:

Tim Terry (Chair), Trustee of RCS Council

Heather Blake, Director of Support and Influencing, Prostate Cancer UK

Roger Kockelbergh, University Hospitals of Leicester NHS Trust

Gokul KandaSwamy, Consultant Urological and Robotic Surgeon, BAUS (Wales)

Simon Russell, Consultant Oncologist, BUG

Yvonne Silove, Associate Director, HQIP

Foreword

This is the 6th Annual Report from the NPCA and with the publication of the latest NICE guidelines we have developed new measures to keep up to date with modern practice. Encouragingly multiparametric MRIs are available onsite at 98% of Trusts/Health Boards and over three quarters are able to perform trans-perineal biopsies. For the first time we report on the national uptake of docetaxel in newly diagnosed men presenting with metastatic prostate cancer. Use of this agent in this setting has appeared in national guidelines for the first time[3] and we have shown that it is now being used in one in every four men with newly diagnosed metastatic disease.

Significant changes have been made in how radiotherapy is delivered for prostate cancer and we have incorporated these changes into this year's report. Our organisational survey of radiotherapy centres has confirmed that rotational IMRT (e.g. Rapid Arc Volumetric Arc Based Therapy) is almost universally available in England and Wales. Importantly, we report on the use of hypofractionated radiotherapy, which seems to have been adopted widely for intermediate-risk disease. Another significant finding was the availability of a brachytherapy boost for high-risk/locally advanced disease, where approximately one in two specialist MDTs have a referral pathway for this therapy. Seven regions have used it more frequently than the remaining 40 regions (for high-risk/locally advanced disease). This highlights the need for additional referral pathways to be considered so that this treatment becomes more widely accessible.

The rates of over-treatment of low-risk disease and under-treatment of high-risk/locally advanced disease have seen continual declines year on year since 2014: the recent estimates from this report have shown consistency with last year's results. The proportion of men experiencing a gastrointestinal complication within 2 years of radiotherapy has remained static at 10% but 2-year genitourinary complications following surgery have improved slightly since last year (9% down from 11%). It will be important to continue measuring these trends and see if improvement can be made after ongoing engagement with the outlier process.
In December 2019 the NPCA team will also run its first Quality Improvement workshop. We hope that you attend so that direct input from Clinical Leads can help us refine and improve the audit for the future.

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

Heather Payne
Oncological Clinical Lead representing the British Uro-oncology Group

[3] NICE Guideline [NG131], 2019.

Executive Summary

Background

The aim of the NPCA is to assess the process of care and its outcomes in men diagnosed with prostate cancer in England and Wales. The NPCA determines whether the care received by men diagnosed with prostate cancer in England and Wales is consistent with current recommended practice and provides information to support healthcare providers, commissioners, regulators, patient groups and patients in helping improve care for patients. This is the first national audit which is able to report on process and outcome measures from all aspects of the care pathway for men with prostate cancer.

Data collection and analysis

This report presents results from the prospective audit for men diagnosed with, or treated for, prostate cancer between 1st April 2017 and 31st March 2018 in England and Wales.[4] The basis of the audit are routine data sources which include: Cancer Registry data, Cancer Outcomes and Services Dataset (COSD), Hospital Episode Statistics (HES), the Office for National Statistics (ONS), the Radiotherapy Data Set (RTDS) and the Systemic Anti-Cancer Therapy (SACT) database in England, and CaNISC, Patient Episode Database for Wales (PEDW) and ONS in Wales.

We report on specific information relating to diagnosis, staging and treatment, as well as core performance indicators, in order to compare diagnostic specialist MDTs and/or treatment centres. This is the first time we report on the use of docetaxel, brachytherapy boost (high-dose rate and low-dose rate) and radiotherapy hypofractionation.

We report on 9 performance indicators:

1. Proportion of men diagnosed with metastatic disease at first presentation.
2. Proportion of men with low-risk localised prostate cancer undergoing radical prostate cancer therapy.
3. Proportion of men with high-risk/locally advanced disease receiving radical prostate cancer therapy.
4. Proportion of men with newly diagnosed metastatic disease who receive docetaxel in combination with androgen deprivation therapy (ADT).
5. Proportion of men having radical radiotherapy for intermediate- or high-risk/locally advanced disease receiving a hypofractionated regimen.
6. Proportion of men having radical radiotherapy for high-risk/locally advanced disease receiving a brachytherapy boost.
7. Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.
8. Proportion of patients experiencing at least one severe genitourinary (GU) complication within 2 years of radical prostatectomy.
9. Proportion of patients experiencing at least one severe gastrointestinal (GI) complication within 2 years of radical external beam radiotherapy.

NICE Quality Standards, 2015[5]

1. QS 1: men with prostate cancer have a discussion about treatment options and adverse effects with a named nurse specialist.
2. QS2: men with low-risk prostate cancer for whom radical treatment is suitable are also offered the option of active surveillance.
3. QS3: men with intermediate- or high-risk/locally advanced localised prostate cancer who are offered non-surgical radical treatment are offered radical radiotherapy and ADT in combination.
4. QS4: men with adverse effects of prostate cancer treatment are referred to specialist services.
5. QS5: men with hormone-relapsed metastatic prostate cancer have their treatment options discussed by the urological cancer MDT.

Although the NPCA started prior to the publication of the NICE Quality Standards, the Audit provides results that can be used to evaluate to what extent prostate cancer care providers meet most of these standards.

Last year we reported results from the NPCA patient survey which asked about how men were informed about their treatment options, how treatment decisions were made and to what extent they had access to a named clinical nurse specialist (CNS) (QS1). Further patient surveys are planned for 2020 and current information with respect to CNS provision can be found in section 3.6. We also present results for indicators of possible over-treatment in men with low-risk disease and potential under-treatment in men with high-risk/locally advanced disease which can be found in section 3.4 (QS2 and QS3).

The results from our annual organisational survey[6] indicate whether providers of cancer services have specialist services on-site and can be found in section 3.6 (QS4).

[4] Medium-term indicators require longer follow-up (up to two years' post-treatment) so the reporting time period for severe GU or GI complications is 1st January to 31st December 2016.

[5] Prostate Cancer. NICE Quality Standard [QS91], 2015.

[6] https://www.npca.org.uk/reports/npca-organisational-audit-2019/

Currently data with respect to hormone-relapse and recurrence are not available from routine national datasets and so an assessment of treatment options for these men is not possible (QS5).

In addition to the results linked directly to the NICE Quality Standards, the NPCA reports on aspects of care that capture ongoing developments in the way men with prostate cancer are being assessed and treated. The Audit also provides evidence on the adoption of newer technologies (e.g. use of multiparametric MRI scanning before the prostate biopsy and the type of biopsy used) and treatments (robotic-assisted prostatectomy and intensity-modulated radiotherapy), as well as the impact on patient outcomes.

Further to the publication of updated NICE guidelines in May 2019[7] we report, for the first time, the uptake of docetaxel in men with newly presenting metastatic disease, the use of hypofractionated radiotherapy and the use of brachytherapy boost in men with high-risk/locally advanced prostate cancer.

How to use this report and the NPCA website

The information presented here compares prostate cancer services locally and nationally. We recommend that this be a starting point for reflection on the reasons behind variation in practice and outcomes, and that this report be used to identify areas for potential quality improvement.

A breakdown of results at the level of each Trust and specialist MDT are provided in the appendices and a full breakdown of the organisational survey is also available on our website.[8] Users of this report should take time to identify areas for improvement in data completeness, service availability and patient outcomes. We also encourage clinical leads to attend our Quality Improvement workshop later this year and these results will be the basis for discussion and improvement planning. We welcome feedback on how the audit outputs can be made more useful.

It is also important to highlight that treatment outcome results are published as part of the Clinical Outcomes Programme (COP) and the National Clinical Audit Benchmarking (NCAB) to enable dissemination of our findings to clinicians, stakeholders, patients and the wider public. We also encourage that users of this report also access these resources to drive quality improvement.

Patients can use these results to start conversations with their care providers and a lay summary of the report will be published early next year. Previous lay summaries of our Annual Reports can be found on our website at: www.npca.org.uk

[7] Prostate cancer: diagnosis and management. NICE Guideline [NG131], 2019.
[8] https://www.npca.org.uk/reports/npca-organisational-audit-2019/

Key Messages

Data quality

1. Completeness of key variables remains low in England (multiparametric MRI and prostate biopsy type). New data items for multiparametric MRI and prostate biopsy type will be introduced into COSD from April next year. We encourage all prostate MDTs in England to use these data items so that they can provide reliable results about key parts of the diagnostic pathway.

Service organisation

2. Multiparametric MRI is available at 98% of the diagnostic Trusts in England and Wales. Its use is increasing, with a concomitant increase in its use prior to biopsy.

3. Trans-perineal biopsy is performed in 77% of the diagnosing Trusts in England and Wales and its use has increased since 2018.

4. Nurse specialists are available in 98% of diagnostic Trusts.

5. The availability of support services is very good. 98% of specialist MDTs have sexual function and continence services available and all have psychological counselling available. However, less than half of radiotherapy centres have a specialist gastrointestinal service.

6. The majority of radiotherapy centres use rotational IMRT with cone beam CT (and not fiducial markers or kilovoltage (KV) imaging).

7. According to the organisational survey, there is a consensus across oncology centres about when to administer docetaxel for newly diagnosed hormone sensitive disease, with the majority of centres supporting its use in high and low volume M1 disease.

8. There is substantial variation in neo-adjuvant and adjuvant ADT treatment duration across the country for low-risk and all high-risk disease.

Prospective audit

9. The proportion of men presenting with metastatic disease at diagnosis is stable.

10. The potential "over-treatment" of men with low-risk disease has remained low at 4%.

11. The potential "under-treatment" of men with high-risk/locally advanced disease has decreased slightly (32%).

12. This is the first time the NPCA have reported on the use of primary docetaxel use in metastatic disease (27%).

13. This is the first time the NPCA has reported the use of hypofractionated radiotherapy. We report its use at 91% in intermediate-risk cases and 59% in high-risk/locally advanced cases, with substantial national variation in the latter.

14. This is the first time the NPCA have reported on the use of brachytherapy boost. We report its use at 5% in high-risk/locally advanced cases, the majority of which a restricted to a few specialist MDTs.

15. Genitourinary complications following radical prostatectomy have improved. Approximately one in ten men experience at least one severe genitourinary complication within two years of their prostatectomy.

16. The rate of bowel dysfunction following radical radiotherapy is stable and consistent with that reported last year. One in ten men experience a severe gastrointestinal complication within two years of their radiotherapy.

Recommendations

For prostate cancer teams (local and specialist MDTs) within NHS Trusts/Health Boards

- Where appropriate, every man should get a multiparametric MRI prior to initial prostate biopsy (R1).

- Where appropriate, increase the use of trans-perineal prostate biopsy to maximise diagnostic accuracy (specifically anterior tissue), whilst balancing against resource constraints and the risk of side effects (R2).

- NHS Organisations in England should aim to achieve high completeness of key data items capturing performance status, mpMRI and prostate biopsy type submitted to the national cancer registration service and use the updated Cancer Outcomes Services Dataset (COSD) from April 2020. A clinician responsible for reviewing and checking their team's data returns should be identified, mirroring the approach in Wales where data completeness remains high (R3).

- Continue to advocate active surveillance in the first instance for men with low-risk prostate cancer (R4).

- Investigate why men with high-risk/locally advanced disease are not considered for radical treatment (R5).

- Where appropriate, offer primary docetaxel to people with newly diagnosed metastatic disease (R6).

- Radiotherapy centres should continue to increase the use of hypofractionated radiotherapy, especially in intermediate-risk disease (R7).

- Consider establishing radiotherapy centre specialist gastrointestinal services to offer advice to people with bowel-related side effects of radiotherapy (R8).

- Consider brachytherapy in combination with external beam radiotherapy for patients with intermediate- or high-risk prostate cancer (R9).

- Ensure access to nurse specialists and their services for patients with prostate cancer (R10).

For patients

- Seek advice from a doctor if you experience any of the following: urinary symptoms, erectile problems, blood in your urine or unexplained back pain (R11).

- Men with a family history of prostate, breast or ovarian cancer should have a higher vigilance for seeking advice from their GP (R12).

- Men who are referred to a specialist for suspected prostate cancer should have a multiparametric MRI scan before having a biopsy (R13).

- Men with low-risk prostate cancer ensure should be offered disease monitoring in the first instance as treatment is only needed if your cancer progresses (R14). This protects men against the side-effects of treatment, discussed below.

- Men newly diagnosed with metastatic disease should be offered chemotherapy according to new prostate cancer guidelines (R15).

- Ensure men who are offered prostate cancer treatment are aware of the side effects including: loss of libido, problems getting or keeping erections, loss of ejaculatory function, a worsening of sexual experience, urinary incontinence and/or bowel side effects (R16).

- Specialist support services should be available for any man experiencing physical or psychological side effects during or following prostate cancer treatment. There should be early and ongoing access to these services, in keeping with national recommendations (R17).

- Sources of further information and support should be available for men with prostate cancer and carers. These are accessible via GP services and from prostate cancer charities including Prostate Cancer UK (www.prostatecanceruk.org) and Tackle Prostate Cancer (www.tackleprostate.org). Both of these charities operate nationwide support networks (R18).

For commissioners and health care regulators

Review and identify regional performance indicators for prostate cancer. Pay particular attention to variations in service provision for neo-adjuvant and adjuvant ADT treatment duration for low-risk and all high-risk disease. Where variation is apparent, agree quality improvement action plans and present these to the Trust Board and/or CCG. Trust Boards and CCGs should follow-up implementation progress (R19).

Table 1. NPCA Annual Report 2019: Recommendations, key findings and related national guidance					
No.	**Recommendation**	**Audience**	**Annual Report 2019 findings underlying recommendation**	**Annual Report 2018 results**	**National guidance**
R1	Where appropriate, every man should get a multiparametric MRI prior to initial prostate biopsy.	Prostate cancer teams	98% of NHS Organisations in England and Wales are able to perform mpMRI onsite (Results 3.6). If a multiparametric MRI was used, 87% were performed pre-biopsy in England and 67% in Wales. (Results 3.3 and Table 2).	Increase compared with previous year - 80% of men in England and 41% in Wales.	NICE Guideline [NG131], 2019 *1.2.2 Offer multiparametric MRI as the first-line investigation for people with suspected clinically localised prostate cancer.*
R2	Where appropriate, increase the use of trans-perineal prostate biopsy to maximise diagnostic accuracy (specifically anterior tissue), whilst balancing against resource constraints and the risk of side effects.	Prostate cancer teams	17% of men in England and 7% of men in Wales had a trans-perineal prostate biopsy. 75% of NHS Organisations in England and Wales are able to perform trans-perineal prostate biopsy (Results 3.6).	Increase compared with previous year - 12% of men in England and 4% in Wales.	National guidance currently unavailable.
R3	NHS Organisations in England should aim to achieve high completeness of key data items capturing performance status, mpMRI and prostate biopsy type submitted to the national cancer registration service and use the updated Cancer Outcomes Services Dataset (COSD) from April 2020. A clinician responsible for reviewing and checking their team's data returns should be identified, mirroring the approach in Wales where data completeness remains high.	Prostate cancer teams	Data completeness in England: Performance status (52%) mpMRI performed (51%) Biopsy performed (52%) Data completeness in Wales: Performance status (100%) mpMRI performed (98%) Biopsy performed (100%) (Results 3.2, Table 1, Table 2).	Minimal change in England compared with previous year: Performance status (51%) mpMRI (51%)	*The Cancer Outcome and Services Data set (COSD) has been the national standard for reporting cancer in the NHS in England since January 2013. Feedback reports for the data submitted are available through the CancerStats website.*
R4	Continue to advocate active surveillance in the first instance for men with low-risk prostate cancer.	Prostate cancer teams	4% of men diagnosed with low-risk localised cancer in England Wales underwent radical prostate cancer therapy within 12 months of diagnosis. There were no specialist MDTs with significantly higher levels of 'potential over-treatment' compared with the national average after case-mix adjustment. (Results 3.4, Performance indicator 2, Figure 2).	No change compared with previous year - 4% of men in England and Wales.	NICE Quality Standard [QS91], 2015 *QS2: men with low-risk prostate cancer for whom radical treatment is suitable are also offered the option of active surveillance.* NICE Guideline [NG131], 2019 *1.3.7 Offer a choice between active surveillance, radical prostatectomy or radical radiotherapy to people with low-risk localised prostate cancer for whom radical treatment is suitable.*

/Table 1 continued

No.	Recommendation	Audience	Annual Report 2019 findings underlying recommendation	Annual Report 2018 results	National guidance
R5	Investigate why men with high-risk/locally advanced disease are not considered for radical treatment.	Prostate cancer teams	68% of men diagnosed with locally-advanced prostate cancer underwent radical treatment within 12 months of diagnosis in England and Wales equating to 32% of men being potentially undertreated. 'Potential under-treatment' by NHS provider varied (15% to 56%) and there were four specialist-MDTs which had significantly higher levels compared with the national average following adjustment for case-mix. (Results 3.4, Performance indicator 3, Figure 3).	Slight reduction compared with previous year – 67% of men in England and Wales.	NICE Guideline [NG131], 2019 *1.3.13 Do not offer active surveillance to people with high-risk localised prostate cancer.* NICE Guideline [NG131], 2019 *1.3.14 Offer radical prostatectomy or radical radiotherapy to people with high-risk localised prostate cancer when it is likely the person's cancer can be controlled in the long term.*
R6	Where appropriate, offer primary docetaxel to people with newly diagnosed metastatic disease.	Prostate cancer teams	27% of men received primary docetaxel in combination with standard ADT (ranging from 0% to 39% by NHS provider in England). (Results 3.4, Performance indicator 4, Figure 4).	N/A*	NICE Guideline [NG131], 2019 *1.5.6 Offer docetaxel chemotherapy to people with newly diagnosed metastatic prostate cancer who do not have significant comorbidities*
R7	Radiotherapy centres should continue to increase the use of hypofractionated radiotherapy, especially in intermediate-risk disease.	Prostate cancer teams	91% of men receiving radical radiotherapy for intermediate-risk disease received a hypofractionated regimen (ranging from 12% to 100% by NHS provider in England).	N/A*	NICE Guideline [NG131], 2019 *1.3.17 For people having radical external beam radiotherapy for localised prostate cancer: offer hypofractionated radiotherapy (60 Gy in 20 fractions) using IMRT, unless contraindicated*
R8	Consider establishing radiotherapy centre specialist gastrointestinal services to offer advice to people with bowel-related side effects of radiotherapy.	Prostate cancer teams	37.5% of radiotherapy centres have a specialist gastrointestinal service (33/56 centres). (Results 3.6, Organisational Audit)	N/A*	NICE Guideline [NG131], 2019 *1.3.39 Offer people with signs or symptoms of radiation-induced enteropathy care from a team of professionals with expertise in radiation-induced enteropathy (who may include oncologists, gastroenterologists, bowel surgeons, dietitians and specialist nurses).*
R9	Consider brachytherapy in combination with external beam radiotherapy for patients with intermediate- or high-risk prostate cancer.	Prostate cancer teams	5% of men receiving radical radiotherapy for high-risk/locally advanced disease received a brachytherapy boost. There were seven specialist MDTs which saw a substantially higher proportion of men receiving this multimodal approach than the others (between 14% and 40%). (Results 3.4, Performance indicator 6, Figure 7).	N/A*	NICE Guideline [NG131], 2019 *1.3.22 Consider brachytherapy in combination with external beam radiotherapy for people with intermediate- and high-risk localised prostate cancer.*

/Table 1 continued

No.	Recommendation	Audience	Annual Report 2019 findings underlying recommendation	Annual Report 2018 results	National guidance
R10	Ensure access to nurse specialists and their services for patients with prostate cancer.	Prostate cancer teams	98% of Trusts/Health Boards had a CNS but the type of CNS varied across the country. 91% had a CNS dedicated to prostate cancer with 65% having a general urology nurse specialist (Figure 11). Approximately one third of Trusts had either an oncology CNS (33%) or an advanced prostate cancer CNS (31%). (Results 3.6, Organisational Audit)	Organisational audit results were previously reported in the 2014 Annual Report. 97% of providers in England and 90% in Wales had a CNS.	NICE Quality Standard [QS91], 2015 *QS 1 Men with prostate cancer should have a discussion about treatment options and adverse effects with a named nurse specialist.*
R11	Seek advice from a doctor if you experience any of the following: urinary symptoms, erectile problems, blood in your urine or unexplained back pain.	Patients	Overall 16% of men in England Wales were diagnosed with metastatic disease at presentation (ranging from 10% to 26% by specialist MDT). (Results 3.4, Performance indicator 1, Figure 1).	No change compared with previous year – 16% of men in England and Wales	NHS Long Term Plan for Cancer 2019 *'..build on work to raise greater awareness of symptoms of cancer, lower the threshold for referral by GPs, accelerate diagnosis and treatment..'* Cancer delivery plan for Wales 2016 - 2020 *'… develop a programme of awareness campaigns for cancer'*
R12	Men with a family history of prostate, breast or ovarian cancer should have a higher vigilance for seeking advice from their GP.	Patients	Overall 16% of men in England Wales were diagnosed with metastatic disease at presentation (ranging from 10% to 26% by specialist MDT). (Results 3.4, Performance indicator 1, Figure 1).	No change compared with previous year – 16% of men in England and Wales	NHS Long Term Plan for Cancer 2019 *'..build on work to raise greater awareness of symptoms of cancer, lower the threshold for referral by GPs, accelerate diagnosis and treatment..'* Cancer delivery plan for Wales 2016 - 2020 *'…develop a programme of awareness campaigns for cancer'*
R13	Men who are referred to a specialist for suspected prostate cancer should have a multiparametric MRI scan before having a biopsy.	Patients	If a multiparametric MRI was used, 87% were performed pre-biopsy in England and 67% in Wales. (Results 3.3 and Table 2). 98% of NHS Organisations in England and Wales are able to perform mpMRI onsite (Results 3.6).	Increase compared with previous year - 80% of men in England and 41% in Wales.	NICE Guideline [NG131], 2019 *1.2.2 Offer multiparametric MRI as the first-line investigation for people with suspected clinically localised prostate cancer.* *1.2.1 Do not routinely offer multiparametric MRI to people with prostate cancer who are not going to be able to have radical treatment.*
R14	Men with low-risk prostate cancer should be offered disease monitoring in the first instance as treatment is only needed if your cancer progresses.	Patients	4% of men diagnosed with low-risk localised cancer in England Wales underwent radical prostate cancer therapy within 12 months of diagnosis. There were no specialist MDTs with significantly higher levels of 'potential over-treatment' compared with the national average after case-mix adjustment.	No change compared with previous year - 4% of men in England and Wales.	NICE Quality Standard [QS91], 2015 *QS2: men with low-risk prostate cancer for whom radical treatment is suitable are also offered the option of active surveillance.* NICE Guideline [NG131], 2019 *1.3.7 Offer a choice between active surveillance, radical prostatectomy or radical radiotherapy to people with low-risk localised prostate cancer for whom radical treatment is suitable.*

/Table 1 continued

No.	Recommendation	Audience	Annual Report 2019 findings underlying recommendation	Annual Report 2018 results	National guidance
R15	Men newly diagnosed with metastatic disease should be offered chemotherapy according to new prostate cancer guidelines.	Patients	27% of men received primary docetaxel in combination with standard ADT (ranging from 0% to 39% by NHS provider in England). (Results 3.4, Performance indicator 4, Figure 4).	N/A	NICE Guideline [NG131], 2019 *1.3.24 Discuss the option of docetaxel chemotherapy with people who have newly diagnosed non-metastatic prostate cancer and are starting long-term ADT, have no significant comorbidities and have high-risk disease.*
R16	Ensure men who are offered prostate cancer treatment are aware of the side effects including: loss of libido, problems getting or keeping erections, loss of ejaculatory function, a worsening of sexual experience, urinary incontinence and/or bowel side effects.	Patients, Commissioners and health care regulators	9% of men experienced at least one severe genitourinary (GU) complication within two years after radical prostatectomy. Following adjustment, two surgical centres had significantly worse rates of severe bowel toxicity compared with other NHS providers in England and Wales. (Results 3.4, Performance indicator 8, Figure 9). 10% of men experienced at least one severe bowel complication within two years after radical radiotherapy. Following adjustment, three centres had significantly worse rates of severe bowel toxicity compared with other NHS providers in England and Wales. (Results 3.4, Performance indicator 9, Figure 10).	Small improvement in GU complications compared with previous report – 10% of men in England and Wales. No change in GI complications compared with previous report – 10% of men in England and Wales.	NICE Guideline [NG131], 2019 *1.1.12 Tell people with prostate cancer and their partners or carers about the effects of* *prostate cancer and the treatment options on their:* *sexual function* *physical appearance continence other aspects of masculinity.* *Support people and their partners or carers in making treatment decisions, taking into account the effects on quality of life as well as survival.* NICE Quality Standard [QS91], 2015 *QS4: men with adverse effects of prostate cancer treatment are referred to specialist services.*
R17	Specialist support services should be available for any man experiencing physical or psychological side effects during or following prostate cancer treatment. There should be early and ongoing access to these services, in keeping with national recommendations.	Patients, Commissioners and health care regulators	Support services were found to be widely available in England and Wales. 98% of specialist MDTs had sexual function and continence services with all specialist MDTs having psychological counselling services. However, less than half of radiotherapy centres have a specialist gastrointestinal service. (Results 3.6).	Organisational audit results were previously reported in the 2014 Annual Report. The provision of support services has increased since this time - 50% of providers in England and 60% in Wales provided the full array of support services including cancer advisory centres, sexual function and	NICE Guideline [NG131], 2019 1.1.11 Ensure that mechanisms are in place so people with prostate cancer and their primary care providers have access to specialist services throughout the course of their disease.
R18	Sources of further information and support should be available for men with prostate cancer and carers. These are accessible via GP services and from prostate cancer charities including Prostate Cancer UK (www.prostatecanceruk.org) and Tackle Prostate Cancer (www.tackleprostate.org). Both of these charities operate nationwide support networks	Patients	Recommendation in light of R13 and R14.	N/A	NICE Guideline [NG131], 2019 *1.1.3 Offer people with prostate cancer advice on how to get information and support from websites, local and national cancer information services, and from cancer support groups.* *1.1.4 Choose or recommend information resources for people with prostate cancer that are clear, reliable and up to date. Ask for feedback from people with prostate cancer and their carers to identify the highest quality information resources.*

/Table 1 continued

No.	Recommendation	Audience	Annual Report 2019 findings underlying recommendation	Annual Report 2018 results	National guidance
R19	Review and identify regional performance indicators for prostate cancer. Pay particular attention to variations in service provision for neo-adjuvant and adjuvant ADT treatment duration for low-risk and all high-risk disease. Where variation is apparent, agree quality improvement action plans and present these to the Trust Board and/or CCG. Trust Boards and CCGs should follow-up implementation progress.	Commissioners and health care regulators	Recommendation in light of R1 – R13.	N/A	*N/A*
*Further to the recent publication of updated NICE guidance comparative data for these performance indicators will be published in future reports					

NPCA
National Prostate Cancer Audit

Annual Report 2019 Infographic

DIAGNOSIS AND STAGING

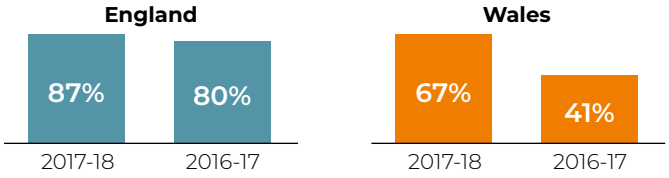
42,668

men were diagnosed with prostate cancer in England and Wales between **1st April 2017 and 31st March 2018**

56% OF MEN WERE 70 YEARS OR OLDER

16% of men presented with metastatic disease – no change from 16/17

Of the men having a **multiparametric MRI**, more are having this carried out **pre-biopsy**



the use of **transperineal biopsy** is increasing **17%** in 17/18 compared with **12%** in 16/17 **7%** in 17/18 compared with **4%** in 16/17

TREATMENT ALLOCATION

Low-risk, localised disease

4% of men had radical treatments and were potentially **'over-treated'** - no change from 16/17

Intermediate-risk disease

91% of men having radical radiotherapy in England had a hypofractionated regimen*

High-risk/locally advanced disease

32% of men did no have radical treatments and were potentially **'under-treated' - 33%** of men in 16/17

In England **5%** of men having radical radiotherapy also had a brachytherapy boost*

Metastatic disease

27% of men had primary docetaxel chemotherapy in England*

* data currently unavailable in Wales

TREATMENT OUTCOMES

14%

of men diagnosed 17/18 were **readmitted** within 3 months **following surgery**

This short-term outcome is stable compared with 16/17

Medium term outcomes are also stable – no change for men undergoing treatment in 2016 compared with 2015

Within **2 years of treatment** 1 in 10 men experienced a **severe genitourinary complication after surgery** or a **severe gastrointestinal complication after radical radiotherapy**

NURSE SPECIALISTS

98% of trusts/health boards have clinical nurse specialists (CNS)

91% have a **dedicated prostate cancer CNS**

SUPPORT SERVICES

100% of specialist MDTs have **psychological counselling** available

98% have **sexual function** and **continence services**

1. The National Prostate Cancer Audit (NPCA): Introduction

1.1 Background

The NPCA is now able to report on the whole patient care pathway from diagnosis through to treatment and treatment-related outcomes. The key indicators with regard to potential 'over-treatment' of low-risk disease and potential 'under-treatment' of high-risk/locally advanced disease have shown improving trends over the first three years of the Audit and they remain a priority area for the NPCA.

Limiting the impact of the adverse events of radical treatments is another priority area. We have previously developed and validated performance indicators which can identify men experiencing severe genitourinary (GU) complications following surgery (radical prostatectomy) and severe GI toxicity following radiotherapy (external beam radiation [EBRT]).[9] [10] These indicators are used by the NPCA to compare surgical and radiotherapy providers and also feed into the Clinical Outcomes Programme (COP) and the National Clinical Audit Benchmarking (NCAB). We hope that these processes can drive quality improvement in sites across the country so that they can reach the highest standards possible.

With the publication of the new National Institute for Health and Care Excellence (NICE) guidelines for prostate cancer earlier this year, it has been an appropriate time to update the performance indicators used in the NPCA.[11] Docetaxel is now advised as a treatment option for men with high-risk non-metastatic prostate cancer and recommended for metastatic prostate cancer and it will be important to monitor its use nationally. Important transitions have also been made with regards to radiotherapy hypofractionation and use of a brachytherapy boost. We have never reported on these aspects of radiotherapy treatment before but it will be important to monitor the uptake of these methods currently and in subsequent Annual Reports.

1.2 Aim and objectives

The aim of the NPCA is to assess the process of care and its outcomes in men diagnosed with prostate cancer in England and Wales.

The key objectives of the Audit are to investigate:

- Service delivery and organisation of prostate cancer care in England and Wales.
- The characteristics of men newly diagnosed with prostate cancer.
- The diagnostic and staging process and planning of initial treatment.
- The initial treatments that men received.
- The experiences of men receiving care and their health outcomes 18 months after diagnosis.
- Overall and disease-free survival.[12]

The NPCA determines whether the care received by men diagnosed with prostate cancer in England and Wales is consistent with current recommended practice and provides information to support healthcare providers, commissioners and regulators in helping improve care for patients. With the introduction of new performance indicators in this year's Annual Report, the NPCA is now the first national audit which is able to report on process and outcome measures from all aspects of the care pathway for men with prostate cancer.

1.3 Previous Annual Report

Previous NPCA Annual Report

The 2018 Annual Report[13] reported on prostate cancer services provided by individual NHS providers to men diagnosed between 1st April 2016 to 31st March 2017 in England and Wales. Key findings include:

- Increases in the use of multiparametric MRI.
- The potential 'over-treatment' of men with low-risk disease is continuing to decline.
- The potential 'under-treatment' of men with high-risk/locally advanced disease has increased slightly despite initial reductions seen in previous Annual Reports.
- According to the NPCA patient survey, patient experiences were positive regarding information received, patient involvement and overall happiness with their care.
- Genitourinary complications at 2 years following radical prostatectomy, or bowel dysfunction following radical radiotherapy, were stable (1 in 10 men).
- Sexual function scores following radical treatment were generally poor at 17 out of 100 for radiotherapy and 23 out of 100 for surgery (where 0 and 100 represent the worst and best function, respectively).

[9] Sujenthiran A, Charman S et al. Quantifying severe urinary complications after radical prostatectomy: the development and validation of a surgical performance indicator using hospital administrative data. *BJU int* (2017); 120:219-225

[10] Sujenthiran A, Nossiter J et al. National population-based study comparing treatment-related toxicity in men who received Intensity-modulated versus 3D-Conformal Radical Radiotherapy for prostate cancer. *Int J Radiat Oncol Biol Phys.* (2017); 99: 1253–1260

[11] Prostate Cancer: diagnosis and management. NICE Guideline [NG131], 2019.

[12] Outcome measures of survival are not used in this year's Annual Report but will be used in future reports when the NPCA data has sufficient follow-up

[13] NPCA Annual Report 2018. Download from: http://www.npca.org.uk/reports/

2. Methods

2.1 Inclusion criteria & prospective audit period

Patients are eligible for inclusion in the prospective audit if they have newly diagnosed prostate cancer using the ICD-10 diagnostic code of "C61" (malignant neoplasm of the prostate). The data collection period reported here includes men diagnosed between 1st April 2017 and the 31st March 2018 in England and Wales, which allows an assessment of all short-term indicators.

Medium-term indicators require longer follow-up (up to two years' post-treatment) so the diagnostic period is earlier. The reporting time period is therefore over a whole calendar year (1st January 2016 to 31st December 2016).

2.2 Routine data collection

In England the NPCA works with the National Cancer Registration and Analysis Service (NCRAS), Public Health England, as a data collection partner. NCRAS collects patient-level data from all NHS acute providers using a range of national data-feeds. This includes the Cancer Outcomes and Services Dataset (COSD), which specifies the data items that need to be submitted. Data is submitted to the National Cancer Data Repository (NCDR) on a monthly basis via MDT electronic data collection systems. Clinical sign-off of data submitted to NCRAS is not mandated in England.

The NPCA's data collection partner in Wales is the Wales Cancer Network (WCN), Public Health Wales. The NPCA dataset (section 2.3) is captured through a national system, Cancer Information System for Wales (CaNISC), after identification by hospital cancer services and uploaded via electronic MDT data collection systems. Prior to submission of NPCA data to the WCN, each patient record is validated (frequently by an MDT coordinator) and signed off by a designated clinician. Patient records are signed off when all key data items have been completed.

2.3 NPCA dataset

The audit collects data on the diagnosis, management and treatment of every patient newly diagnosed with prostate cancer and discussed at an MDT meeting in England and Wales. In addition to the routine datasets described above, the NPCA has been collecting a dataset consisting of both COSD and NPCA data items:

1. NPCA Minimum data set 1 (MDS-1): The first category of data items are collected for **all men newly diagnosed with prostate cancer** during the initial phase of management.
2. NPCA Minimum data set 2 (MDS-2): The second category of data items are collected for all patients who have **undergone radical prostatectomy**.
3. NPCA Minimum data set 3 (MDS-3): The third category of data items are collected for **all men for whom external beam radiation therapy or brachytherapy is planned, with or without hormone deprivation therapy**.

For men newly diagnosed with prostate cancer from 1st April 2019 in England, only COSD data items will be collected.

A summary of the NPCA dataset collected for patients diagnosed between 1st April 2017 and 31st March 2018 can be found on the website.[14] These data are linked to other national datasets to provide extra information. In England these supplementary datasets are Cancer Registry data, Hospital Episode Statistics (HES) data, the Office for National Statistics (ONS) dataset, the National Radiotherapy Dataset (RTDS) and the Systemic Anti-Cancer Dataset (SACT).

In Wales, NPCA data are linked to additional data items from the Patient Episode Database for Wales (PEDW), ONS and CaNISC. The NPCA dataset is captured through CaNISC, which also provides information regarding radiotherapy intent, site and dosing. The radiotherapy centres are currently implementing the collection of the RTDS, which will be available to the NPCA in the near future.

2.4 Level of reporting

It is recommended that the care of patients eligible for radical prostate cancer treatments should be coordinated by specialist MDTs.[15] These hubs are made up of one or more specialist cancer centres coordinating services for referring local Trusts or Health Boards.

Results are presented at the level of the specialist MDT except for treatment specific outcomes which are reported at the level of the surgery or radiotherapy centre. The arrangement of NHS providers, both local and specialist MDTs, and the range of services they provide for the staging and management of prostate cancer was determined by the NPCA Organisational Audit 2019.[16] Results from this Organisational Audit are also reported focusing on the availability of multiparametric MRI, trans-perineal biopsies and support services at the level of diagnostic Trust or specialist MDT where appropriate. We also report on the results of the NPCA survey of radiotherapy centres in England and Wales which provided information on the availability of specific radiotherapy and chemotherapy services.

[14] https://www.npca.org.uk/resources/npca-minimum-dataset/

[15] NICE 2002. Improving outcomes in urological cancer.

[16] NPCA Organisational Audit 2019. Download from: https://www.npca.org.uk/reports/npca-organisational-audit-2019/

2.5 Patient inclusion and data quality

A patient is included in the prospective audit in England if he has a record of newly diagnosed prostate cancer in the English Cancer Registry. Patients newly diagnosed with prostate cancer are identified through the Cancer Registry and so 'per definition' we report case ascertainment at 100%.

A patient is included in the prospective audit in Wales if a completed NPCA record was submitted and the Wales Cancer Network (WCN) can assign that record to a diagnosing Health Board. The total expected number of cases was determined from the number of men newly diagnosed with prostate cancer in the Welsh Cancer Intelligence and Surveillance Unit (WCISU) in 2016. WCISU were not able to provide exact numbers for the time frame of NPCA data collection and so figures from 2016 were used as the closest approximation. As only data for men with an NPCA record is available for analysis, case ascertainment for the Health Boards in Wales is presented and defined as the proportion of the expected number of newly diagnosed men present in the WCISU dataset for whom an NPCA record was submitted which contained at least one NPCA tumour staging data item.

The completeness of five key data items (PSA, Gleason score, TNM, performance status and multiparametric MRI performed) in England and Wales provided a marker of data quality.

2.6 Definition of disease status and risk stratification

In England, men were assigned to a disease status category according to their TNM stage, Gleason score and PSA using a previously developed algorithm.[17] TNM and Gleason score are received from the Cancer Registry. PSA is collected from the COSD dataset as is not routinely collected within the Cancer Registry.

In Wales, cancer stage was defined using "T category (pre-treatment)", "N category (pre-treatment)" and "M category (pre- treatment)". Where pre-treatment information was missing for T or N, the corresponding pathological staging items were used if available. All men were assigned to a disease status category in the same way as the English men. All data items were collected as part of the NPCA dataset in Wales.

2.7 Definition of radical prostate cancer treatment

A patient was considered to have undergone radical prostate cancer therapy if he was identified as having received a radical prostatectomy, radical external beam radiotherapy or brachytherapy within 12 months of their diagnosis date.

HES and PEDW records, for England and Wales respectively, were used to identify patients who had undergone a radical prostatectomy using the OPCS-4 procedure code "M61".

For England the RTDS data-item "treatment modality" was used to identify men who received external beam radiotherapy and/or brachytherapy. Men receiving radiotherapy for metastases or radiotherapy with palliative intent were excluded. Men were assigned to a standard or hypofractionated regimen (with or without a brachytherapy boost – both low dose rate and high dose rate) based on the doses documented in the RTDS. HES and PEDW records were also used to identify brachytherapy patients using OPCS-4 procedure codes ("M706" + "X653" + "Y363 / M706 + "X653/ M712" +"X653").

For Wales, CaNISC was used in a similar way to the RTDS to identify men receiving curative radiotherapy and to exclude those receiving palliative radiotherapy. Data were not available with regard to radiotherapy dosing in Wales and so no reporting was possible for hypofractionation or use of a brachytherapy boost.

SACT was used to identify the men receiving docetaxel and was only available for English men.

2.8 NPCA performance indicators

2.8.1 Definition

In this Annual Report the NPCA report on nine performance indicators which are summarised here:

Disease presentation

- ***Performance indicator 1: Proportion of men diagnosed with metastatic disease (presented at the level of the SMDT).***

  This process indicator provides information on the potential late diagnosis of prostate cancer.

[17] NPCA Annual Report 2016. Download from: https://www.npca.org.uk/reports/npca-annual-report-2016/

Treatment allocation

- ***Performance indicator 2: Proportion of men with low-risk localised prostate cancer undergoing radical prostate cancer therapy (presented at the level of the SMDT).***

  This process indicator provides information about the potential "over-treatment" of men with low-risk prostate cancer.

- ***Performance indicator 3: Proportion of men with high-risk/locally advanced disease receiving radical prostate cancer therapy (presented at the level of the SMDT).***

  This process indicator provides information about potential "under-treatment" of men with high-risk/locally advanced disease.

- ***Performance indicator 4: Proportion of men with metastatic disease receiving docetaxel in combination with standard ADT (presented at the level of the SMDT).***

  This process indicator provides information about the use of docetaxel as primary treatment for metastatic disease. Docetaxel is a chemotherapeutic treatment new to the NICE 2019 prostate cancer guidelines and should be 'discussed' with men with high-risk non-metastatic disease and 'offered' to men with metastatic disease. As the data collection period was prior to the publication period of the new NICE guidelines only metastatic patients were included for this indicator.

Radiotherapy regimen allocation

- ***Performance indicator 5: Proportion of men having radical radiotherapy for intermediate- or high-risk/locally advanced disease receiving a hypofractionated regimen (presented at the level of the radiotherapy centre).***

- ***Performance indicator 6: Proportion of men having radical radiotherapy for high-risk/locally advanced disease receiving a brachytherapy boost (presented at the level of the SMDT).***

  These process indicators provide information about the use of radiotherapy hypofractionation and a brachytherapy boost using data from the RTDS. This ensures that we report the proportions of men actually receiving this treatment and does not use the results from the organisational audit about service availability.

Outcomes of treatment: short-term

- ***Performance indicator 7: Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery (presented at the level of the surgery centre).***

- This outcome indicator was derived from linkage with HES/PEDW admissions. Emergency readmission may reflect that patients experienced a complication related to radical prostate cancer surgery after discharge from hospital.

Outcomes of treatment: medium-term

- ***Performance indicator 8: Proportion of patients experiencing at least one severe genitourinary (GU) complication within 2 years of radical prostatectomy (presented at the level of the surgery centre).***

  We used a coding-framework based on OPCS-4 procedure codes to capture genitourinary complications severe enough to require an intervention.[18] These included complications of the urinary tract as opposed to those related to sexual dysfunction. Men with an associated diagnosis of bladder cancer (ICD-10 "C67" code) or who received post-operative radiotherapy were excluded.

- ***Performance indicator 9: Proportion of patients experiencing at least one severe gastrointestinal (GI) complication within 2 years of radical external beam radiotherapy (presented at the level of the surgery centre).***

  We used a coding-framework based on OPCS-4 procedure codes to capture interventions required to treat GI toxicity. This indicator also required the presence of specific ICD-10 diagnosis codes relating to GI toxicity.[19] This combination approach allowed us to exclude the men who had GI interventions for reasons unrelated to radiotherapy, such as part of a screening programme. Men with an associated diagnosis of bladder cancer, those who received additional brachytherapy and those who had received a radical prostatectomy prior to radiotherapy were excluded.

[18] Sujenthiran A, Charman S et al. Quantifying severe urinary complications after radical prostatectomy: the development and validation of a surgical performance indicator using hospital administrative data. *BJU int* (2017); 120:219-225

[19] Sujenthiran A, Nossiter J et al. National population-based study comparing treatment-related toxicity in men who received Intensity-modulated versus 3D-Conformal Radical Radiotherapy for prostate cancer. *Int J Radiat Oncol Biol Phys.*(2017); 99: 1253 -1260

2.8.2 Funnel plots

Funnel plots were generated for the performance indicators using control limits defining differences corresponding to two standard deviations (inner limits) and three standard deviations (outer limits) from the national average population. Funnel plots are able to display variation across specialist MDTs/Trusts/Health Boards for our performance indicators according to patient volume. Centres which performed less than 10 procedures per year were excluded.

Surgical and radiotherapy treatment centres outside the inner or outer funnel limits (alerts and alarms, respectively) for adjusted treatment-related outcomes (performance indicators 7-9) were considered as potential outliers and were contacted, where necessary, according to the NPCA Outlier Policy.[20] Funnel plots were also used to graphically display variation in process measures across the country (performance indicators 1-6).

Multivariable logistic regression was carried out with adjustment for patient age, socio-economic status and comorbidity to determine adjusted outcomes for performance indicators 2-6. Comorbidity was captured using the Royal College of Surgeons (RCS) Charlson comorbidity score[21] using ICD-10 diagnosis codes in HES/PEDW. The Index of Multiple Deprivation (IMD) was used to categorise patients into five socioeconomic groups (1=least deprived; 5=most deprived) based on the areas in which they lived. The five categories were fifths of the national IMD ranking of these areas. Stage was also included in the adjustment model for all treatment outcomes (performance indicators 7-9).

[20] https://www.npca.org.uk/resources/npca-outlier-policy-2019/

[21] Armitage JN, et al. Identifying co-morbidity in surgical patients using administrative data with the Royal College of Surgeons Charlson Score. *Br J Surg* 2010; 97:772-81.

3. Results

3.1 Audit participation

40,429 men were identified with prostate cancer in England from 1st April 2017 to 31st March 2018, of which 39,855 could be assigned a valid NHS provider. Prostate cancer services are provided at 133 NHS Trusts across 47 specialist MDTs in England and 6 Health Boards across 4 specialist MDTs in Wales.[22]

In Wales we received a total of 2,239 NPCA records of newly diagnosed men and all could be assigned to a valid NHS provider. The number of prostate cancer diagnoses appearing in WCISU for calendar year 2016 was 2,649 resulting in approximate case ascertainment of 85%.

3.2 Data completeness

Completeness of pre-treatment data items

Data completeness is high for Wales, and remains consistent with previous year's results, with key variables reaching completeness of at least 98% (performance status and mpMRI performed). 96% of Welsh men could be assigned to a risk category due to the high completeness of PSA, Gleason score and TNM variables (87%, 87% and 78%, respectively).

Data completeness in England is lower than in Wales. Performance status and multiparametric MRI are 52% and 51% complete, respectively. However, the completeness of the diagnostic information is substantially better with completeness for PSA, Gleason score and TNM reported at 72%, 82% and 77%, respectively. It is possible to place 91% of English men into a risk category showing that the quality of the cancer data items is very good.

Overall data completeness can be seen in Table 2 and completeness of all data items by diagnosing Trust/Health Board and specialist MDT can be found on our website (www.npca.org.uk).

Table 2. Data completeness for selected data items for men newly diagnosed with prostate cancer in England and Wales over the period of 1 April 2016 and 31 March 2017.

Data variable	England		Wales	
	N	%	N	%
Diagnostic and staging variables				
No. of men with new diagnosis of prostate cancer	40,429 [CR]		2,239 [NPCA]	
Performance status completed	21,079 [COSD]	52%	2,239 [NPCA]	100%
mpMRI performed completed	20,727 [NPCA]	51%	2,204 [NPCA]	98%
Biopsy performed	20,841 [NPCA]	52%	2,239 [NPCA]	100%
PSA completed	28,922 [COSD]	72%	1,955 [NPCA]	87%
Gleason score completed	33,184 [CR]	82%	1,955 [NPCA]	87%
TNM completed	31,075 [CR]	77%	1,757 [NPCA]	78%

Acronyms: CR = Cancer Registry; NPCA = National Prostate Cancer Audit; mpMRI = multi-parametric Magnetic Resonance Imaging; PSA = Prostate Specific Antigen; TNM = Tumour, Nodes, Metastases Classification of Malignant Tumours.

[22] https://www.npca.org.uk/reports/npca-organisational-audit-2019/

3.3 Audit findings

Patient and diagnostic characteristics are summarised in Table 3.

Patient characteristics

Over one third of men are aged between 70 and 80 (38% and 41% for England and Wales, respectively) and another third are aged between 60 and 70. Prostate cancer is a disease of the elderly shown with a high number being diagnosed above 80 years old (17% and 16% in England and Wales, respectively). This remains consistent with last year's report. In England, 68% of the men had a performance status of 0 (fully active) versus 59% for Wales, again consistent with last year's report, although data completeness was better for the Welsh, compared to English data (100% versus 52%).

Diagnostic investigations

The trans-rectal ultrasound guided method remains the most common biopsy technique in England (83% down from 88%), with the remainder of men undergoing a trans-perineal biopsy. Significantly more men underwent a trans-rectal ultrasound guided biopsy in Wales at 93% (although this has also declined from last year's frequency of 96%).

The use of multiparametric MRI is increasing: over the last 3 years it has risen from 51% to 59% to 62% in England, and from 54% to 58% to 62% in Wales. If a multiparametric MRI was used, 87% were performed pre-biopsy in England and 67% in Wales (up from last year estimates of 80% and 41%, respectively).

Disease status at presentation

The distribution of PSA, Gleason score and TNM staging is shown in Table 2 and has remained consistent with last year's results. Stage at diagnosis has remained stable compared to last year and currently 17% of men in England were diagnosed with metastatic disease compared to 13% in Wales. 41%, 36% and 7% of men were assigned to high-risk/locally advanced, intermediate-risk and low-risk disease in England. The respective figures for Wales were 34%, 45% and 8%.

Table 3. Patient and diagnostic characteristics for men newly diagnosed with prostate cancer in England and Wales over the period of 1 April 2017 and 31 March 2018.				
Data variable	**England**		**Wales**	
	N	**%**	**N**	**%**
No. of men with new diagnosis of prostate cancer	40,429		2,239	
Age				
<60	5,168	13%	230	10%
60-70	12,798	32%	738	33%
70-80	15,461	38%	923	41%
≥80	7,002	17%	348	16%
Total	40,429	100%	2,239	100%
Missing	0		0	
Performance status				
0	14,399	68%	1,313	59%
1-2	6,258	30%	861	38%
≥3	421	2%	65	3%
Total	21,078	100%	2,239	100%
Missing	19,351		0	
Charlson score				
0	28,428	70%	1,783	90%
1	7,428	18%	310	14%
≥2	4,573	11%	146	7%
Total	40,429	100%	2,239	100%
Missing	0		0	
Biopsy performed				
Transrectal sampling	14,543	80%	1,759	93%
Transrectal saturation	472	3%	8	0%
Perineal sampling	1,591	9%	2	0%
Perineal template	1,503	8%	123	7%
Other	897		72	
None	1,835		275	
Total	20,841	100%	2,239	100%
Missing	19,588		0	

/Table 3 continued

Data variable	England		Wales	
	N	%	N	%
mpMRI performed				
No	7,994	39%	824	37%
Yes	12,733	62%	1,380	62%
Total	20,727	100%	2,204	100%
Missing	19,702		35	
mpMRI timing				
Before biopsy	11,110	87%	929	67%
After biopsy	1,623	13%	451	33%
Total	12,733	100%	1,380	100%
Prostate Specific Antigen (PSA)				
<10	13,464	47%	1,024	52%
10-20	6,367	22%	482	25%
>20	9,091	31%	449	23%
Total	28,922	100%	1,955	100%
Missing	11,507		284	
Gleason score				
≤6	6,985	21%	685	35%
7	16,066	48%	879	45%
≥8	10,133	31%	391	20%
Total	33,184	100%	1,955	100%
Missing	7,245		284	
T stage				
T1	5,217	15%	354	16%
T2	15,179	43%	1,082	50%
T3	12,644	36%	585	27%
T4	1,857	5%	156	7%
Total	34,897	100%	2,177	100%
Missing	5,532		62	
N stage				
No	28,670	88%	1,857	91%
N1	4,007	12%	188	9%
Total	32,677	100%	2,045	100%
Missing	7,752		194	

/Table 3 continued

Data variable	England		Wales	
	N	%	N	%
M stage				
M0	29,006	83%	1,611	85%
M1	6,135	17%	282	15%
Total	35,141	100%	1,893	100%
Missing	5,288		346	
Risk group				
Metastatic	6,135	17%	282	13%
High risk/Locally advanced	14,957	41%	722	34%
Intermediate	13,148	36%	976	45%
Low risk	2,456	7%	171	8%
Total	36,696	100%	2,151	100%
Insufficient	3,733		88	

Acronyms: mpMRI = multi-parametric Magnetic Resonance Imaging; PSA = Prostate Specific Antigen; TNM = Tumour, Nodes, Metastases Classification of Malignant Tumours.

Treatment Information

Treatment characteristics are summarised in Table 4.

7,018 men were identified as undergoing an RP in England; most were robotically assisted (85%), with the remainder being performed laparoscopically (6%) or through open surgery (8%). This has shown continual increase towards a robotic approach and higher than previous estimates of 81% (2016/2017) and 74% (2015/2016). Robotic prostatectomies were performed less frequently in Wales (68%) but this is steadily increasing from 63% last year. One third of the prostatectomies were performed with a lymphadenectomy in England (30%) but more so in Wales (48%).

13,416 men underwent radical radiotherapy in England; the vast majority were performed with IMRT (90%) which is consistent with the figure reported last year (89%; Table 3). Only 13% received radiotherapy to the pelvic lymph nodes as well as the prostate, with most receiving radiotherapy to the prostate +/- seminal vesicles. Wales used IMRT routinely and more Welsh men appear to be having radiotherapy to the pelvic lymph nodes (17%). At present the Welsh and English use different data sources for radiotherapy information but once Wales has transitioned onto using the RTDS a better comparison between countries will be possible.

Table 4. Treatment characteristics for men receiving radical radiotherapy or prostatectomy in England and Wales over the period of 1 April 2017 and 31 March 2018.				
Data variable	**England**		**Wales**	
	N	**%**	**N**	**%**
Radical prostatectomy information				
No. of men undergoing radical prostatectomy	7,018		251	
Prostatectomy type				
Robotic	5,992	85%	160	68%
Open	572	8%	48	20%
Laparoscopic	454	6%	27	11%
Total	7,018	100%	235	100%
Missing	0		16	
Lymphadenectomy performed				
No	4,929	70%	131	52%
Yes	2,089	30%	120	48%
Total	7,018	100%	251	100%
Missing	0		0	
Radical radiotherapy information				
No. of men undergoing radical radiotherapy	13,891		736	
Radiotherapy modality				
IMRT	12,509	90%	717	100%
3D conformal	1,382	10%	717	100%
Total	13,891	100%	717	100%
Missing	0		19	
Planned radiotherapy region				
Prostate and/or seminal vesicles	11,618	87%	590	83%
Whole pelvis incl. lymph nodes	1,798	13%	125	17%
Total	13,416	100%	715	100%
Missing	475		21	

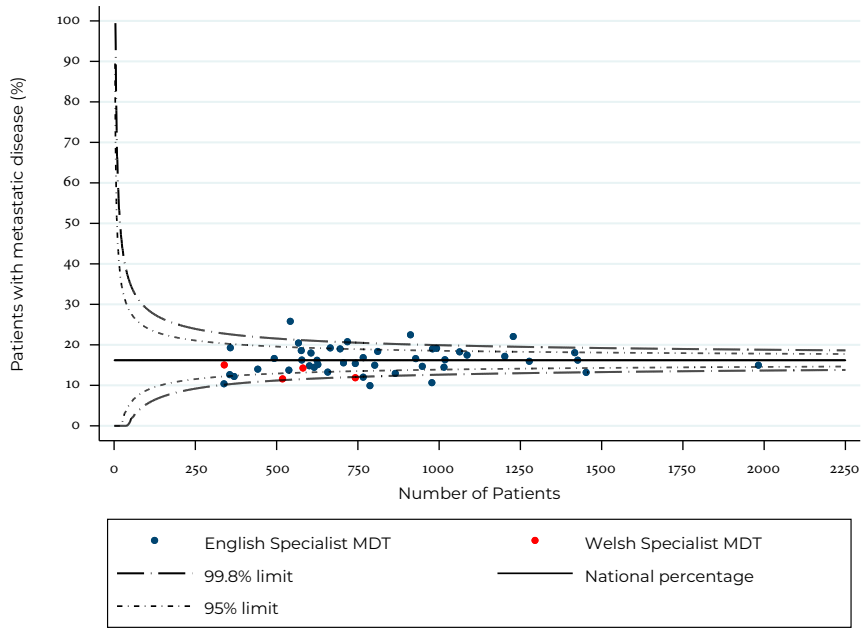
3.4 NPCA 'short-term' performance indicators

We were able to determine disease status and allocate a provider to 36,358 patients in England (90%) and 2,151 in Wales (96%).

Performance indicator 1: Proportion of men diagnosed with metastatic disease

Overall 16% of men were diagnosed with metastatic disease at presentation which is static compared to last year. An unadjusted funnel plot (Figure 1) demonstrates the variation in the proportion of men diagnosed with metastatic disease across 51 specialist MDTs (ranging from 10% - 26%).

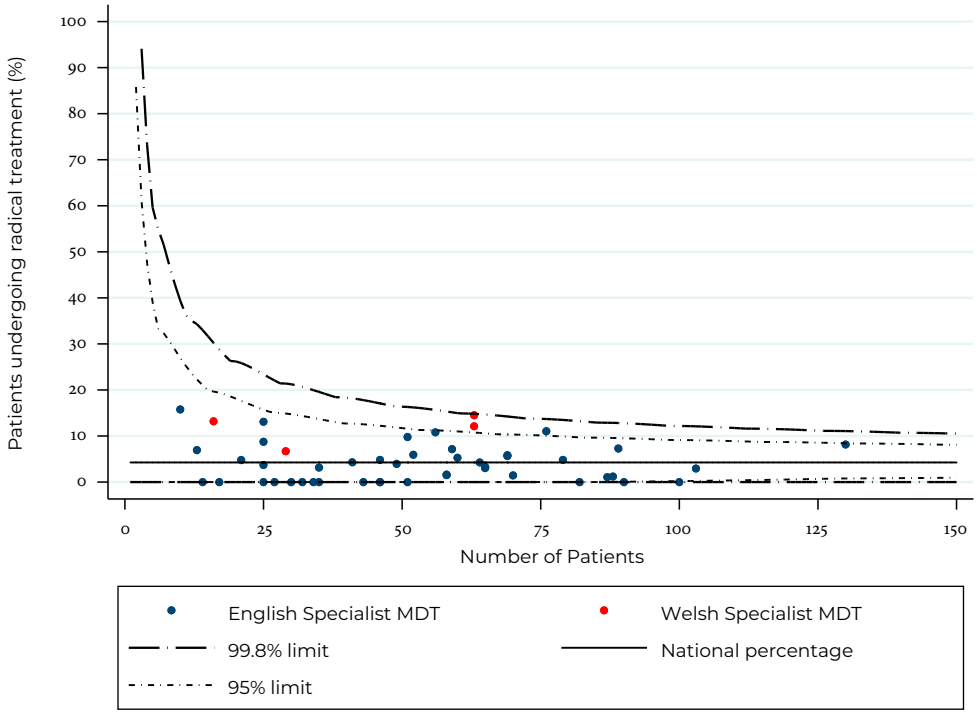
Figure 1. Unadjusted funnel plot for the proportion of patients with metastatic disease at diagnosis across the specialist MDTs in England and Wales.



Performance indicator 2: Proportion of men with low-risk localised cancer undergoing radical prostate cancer treatment

4% of men diagnosed with low-risk localised cancer underwent radical prostate cancer therapy within 12 months of diagnosis (range: 0% - 16%). An adjusted funnel plot demonstrates that all specialist MDTs had comparable levels of over-treatment with no negative or positive outliers (Figure 2).

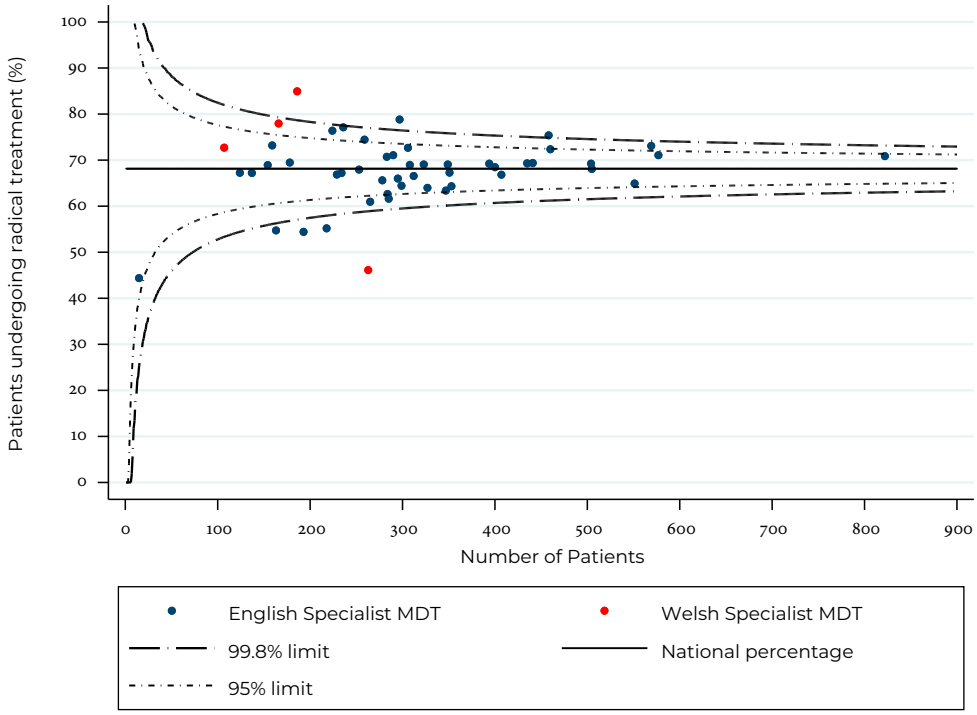
Figure 2. Adjusted funnel plot for the proportion of patients with low-risk prostate cancer undergoing radical treatment by specialist MDTs in England and Wales.



Performance indicator 3: Proportion of men with high-risk/ locally advanced disease undergoing radical prostate cancer treatment

68% of men diagnosed with high-risk/locally advanced prostate cancer were found to have undergone some form of radical therapy within 12 months of diagnosis (range: 44% - 85%). An adjusted funnel plot demonstrates that of 51 specialist MDTs there were four which had significantly worse levels of under-treatment compared to the others (negative outliers), and three which had significantly better rates of under-treatment (positive outliers) (Figure 3).

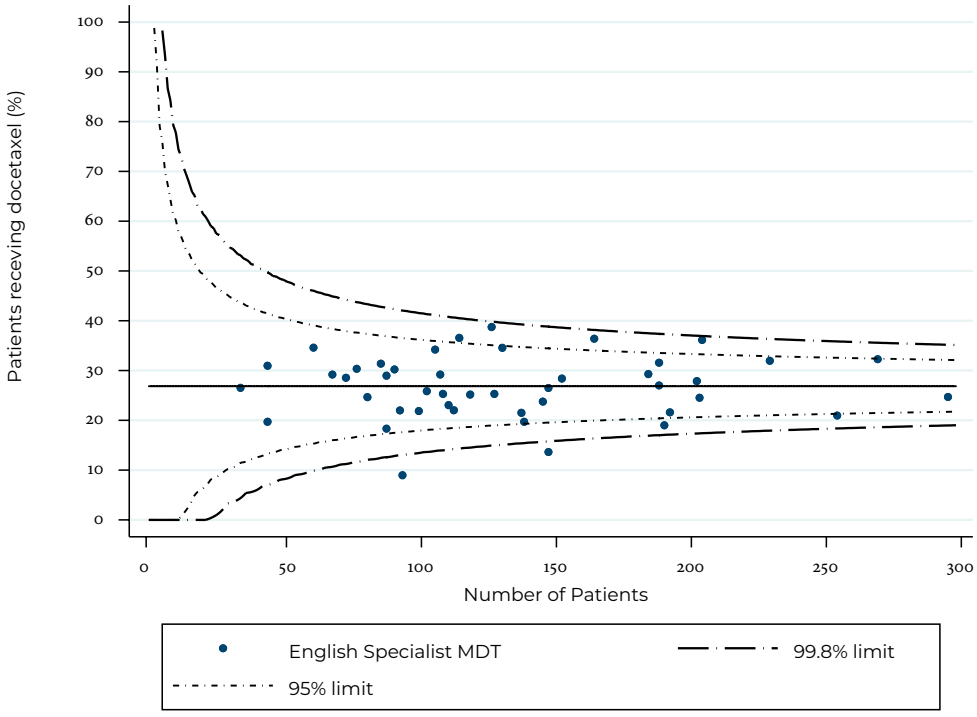
Figure 3. Adjusted funnel plot for the proportion of patients with high-risk/locally advanced prostate cancer undergoing radical treatment by specialist MDTs in England and Wales.



Performance indicator 4: Proportion of men with metastatic disease receiving docetaxel in combination with standard ADT

27% of men with metastatic disease (range: 0% - 39%) received primary docetaxel in combination with standard ADT. Adjusted funnel plots (Figure 4) demonstrate the variation in its use across 47 specialist MDTs in England.

Figure 4. Adjusted funnel plot for the proportion of men with newly diagnosed metastatic disease receiving primary docetaxel by specialist MDTs in England.

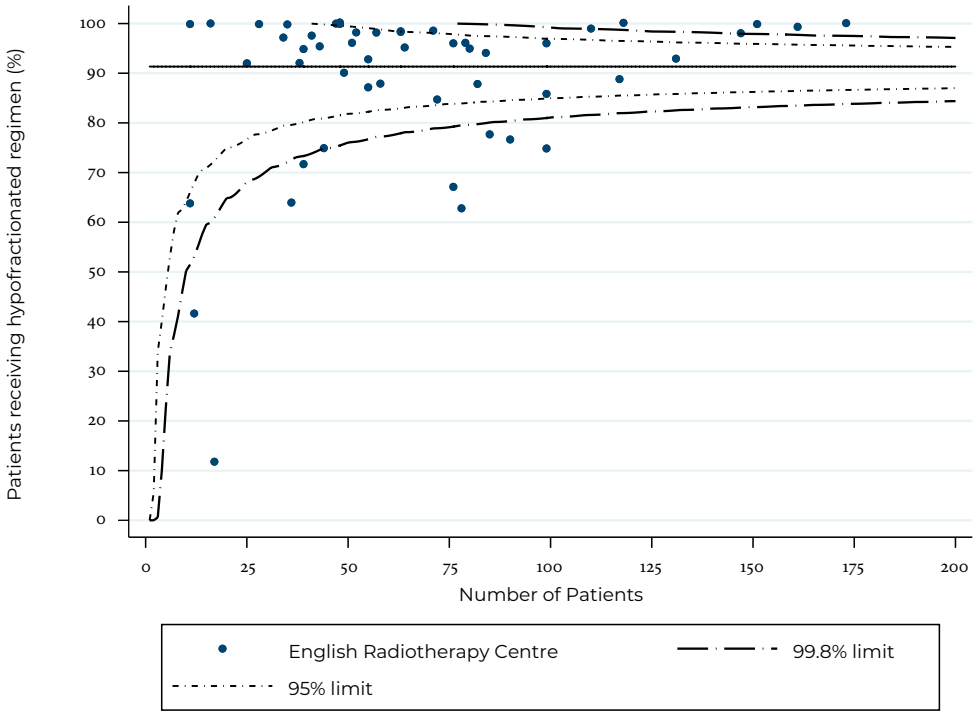


Note: Data was not available for Wales and so Welsh providers were not included.

Performance indicator 5: Proportion of men having radical radiotherapy for intermediate- or high-risk/locally advanced disease receiving a hypofractionated regimen

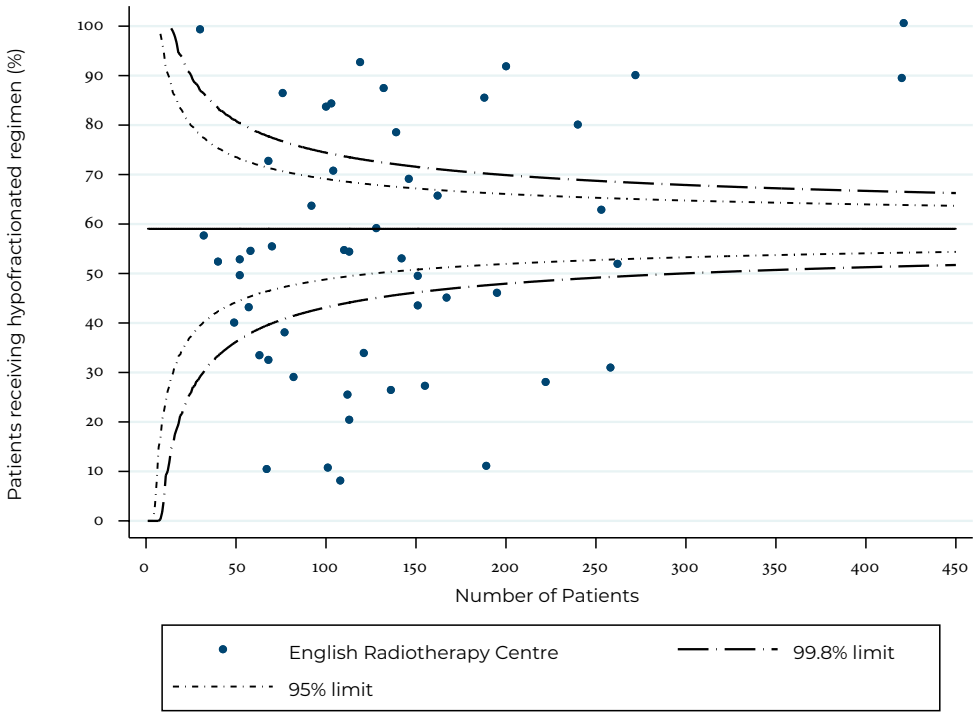
91% of the men receiving radical radiotherapy for intermediate-risk disease received a hypofractionated regimen (range: 12% - 100%). In contrast, 59% of the men receiving radical radiotherapy for high-risk/locally advanced prostate cancer received a hypofractionated regimen (range: 8% - 100%). Adjusted funnel plots (Figure 5 and 6) demonstrate the variation in its use across the 51 radiotherapy centres in England. More variation was seen in the use of hypofractionation for high-risk/locally advanced disease than intermediate-risk disease.

Figure 5. Adjusted funnel plot for the proportion of men having radical radiotherapy for intermediate-risk disease receiving a hypofractionated regimen by radiotherapy centre in England.



Note: Data was not available for Wales and so Welsh providers were not included.

Figure 6. Adjusted funnel plot for the proportion of men having radical radiotherapy for high-risk/locally advanced disease receiving a hypofractionated regimen by radiotherapy centre in England.

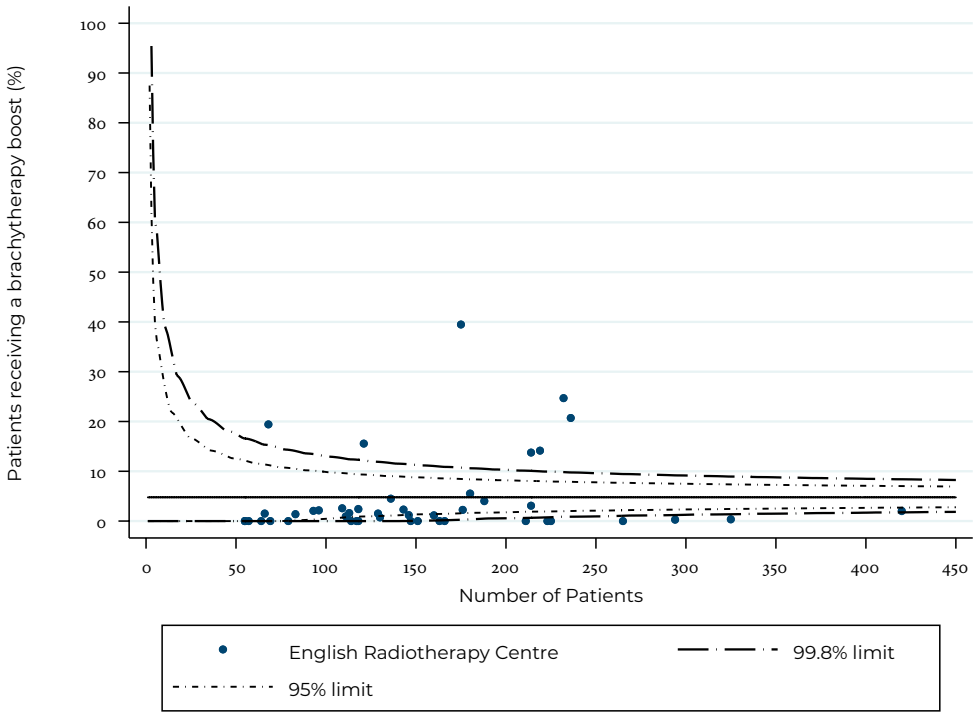


Note: Data was not available for Wales and so Welsh providers were not included.

Performance indicator 6: Proportion of men having radical radiotherapy for high-risk/locally advanced disease receiving a brachytherapy boost

A brachytherapy boost was only given to men who were diagnosed in 25 of 47 specialist MDTs in England. Nationally, only 5% of men receiving radical radiotherapy (with high-risk/locally advanced disease) also received a brachytherapy boost. There were seven specialist MDTs which saw a substantially higher proportion of men receiving this multimodal approach than the others (between 14% and 40%). An adjusted funnel plot (Figure 7) demonstrates the variation in its use across 47 specialist MDTs in England.

Figure 7. Adjusted funnel plot for the proportion of men having radical radiotherapy for high-risk/locally advanced disease receiving a brachytherapy boost by specialist MDTs in England.

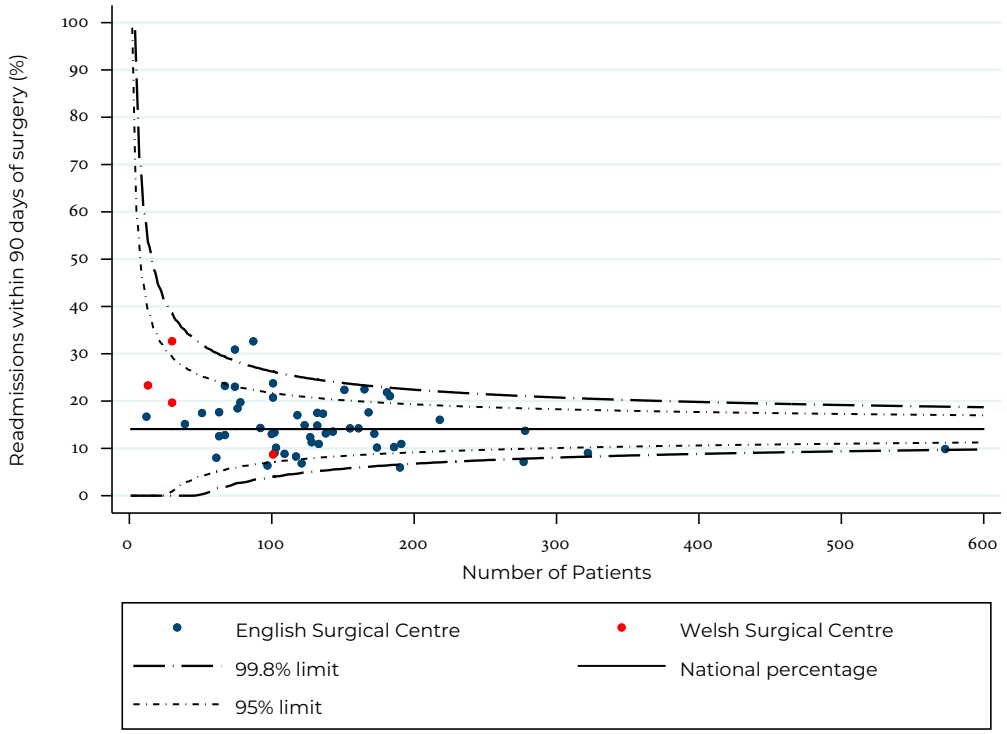


Note: Data was not available for Wales and so Welsh providers were not included.

Performance indicator 7: Proportion of patients readmitted as an emergency within 90 days of radical prostate cancer surgery

7,186 men underwent a radical prostatectomy at 55 Trusts between 1st April 2017 and 31st March 2018. The 90-day emergency readmission rate following radical prostatectomy was 14%. Following adjustment, two surgical centres had a significantly worse readmission rate than the others (negative outlier), and two centres had a significantly better rate (positive outlier) (Figure 8). This outcome measure is also used for the NPCA outlier process and the Trust responses can be found in the Appendix.

Figure 8. Adjusted funnel plot for the proportion of patients readmitted as an emergency within 90 days of radical prostatectomy by surgical centres.

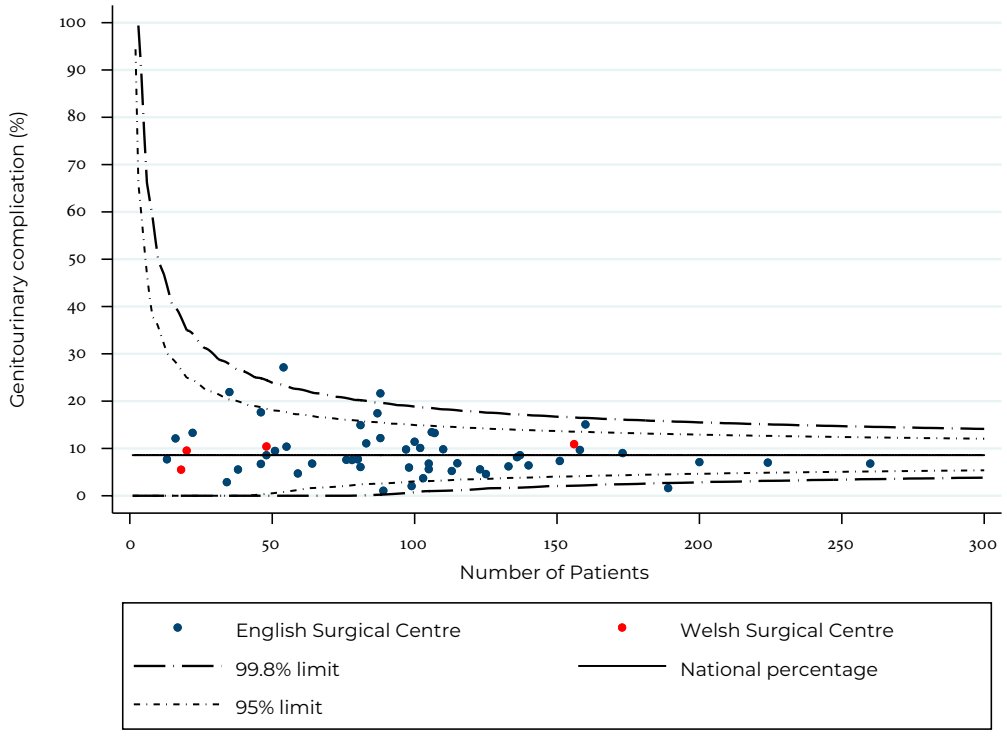


3.5 NPCA 'medium-term' performance indicators

Performance indicator 8: Severe genitourinary toxicity following radical prostatectomy

5,403 men underwent a radical prostatectomy at 56 Trusts during 2016. Overall 9% of men experienced at least one severe treatment-related GU complication within two years following surgery. Following adjustment, there were two surgical centres which had significantly worse rates of severe GU complications than the others (negative outliers), and one centre with significantly better rates of complications (positive outliers) (Figure 9). This outcome measure is also used for the NPCA outlier process and the Trust responses can be found in the Appendix.(Figure 9).

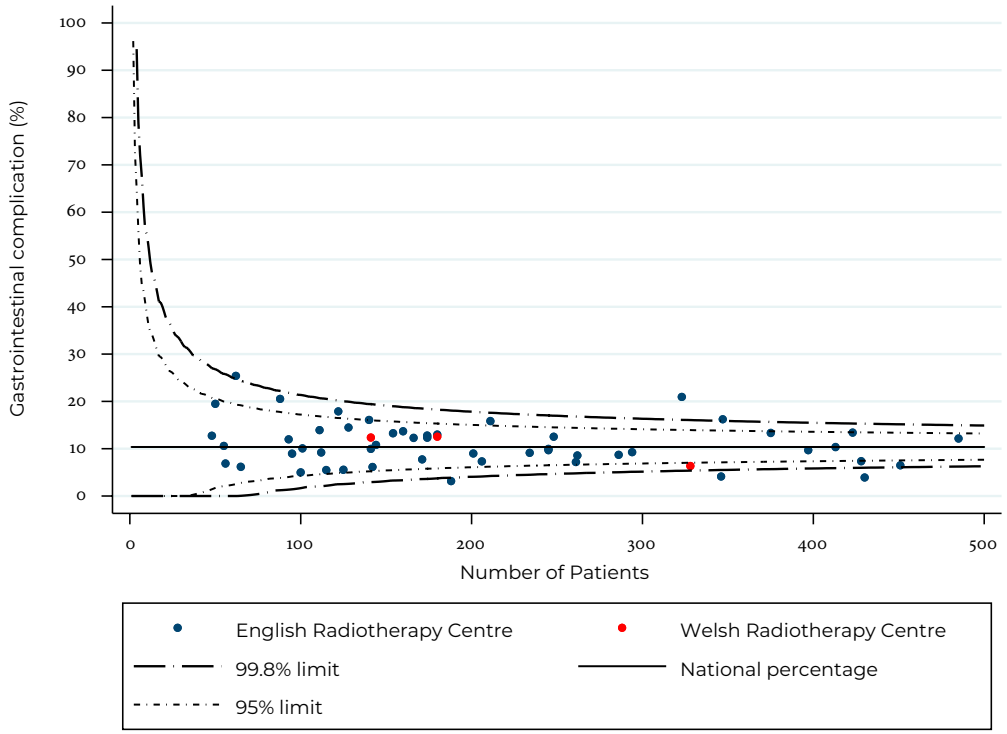
Figure 9. Adjusted funnel plot for the proportion of patients who experienced a severe genitourinary complication within 2 years of radical prostatectomy by surgical centres.



Performance indicator 9: Severe gastrointestinal toxicity following radical external beam radiotherapy (EBRT)

11,252 men received EBRT at 54 Trusts during 2016. Overall 10% experienced at least one severe bowel complication within two years of radiotherapy. Following adjustment, there were three centres with significantly worse rates of severe GI toxicity than the others (negative outliers), and three centres with significantly better rates of complications (positive outliers) (Figure 10). This outcome measure is also used for the NPCA outlier process and the Trust responses can be found in the Appendix.

Figure 10. Adjusted funnel plot for the proportion of patients who experienced a severe gastrointestinal complication within 2 years of radical radiotherapy by radiotherapy centres.

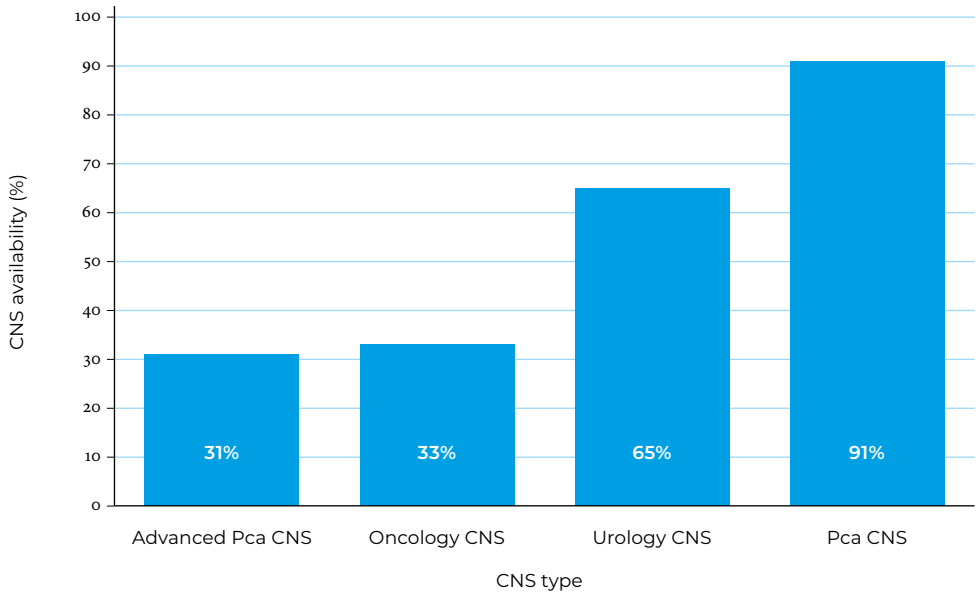


3.6 Organisational audit

The NPCA organisational audit is updated annually and the important aspects are summarised below. The Trust-/Health Board-level results can be found on the NPCA website (www.npca.org.uk).[23] 98% of Trusts/Health Boards are able to perform multiparametric MRIs onsite and three quarters are able to perform trans-perineal biopsies (77%).

The availability of a CNS was also found to be very high. 98% of Trusts/Health Boards had a CNS but the type of CNS varied across the country. 91% had a CNS dedicated to prostate cancer with 65% having a general urology nurse specialist (Figure 11). Approximately one third of Trusts had either an oncology CNS (33%) or an advanced prostate cancer CNS (31%).

Figure 11. Availability of Clinical Nurse Specialists (CNS) according to NHS providers.



[23] https://www.npca.org.uk/reports/npca-organisational-audit-2019/

Support services were also found to be widely available. 98% of specialist MDTs had sexual function and continence services with all specialist MDTs having psychological counselling available.

As part of this year's audit we also carried out an organisational survey of the radiotherapy centres in England and Wales with a response rate of 100% (56 centres). Most centres have an onsite clinical trials unit (49/56 centres; 88%) but less than half have a specialist gastrointestinal service (21/56 centres; 37.5%). Regarding radiotherapy services, most centres provide multiple radiotherapy delivery techniques. All but two centres provide rotational IMRT (96%) with IMRT and 3D conformal radiotherapy available in 71% and 68% of centres, respectively. Other techniques used were stereotactic body radiation therapy (SBRT, 23%), tomotherapy (13%) and cyberknife® (9%). In terms of image guidance most centres used cone beam CT (80%), with 9% using fiducial markers and 11% using combined image guidance. No centres reported using KV imaging or fan beam CT. For adjuvant radiotherapy to the prostate bed, cone beam CT was again the most popular (96%) with 6 centres utilising KV imaging (5%). Only 1 centre offered rectal spacer insertions prior to radiotherapy or brachytherapy.

Regarding the treatment regimen, most centres used nodal status as the key indicator for pelvic lymph node irradiation (91%) with just under two-thirds of centres using it in high-risk disease (64%). A Roach score was not commonly used to guide the use of pelvic lymph node irradiation: only 41% and 16% of centres used a Roach score ≥20 and ≥15, respectively.

There was no agreement regarding adjuvant ADT treatment duration. This was especially evident for low-risk disease with 43% of centres giving 3 months of neo-adjuvant ADT. More than half of the centres (52%) do not give neo-adjuvant ADT. Total durations of ADT for low-risk disease also varied with 55% of centres choosing not to give ADT, 14% giving 3 months and 30% giving 6 months. There was better consensus with intermediate-risk cancer, where the majority of centres give 3 months of neo-adjuvant ADT (79%) and 6 months of ADT in total (73%). For high-risk disease, 57% of centres gave 3 months of neo-adjuvant ADT (23% and 20% giving 6 months and >6 months, respectively). The majority of centres gave at least 2 years of ADT following completion of radiotherapy (38% and 52% for 2 years and 3 years, respectively).

The survey also collected data on docetaxel use in prostate cancer. All centres considered "high volume" M1 disease (according to CHAARTED trial criteria) as a clear indication to offer primary docetaxel chemotherapy, with the majority also considering "low volume" M1 disease (84%) (CHAARTED criteria) to be an appropriate indication. Only 27% of centres considered high-risk non-metastatic disease to be an appropriate indication for neo-adjuvant docetaxel.

4. Discussion

4.1 Participation and data completeness

Data completeness for staging items is high and allows for more than 90% of men to be assigned a risk status. We have previously reported on a 'mixed' group for men who were deemed at least high risk but for whom no data were available regarding metastatic status. This group has now been dropped given that staging completeness has improved year on year and the 'mixed' group now accounts for only a very small proportion of cases.

Other key variables, including multiparametric MRI, are not so comprehensive and data completion varies between Trusts. Given the importance of a multiparametric MRI within the diagnostic pathway for prostate cancer, the NPCA are targeting the completeness of this variable as a priority for subsequent reports. From April 2019, the NPCA moved to using routine databases for all our data analyses. This has therefore replaced the bespoke data items collected through the NPCA minimum datasets so as to avoid replication of information and to ensure an easier data collection process. From April 2020 there will be further COSD data items regarding pre biopsy multiparametric MRI and prostate biopsy type, and we encourage all diagnostic Trusts to ensure that these variables are completed fully.

4.2 Diagnostics

The use of trans-perineal biopsies has increased compared to last year and this procedure is now performed in three-quarters of the Trusts/Health Boards in England and Wales. However, trans-rectal ultrasound guided biopsy is still the dominant biopsy technique being used.

The use of multiparametric MRI is continuing to rise year on year and is up to 62% of patients in both England and Wales, with most Trusts having MRI availability onsite (98%). The majority of these MRIs are also being performed before initial biopsy, another substantial improvement.

4.3 Performance indicators

Diagnosis and treatment selection

The proportion of men diagnosed with metastatic disease at first presentation has remained similar to last year at 16% and there is minimal variation across specialist MDTs in England and Wales. The figures for potential 'over-treatment' in low-risk men and potential 'under-treatment' in high-risk/locally advanced men has remained stable compared to last year at 4% (16/17: 4%) and 32% (16/17: 33%), respectively.

There have been a number of new process measures in the NPCA this year due to the introduction of docetaxel for newly presenting hormone naive metastatic patients into the NICE guidelines and to changes in radiotherapy fractionation/dose-escalation. 27% of men with metastatic disease received primary docetaxel. We expect this to increase year on year and will monitor this trend going forward.

Hypofractionated radiotherapy is now the most common radiotherapy regimen used for both intermediate-risk (91%) and high-risk/locally advanced prostate cancer (59%). Although variation across radiotherapy centres was quite limited for intermediate-risk disease its variation was particularly widespread for high-risk/locally advanced disease. This indicates that the nationwide uptake of a hypofractionated radiotherapy regimen has been greater in intermediate-risk disease. There is a large variation across radiotherapy centres in its use for high-risk/locally advanced disease which is likely to be multi-factorial including reservations amongst clinicians about its role and effectiveness in this setting, as well as logistical and service delivery factors.

Variation was observed for the use of a brachytherapy boost, where only 1 in 2 specialist MDTs referred onto a radiotherapy centre which performed it. Nationally, very few men with high-risk/locally advanced disease who received radical radiotherapy also received a brachytherapy boost (5%). There were seven regions where a substantially higher proportion of men with high-risk/locally advanced disease received this multimodal approach (between 14% and 40%).

Treatment-related outcome measures

The national average for 90-day readmissions after RP is stable at 14% (16/17: 13%) with 2 centres being identified as potential outliers. The proportion of men experiencing a severe treatment-related GU complication within two years of surgery has dropped slightly since last year's report from 11% to 9% with 2 centres being identified as potential outliers. The proportion of men experiencing a severe treatment-related GI complication within two years of radiotherapy remained consistent with last year at 10% with 3 centres being identified as potential outliers.

Centres with potentially outlying performance for the outcome measures should review their treatment pathway and engage with other providers to understand any differences in care. The NPCA are hosting a Quality Improvement workshop later this year and we encourage all clinical leads to attend. It will be a perfect opportunity to learn about the processes of the NPCA and ways to improve care.

4.4 Organisational audit

There is CNS support in the vast majority of Trusts and support services for sexual function, continence and psychological counselling are widely available throughout the country. This highlights the wide availability of these services, not just in the lead up to treatment but continually thereafter. Ensuring that the patients who need this support actually go on to access these services is also important to measure but this was not possible through our cross-sectional survey.

Radiotherapy services have seen a large shift within the last decade with the vast majority of radiotherapy centres now offering rotational IMRT (96%). The majority still use image guidance through cone beam CT, with fiducial markers for

(primary EBRT) and KV imaging (for prostate bed EBRT) being used in a minority of centres. Newer techniques using rectal spacers are rarely used and according to our survey are only available in one centre. A major factor in England is the lack of tariffs for commissioning this service routinely and NHS England are in the process of developing this with selected Trusts.

There was greater consistency regarding the use of docetaxel; the majority of centres used it in high and low volume M1 patients, as well as in castrate resistant disease, however, in relation to the use of ADT in the neo-adjuvant and adjuvant settings for high-risk disease there are clear differences. The duration of ADT treatment varied widely across the country (specifically for low- and high-risk disease). This observed phenomenon requires further study and consultation to engender a more unified national consensus.

4.5 Future Plans for the NPCA

The NPCA in England no longer collects any bespoke data items within the NPCA minimum dataset. For men diagnosed from the 1st April 2019 COSD data items only are collected in keeping with the monthly routine submission of data to the NCRAS, PHE. We encourage Trusts to review their data quality and to ensure the following COSD data items are uploaded to the cancer registry for every newly diagnosed patient with prostate cancer: performance status, CNS availability, PSA, Gleason score, TNM and the two new COSD data items regarding pre biopsy multiparametric MRI and prostate biopsy type.

We reported the results from the NPCA patient survey last year and we plan to follow this up with further PROMs and PREMs in next year's report. We also plan to continue our annual organisational survey in order to provide up to date information about service availability across the country.

We shall continue to publish data in England as part of the Clinical Outcomes Programme (COP) and the National Clinical Audit Benchmarking (NCAB) to enable dissemination of our findings to clinicians, stakeholders, patients and the wider public. The indicators we use for this are those used for our own outlier policy and focus on treatment-related outcomes (90 day readmissions following surgery, 2 year genitourinary complications following surgery and 2 year gastrointestinal complications following radiotherapy).

The success of the NPCA relies solely on the quality of the data received from Trusts and Health Boards across England and Wales. Our data collection partners (NCRAS and WCN) will continue to work directly with individual care providers to help improve data quality. This will ensure the reliability of all the results we present and the reporting of outliers. The NPCA will continue to use our outlier policy to notify outlying providers for which we publish the Trust responses in each Annual Report. This will enable the data to be checked and changes implemented to improve patient outcomes.

Glossary

Active Surveillance
The initial monitoring of prostate cancer that has a low risk of progression.

Adjuvant
Treatment that is given in addition to the primary treatment.

Androgen Deprivation Therapy (ADT)
Hormone therapy is used to control prostate cancer and delay or manage any symptoms. Testosterone makes prostate cancer cells grow faster and hormone therapy works by either stopping your body from making the hormone testosterone, or by stopping testosterone reaching the prostate cancer cells. By doing this the cancer will usually shrink, wherever it is in the body. Hormone therapy can be used when prostate cancer cells have already spread to distant sites but it can also be used with other treatments, such as radiotherapy, to make them more effective.

ASA score
The American Society of Anaesthesiologists (ASA) classification is a scoring system based on the perioperative health and co-morbidities of a surgical patient. A high ASA score denotes a higher risk of perioperative complications in the short and long term. For the NPCA, an ASA score is assigned to all patients regardless of treatment.

Brachytherapy
A treatment for prostate cancer using either the implantation of permanent radioactive seeds into the prostate (termed low dose rate brachytherapy) or the temporary insertion of a source of radiation into the prostate (termed high dose rate brachytherapy). Brachytherapy can deliver a high radiation dose to the prostate gland whilst avoiding radiation to the surrounding healthy tissue. This treatment can be used in isolation or in combination with radiotherapy in higher risk disease.

British Association of Urological Nurses (BAUN)
The British Association of Urological Nurses is a registered charity which aims to promote and maintain the highest standards in the practice and development of urological nursing and urological patient care. Registered charity no: 1140616.

British Association of Urological Surgeons (BAUS)
A professional association for urological surgeons. Registered charity no: 1127044.

British Uro-oncology Group (BUG)
Professional association for clinical and medical oncologists specialising in the field of urology. Registered charity no: 1116828.

Cancer Network Information System Cymru (CaNISC)
An online computer system that provides information for health professionals on cancer patients across Wales.

Cancer Outcomes and Services Dataset (COSD)
The national standard for reporting on cancer in the NHS in England. Trusts submit a data file to the National Cancer Registration and Analysis Service (NCRAS) every month.

Care Quality Commission (CQC)
Independent regulator of health and adult social care in England. The CQC makes sure that health and social care services provide people with safe, effective, compassionate and high-quality care.

Case-mix
Refers to different characteristics of patients seen in different hospitals (for example age, sex, disease stage, social deprivation and general health). Knowledge of differing case-mix enables a more accurate method of comparing quality of care (case-mix adjustment).

Case-mix adjustment
A statistical method of comparing quality of care between organisations that takes into account important and measurable characteristics (also see risk-adjustment).

Castrate Resistant Prostate Cancer
Prostate cancer that keeps growing even when the amount of testosterone in the body is reduced to very low levels.

Charlson Co-morbidity Score
A commonly used scoring system for medical co-morbidities. The score is calculated based on the absence and presence of specific medical problems in the Hospital Episode Statistics (HES) database.

Clinical Effectiveness Unit (CEU)
An academic collaboration between the RCS and the London School of Hygiene and Tropical Medicine (LSHTM). The CEU carries out national surgical audits, develops audit methodologies and produces evidence on clinical and cost effectiveness.

Clinical Nurse Specialist (CNS)
Experienced senior nurses who have undergone specialist training and play an essential role in improving communication and coordinating treatment in cancer patients. They act as the first point of contact for the patient, coordinating and facilitating the patient's treatment.

Clinical Outcomes Publication (COP)
An NHS initiative, managed by HQIP, to publish quality measures at the level of each individual consultant, team and unit using national clinical and administrative data.

Co-morbidity
Medical condition(s) or disease process(es) that are additional to the disease under investigation (in this case, prostate cancer).

Cone Beam Computed Tomography
A medical imaging technique consisting of X-ray computed tomography (CT) where the X-rays are divergent, forming a cone, in order to produce three dimensional images.

Cyberknife®
Cyberknife® is an advanced radiation therapy device which has X-ray cameras that monitor the position of a tumour and sensors that monitor the patient's breathing. This enables the robot to reposition the radiotherapy beam during treatment in order to minimise damage to healthy tissue.

External Beam Radiotherapy (EBRT)
The use of high energy X-ray beams directed at the prostate to kill cancer cells. It is used to treat localised or locally advanced prostate cancer.

Fiducial Markers
Tiny metal objects used during radiotherapy which allows the doctors to line up the beams of radiation to make sure that each radiation therapy is delivered exactly the same way each time.

Gleason Score
The Gleason score is a microscopic measure of how aggressive the prostate cancer is and is graded up to ten. Along with PSA and TNM, the Gleason score can be used to risk stratify patients.

Health Board
A local health organisation that is responsible for delivering all healthcare services within a regional area in Wales. Currently, there are seven Health Boards in Wales and six of these provide prostate cancer services

Healthcare Quality Improvement Partnership (HQIP)
The Healthcare Quality Improvement Partnership (HQIP) aims to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices.

Hospital Episode Statistics (HES)
A database that contains data on all patients treated within NHS trusts in England. This includes details of admissions, diagnoses and treatments.

Intensity-modulated Radiotherapy (IMRT)
A type of conformal radiotherapy. Conformal radiotherapy shapes the radiation beam to closely fit the area of the cancer in order to avoid healthy tissue. The benefit over 3-dimentional conformal radiotherapy is that a higher dose can be given to specific areas of the prostate while limiting the radiation dose to the surrounding tissues.

International Classification of Diseases, Tenth Revision (ICD-10)
The World Health Organisation international standard diagnostic classification. It is used to code diagnoses and complications within the Hospital Episode Statistics database of the English NHS.

KV Imaging
High-resolution, low-dose digital imaging system that makes image-guided radiation therapy more efficient and convenient.

Localised Disease
When cancer is confined within the anatomical boundaries of the prostate.

Locally Advanced Disease
When cancer has spread outside the anatomical boundaries of the prostate (T_3 or T_4). This may be associated with spread to lymph nodes within the pelvis (N_1).

Lymphadenectomy
The surgical removal of one or more groups of lymph nodes (usually in the pelvis in prostate cancer).

Magnetic Resonance Imaging (MRI)
A type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body.

Margin Status
Once the prostate has been removed during surgery, the margin status indicates if the edge of the specimen contains cancer cells or not. A positive margin status would indicate that residual prostate cancer cells may have been left behind in some patients.

Metastatic Disease
When cancer has spread away from the prostate to distant sites of the body, mainly to the bones and lymph nodes in the first instance.

Multidisciplinary Team (MDT)
A team of specialist health care professionals from various backgrounds (e.g. doctors, nurses, administrative staff) who collaborate to organise and deliver care for patients with a specific condition (e.g. prostate cancer).

Multimodal Therapies
The use of multiple treatments for use against prostate cancer. This may be a combination of treatments including radiotherapy, hormone therapy, surgery and/or systemic chemotherapy.

Multiparametric MRI (mpMRI)
A special type of Magnetic Resonance Imaging Scan (MRI) that provides detailed images of the prostate.

National Cancer Data Repository (NCDR)
The NCDR comprises a merged dataset of English cancer registration data, linked to further national datasets including Hospital Episode Statistics (HES), the radiotherapy dataset (RTDS) and Office of National Statistics data (ONS).

National Cancer Registration and Analytical Service (NCRAS)
A national body which collects, analyses and reports on cancer data for the NHS population in England.

Neo-adjuvant
Treatment that is given as a first step before the primary treatment.

Nerve-sparing Surgery
Preservation of the nerves surrounding the prostate during prostatectomy in order to preserve erectile function after the operation. This is not always possible if the cancer has spread outside of the prostatic capsule.

NHS Digital
The provider of professional IT services to the NHS. Their goal is to improve health and social care in England by making better use of technology, data and information.

NHS Hospital Trust
An NHS organisation that provides acute care services in England. A trust can include one or more hospitals.

National Institute for Health and Care Excellence (NICE)
An organisation responsible for providing national guidance on the promotion of good health, and the prevention and treatment of ill health.

Office for National Statistics (ONS)
Government department responsible for collecting and publishing official statistics about the UK's society and economy. This includes cancer registration data.

Patient Episode Database for Wales (PEDW)
A database that contains all inpatient and day case activity undertaken in NHS Welsh hospitals. This includes details of admissions, diagnoses and the treatments undergone.

Performance Status (WHO/ECOG)
The World Health Organisation (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status indicator is a measure of how disease(s) impacts a patient's ability to manage on a daily basis. It was initially developed in the research setting to standardise the reporting of chemotherapy toxicity and the response of cancer patients in clinical trials. However, it is now in the public domain and is routinely used in other research and clinical settings.

Prostate Specific Antigen (PSA)
A protein produced by the cells of the prostate gland. A high PSA may indicate prostate cancer or prostate cancer recurrence but it also may indicate benign conditions such as an enlarged prostate or infection.

Prostatectomy
The surgical removal of the prostate gland.

Radical treatment
Treatment aimed at curing prostate cancer (removing cancer tissue). These treatments include radical prostatectomy and radiotherapy (including brachytherapy).

Radiotherapy
The use of radiation to destroy cancer cells. There are different types of radiotherapy, including external beam radiotherapy and brachytherapy.

Radiotherapy Data Set (RTDS)
A database that contains standardised data from all NHS Trust providers of radiotherapy services in England.

Rectal Spacer
Rectal spacers are used prior to radiotherapy and are placed between your prostate and rectum in order to move your rectum away from your prostate. This protects your rectum from radiation and reduces some side effects of radiation therapy.

Risk Stratification
Classification of prostate cancer according to individual risk profile. This is done by taking into account how aggressive the cancer is and how far it has spread.

Risk-adjustment
A statistical method that takes into account important and measurable characteristics (also see case-mix adjustment).

Roach Score
A formula which uses PSA and Gleason score to predict the risk of pelvic node involvement in prostate cancer patients.

Robotic-assisted Prostatectomy
A key-hole laparoscopic operation that uses a robot console to help the operating surgeon. The robot allows for more controlled and precise movements during the operation. Advantages over traditional open surgery include less blood loss, less post-operative pain, a shorter hospital stay, smaller scars and a greater likelihood of sparing the nerves and bloods vessels which are attached to the prostate.

Royal College of Surgeons of England (RCS)
An independent professional body committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care. As part of this it supports audit and the evaluation of clinical effectiveness of surgery.

Specialist Multidisciplinary Team (sMDT)
A team of specialists who coordinates the specialist treatment of men with prostate cancer. The sMDT enables local cancer units to access specialist prostate cancer services which may not be locally available. Specialist services include prostatectomy and radiotherapy.

Staging/stage
The anatomical extent of a cancer.

Stereotactic Body Radiation Therapy (SBRT)
SBRT is a type of radiotherapy which delivers precise, intense doses of radiation to cancer cells using image guidance and in doing so minimises the damage to the surrounding healthy tissue.

Systemic Anti-Cancer Therapy (SACT)
The SACT database collects systemic anti-cancer therapy activity from all NHS England providers. This database has been used to identify the men receiving docetaxel chemotherapy for their prostate cancer.

TNM stage
This is a classification that describes how advanced the cancer is and stands for Tumour (T), Node (N) and Metastasis (M). T describes the size of the tumour, N describes the involvement of lymph nodes and M describes if the cancer has spread to a different part of the body.

Tomotherapy
Tomotherapy is a form of radiotherapy which combines a personalised treatment plan with intensity modulation and image guidance to treat cancer efficiently.

Trans-perineal biopsy
Biopsy of the prostate through the perineum (the area of skin between the back of the scrotum and the front of the anus). This is performed under general anaesthetic and needle placement can be more precise than trans-rectal ultrasound biopsies.

Trans-rectal Ultrasound (TRUS) Biopsy
The use of thin needles to takes tissue samples from the prostate after numbing the area with local anaesthetic. The biopsy is done through the rectum (back passage). The placement of these needles is enabled by use of an ultrasound scanner in the rectum to guide the biopsy.

Treatment-related Toxicity
Complications following radical treatment. Genitourinary and gastrointestinal complications can be expected following radiotherapy, but only genitourinary complications are expected following prostatectomy.

Wales Cancer Network (WCN)
A new organisation that has evolved from the merger of the two Cancer Networks in Wales and the Cancer National Specialist Advisory Group (NSAG) and is designed to collect cancer-specific information in Wales.

Welsh Cancer Intelligence and Surveillance Unit (WCISU)
WCISU is the National Cancer Registry for Wales. Its primary role is to record, store and report on all incidences of cancer for the resident population of Wales.

Appendix 1: Outlier Communications

Responses from Trusts with a confirmed 'case to answer' during the NPCA Outlier Process[24]

Surgical centres

Performance indicator 7: Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.

Shrewsbury and Telford Hospital NHS Trust

Performance indicator 8: Proportion of patients experiencing at least one severe genitourinary (GU) complication within 2 years of radical prostatectomy.

Manchester University NHS Foundation Trust

Radiotherapy centres

Performance indicator 9: Proportion of patients experiencing at least one severe gastrointestinal (GI) complication within 2 years of radical radiotherapy.

Norfolk & Norwich University Hospitals NHS Foundation Trust

Sheffield Teaching Hospitals NHS Foundation Trust

Torbay & South Devon NHS Foundation Trust

[24] https://www.npca.org.uk/resources/npca-outlier-policy-2019/

Response from Shrewsbury and Telford Hospital NHS Trust

Performance indicator 7: *Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.*

Thank you for your letter and sharing your audit. We have relooked at the audit and database you sent. We informed you that A&E and SAU attendances were included in your re-admission calculation. We also noticed that the cohort of patients you audited were patients who had radical prostatectomy between 1st April 2017 and 31st March 2018. They were not patients who were diagnosed with prostate cancer between 1st April 2017 and 31st March 2018 and subsequently had radical prostatectomy.

However, we did have a period of increased 28 day readmissions in 2017-18 which was recognized in 2018 as we monitor our readmissions. Various measures have been introduced since then. These include earlier catheter removal, changing the way bladder neck is handled during surgery and modifying the criteria used for lymph node dissection. Re-admission rates have reduced following these measures. This was confirmed in our internal audit we shared with you in October 2019. CHKS dataset also supports this and I enclose an output which I am sure is available to you as well.

We will be moving our prostatectomies to a centralized centre in 2020 as part of GIRFT initiative. This will hopefully improve our outcome further.

Response from Manchester University NHS Foundation Trust

Performance indicator 8: *Proportion of patients experiencing at least one severe genitourinary (GU) complication within 2 years of radical prostatectomy.*

Response 1

Thank you for your letter regarding our prostate cancer practice for the year 2016. Owing to the short notice given to us and the complex nature of our prostate cancer pathway with multiple providers, we have been unable to robustly validate the data. We accept your findings as such. As a Trust we no longer provide the treatment aspect of the prostate cancer pathway. Therefore this is historical data for a service that we no longer provide.

Response 2

I have been asked to reply on behalf of MFT to your letter raising concerns about genitourinary tract complications following radical prostatectomy. As you are aware this is no longer a procedure which is undertaken within this organisation but we realise that there may be learning which applies to other areas of surgical practice.

In order to understand the issues raised by your enquiry I have asked the urology department to undertake a case note review of all the affected patients […] and will seek to correlate the clinical characteristics of the patients with the occurrence of adverse outcomes. We will also seek to ascertain any underlying identifiable clinical risk factors associated with the development of these adverse outcomes.

I would normally have expected a review of this sort and scope to be complete by the end of January. However, as you may appreciate, the operations in question were performed by an MFT surgeon operating on patients of another Trust as part of a waiting list initiative at a local private hospital. This will make it substantially more difficult for us to obtain the relevant clinical information and so would suggest that this deadline be extended to the end of March to facilitate this information gathering.

It goes without saying that we will share the results of our investigation with you when it is complete I trust that this gives you sufficient reassurance that we are taking this alert seriously and that we have a framework in place which will enable us to understand what has happened and learn lessons from it which will benefit patient care in the future.

Response from Norfolk & Norwich University Hospitals NHS Foundation Trust

Performance indicator 9: Proportion of patients experiencing at least one severe gastrointestinal (GI) complication within 2 years of radical radiotherapy.

Thank you very much for informing us that the NNUH is a potential outlier for radiation proctitis for the year 2016. We have reviewed the patient level data and note one patient who had radiation proctitis in fact had prostate bed radiotherapy. However we agree that this centre's radiation proctitis rate appears to be 20% and that we are a very significant outlier for this complication.

We suspect the reasons for this are multifactorial. On learning that we were a significant outlier last year we have looked closely at our practice. We benchmarked ourselves against the other radiation oncology centres in the Eastern region. As a result of this we reduced our seminal vesicle dose from 55Gy to 52.5 Gy for the 60Gy 20 fraction prostates. We have reduced the seminal vesicle dose to 60Gy for the 74Gy prostates. We adopted margins of 0.6cm/0.5cm for the prostate and 1cm for the seminal vesicles.

We also looked at our image guidance. All of our patients originally had bony matching with a shift if the CTV was not covered. We retrospectively looked at six patients with radiation proctitis from the 2015 cohort. We looked at rectum positioning on the patients' daily cone beams and found in four out of six patients the dose delivered to the rectum was greater than had been planned. We started soft tissue matching to the CTV on the 22.02.2018. When our current imaging protocol was applied retrospectively to these patients the rectal dose was reduced. We believe that this will have a significant effect on our radiation proctitis rate in future patients.

We have instituted weekly peer review meeting for all clinicians who treat prostate cancer with physics and dosimetry support. We prospectively peer review all of our radical contouring and have adopted ESTRO contouring guidance as well as using available trial atlases. We still use PIVOTAL boost dose constraints for all of our patients. We optimize our plans to reduce the dose to the rectum as much as we can.

We note it takes up to two years to develop radiation proctitis. We fear that we will remain an outlier for radiation proctitis in 2017. We are in the process of organising an external review of our prostate practice to ensure that all of the changes we have instituted are sufficient to reduce our rectal toxicity and to ensure that there are no other factors which have been overlooked.

Response from Sheffield Teaching Hospitals NHS Foundation Trust

Performance indicator 9: Proportion of patients experiencing at least one severe gastrointestinal (GI) complication within 2 years of radical radiotherapy.

The toxicity data relates to men treated in 2016 and since 2016 there have been significant changes in our centre.

For whole pelvis treatment we have changed from 3d conformal planning with doses of 69Gy in 37 fractions (Phase 1 45Gy/25 fractions Phase 2 24Gy/12 fractions as per PRO7) to Rapidarc as standard (74/71/55Gy in 37 fractions with contouring and dose constraints as per the Pivotal trial).

We had already switched to fixed field IMRT for prostate only plans – as per the CHHiP protocol – and we took part in the Eagle trial (led by Prof Staffurth). This involved very intensive investigation of GI toxicity following radical radiotherapy for prostate cancer. This has allowed a robust pathway for the referral of men with GI toxicity in Sheffield for investigation and ongoing management. After investigation by the gastroenterology team not all GI toxicity identified was due to radiotherapy but unrelated diagnoses were found and treated.

We are now routinely collecting PROMs and objective measures of GI and GU toxicity as part of routine follow up after prostate radiotherapy. If the 2016 data does show that Weston Park centre is an outlier in terms of GI toxicity, we expect these measures will show improvement.

Response from Torbay & South Devon NHS Foundation Trust

Performance indicator 9: Proportion of patients experiencing at least one severe gastrointestinal (GI) complication within 2 years of radical radiotherapy.

Thank you for giving us the opportunity to review the 16 patients identified with a diagnosis of proctitis on the Torbay 2016 NPCA data. A full clinical review has been carried out on 14/16 patients identified. 2 patients had their investigations at the RD&E Hospital. Of these 2 patients, 1 had a diagnosis of radiation proctitis and was treated accordingly. 1 patient was diagnosed with mild radiation telangiectasia and discharged.

We identified 94 patients who received radical radiotherapy (EBRT) during this period, not including patients post RALP. Of these, 23 had a HDR prostate boost and so are excluded from this audit. This will skew our results, as we use a HDR boost in significantly more men than most other centres ie 23/94 = 24%. This clearly affects the denominator for this audit, as patients not selected for HDR boost may have other co-morbidities which could increase the likelihood of radiation proctitis. However, I do not think this the reason for our outlier status.

Following my initial investigation of the 16 patients identified by the audit the Gastroenterology team also reviewed the clinical notes, endoscopy reports and photographs of 14 patients. They confirmed that 1 patient can be confirmed as having radiation proctitis. In addition, they verified that proctitis and radiation telangiectasia have been used interchangeably, on the sigmoidoscopy reports, and this is where the fault has arisen with our Trust. A diagnosis of proctitis has been recorded on the sigmoidoscopy, when in fact radiation telangiectasia should have been recorded. Our Gastroenterologist has confirmed that only one of the 14 patients had active inflammation at the time of sigmoidoscopy, and required treatment for it. This diagnostic error is being addressed with the Endoscopy clinical team and clinical coders to avoid further data errors going forward.

We have taken this opportunity to review the radiotherapy technique and dose fractionation used for the 16 patients you identified. All had either 5/ 7 field IMRT or VMAT and daily Cone Beam CT (CBCT) as image guidance. 2 patients were re-planned during treatment on the basis of daily CBCT to ensure a 'best fit 'plan.

I'm awaiting the final analysis of rectal dvhs but so far there have been no patients with rectal doses out of tolerance as per the CHHiP Trial.

Of note, although Torbay is one of the smallest radiotherapy centres in the UK, we have been keen to ensure that our radiotherapy matches the high standards of the larger centres. We have done this through participating in clinical trials.

There are 3 other radiotherapy centres in the Peninsula. We were the only centre of the four to be accredited and participate in the CHHiP Trial, (the pivotal prostate radiotherapy study that proved 60Gy in 20 fractions is as safe and effective as 74Gy in 37 fractions). We are also the only centre to be part of the Raider trial - a trial of radical radiotherapy in bladder cancer, which requires treatment radiographers to pass a rigorous externally validated assessment of their use of pelvic CBCT for image guidance.

We were the first centre in the Peninsula to be accredited for the Pivotal Boost trial and have been the 7th highest recruiter nationally to that trial. We have recently submitted and passed the RTQA for the PACE trial of stereotactic radiotherapy in prostate cancer.

All these trials have required review of trial dummy cases, prospective review of the first patients we entered into the trials and random retrospective review. At review, our outlining, planning and CBCT (for Raider) have been externally reviewed and validated. Because of that, I feel we can claim that our radiotherapy is safe and of high quality.

In summary, it does appear that we have been identified as an outlier for GI toxicity following radical pelvic radiotherapy for prostate cancer due to a misdiagnosis and subsequent coding error of proctitis rather than radiation telangiectasia.

Once again thank you for giving us the time to review our data, and the opportunity to correct our sigmoidoscopy diagnoses going forward.

