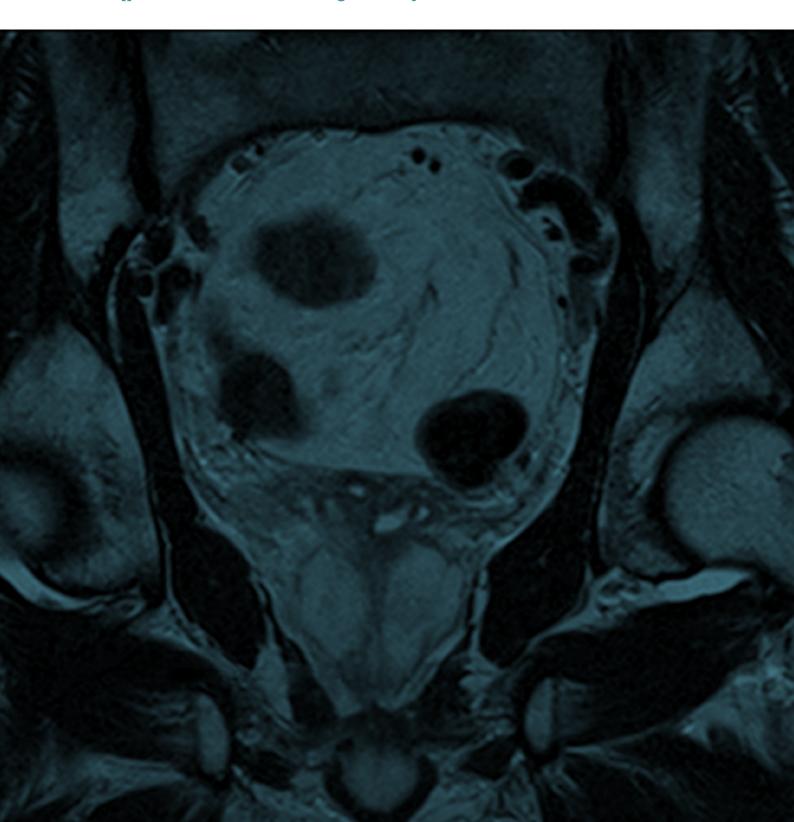


Annual Report 2020

Results of the NPCA Prospective Audit in England and Wales for men diagnosed from 1 April 2018 to 31 March 2019 (published January 2021).



National Prostate Cancer Audit

Seventh Year Annual Report – Results of the NPCA Prospective Audit in England and Wales for men diagnosed 1 April 2018 – March 2019

London: The Royal College of Surgeons of England, 2021.



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, 2020.

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 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 www.hqip.org.uk/national-programmes

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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)

Patient and Public Involvement (PPI)

Prostate Specific Antigen (PSA)

Public Health England (PHE)

Radical Prostatectomy (RP)

Royal College of Surgeons (RCS)

Specialist Multidisciplinary Team (SMDT)

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 NPCA Project Team would like to thank all men in England and Wales who have completed the NPCA Patient Survey and for sharing their views on the quality of care and the impact of radical treatment on their daily lives.

We would also 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. The NPCA compares NHS Providers in England and Wales identifying any potential outlying performance related to both short and medium-term treatment outcomes following radical treatment.

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 particularly appreciate the efforts of the cancer intelligence analysts and cancer information specialists at NCRAS and the Wales Cancer Network who supplied the data in the midst of the COVID-19 pandemic.

We would like to thank BAUS and BUG for their continued professional guidance and for raising awareness amongst urological and uro-oncological colleagues. We would also like to thank all members of the newly-formed NPCA Patient and Public Involvement (PPI) Forum for providing advisory support and ensuring the voice of patients is central to the direction and delivery of the NPCA. A lay report summarising the key results will be developed in consultation with the NPCA PPI Forum and published in Spring 2021.

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² This work uses data that has been provided by patients and collected by the NHS as part of their care and support. The data are collated, maintained and quality assured by the National Cancer Registration and Analysis Service (NCRAS), which is part of Public Health England (PHE). Access to the data was facilitated by the PHE Office for Data Release. http://www.ndrs.nhs.uk/

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Foreword

This 2020 NPCA report has been produced in exceptional circumstances. There has been a 23% surge in prostate cancer cases diagnosed as a consequence of the "Fry-Turnbull" effect. Also, the COVID-19 crisis has brought special challenges for local data-gathering and a combination of innovation, resourcefulness and sheer hard work has ensured that future NPCA reports can be produced. We would like to thank all teams for their outstanding efforts, meeting and overcoming the exceptional challenges engendered by these events.

This, the 7th NPCA Annual Report covering the diagnostic period between April 1st 2018 and March 31st 2019, brings clinicians and patients right up to date with the prostate cancer landscape in 2020 in England and Wales. It is reassuring to see that the overall quality of the diagnostic and treatment services are good, and that patient reported satisfaction is high.

That said, there are areas of practice highlighted in the report where there is significant variation between hospitals in aspects of prostate cancer diagnosis and treatment, particularly for those men with high-risk disease and those in the older age groups. Consider the use of docetaxel in newly diagnosed prostate cancer patients: although there has been a modest increase in usage from 27 to 36%, the overall figure is still low.

The NPCA Quality Improvement (QI) Programme will continue to address issues such as this, building on its successes in 2019 and 2020, which include the addition of new quality standards, the organisation of a highly effective QI workshop and a designated QI section on the NPCA web site. This web site has information about individual units. Please take a look and use it when you can!

This year's Annual Report includes the results of the second survey of individual patient-reported outcomes. Detailed questionnaires were sent to just under 11,000 men 18 months after they were diagnosed with prostate cancer. We would like to thank all the men who completed the survey enabling us to achieve an excellent response rate (78%). These results build on those of the highly successful first survey that were reported in the 2018 Annual Report and will enable future benchmarking. The first survey provided detailed comparative outcome information, collecting patient-reported outcomes in more than 45,000 men. It also led to numerous papers demonstrating how prostate cancer care can be further improved, published in journals such as the Lancet Oncology, Journal of Clinical Oncology, BJUI and others.

In addition to the Annual Report, the NPCA team has produced short reports, including one on 'under-treatment' of men with high risk localised disease. All this demonstrates that the NPCA has now created a unique prostate cancer data resource of national and international importance. This is an achievement that the UK prostate cancer community can justifiably be proud of.

For 2021, the NPCA will continue to develop its activities aimed at performance assessment and quality improvement using data that we receive from our data collection partners in England and Wales, the National Cancer Registration and Analysis Service and the Wales Cancer Network. A further organisational audit will be carried out, giving a 'state-of-thenation' overview of how prostate cancer services are being organised and delivered in England and Wales, in particular the provision of support services.

We will also strengthen our collaborations with existing partners such as the British Association of Urological Surgeons, the British Uro-oncology Group, and NHS Improvement's Getting It Right First Time programme in England, whilst reaching out to other groups to use the power of the NPCA prostate cancer data resource to monitor and improve the quality of care. A programme to establish formal collaborations will also be developed and instituted in the next two years.

Finally, we would like to express our great thanks to the members of the NPCA PPI Forum and patient organisations, including Tackle Prostate Cancer and Prostate Cancer UK, for their support. A very special thanks goes to the hard-working local, regional and national teams for their endeavours in making the NPCA such a success. Their work has been a substantial and sustained effort over years which has put prostate cancer and prostate cancer patients' welfare at the forefront of the national cancer agenda. Given the incidence and importance of this disease, this is exactly where it should be.





NW Combe

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Urological Clinical Lead
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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 their prostate cancer care is consistent with current recommended practice and it provides information to support healthcare providers, commissioners, regulators, patient groups and patients in helping improve prostate cancer diagnosis and treatment. In this report we continue our work as 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 2018 and 31st March 2019 in England and Wales.³ 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. We also report the results from the latest round of the NPCA patient survey including patients' views of their experience of care and their functional outcomes after radical treatment. The NPCA patient survey includes key questions from the National Cancer Patient Experience Survey (NCPES) and the Expanded Prostate Cancer Index Composite 26-item version (EPIC-26) and is collected at least 18 months after diagnosis for men diagnosed between 1st April 2018 and 30th September 2018.

We report on 14 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.
- Proportion of men with high-risk localised/locally advanced disease receiving radical prostate cancer therapy.
- 4. Proportion of men with newly diagnosed metastatic disease who received docetaxel in combination with androgen deprivation therapy (ADT).
- 5. Proportion of men with high-risk localised/locally advanced disease receiving both prostate and pelvic lymph node irradiation, as opposed to prostate-only irradiation.
- 6. Proportion of patients who were given the name of a clinical nurse specialist.
- 7. Proportion of patients rating their overall care as at least 8 out of 10.
- 8. Proportion of patients who had an emergency readmission within 90 days of radical prostatectomy.
- Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/ surgical intervention within 2 years of radical prostatectomy.
- 10. Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy.
- 11. Mean urinary incontinence score after radical prostatectomy
- 12. Mean sexual function score after radical prostatectomy
- 13. Mean bowel function score after radical radiotherapy
- 14. Mean sexual function score after radical radiotherapy.

³ Medium-term indicators require longer follow-up (up to two years' post-treatment) so the reporting time period for GU or GI complications is 1st January to 31st December 2017.

NICE Quality Standards, 2015⁴

- 1. QS1: men with prostate cancer have a discussion about treatment options and adverse effects with a named nurse specialist.
- 2. QS2: men with low-risk localised prostate cancer for whom radical treatment is suitable are offered a choice between active surveillance, radical prostatectomy or radical radiotherapy.
- 3. QS3: men with intermediate- or high-risk localised/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.

This year we present results from the second NPCA patient survey, which provides information on 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). 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 localised/locally advanced disease (see section 3.4, QS2 and QS3).

Previous results from our annual organisational survey⁵ indicate whether providers of cancer services have specialist services on-site (QS4). These will be updated early next year as the planned implementation of this survey has been delayed due to the COVID-19 pandemic.

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. 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 2019⁶ we report, for the second time, the uptake of docetaxel in men with newly presenting metastatic disease, and the extent of the use of prostate plus pelvic lymph node irradiation for men with high-risk localised or locally advanced disease.

Prostate Cancer. NICE Quality Standard [QS91], 2015 (Updated May 2019).

⁵ https://www.npca.org.uk/reports/npca-organisational-audit-2019/

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

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. It also provides an impetus to maintain and improve data collection for the most accurate reflection of prostate cancer care in England and Wales.

A breakdown of results at the level of each Trust/Health Board and specialist MDT are provided on our website.⁷ 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 next Quality Improvement workshop in April 2021. These results will be the basis for discussion and improvement planning. We welcome feedback on how the audit outputs can be improved.

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 users of this report to access these resources to facilitate quality improvement.

Patients can use these results to start conversations with their care providers and a lay summary of the report will be published in early 2021. Previous lay summaries of our Annual Reports and patient-friendly slide sets for use by support groups can be found on our website at: www.npca.org.uk

https://www.npca.org.uk/provider-results/

Key Messages

Data quality

 Completeness of key variables remains low in England (e.g. performance status 52% – no change from 2019). New data items for multiparametric MRI have been introduced into COSD and we encourage all prostate MDTs in England to submit these data items so that they can provide reliable results about key parts of the diagnostic pathway.

Prospective audit

- 2. The number of men diagnosed with prostate cancer has increased by 23% (52,580 compared to 42,668 in 2019), which might be explained by increased public awareness following media reporting of the diagnosis of two high-profile celebrities in February/March 2018.
- 3. The proportion of men presenting with metastatic disease at diagnosis has reduced (13% compared to 16% in 2019).
- 4. The potential 'over-treatment' of men with low-risk disease has remained low at a national average of 5% (compared to 4% in 2019) although some centres have a persistently higher level.
- 5. The potential 'under-treatment' of men with high-risk localised/locally advanced disease has decreased slightly (29% compared to 32% in 2019).
- 6. The use of primary docetaxel in metastatic disease has increased in this second year of reporting (36% compared to 27% in 2019).
- 7. The proportion of men with intermediate-risk disease receiving a hypofractionated radiotherapy regimen has increased (96% compared to 91% in 2019).
- 8. Brachytherapy boost combined with EBRT was given to 5% of men with high-risk localised/locally advanced disease who received radical radiotherapy, as was found last year (5% in 2019).

- 9. We report a national average (England only) of 18% of these men having prostate and pelvic lymph node irradiation with substantial national variation (a new indicator).
- 10. Emergency readmission within 90 days of radical prostate cancer surgery remains the same as in 2019 at 14%.
- 11. Genitourinary complications following radical prostatectomy have remained stable with 9% of men experiencing at least one genitourinary complication within two years of their prostatectomy (compared to 9% in 2019).
- 12. Gastrointestinal complications following radical radiotherapy are stable at 11% of men experiencing a gastrointestinal complication within two years of their radiotherapy (compared to 10% in 2019).

Patient-reported outcomes

- 13. The majority of men (87%) were given the name of a clinical nurse specialist, an increase from the last reporting of this measure in the 2018 annual report (83%). A high proportion of men (91%) rate their care at least 8 of out 10 (compared to 89% in 2018).
- 14. Following radical prostatectomy, the mean sexual function score was generally poor at 24 on a scale of 0-100, an improvement of 1 point compared with the previous round of reporting in 2018.
- 15. The urinary incontinence score was an average of 73 on a scale of 0-100 following radical prostatectomy, an increase in 2 points.
- 16. Following radical radiotherapy, the average sexual function score was generally poor at 18 on a scale of 0-100, an improvement in 1 point compared with 2018.
- 17. The mean bowel function score after radical radiotherapy was 85 on a scale of o-100. This is unchanged from the previous round of reporting.

Table 1. Recommendations, key findings and related national guidance

These recommendations are based on results from data collected in the audit period of 1st April 2018 to 31st March 2019 which therefore do not cover the period of the COVID-19 pandemic. This should be borne in mind if implementing a recommendation below in a time when services are impacted by the pandemic situation.

No.	Recommendation	Audience	Annual Report 2020 findings underlying recommendation	Previous results	National guidance
Rı	Where appropriate increase the use of transperineal biopsy methods when targeting lesions in the anterior region of the prostate, whilst balancing against resource constraints and the risk of side effects.	Prostate cancer teams (local and specialist MDTs) within NHS Trusts/Health Boards	21% of men in England and 6% of men in Wales had a trans-perineal prostate biopsy. (Results 3.3, Table 3).	Increase: 17% of men in England and 7% in Wales in NPCA Annual Report 2019	National guidance currently unavailable. This recommendation is based on the views of the NPCA Clinical Reference Group (CRG).
R2	NHS Organisations in England should aim to	Prostate cancer teams	Data completeness in England:	No change:	NICE Guideline [NG131], 2019
capt Can	achieve high completeness of key data items, capturing performance status and NEW	(local and specialist MDTs) within NHS	Performance status (52%)	England - Performance status (52%)	1.2.2 Offer multiparametric MRI as the first-
	Cancer Outcomes Services Dataset (COSD)	Trusts/Health Boards	Data completeness in Wales:	Wales - Performance status (100%)	line investigation for people with suspected clinically localised prostate cancer.
	data items related to mpMRI and prostate biopsy type available from July 2020.	with support from the National Cancer Team	Performance status (100%)	in NPC A Annual Report 2010	The Cancer Outcome and Services Data
	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.		(Results 3.3, Table 2).		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.
R ₃	NHS Organisations in Wales should aim to improve their case ascertainment working with data specialists in the Wales Cancer Network.	Prostate cancer teams (local and specialist MDTs) within NHS Trusts/Health Boards	Case ascertainment in Wales: 89% (Results 3.3, first paragraph).	Small increase: 85% in NPCA Annual Report 2019	The Welsh Cancer Intelligence and Surveillance Unit collects, analyses and releases information about cancer in Wales.
R4	Continue to advocate active surveillance in the first instance for men with low-risk prostate cancer.	Prostate cancer teams (local and specialist MDTs) within NHS Trusts/Health Boards	5% of men diagnosed with low-risk localised cancer in England and Wales underwent radical prostate cancer therapy within 12 months of diagnosis.	Small increase: 4% of men in England and Wales in NPCA Annual Report 2019	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.
			There were two specialist MDTs with significantly higher levels of 'potential over-treatment' compared with the national average after case-mix adjustment.		NICE Guideline [NG131], 2019
			(Results 3.4, Performance indicator 2, Figure 3).		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.

R6 Where a therapy, androger	ate cancer teams should investigate why with high-risk/locally advanced disease ot considered for radical treatment.	Prostate cancer teams			- I
therapy, androger		(local and specialist MDTs) within NHS Trusts/Health Boards	71% of men diagnosed with locally-advanced prostate cancer underwent radical treatment within 12 months of diagnosis in England and Wales equating to 29% of men being 'potentially under-treated'. 'Potential under-treatment' by NHS provider varied (18% to 61%) and there were five specialist-MDTs which had significantly higher levels of 'under-treatment' compared with the national average following adjustment for casemix. (Results 3.4, Performance indicator 3, Figure 4).	Reduction: 32% of men in England and Wales were 'potentially undertreated' in NPCA Annual Report 2019	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.
	re appropriate, offer combined systemic py, either with docetaxel or novel anti- ogenic therapy, to people with newly nosed metastatic disease	Prostate cancer teams (local and specialist MDTs) within NHS Trusts/Health Boards	36% of men received primary docetaxel in combination with standard ADT (ranging from 0% to 47% by NHS provider in England).* (Results 3.4, Performance indicator 4, Figure 5).	Increase: 27% of men received primary docetaxel in combination with standard ADT in NPCA Annual Report 2019	NICE Guideline [NG131], 2019 1.5.6 Offer docetaxel chemotherapy to people with newly diagnosed metastatic prostate cancer who do not have significant comorbidities NICE Guideline [NG161], 2020. NHS England interim treatment changes during the COVID-19 pandemic Option to give enzalutamide with androgen deprivation therapy for patients with newly diagnosed metastatic disease instead of docetaxel to reduce toxicity and potential for admission. For patients who are intolerant of enzalutamide, give the option of switching treatment to abiraterone
consensu making a node irra	irradiation for high risk localised/locally nced disease	Prostate cancer teams (local and specialist MDTs) within NHS Trusts/Health Boards with support from the National Cancer Team	18% of men with high-risk localised /locally advanced prostate cancer received prostate plus pelvic lymph nodes irradiation, with wide variation by provider (ranging from 0% to 68% by RT centre in England).* (Results 3.4, Performance indicator 5, Figure 6).	N/A*	National guidance currently unavailable.

No.	Recommendation	Audience	Annual Report 2020 findings underlying recommendation	Previous results	National guidance		
R8	Consider establishing radiotherapy centre specialist gastrointestinal services to offer advice to people with bowel-related side effects of radiotherapy.	Prostate cancer teams (local and specialist MDTs) within NHS Trusts/Health Boards	11% of men experienced at least one bowel complication (defined as receiving a procedure of the large bowel and confirmed diagnosis of radiation toxicity) within two years after radical radiotherapy. Following adjustment, two centres had significantly worse rates of severe bowel toxicity compared with other NHS providers in England and Wales. (Results 3.4, Performance indicator 10, Figure 11).	Small increase: 10% of men in England and Wales in NPCA Annual Report 2019	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 high dose rate brachytherapy in	Prostate cancer teams	5% of men receiving radical radiotherapy for high-risk/	No change: 5% of men in England in NPCA	NICE Guideline [NG131], 2019		
	combination with external beam radiotherapy for patients with intermediate- or high-risk prostate cancer.	(local and specialist MDTs) within NHS Trusts/Health Boards	locally advanced disease received a brachytherapy boost in England.* (Table 4).	Annual Report 2019	1.3.22 Consider brachytherapy in combination with external beam radiotherapy for people with intermediate- and high-risk localised prostate cancer.		
R10	Ensure access to nurse specialists and their	Prostate cancer teams	87% of men reported that they were 'given the name of a	Increase: 83% of men in NPCA Annual	NICE Quality Standard [QS91], 2015		
	services for patients with prostate cancer.	(local and specialist MDTs) within NHS Trusts/Health Boards	S', which varied from 73% - 100% by provider. Report 2018 sults 3.4, Figure 7),	Report 2018	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 new symptoms: urinary symptoms, erectile problems, blood in your urine or unexplained back pain.	any of the following new symptoms: urinary symptoms, erectile problems, blood in your			Overall 13% of men in England and Wales were diagnosed	Reduction: 16% of men in England and	NHS Long Term Plan for Cancer 2019
			to 22% by specialist MDT).	Wales in NPCA Annual Report 2019	'build on work to raise greater awareness of symptoms of cancer, lower the threshold for referral by GPs, accelerate diagnosis and treatment.'		
			(Results 3.4, Performance indicator 1, Figure 2).		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	Patients	Overall 13% of men in England and Wales were diagnosed	Reduction: 16% of men in England and	NHS Long Term Plan for Cancer 2019		
	ovarian cancer should ensure this is reported to their healthcare provider with a view to a possible genetic counselling referral.		with metastatic disease at presentation (ranging from 7% to 22% by specialist MDT). (Results 3.4, Performance indicator 1, Figure 2).	Wales in NPCA Annual Report 2019	'build on work to raise greater awareness of symptoms of cancer, lower the threshold for referral by GPs, accelerate diagnosis and treatment.'		
			Accounts 5.4, refrontiance mulcator 1, rigure 2).		'routinely offer genomic testing to all people with cancer for whom it would be of clinical benefit'		
					Cancer delivery plan for Wales 2016 - 2020		
				' develop a programme of awareness campaigns for cancer'			
*Information	currently unavailable for Wales						

No.	Recommendation	Audience	Annual Report 2020 findings underlying recommendation	Previous results	National guidance
R13	Men with low-risk prostate cancer should discuss with their specialist the option of disease monitoring with active surveillance in the first instance.	Patients	5% of men diagnosed with low-risk localised cancer in England and Wales underwent radical prostate cancer therapy within 12 months of diagnosis. There were two 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 3).	Small increase: 4% of men in England and Wales in NPCA Annual Report 2019	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.
R14	Men who are offered prostate cancer treatment should be 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 and prostate cancer teams	Radical prostatectomy – urinary complications and sexual function 9% of men experienced at least one genitourinary complication requiring a procedural/surgical intervention within two years after radical prostatectomy. Following adjustment, three surgical centres had significantly worse rates of severe urinary toxicity compared with other NHS providers in England and Wales. (Results 3.4, Performance indicator 9, Figure 10). Overall, the mean urinary incontinence score was 73 and the mean sexual function score was 24 (with higher scores representing improved function). (Results 3.4, Performance indicators 11 [Figure 12] and 12 [Figure 13]). Radical radiotherapy – bowel complications and sexual function 11% of men experienced at least one bowel complication within two years after radical radiotherapy. Following adjustment, one centre had significantly worse rates of severe bowel toxicity compared with other NHS providers in England and Wales. (Results 3.4, Performance indicator 10, Figure 11). Overall, the mean bowel function score was 85 and mean sexual function was 18 on a scale of 1 to 100. (Results 3.4, Performance indicators 11 [Figure 14] and 12 [Figure 15]).	No change in urinary complications compared with previous report – 9% of men in England and Wales in NPCA Annual Report 2019 Small increase compared with the previous reporting period (urinary incontinence - a score of 71 and sexual function – a score of 23) in NPCA Annual Report 2018 Bowel complications are consistent with previous report – 10% of men in England and Wales in NPCA Annual Report 2019 No change in reported bowel function (a score of 85) and a small increase in sexual function score (a score of 17) in NPCA Annual Report 2018	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.

No.	Recommendation	Audience	Annual Report 2020 findings underlying recommendation	Previous results	National guidance
R15	Men experiencing physical or psychological side effects during or following prostate cancer treatment should be referred to specialist support services. These should be offered early and on an ongoing basis, in keeping with national recommendations.	Patients and prostate cancer teams	Recommendation in light of R14. 87% of men reported that they were 'given the name of a CNS', which varied from 73% - 100% by provider. (Results 3.4, Figure 7).	Increase compared with previous reporting year – 83% of men in NPCA Annual Report 2018	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.
R16	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 and prostate cancer teams	Recommendation in light of R14 and R15.	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.
R17	Review and identify regional performance indicators for prostate cancer. Pay particular attention to variations in service provision (diagnostics, treatment and support services) and treatment outcomes. 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.	ticular sision ervices) tion is action oard		N/A	This recommendation is based on the views of the NPCA CRG.
R18	Local commissioners should ensure that radiotherapy centres are able to deliver a full range of radiotherapy techniques and support services for patients	Commissioners and health care regulators	Recommendation in light of R7 – 9, R14 and R15.	N/A	This recommendation is based on the views of the NPCA CRG.
*Informatio	on currently unavailable for Wales				,



DIAGNOSIS AND STAGING

for men diagnosed 18/19

2,580

men were diagnosed with prostate cancer in England and Wales between 1st April 2018 and 31st March 2019



of men were 70 years or older - 56% of men in 17/18



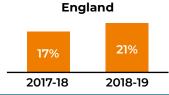
increase compared with 42,668 men in 17/18

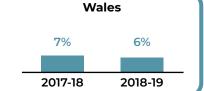
This may be explained by the diagnosis of two high-profile celebrities during the period, which was publicised by the media

13%

of men presented with metastatic disease -16% of men in 17/18

the use of transperineal biopsy is increasing in England





TREATMENT ALLOCATION

for men diagnosed 18/19

Low-risk, localised disease

of men had radical treatments and were potentially 'over-treated' - 4% in 17/18

TREATMENT OUTCOMES

of men undergoing surgery 18/19 were readmitted within 3 months following surgery

This short-term outcome is stable compared with 17/18

High-risk/locally advanced disease

of men did no have radical treatments and were potentially 'under-treated' -**32%** of men in 17/18

of men received radiation to their prostate plus lymph nodes**

Medium term outcomes are stable for men undergoing treatment in 2017 compared with 2016



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



After surgery, men reported their sexual function to be 24 and urinary continence to be 73**

After external beam radiation, men reported their sexual function to be 18 and bowel function to be 85**

Metastatic disease

of men had primary docetaxel chemotherapy in England - 27% of men in 17/18*

**mean scores on a scale of 1-100 with higher scores with higher scores representing better function

PATIENT EXPERIENCE OF CARE





of men said they were 'given the name of a clinical nurse specialist' -83% of men in the previous survey in 2018

of men rated their care as – 89% of men in 2018

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

Background 1.1

The National Prostate Cancer Audit has been reporting annually for seven years, developing and adding indicators year-on-year. The NPCA reports 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 localised/locally advanced disease have shown improving trends over the first years of the Audit and they remain a priority area for the NPCA. Future audits will use an updated, widelyaccepted risk stratification score (Cambridge Prognostic Grouping⁸) which will give more detail about treatment allocation for different risk groups, in particular whether men with low risk disease are potentially receiving treatment unnecessarily.

Limiting the impact of the adverse events of radical treatments is another priority area. We use our previously developed and validated performance indicators to identify men experiencing moderate genitourinary (GU) complications following surgery (radical prostatectomy) and moderate GI toxicity following radiotherapy (external beam radiation [EBRT]).9,10 Comparisons of surgical and radiotherapy providers across the country by these indicators 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.

This is the second year that we report on the use of docetaxel in addition to androgen deprivation therapy for metastatic prostate cancer in keeping with the NICE 2019 recommendation for patients who are fit and willing to receive chemotherapy.11 However, we note that this guidance has been updated during the COVID-19 pandemic in 2020 to include the use of enzalutamide/abiraterone.12

We have started this year to report on the proportion of men with high-risk localised/locally advanced disease given prostate plus pelvic lymph node irradiation. We have not reported on this aspect of radiotherapy treatment before but it will be important to monitor the use of this approach 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
- 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 with further follow-up. 13

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 its full suite of performance indicators, including those from patient-reported outcomes, the NPCA 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.

Parry MG, Cowling TE, Sujenthiran A, et al. Risk stratification for prostate cancer management value of the Cambridge Prognostic Group classification for assessing treatment allocation. *BMC*

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

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

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

NICE Guideline [NG161], 2020. NHS England interim treatment changes during the COVID-19

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

1.3 Previous Annual Report

The 2019 Annual Report¹⁴ reported on prostate cancer services provided by individual NHS providers to men diagnosed between 1st April 2017 to 31st March 2018 in England and Wales. Key findings included:

- Increases in the use of multiparametric MRI and of trans-perineal biopsy.
- The proportion of men diagnosed with metastatic disease remained stable.
- The potential 'over-treatment' of men with low-risk disease remained low.
- The potential 'under-treatment' of men with high-risk/locally advanced disease decreased slightly.
- The use of hypofractionated radiotherapy was reported for 91% in intermediate-risk cases
- Brachytherapy boost for high-risk/locally advanced cases was reported at 5%
- Genitourinary complications at 2 years following radical prostatectomy improved with 1 in 10 men experiencing such a complication
- 1 in 10 men experienced bowel dysfunction following radical radiotherapy, which was consistent with previous years.

From the 2019 organisational audit:15

- The service organisation survey showed that the majority of radiotherapy centres use rotational IMRT (96%) with cone beam CT (80%) (with few using fiducial markers (9%) and none using kilovoltage (KV) imaging).
- The majority of oncology centres support the use of docetaxel in high volume (100%) and low volume (84%) M1 disease.
- There was little agreement across centres in the duration of neo-adjuvant and adjuvant ADT treatment duration for low-risk and high-risk disease.

¹⁴ NPCA Annual Report 2019. Download from: http://www.npca.org.uk/reports/

¹⁵ NPCA Organisational Audit 2019. Download from: https://www.npca.org.uk/reports/npca-organisational-audit-2019/

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 2018 and the 31st March 2019 in England and Wales. This duration of follow-up 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 2017 to 31st December 2017).

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 in England and Wales. Only COSD data items are collected for men newly diagnosed with prostate cancer from 1st April 2019 in England in the following categories of the NPCA dataset:

 NPCA Minimum data set 1 (MDS-1): The first category of data items is 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**.

A summary of the COSD data items in the NPCA dataset collected for patients diagnosed between 1st April 2018 and 31st March 2019 can be found on the website. ¹⁶ 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, RTDS data are currently unavailable so the following additional category in the NPCA dataset is collected:

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 androgen deprivation therapy.

NPCA Minimum dataset items 1-3 in Wales 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.

We urge centres to work with their data collection leads to ensure prostate cancer data is collected as completely as possible as the audit is only as accurate as the data we receive.

2.4 Patient-reported outcome and experience measures (PROMs/PREMs)

The NPCA Patient Survey was designed by the NPCA Project Team following review of current literature/guidelines and in consultation with clinical and patient representatives in the Audit's Clinical Reference Group. The questionnaire includes PROMs and PREMs including:

- Selected questions from the National Cancer Patient Experience Survey (NCPES) – a national survey commissioned by NHS England to determine patients' views of their experience of care.
- The Expanded Prostate Cancer Index Composite 26item version (EPIC-26) –a validated instrument to measure prostate cancer related quality of life after radical treatments for prostate cancer including urinary, bowel and sexual functioning¹⁷

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

The EPIC-26 produces a validated summary score for each domain that ranges from 0 to 100, with higher scores representing better function. The urinary incontinence domain, includes questions related to urinary frequency and leakage, the bowel function domain assesses bowel frequency, urgency, bleeding and pain and the sexual function domain asks questions related to the quality and frequency of erections. Szymanski K, Wei, J et al. Development and validation of an abbreviated version of the expanded prostate cancer index composite instrument for measuring health-related quality of life among prostate cancer survivors. *Urology* (2010), 76, 1245-50.

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

Nossiter J, Sujenthiran A et al. Robot-assisted radical prostatectomy vs laparoscopic and open retropubic radical prostatectomy: functional outcomes 18 months after diagnosis from a national cohort study in England. Br J Cancer (2018); 118: 489-494

The survey cohort included men diagnosed between 1st April and 30th September 2018 who subsequently underwent radical prostatectomy or EBRT. The mechanism for data collection has been described previously. 18,19 In summary, further to identification of the patient cohort by the NPCA team, the NPCA data collection partners in England (NCRAS, PHE) and Wales (WCN, PHW) securely transferred the relevant identifiable patient data (name, address, date of birth, NHS number and NPCA identifier) to Quality Health, the NPCA's survey provider. Before sending out the surveys, Quality Health access NHS Digital's automated National Data Opt-out service and automated PDS/DBS service to remove men who had raised a type-II objection, to determine a current address and whether a patient had died. Questionnaires were mailed to the homes of all identified men ≥18 months after diagnosis. Two reminders were sent to non-responders with the final reminder \leq 8 weeks after the first mail out.

De-identified survey response data was securely transferred to the NPCA team for linkage to de-identified patient-level clinical data and analyses.

2.5 Level of reporting

It is recommended that the care of patients eligible for radical prostate cancer treatments should be coordinated by specialist MDTs.²⁰ These hubs are made up of one or more specialist cancer centres coordinating services for referring local Trusts or Health Boards.²¹

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 2019²² but could not be updated in time for this report due to the pandemic. Updated information will be reported in 2021.

2.6 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 2017. WCISU were not able to provide exact numbers for the time frame

of NPCA data collection and so figures from 2017 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 four key data items (PSA, Gleason score, TNM and performance status) in England and Wales provided a marker of data quality.

2.7 Definition of disease status and risk stratification

In England, men were assigned to a prostate cancer risk according to a modified D'Amico classification, which is a three-tiered disease status category, assigned according to their TNM stage, Gleason score and PSA, using an algorithm previously developed by the NPCA.²³ 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 (pretreatment)", "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.

2.8 Treatment allocation

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 his 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". Where information on radical prostatectomy was missing in the PEDW data for Wales, this information was added from the NPCA dataset.

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 fractionated 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

 $^{^{\}rm 20}$ $\,$ NICE 2002. Improving outcomes in urological cancer.

Aggarwal A, Nossiter et al. Organisation of Prostate Cancer Services in the English National Health Service. Clin Oncol (R Coll Radiol) 2016; 28:482-9.

²² NPCA Organisational Audit 2019. Download from: https://www.npca.org.uk/reports/npca-organisational-audit-2019/

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

procedure codes ("M706" + "X653" + "Y363 / M706" + "X653 / M712" + "X653"). In England, the data-item "radiotherapy treatment region" was used to determine whether men had irradiation of their prostate plus pelvic lymph nodes or just to the prostate and seminal vesicles.

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. Comparable data were not available with regard to radiotherapy dosing or treatment region in Wales and so no reporting was possible for the actual receipt of prostate plus pelvic lymph node irradiation, hypofractionation or use of a brachytherapy boost.

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

2.9 NPCA performance indicators

2.9.1 Definition

In this Annual Report the NPCA report on 14 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.

Treatment allocation

• Performance indicator 2: Proportion of men with lowrisk 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 highrisk/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).²⁴

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 with highrisk/locally advanced disease receiving prostate and pelvic lymph node irradiation (presented at the level of the radiotherapy centre).

This *process* indicator provides information about the extent of irradiation used for patients with high-risk or locally advanced disease using data from the RTDS.

Patient experience of care

- Performance indicator 6: Proportion of patients who were given the name of a clinical nurse specialist (presented at the level of the SMDT).
- Performance indicator 7: Proportion of patients rating their overall care as at least 8 out of 10 (presented at the level of the SMDT).

These process indicators provide information on key aspects of a man's experience of care following a prostate cancer diagnosis and were derived from selected NCPES questions in the NPCA patient survey

Outcomes of treatment: short-term

• Performance indicator 8: 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.

 $^{{}^{24}\}quad \underline{NICE\ Guideline\ [NG161],\ 2020.\ NHS\ England\ interim\ treatment\ changes\ during\ the\ COVID-19\ pandemic\ pan$

Outcomes of treatment: medium-term

• Performance indicator 9: Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).

We used a coding-framework based on OPCS-4 procedure codes to capture genitourinary complications that required an intervention. ²⁵ 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 10: Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal (GI) complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).

We used a coding-framework based on OPCS-4 procedure codes to capture interventions required to treat gastrointestinal (GI) toxicity. ²⁶ This indicator also required the presence of specific ICD-10 diagnosis codes relating to GI toxicity. 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.

Outcomes of treatment: patient-reported

These performance indicators present the validated summary score for each EPIC-26 domain, which ranges from 0 to 100 with higher scores representing better function.

- Performance indicator 11: Mean urinary incontinence score after radical prostatectomy (presented at the level of the surgery centre).
- Performance indicator 12: Mean sexual function score after radical prostatectomy (presented at the level of the surgery centre).
- Performance indicator 13: Mean bowel function score after radical radiotherapy (presented at the level of the radiotherapy centre).

• Performance indicator 14: Mean sexual function score after radical radiotherapy (presented at the level of the radiotherapy centre).

2.9.2 Outlier identification

Multivariable logistic regression was carried out for performance indicators 2 and 3 and 5-10, and multivariable linear regression for performance indicators 11-14. Centres which performed less than 10 procedures per year were excluded.

The analyses for indicators 2 and 3 were adjusted for patient age and comorbidity, and additionally for socio-economic status for indicators 5-7. Risk group was also included in the adjustment model for all treatment and patient-reported outcomes (performance indicators 8-14).

Comorbidity was captured using the Royal College of Surgeons (RCS) Charlson comorbidity score²⁷ based on 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.

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 graphically display variation across specialist MDTs/Trusts/Health Boards for our performance indicators according to patient volume. These are shown for process measures and patient-reported measures across the country (performance indicators 1-7 and 11-14).

For the adjusted treatment-related outcomes (performance indictors 8-10), surgical and radiotherapy treatment centres outside the inner or outer funnel limits (alerts and alarms, respectively) were considered as potential outliers and were contacted, where necessary, according to the NPCA Outlier Policy.²⁸

More detail of the genitourinary procedure codes can be found here: Sujenthiran A, Charman S, Parry M 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

More detail of the gastrointestinal procedure codes and diagnostic codes indicating radiation toxicity can be found here: Sujenthiran A, Nossiter J, Charman S 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

Armitage JN and van der Meulen J. Identifying co-morbidity in surgical patients using administrative data with the Royal College of Surgeons Charlson Score. Br J Surg 2010; 97:772-81.

https://www.npca.org.uk/resources/npca-outlier-policy-2020/

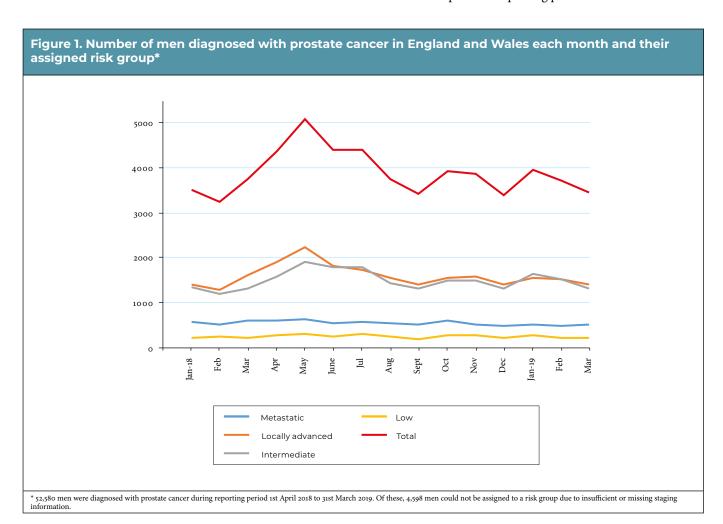
3. Results

3.1 Audit participation

49,804 men were identified with prostate cancer in England from 1st April 2018 to 31st March 2019, of whom 49,509 were confirmed as diagnosed within the NHS and 49,492 could be assigned a valid NHS provider in England. Prostate cancer diagnostic services are provided at 132 NHS Trusts across 47 specialist MDTs in England and 6 Health Boards across 4 specialist MDTs in Wales.²⁹ Surgical services were provided by 54 centres and radiotherapy services by 54 centres during this time period.

In Wales we received a total of 2,776 NPCA records of newly diagnosed men and all could be assigned to a valid NHS provider. In the most recent case ascertainment data available, for calendar year 2017, the number of prostate cancer diagnoses appearing in WCISU was 2,705 compared to 2,396 found in NPCA data, resulting in approximate case ascertainment of 89%.

The number of men diagnosed with prostate cancer has risen quite significantly in the diagnosis period of 1st April 2018 to 31st March 2019 compared to the previous year: by 23% in both England (40,429 to 49,804) and Wales (2,239 to 2,776). This is a larger year-on-year increase than we have seen previously and might be explained by the diagnosis of two high-profile celebrities with prostate cancer in February/ March 2018 which were publicised in the media. Indeed, we do see a rise in diagnoses made in the period just after this, peaking in May 2018 (Figure 1). These diagnoses appear to be predominantly for men with intermediate risk and locally advanced disease, with little change evident in the numbers of men diagnosed in that period with low risk or metastatic disease. Further exploration of this phenomenon will be undertaken to determine if there were differences in the distribution of socio-demographic characteristics of the men diagnosed, and in the subsequent diagnostic investigations and treatments received in that period. For this report, the surge in numbers may give context to some of the changes seen from the previous reporting period.



²⁹ https://www.npca.org.uk/reports/npca-organisational-audit-2019/

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 performance status reaching 100% completeness. 95% of Welsh men could be assigned to a risk category due to the high completeness of PSA, Gleason score and TNM variables (89%, 89% and 80%, respectively).

Data completeness in England is lower than in Wales. Performance status is 52% complete, however, the

completeness of the diagnostic information is substantially better with completeness for PSA, Gleason score and TNM reported at 68%, 84% and 79%, 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 2018 and 31 March 2019.

Data variable	Eng	England		les
	N	%	N	%
Diagnostic and staging variables				
No. of men with new diagnosis of prostate cancer	49,804 [CR]		2,776 [NPCA]	
Performance status completed	25,857 [COSD]	52%	2,776 [NPCA]	100%
Biopsy performed	21,815 [NPCA]	44%	2,775 [NPCA]	100%
PSA completed	33,671 [COSD]	68%	2,472 [NPCA]	89%
Gleason score completed	41,858 [CR]	84%	2,472 [NPCA]	89%
TNM completed	39,434 [CR]	79%	2,212 [NPCA]	80%

Acronyms: COSD = Cancer Outcome and Services Dataset; CR = Cancer Registry dataset; NPCA = National Prostate Cancer Audit dataset; PSA = Prostate Specific Antigen; TNM = Tumour, Nodes, Metastases Classification of Malignant Tumours

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 (39% and 42% for England and Wales, respectively) and another third are aged between 60 and 70. Prostate cancer is a disease of the older man as is shown by the significant proportion being diagnosed above 80 years old (15% and 12% in England and Wales, respectively). This is consistent with last year's report. In England, 72% of the men who had a performance status had one of 0 (fully active) versus 65% for Wales, a little higher for Wales compared to last year's report. Data completeness was again better for the Welsh, compared to English, data (100% versus 52%).

Diagnostic investigations

Although the trans-rectal ultrasound guided method remains the most common biopsy technique there has been a reduction in the use of this approach in England (70% this year compared with 83% in 2017/18) and Wales (79% compared with 93%), with 21% and 6% of men undergoing a trans-perineal biopsy (in England and Wales respectively), although incomplete data makes these figures difficult to compare across the years.

Disease status at presentation

The distribution of PSA, Gleason score and TNM staging is shown in Table 3 and has remained consistent with last year's results. Stage at diagnosis has remained stable compared to last year: 42%, 39% and 6% of men were assigned to high-risk/locally advanced, intermediate-risk and low-risk disease in England. The respective figures for Wales were 33%, 46% and 8%. Slightly fewer men were diagnosed with metastatic disease in England compared to last year (13% compared to 16%, which may be due to the higher numbers in other risk groups this year) but the proportion in Wales remained similar to last year at 14%.

Table 3. Patient and diagnostic characteristics for men newly diagnosed with prostate cancer in England and Wales over the period of 1 April 2018 and 31 March 2019.

Data variable		Eng	land	W	Wales	
		N	%	N	%	
No. of men with new diagnosis of prostate cancer	49,	,804		2,776		
Age						
<60	6,0	665	13%	311	11%	
60-70	16,	,075	32%	965	35%	
70-80	19,	,417	39%	1,162	42%	
≥80	7,0	647	15%	338	12%	
Tot	tal 49,	,804	100%	2,776	100%	
Missin	ng	0		0		
Performance status						
0	18,	660	72%	1,807	65%	
1-2	6,	805	26%	922	33%	
≥3	3	92	2%	47	2%	
Tot	tal 25,	,857	100%	2,776	100%	
Missin	ng 23,	947		0		
Charlson score						
0	37,	892	76%	2,172	78%	
1	8,	014	16%	320	12%	
≥2	3,8	898	8%	284	10%	
Tot	tal 49,	,804	100%	2,776	100%	
Missin	ng	0		0		
Biopsy performed						
Transrectal sampling	14,	,438	66%	2,201	79%	
Transrectal saturation	9	34	4%	13	0%	
Perineal sampling	2,4	469	11%	2	0%	
Perineal template	2,	182	10%	178	6%	
Other	8	66	4%	84	3%	
None	9	26	4%	297	11%	
Tot	tal 21,	,815	100%	2,775	100%	
Missin	ng 27,	989		1		
Prostate Specific Antigen (PSA)						
<10	16,	,705	50%	1,285	52%	
10-20	7,5	585	23%	579	23%	
>20	9,	381	28%	608	25%	
Tot	tal 33,	,671	100%	2,472	100%	
Missin	ng 16	,133		304		
Gleason score						
≤6	8,	317	20%	820	33%	
7	21,	788	52%	1,177	48%	
≥8	11,	753	28%	475	19%	
Tot	tal 41,	,858	100%	2,472	100%	
Missin	ng 7,9	946		304		

Data variable	England		Wales	
	N	%	N	%
T stage				
T1	6,765	15%	439	16%
T ₂	19,420	44%	1,352	50%
T ₃	15,710	36%	731	27%
T ₄	2,047	5%	158	6%
Total	43,942	100%	2,680	100%
Missing	5,862		96	
N stage				
No	37,177	89%	2,346	91%
N1	4,430	11%	222	9%
Total	41,607	100%	2,568	100%
Missing	8,197		208	
M stage				
Mo	37,537	86%	2,020	86%
M1	6,153	14%	335	14%
Total	43,690	100%	2,355	100%
Missing	6,114		421	
Risk group				
Metastatic	6,153	14%	335	13%
High risk/Locally advanced	18,816	42%	887	33%
Intermediate	17,481	39%	1,225	46%
Low risk	2,882	6%	203	8%
Total	45,332	100%	2,650	100%
Insufficient	4,472		126	

Treatment Information

Treatment characteristics are summarised in Table 4.

8,957 men were identified as undergoing a radical prostatectomy in England; most were robotically assisted (89%), with the remainder being performed laparoscopically (5%) or through open surgery (6%). There has been a continued adoption of the robotic-assisted approach with previous proportions being 85% (2017/2018), 81% (2016/2017) and 74% (2015/2016). Robotic prostatectomies were performed less frequently in Wales (76%) but this is steadily increasing from 68% last year and 63% the year before. Just under one third of the prostatectomies were performed with a lymphadenectomy in England (28%) but more so in Wales (50%).

17,121 men underwent radical radiotherapy in England; the vast majority were performed with IMRT (Table 4) for first line therapy, which is consistent with the figure reported last year, but 9% still had 3D conformal radiotherapy. Of all men receiving radiotherapy, 15% received radiotherapy to the pelvic lymph nodes as well as the prostate, with the remainder of men receiving radiotherapy to the prostate +/- seminal vesicles only. Wales used IMRT routinely and 18% of Welsh men appear to be having "regional" vs "prostate only" radiotherapy, although these figures rely on data on 'planned region of treatment'. Wales is transitioning to using the same radiotherapy dataset (RTDS) system as England, after which a better comparison between countries will be possible.

The proportion of men receiving a brachytherapy boost for high-risk or locally advanced disease has stayed low at 5%, while the proportion of men with intermediate-risk disease receiving a hypofractionated regimen increased from 91% last year to 96%.

Table 4. Treatment characteristics for men receiving radical radiotherapy or prostatectomy in England and Wales over the period of 1 April 2018 and 31 March 2019. Data variable **England** Wales Ν % **Radical prostatectomy information** No. of men undergoing radical prostatectomy 8,957 319 Prostatectomy type Robotic 76% 89% 7,950 232 Open 466 5% 46 15% Laparoscopic 6% 9% 541 29 Total 8,957 100% 100% 307 Missing 0 12 Lymphadenectomy performed No 6,463 72% 160 50% Yes 28% 2,494 159 50% Total 8,957 100% 319 100% Missing o 0 Radical radiotherapy information No. of men undergoing radical radiotherapy 17,121 951 Radiotherapy modality Intensity Modulated Radiation Therapy 15,538 91% 920 100% 3D conformal 1,583 9% 2 0% Total 17,121 100% 922 100% Missing 0 29 Planned radiotherapy region Prostate and/or seminal vesicles 14,011 85% 760 82% Whole pelvis including lymph nodes 166 18% 2,505 15% Total 16,516 100% 926 100% Missing 605 25 No. of men with locally advanced disease undergoing radical radiotherapy 8,791 **Brachytherapy boost*** No 95% 8,389 Yes 402 5% Total 8,791 100% Missing O No. of men with intermediate risk disease undergoing radical radiotherapy 4,419 **Hypofractionated regimen*** No 171 4% Yes 4,248 96% Total 4,419 100%

Missing

0

*comparable data not available for Wales

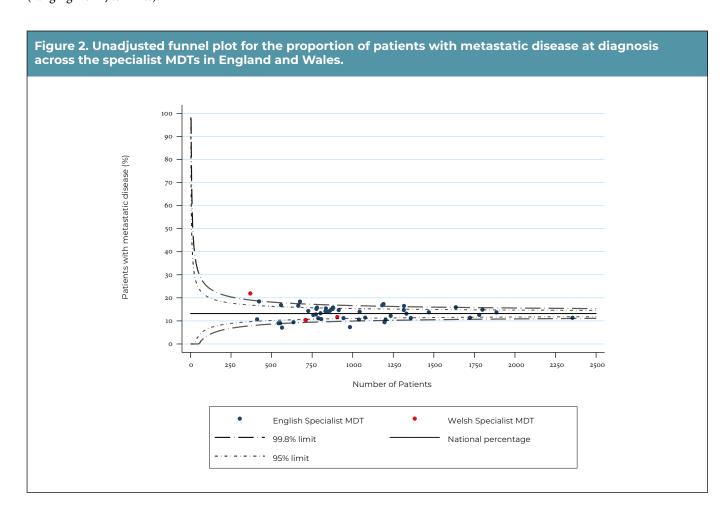
3.4 NPCA performance indicators

We were able to determine disease status and allocate a provider to 45,174 patients in England (91%) and 2,650 in Wales (95%).

Disease presentation

Performance indicator 1: Proportion of men diagnosed with metastatic disease

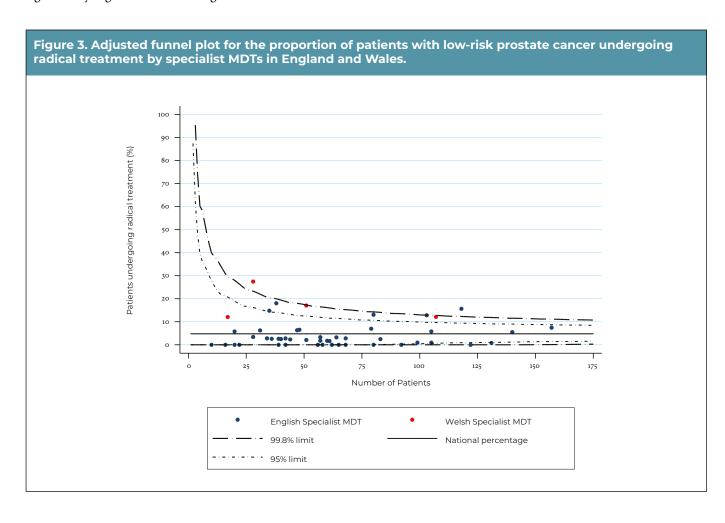
Overall 13% of men were diagnosed with metastatic disease at presentation which is a small reduction compared to last year's figure of 16%. An unadjusted funnel plot (Figure 2) demonstrates the variation in the proportion of men diagnosed with metastatic disease across 49 specialist MDTs (ranging from 7% - 22%).



Treatment allocation

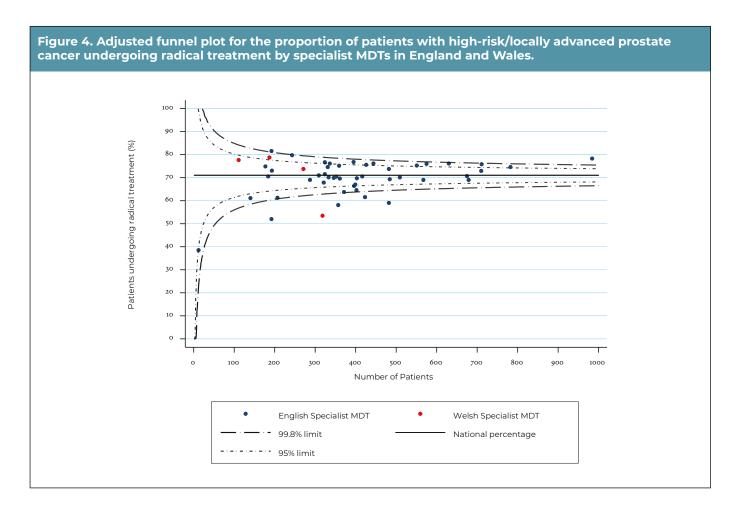
Performance indicator 2: Proportion of men with lowrisk localised cancer undergoing radical prostate cancer treatment

5% of men diagnosed with low-risk localised cancer underwent radical prostate cancer therapy within 12 months of diagnosis (range: 0% - 27%). The average has not changed substantively since last year, but the range and variation across providers has increased. An adjusted funnel plot demonstrates that some specialist MDTs still have unusually high levels of over-treatment (Figure 3) with two significantly higher than the average.



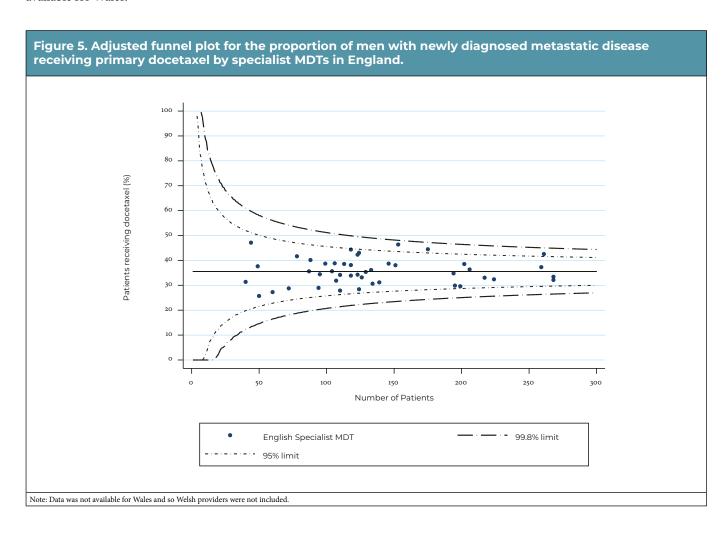
Performance indicator 3: Proportion of men with high-risk/ locally advanced disease undergoing radical prostate cancer treatment

71% of men diagnosed with high-risk/locally advanced prostate cancer were found to have undergone some form of radical local therapy within 12 months of diagnosis (range: 39% - 82%). An adjusted funnel plot demonstrates that of 49 specialist MDTs there were five which had significantly worse levels of 'under-treatment' compared to the others (negative outliers), and two which had significantly better rates of 'under-treatment' (positive outliers) (Figure 4).



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

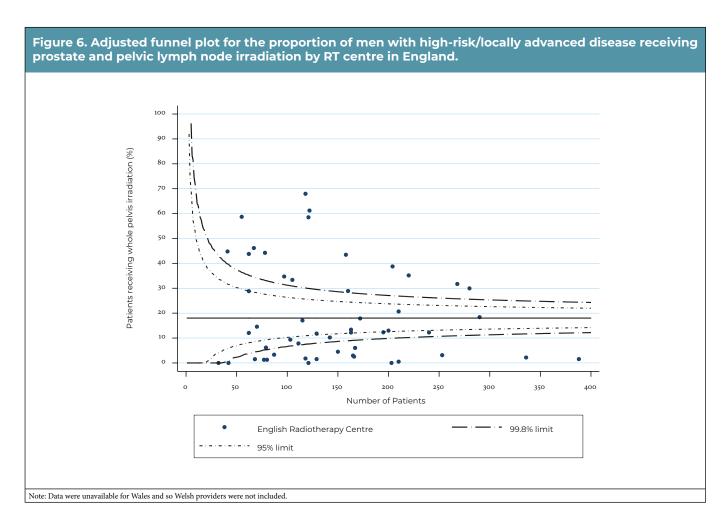
36% of men with metastatic disease (range: 0% - 47%) received primary docetaxel in combination with standard ADT, which is an increase from last year. The adjusted funnel plot (Figure 5) demonstrates the variation in its use across 46 specialist MDTs in England. This information is currently not available for Wales.



Radiotherapy regimen allocation

Performance indicator 5: Proportion of men with high-risk localised /locally advanced disease receiving prostate and pelvic lymph node irradiation

18% of the men receiving radical radiotherapy for high-risk/locally advanced prostate cancer received prostate plus pelvic lymph nodes irradiation (range: 0% - 68%). The adjusted funnel plot (Figure 6) demonstrate the wide variation in the use of this method across 51 radiotherapy centres in England. This information is currently not available for Wales.

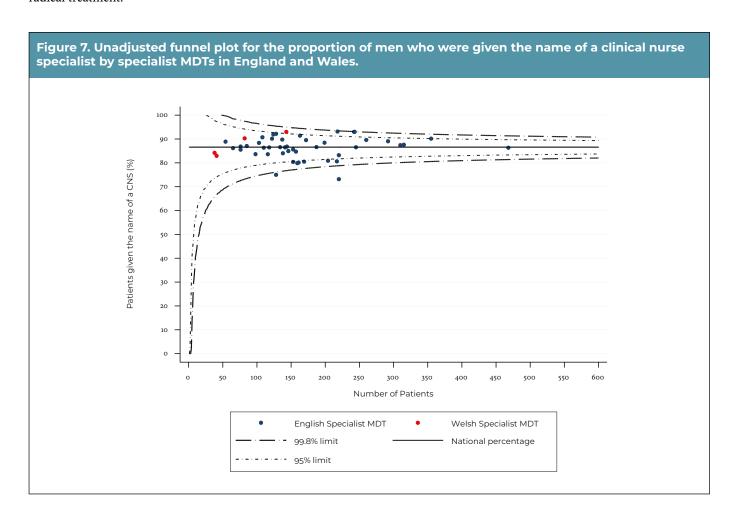


Patient experience of care

The NPCA Patient Survey was sent to 10,756 men who were diagnosed with prostate cancer from 1st April 2018 to 30th September 2018 in England and Wales and who subsequently underwent radical prostatectomy or radical radiotherapy. 8,356 men responded resulting in a response rate of 78%.

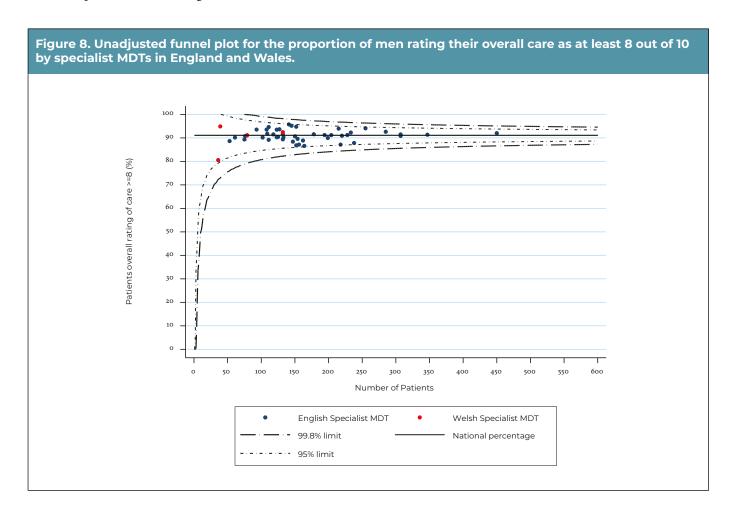
Performance indicator 6: Proportion of patients who were given the name of a clinical nurse specialist (presented at the level of the SMDT).

87% of men (range 73-100%) were given the name of a clinical nurse specialist. An adjusted funnel plot (Figure 7) demonstrates the variation across 49 specialist MDTs in England and Wales with some SMDTs providing the name of a CNS to a surprisingly low proportion of men receiving radical treatment.



Performance indicator 7: Proportion of patients rating their overall care as at least 8 out of 10 (presented at the level of the SMDT).

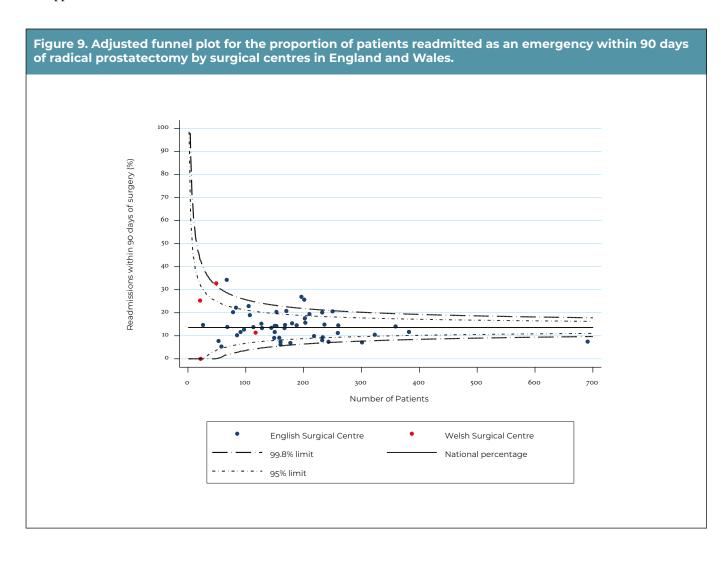
91% of men (range 81–100%) rated their care very highly. An adjusted funnel plot (Figure 8) demonstrates low variation across 49 specialist MDTs in England and Wales.



Outcomes of treatment: short-term

Performance indicator 8: Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery (presented at the level of the surgery centre).

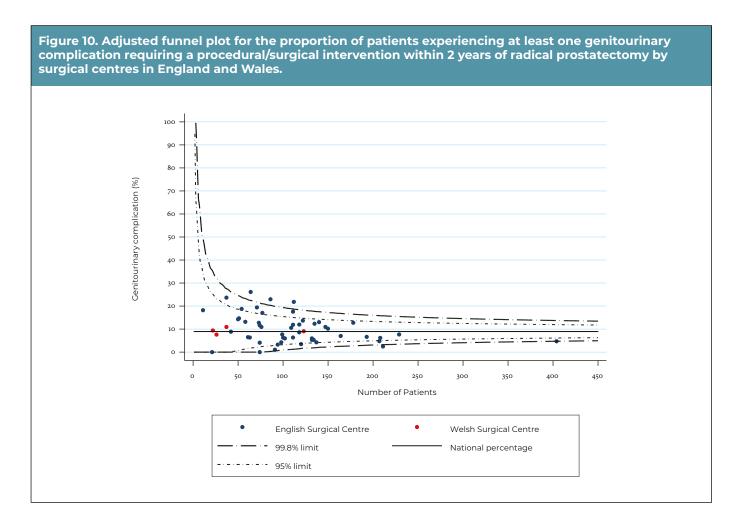
9,276 men underwent a radical prostatectomy at 54 surgical centres between 1st April 2018 and 31st March 2019. The 90-day emergency readmission rate following radical prostatectomy was 14% (range o - 34%), consistent with last year. Following adjustment, four surgical centres had a significantly worse readmission rate than the others (negative outlier), and two centres had a significantly better rate (positive outlier) (Figure 9). This outcome measure is also used for the NPCA outlier process and the outlier Trust responses to notification of their outlier status can be found in the Appendix.



Outcomes of treatment: medium-term

Performance indicator 9: Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (presented at the level of the surgical centre).

5,842 men underwent a radical prostatectomy at 54 surgical centres during 2017. Overall 9% of men experienced at least one treatment-related GU complication within two years following surgery, with a range of o - 26%. Following adjustment, there were three surgical centres which had significantly worse rates of GU complications 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 outlier Trust responses to notification of their outlier status can be found in the Appendix.



Performance indicator 10: Proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy (presented at the level of the radiotherapy centre).

11,683 men received EBRT at 54 radiotherapy centres during 2017. Overall 11% (range 2 – 26%) experienced at least one bowel complication within two years of radiotherapy. Following adjustment, there were two centres with significantly worse rates of GI toxicity than the others (negative outlier). Three centres had significantly better rates of complications (positive outliers) (Figure 11). This outcome measure is also used for the NPCA outlier process and the outlier Trust responses to notification of their outlier status can be found in the Appendix.

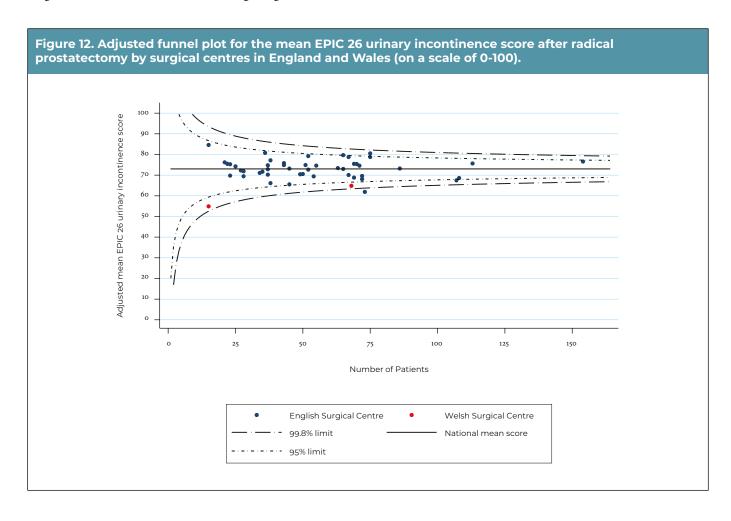
Figure 11. Adjusted funnel plot for the proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity up to 2 years following radical prostate radiotherapy. 100 80 Gastrointestinal complication (%) 40 30 20 10 100 200 300 500 400 Number of Patients English Radiotherapy Centre Welsh Radiotherapy Centre 99.8% limit National percentage 95% limit

Outcomes of treatment: patient-reported

Of the 8,356 men diagnosed with prostate cancer from 1st April 2018 to 30th September 2018 in England and Wales who responded to the NPCA Patient Survey, 2,790 (33%) had a radical prostatectomy at 49 surgical centres and 5,569 (67%) had EBRT at 53 radiotherapy centres. The following performance indicators use results from the EPIC-26 questionnaire which ranks patient function on a scale of o to 100 representing bad (low score) to good (high score) function.

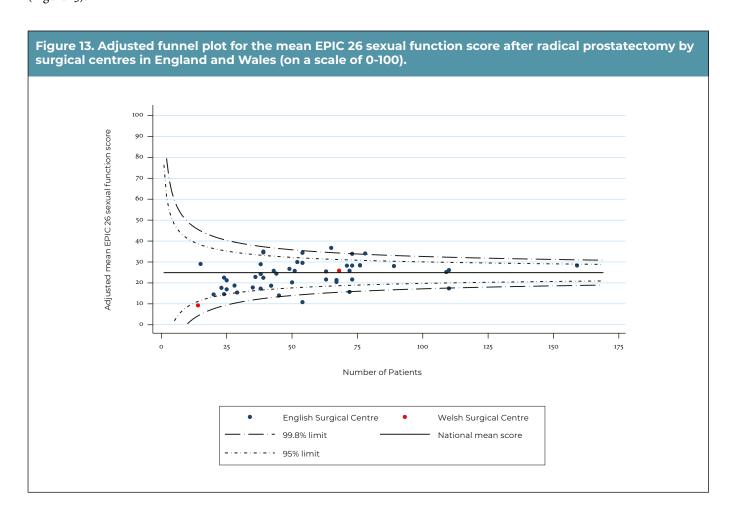
Performance indicator 11: Mean urinary incontinence score after radical prostatectomy (presented at the level of the surgery centre).

2,667 men (96%) who had radical surgery completed sufficient information to be assigned an EPIC-26 urinary incontinence score. Overall, the mean urinary incontinence score after a radical prostatectomy was 72.8 (range: 54.9 -84.6). An adjusted funnel plot demonstrates that out of 49 surgical centres, only one had a significantly worse score (negative outlier) than the national average (Figure 12).



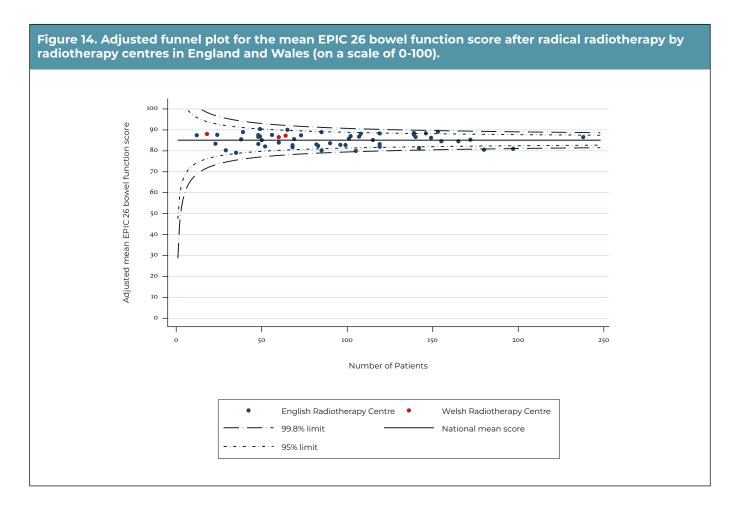
Performance indicator 12: Mean sexual function score after radical prostatectomy (presented at the level of the surgery centre).

2,701 men (98%) completed sufficient information to be assigned an EPIC-26 sexual function score. Sexual function is generally low following radical prostatectomy across 49 surgical centres in England and Wales. Overall, the mean sexual function score after a radical prostatectomy was 23.8 (range: 9.3 – 34.6). An adjusted funnel plot demonstrates that out of 49 surgical centres, three had significantly worse scores (negative outliers), and two had significantly better scores than the national average for this domain (positive outliers) (Figure 13).



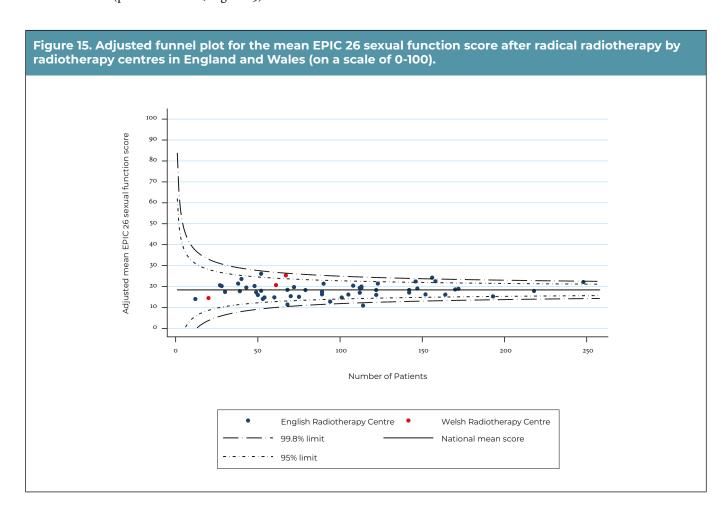
Performance indicator 13: Mean bowel function score after radical radiotherapy (presented at the level of the radiotherapy centre).

4,875 men who had EBRT (88%) completed sufficient information to be assigned an EPIC-26 bowel function score. Overall, the mean bowel function score after radical radiotherapy was 85.2 (range: 79.1 - 90.4). The adjusted funnel plot demonstrates limited variation across 53 radiotherapy centres. However, two had significantly worse scores (negative outliers) and one had a significantly better score than the national average (positive outliers) (Figure 14).



Performance indicator 14: Mean sexual function score after radical radiotherapy (presented at the level of the radiotherapy centre).

5,070 men (92%) who had EBRT completed sufficient information to be assigned an EPIC-26 sexual function score. Overall, the mean sexual function score after radical radiotherapy was 18.2 (range: 10.9 – 26.1). An adjusted funnel plot demonstrates that out of 53 radiotherapy centres, one had significantly worse scores (negative outliers), and one had significantly better scores than the national average for this domain (positive outliers; Figure 15).



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. In future reports we will move to using a validated five-tiered risk stratification metric which will allow for even finer-grained reporting of outcomes (Cambridge Prognostic Grouping³⁰). Other key variables, however, are not so comprehensive and data completion varies between Trusts. For instance, the use of multiparametric MRI was not included in this report due to poor data completeness. However, data from our organisational audits provide an alternative source of its use at a Trust-level. The NPCA are targeting the completeness of this variable as a priority for subsequent reports. From April 2019, the NPCA has moved to using routine databases for all our data analyses in England. 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 July 2020 there were new data items added to COSD including pre-biopsy multiparametric MRI. We encourage all Trusts carrying out diagnostic procedures to ensure that these variables are completed fully.

Performance status is a measure of how well a person is able to carry on ordinary daily activities and provides an indication of what treatments a person may tolerate, thereby helping to guide decisions about the appropriateness of certain treatments. Although completeness of performance status is high in Wales (100%), this remains low in England (52%). Improving the completeness of this key clinical data item is a key quality improvement goal for clinical teams in England.

New data items in the <u>Urology/ Prostate Cancer section of COSD V9.0.1</u> to capture information on diagnostic procedures			
Data item No.	Data Item Name	Data Item Description	National code definition
UR15440	BIOPSY ANAESTHETIC	Record the type of anaesthetic used during the biopsy	Local
			Sedation
			General
			Not Known
UR15500	mpMRI PRE- BIOPSY	Was a multiparametric mpMRI performed on the patient before the biopsy?	Yes
			No
			Not Known
UR15510	MRI/FUSION BIOPSY	Was a MRI/Fusion Biopsy performed on the patient?	Yes
			No
			Not Known

4.2 Diagnostics

The use of trans-perineal biopsies has increased compared to last year and this procedure was being performed in three-quarters of the Trusts/Health Boards in England and Wales in the period of this audit (2018/19). However, trans-rectal ultrasound guided biopsy was still the most common biopsy technique being used, although trans-perineal biopsy is accepted as the best way to diagnose anterior lesions.³¹ Further questions in this area, around the type of transperineal biopsy (targeted or systematic) and if it is performed under local anaesthetic or sedation, will be explored in the upcoming organisational survey.

4.3 Performance indicators

Diagnosis and treatment selection

The proportion of men diagnosed with metastatic disease at first presentation has reduced slightly from last year to 13% and there is minimal variation across specialist MDTs in England and Wales. The reduction may be due to the higher numbers in other risk groups this year which may be due to the impact of high-profile celebrities encouraging men to be checked for prostate cancer. This has led to a rise primarily in the intermediate risk and locally advanced categories, and with little change evident in the numbers of men diagnosed in that period with low risk or metastatic disease, the relative proportions for these may appear lower.

Parry MG, Cowling TE, Sujenthiran A, et al. Risk stratification for prostate cancer management: value of the Cambridge Prognostic Group classification for assessing treatment allocation. BMC Med. 2020;18(1):114.

Berry B, Parry MG, Sujenthiran A, et al. Comparison of complications after transrectal and transperineal prostate biopsy: a national population-based study. BJU Int. 2020; 126:97-103

The figures for potential 'over-treatment' 32 in low-risk men and potential 'under-treatment' in high-risk/locally advanced men has remained stable compared to last year at 5% (17/18: 4%) and 29% (17/18: 32%), respectively.

The recently added process measure of the receipt of primary docetaxel by newly-presenting hormone-naive metastatic patients has shown an increase from 27% last year to 36% this year. However, given that this was added to the NICE guidelines in 2019 as a standard of care and was established as effective in the Stampede Trial in 2015,³³ this still seems low. We do expect this to keep increasing year on year although there may be an upper limit as docetaxel is less suitable for treating older men, who make up a significant proportion of patients with metastatic disease. We will continue to monitor this trend going forward.

We continue to follow changes in radiotherapy fractionation. Hypofractionated radiotherapy is now the most common radiotherapy regimen used for intermediaterisk (96%) prostate cancer in the primary setting.^{34,35} Nationally, very few men with high-risk/locally advanced disease who received radical radiotherapy also received a brachytherapy boost, still at 5%. We have added an indicator to capture the use of irradiation for the prostate plus pelvic lymph nodes vs prostate-only radiation in the primary setting. This was found to be at a national average of 18% in England but the variation seen was concerning and will need further evaluation. It seems there is little consistency in the use of radiotherapy delivered to both the prostate and the pelvic lymph nodes, although it has been found to be well-tolerated.³⁶ More work needs to be done to understand why some centres do not adopt this method of treatment: we propose the development of a national working group to provide consensus guidelines to support decision making in this area of prostate cancer treatment.

Patient-reported experience measures

Only men diagnosed in a 6-month period (April 2018 -September 2018) and who subsequently underwent radical prostatectomy or EBRT, were sent a survey in this current round of data collection. An excellent high response rate (78%) was achieved (an increase compared with 73% of all non-metastatic men diagnosed April 2014 to September 2016 in the previous round of data collection) demonstrating that patients in England and Wales have continued to engage successfully with the NPCA Patient Survey.

The results of the PREMs demonstrate that the majority of men rate their overall care very highly. Most (91%) rated their care at least eight out of ten (where ten represents 'very good' care). There was only limited variation across SMDTs. Reflecting the

key NICE Quality Standard 'men with prostate cancer should have a discussion about treatment options and adverse effects with a named nurse specialist, the majority of men who had radical treatment stated they were given the name of a CNS (87%). However, this varied by provider and was low for a number of SMDTs. Furthermore, we have no indication as to whether this translated into use of specific nurse-led services. SMDTs should ensure the involvement of a CNS for every new diagnosis of prostate cancer. The NPCA will explore further the availability of specific nurse-led services in the 2020 organisational audit.

Treatment-related outcome measures

The national average for 90-day readmissions after RP is stable at 14% with four centres being identified as potential negative outliers. The proportion of men experiencing a treatment-related GU complication within two years of surgery has remained stable since last year's report at 10% with five centres being identified as potential outliers, which is up from two centres being outside the expected range last year. It is important to note that 89% of the RPs were carried out robotically and a recent study carried out by the NPCA indicates that there is no evidence that GU outcomes would be better if this percentage would increase further.³⁷ The proportion of men experiencing a treatment-related GI complication within two years of radiotherapy remained consistent with last year at 11%, and although three centres were outliers last year, only two centres were identified as a potential outlier this year. One of the centres was previously an outlier and has since made changes to their processes which would not be captured as yet by the data period analysed here. Their negative outlier status is therefore a reflection of outcome in patients treated at that centre using different methods. This is expected to improve with the changes facilitated by the NPCA outlier process.

Although patient-reported sexual function scores have increased by one-point at a national level since the previous round of the NPCA Patient Survey, these scores remain low following radical surgery or radiotherapy at 24 and 18 (out of 100), respectively. There was also significant variation between providers with three surgical centres and one radiotherapy centre having significantly worse outcomes for sexual function compared with the national average. Patients should be counselled appropriately and honestly regarding their likelihood of experiencing urinary and/or sexual dysfunction following radical surgery or radiotherapy.

Centres should review their survivorship programmes to ensure they are equipped to provide support to patients experiencing post-treatment problems which may need physical or pastoral help.

The recently published NPCA Short Report 2020 examines geographical variation in the management of high-risk/locally advanced prostate cancer in England and explores determinants of potential 'under-treatment' of men https://www.npca.org.uk/content/uploads/2020/10/NPCA-Short-Report-2020_Undertreatment_Final-o8.10.20.pdf

³³ James ND, Sydes MR, Clarke NW, et al. Addition of docetaxel, zoledronic acid, or both to first-line long-term hormone therapy in prostate cancer (STAMPEDE); survival results from an adaptive, multiarm, multistage, platform randomised controlled trial. The Lancet; 2015; 387(10024):1163-1177

Nossiter J, Sujenthiran A, Cowling TE et al. Patient-Reported Functional Outcomes After Hypofractionated or Conventionally Fractionated Radiation for Prostate Cancer: A National Cohort Study in England. J Clin Oncol. 2020; 38(7):744-752.

Sujenthiran A, Parry MG, Nossiter J, et al. Comparison of Treatment-Related Toxicity With Hypofractionated or Conventionally Fractionated Radiation Therapy for Prostate Cancer: A National Population-Based Study. Clin Oncol. 2020; 32(8):501-508

Parry MG, Sujenthiran A, Cowling TE, et al. Treatment-Related Toxicity Using Prostate-Only Versus Prostate and Pelvic Lymph Node Intensity-Modulated Radiation Therapy: A National Population-Based Study. *J Clin Oncol.* 2019; 37(21):1828-1835

Nossiter J, Sujenthiran A, Charman SC et al. Robot-assisted radical prostatectomy vs laparoscopic and open retropubic radical prostatectomy: functional outcomes 18 months after diagnosis from a national cohort study in England. *Br J Cancer*. 2018; 118(4):489-494.

Centres with performance that lies outside the expected range for the outcome measures should review their treatment pathway and engage with other providers to understand any differences in care. The next NPCA Quality Improvement workshop will take place in Q2 2021 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 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 have been 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 use of pre biopsy multiparametric MRI and prostate biopsy type.

The NPCA are working with our data collection partners to access available data more rapidly. This will enable the NPCA to determine the impact of COVID-19 on the diagnosis and treatment of men with prostate cancer, including treatment delay and potential receipt of sub-optimal treatment, and how this varies by region and individual hospitals. With further follow-up, the NPCA will determine the impact of changes in diagnostic and treatment pathways during the COVID-19 pandemic on the outcomes of men with prostate cancer.

We plan to continue our annual organisational survey, although it has been delayed this year, in order to provide up to date information about service availability across the country. Data was gathered in the latter part of 2020 and will be published early in 2021.

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 heavily 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 with low risk clinical characteristics.

Adjuvant

Treatment that is given following the primary treatment. Neo-adjuvant treatment is treatment before the definitive therapy.

Androgen Deprivation Therapy (ADT)

Androgen deprivation therapy is a hormone therapy used to control prostate cancer and delay or manage any symptoms arising from it. Testosterone makes prostate cancer cells grow faster and this therapy works by either stopping the 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. Androgen deprivation 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 reducing 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)

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 other important and measurable characteristics which might affect outcome (also see risk-adjustment).

Castrate Resistant Prostate Cancer

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

Charlson Co-morbidity Score

A scoring system used commonly to quantify the co-existence of other medical conditions (medical co-morbidities: see below) that patients may have in addition to their prostate cancer. 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 to promote data transparency and support wider engagement with national clinical audit data via publication of a directory of audits on myNHS.

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). These are focussed in a specific way to enable the computer assisted generation of three dimensional images.

Cyberknife®

Cyberknife* is an advanced radiation therapy device which has X-ray linked 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 deliver X Ray treatment precisely and minimise damage to healthy tissue close to the cancer.

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

A validated survey comprising questions for patients to measure prostate cancer related quality of life after radical treatments including urinary, bowel and sexual functioning.

External Beam Radiotherapy (EBRT)

The use of high energy X-ray beams directed at the prostate to kill cancer cells. It is used as a standard method to treat localised or locally advanced prostate cancer.

Fiducial Markers

Tiny metal objects used during radiotherapy which allows greater precision in directing radiation enabling radiation therapy to be delivered to the same area of the cancer each time it is given.

Gleason Score

The Gleason score is a microscopic measure assigned by a pathologist to determine how aggressive an individual's prostate cancer is. It is made up of two separate scores which are then added together to make a final score graded between 6 and ten. Along with PSA and TNM, the Gleason score can be used to predict how a prostate cancer might behave in the future. This process is known as risk stratification.

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 (HOIP)

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 enabling higher doses of radiotherapy to be given to specific higher risk areas within the prostate gland. 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

A 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 (T₃ or T₄) but is still contained within the prostate gland's pelvic location. This may be associated with spread to lymph nodes within the pelvis (N+).

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. The term "multi-parametric" (mpMRI) refers to variation in the types of MR image obtained during a scan. This adds to the ability of the clinical team to determine the presence of a cancer and its chance of being a more aggressive type of cancer growth.

Margin Status

Once the prostate has been removed during surgery, the margin status indicates whether the edge of the specimen contains cancer cells or not. A positive margin status does not always indicate that residual prostate cancer cells may have been left behind.

Metastatic Disease

When cancer has spread from its initial site of development in the prostate (the primary site) to distant sites of the body (the metastatic site(s)). These sites are mainly in 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 assess diagnosis and treatment and organise and deliver care for patients with conditions such as prostate cancer. The specialist MDT enables local cancer units to access specialist prostate cancer services which may not be locally available (see Specialist Multidisciplinary Team).

Multimodal Therapies

The use of multiple treatments used in combination against prostate cancer. These combinations may include radiotherapy, hormone therapy, surgery and/or systemic chemotherapy.

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 Patient Experience Survey (NCPES)

A national survey commissioned by NHS England to determine patients' views of their experience of care.

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 is extensive within the prostate or has spread outside the anatomical boundaries of the prostate.

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 hospitals in Wales. This includes details of admissions, diagnoses and the treatments.

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.

Radical Prostatectomy

The surgical removal of all the prostate gland and the associated seminal vesicles. The latter are structures integrally associated with the prostate. Their function is to produce and store fluid which sustains the viability of sperm when it leaves the prostate.

Radical treatment

Treatment aimed at curing prostate cancer (removing cancer tissue or filling all cancer cells in their primary location). These treatments include radical prostatectomy and radiotherapy.

Radiotherapy

The use of radiation to destroy cancer cells. There are different types of radiotherapy, including external beam radiotherapy (radiotherapy delivered from a radiation source outside the body) and brachytherapy (radiotherapy delivered directly by implanting a radiation source within the tumour itself).

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 their effectiveness is currently under evaluation. They are placed between the prostate and rectum in order to move the rectum away from the prostate. The belief is that this may protect the rectum from radiation and reduce side effects of radiation therapy. Results from further trials of this technique are awaited.

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 (see Gleason score).

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 controlled from a separate console by a surgeon to carry out removal of the prostate. 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 which run within the outer margin of 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 (see Multidisciplinary Team).

Staging/stage

The anatomical extent of a cancer. This determines whether a cancer is confined within its primary site (localised disease) or whether it has spread to other areas of the body (metastatic spread). It is usually denoted by the TNM staging process where "T" represents the local stage, "N" the presence of cancer spread to lymph nodes and "M" spread to metastatic sites.

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 data on the use of systemic anti-cancer therapy from all NHS England providers. This database has been used to identify the men receiving docetaxel chemotherapy for their prostate cancer.

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 using a fine needle through the perineum (the area of skin between the back of the scrotum and the front of the anus) guided using an ultrasound probe placed in the rectum (back passage). This is performed under general or local anaesthetic. The needle placement can be more precise than trans-rectal ultrasound biopsies if the prostate cancer sits in the forward portion of the prostate gland.

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 or 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: Outlier Communications

Introduction to the NPCA Outlier Process

Surgical and radiotherapy treatment centres outside the inner or outer funnel limits ('alerts' and 'alarms', respectively) for the adjusted treatment-related outcomes listed below were considered as potential outliers and were contacted, where necessary, according to the NPCA Outlier Policy.

<u>Performance indicator 8:</u> The proportion of patients who had an emergency readmission within 90 days of radical prostatectomy.

<u>Performance indicator 9:</u> The proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy.

Performance indicator 10: The proportion of patients receiving a procedure of the large bowel and a diagnosis indicating radiation toxicity (gastrointestinal [GI] complication) up to 2 years following radical prostate radiotherapy.

The NPCA team reviews the individual patient data returned by the treatment centres after they have carried out case reviews, to determine whether any patients need to be excluded from the analysis. This only happens if coding errors or misclassification of a patient's outcomes can be shown. Data not provided to the NPCA and limitations of case mix adjustment are not considered as these have been applied consistently across all providers.

A final determination of outlier status is made and if the 'alarm' outlier status is confirmed, the NPCA informs the CQC of their 'alarm' status. The responsible NHS Hospital Trust or Health Board is asked for a formal response to the findings, outlining the steps they will take for quality improvement.

If a treatment centre is confirmed to be an 'alert' outlier two years in a row, in keeping with the '<u>Detection and Management of Outliers for National Clinical Audit'</u> guidance, the NPCA informs the CQC of their 'alert' status.

Several instances of coding inaccuracies within treatment centres have led to the misclassification of patients in the first analysis. Following NPCA review and discussion of data with the individual centre these misclassifications have been accepted as a reason for excluding these patients from the indicator analyses. The treatment centres with this type of erroneous classification had their data re-analysed and were each found not to be an 'alarm' outlier following correction. This was the case, this year, for treatment centres in the following Hospital Trusts or Boards:

Emergency Readmissions -

- · Aneurin Bevan University Health Board
- Oxford University Hospitals NHS Foundation Trust
- University Hospitals of North Midlands NHS Trust

GU Complications -

• Worcestershire Acute Hospitals NHS Trust

These data quality issues are important to address as they are likely to be widespread, not just in those treatment centres that initially fell outside the limits this year. We urge all Hospital Trusts and Health Boards to examine their coding practices to ensure that admissions are coded appropriately and that follow-up episodes are accurately captured so that true improvement of the quality of care for men with prostate cancer can be pursued.

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

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

Responses from Trusts with a confirmed 'case to answer' during the NPCA Outlier Policy¹

Following identification as a true outlier each Trust was contacted by means of a letter to the MDT lead and Medical Director. The following trusts were contacted in relation to the following specific performance indicators:

Surgical centres

<u>Performance indicator 8:</u> Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.

Bradford Teaching Hospitals NHS Foundation Trust

<u>Performance indicator 9:</u> Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy.

East Lancashire Hospitals NHS Trust Gloucestershire Hospitals NHS Foundation Trust

Radiotherapy centres

<u>Performance indicator 10:</u> 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 radiotherapy centre).

Norfolk & Norwich University Hospitals NHS Foundation Trust

https://www.npca.org.uk/resources/npca-outlier-policy-2020/

Following notification of outlier status each trust was given the opportunity to review their individual data and check this against the NPCA data gathered from their hospital. The trust was then invited to respond by letter to the NPCA executive. The responses from individual outlier trusts in relation to their highlighted status are as follows:

Response from Bradford Teaching Hospitals NHS Foundation Trust

Performance indicator 8: Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.

Response 1

Thank you for your letter dated the 28th of September 2020 regarding our potential outlier position in terms of 90 day re-admission rates for men undergoing radical prostatectomy between 1 April 2018 and 31 March 2019. As advised I contacted M/s Karen Graham, National Cancer Registration and Analysis Data Improvement Lead who kindly provided us the NHS numbers for our patients who were readmitted to BTHFT. We have since had the opportunity to assess our patient records for this period, in particular, we have looked at the causes of re-admission in the 54 patients noted by the NPCA.

BTHFT (Bradford Teaching Hospitals NHS Foundation Trust) started the Robotic prostatectomy programme in late 2012 and we have since performed over 1200 cases. Our trust has been actively engaging with NPCA and have not previously been noted to be an outlier. In the period between 1 April 2018 and 31 March 2019 we had performed 223 Radical prostatectomies higher than the denominator of 196 noted by the NPCA. All of these were robotically assisted (RALP). During this period the majority of cases were performed by 3 surgeons Mr R Chahal, Mr R Singh and Mr C Molokwu. The first two of these surgeons have experience with over 500 radical prostatectomies each and Mr Molokwu with 100 case experience. Mr S Addla, a previous colleague, was the 4th surgeon who performed 5 cases in a locum capacity to cover a gap in service.

54 patients were noted to have been admitted in 90days post prostatectomy. I have grouped the reasons for re-admissions to understand any patterns and suggested actions undertaken and plans going forward.

Presumed UTI: (12) The largest group of patients who re-attended were patients who had UTI (or possible UTI). They had presented after variable intervals after RALP. Six patients presented with urosepsis and required admission for intravenous antibiotics, of these, 2 were after trial without catheter (TWOC) and one after a cystogram. Four patients complained of testicular pain with no evidence of epididymitis and were empirically started on antibiotics without admission, another patient had peri-catheter ooze. A further patient had retention one day after his TWOC which was relieved by an in and out catheter and once again treated with antibiotics empirically.

Plan:

- -We have changed our antibiotic prophylaxis from gentamycin (2mg/kg) and metronidazole to gentamycin and co-amoxiclav following discussion with the Microbiologist. This was implemented a year ago
- -We have reinforced the need for and improved the strict pre-operative culturing of urine and now review those cultures prior to admission.

Pelvic Haematoma: (6) Six patients were admitted with abdominopelvic pain and CTs demonstrated pelvic haematomas. All these were managed with percutaneous drainage. In review of the operating notes it was noted that all these had descriptions of difficult surgery with high BMIs. I noted that none of these patients had "Rocco" stitches.

Action: "Rocco" stitches are now routinely performed by all 3 surgeons for all cases for over a year now. We expect the haematoma risks to decrease and an audit of this is planned and we would be happy to share the results.

Response from Bradford Teaching Hospitals NHS Foundation Trust

<u>Performance indicator 8:</u> Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.

Lymphocoele (5) Five patients were admitted with abdominopelvic pain and or fever and CTs demonstrated collections in relation to the areas of lymph node dissection. All these were managed with percutaneous drainage with or without antibiotics.

Action: Following discussions noted at the ERUS meeting last year on lymph node dissection we have modified our template for prostate cancer lymph node dissections to exclude the dissection lateral to the external Iliac. The symptomatic lymphocoele rates will also be audited and again we would be happy to share the results when available.

<u>Urinoma:</u> (1) One patient developed significant pain and sepsis and was noted to have a urinoma which was drained. Catheter was kept in <u>situ for several weeks</u> until a cystogram showed no leak

Plan: No action as routine testing for water-tightness is assessed intra-operatively in all cases and we do not believe this is a recurring issue.

Abdominal and pelvic discomfort (7) Six patients were reviewed for complaints of excessive pain. Clinical evaluation and CT scans failed to identify any adequate explanation. Patients were managed with anti-inflammatories and on subsequent follow up no issues have been noted.

In a seventh patient CT suggested a small suspected leak of urine although no pelvic collection was noted. The patient was re-catheterised with a cystogram showing no further leak at 1 week.

Bowel complications (4)

- -Patient 1: A patient who had previous gastro-jejunostomy required significant adhesiolysis to gain access at the time of RALP. He presented a week after discharge with high intestinal obstruction. He had a CT and surgical review. At laparotomy he was found to have dense adhesions at the site of the previous gastroenterostomy which were causing a kink in the efferent loop of the gastroenterostomy. The release of these adhesions relieved the obstruction. No bowel resection was necessary.
- -Patient 2: During the prostatectomy he was noted to have adhesions of the sigmoid, possibly from a previous appendicetomy. These adhesions were released and the surgery was otherwise uneventful. 6 days post operatively the patient presented with signs of peritonitis. The CT scan and subsequent laparotomy by the surgical team confirmed a diverticular abscess and perforation. The surgeon noted that this was unrelated to the recent RALP and was consistent with diverticular perforation which was distant from the area of adhesionolysis.
- Patient 3: The Urologist noted significant adhesions of the sigmoid to the bladder which were likely due to severe diverticulitis. No fistulous connection was demonstrated with the bladder but the sigmoid was repaired in 2 layers where a small hole had been noted while taking it off the bladder. The patient was discharged but subsequently re-admitted 5 days post-operatively with abdominal pain and distension. He had a laparotomy which did not reveal any peritoneal contamination and the sigmoid stitches were noted to be intact. Due to significant inflammatory changes around the sigmoid on the CT scan the surgeon performed a loop colostomy.

Patient 4: He was admitted with diarrhoea post RALP and was found to have C difficile. He was treated with oral Vancomycin as per our Trust protocols.

<u>Ureteric complication</u> (1) The patient was undergoing a RALP with a posterior approach to the seminal vesicles. A "Hemolock" was applied which the <u>urologist</u> had thought would be the tip of the seminal vesical. Post op it was apparent on CT scan that the left lower ureter had a "Hemolock" across it. The patient had a nephrostomy placed and 6 weeks later had a left ureteric re-implantation performed.

Action: Team reflection on this complication: particular care to be taken in posterior dissections to not dissect laterally beyond the seminal vesicle and apply clips on the surface of the tip rather than laterally

N.B: for the last 2.5 years all 3 surgeons perform an initial posterior dissection to release the seminal vesicles prior to dropping the bladder. No other case of ureteric injury has been noted

Suspected Thrombosis/Thromboembolism (2) One patient presented with shortness of breath after RALP. A CTPA ruled out Pulmonary embolism. A second patient complained of calf pain and had a Doppler which ruled out a DVT

Catheter problems (2) Two patients were assessed in the Surgical Assessment Unit (SAU) for blocked catheters. In the first the blockage had already relieved at time of review. In the second patient the blockage was relieved with a simple washout of a small clot in the catheter.

Please note that the only area for urgent clinical review of patients at our Trust is the Surgical Assessment Unit; this sometimes leads to patients coming for acute review being counted as "admitted".

Response from Bradford Teaching Hospitals NHS Foundation Trust

<u>Performance indicator 8:</u> Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.

Drain review (5) and lost drain (1) Following lymph node dissection an increased drain output is often noted. The ward staff routinely send drain fluid for chemical analysis on the first post-operative day and if this is consistent with lymph the instructions are to remove the drains. On weekends there were occasions where this process did not work. Patients were discharged with drains and brought in a few days later for removal – this was consistent with historic practice that persisted on occasion. These 5 have all been recorded as re-admissions when they returned for drain removal.

In one patient the staff whilst removing the drain inadvertently cut the drain itself which retracted into the abdomen. Patient required a laparoscopic removal of the cut end of drain

Action: Staff education

Wound complications (2) One patient was worried about a slight ooze noted from a port site, this had settled without any action. A second patient had wound infection and was treated with antibiotics.

We do not feel this is a significant problem our case series.

Scrotal oedema and pain (2) One patient was reviewed for scrotal oedema and was reassured. A second patient complained of scrotal pain but no abnormality was noted and he was also re assured.

Action: We have improved education of our patients about the possibility of scrotal oedema after discharge and what signs or symptoms might warrant review.

Symphisitis (1) Patient complained of significant pain and tenderness in the area of the symphysis. CT showed significant inflammation around symphysis with no collection. He was managed with ant-inflammatory drugs.

No Action

Cystogram (1) No re-admission record. There were several other patients with cystograms but none had been recorded as a re-admission.

No readmission recorded for patients (2) Of 2 patient details provided by NPCA we have not found any record of re-admission.

Summary:

Of the 54 readmissions noted by NPCA we did not find any evidence of readmission in 3 patients. Of the remaining 51, 5 were patients who attended our ward for review of the drain outputs. We do not believe these should be regarded as re-admissions for complications. We have reinforced the current protocols for fluid analysis and drain removal prior to discharge.

A further 12 patients were assessed in the SAU by the team for minor complaints related to catheters, wound issues, scrotal issues and suspected UTIs. These patients were reviewed and reassured and a small number given oral antibiotics. All these 12 patients were sent home the same day after review without requiring admission.

A further 6 patients required an overnight stay often awaiting a senior review or imaging to confirm absence of any serious complications.

Discussion:

We are grateful that this issue has been raised and the review has given us an opportunity to scrutinise our practise.

We examined the records for all patients who were seemingly re-admitted within 90 days of their surgery. It was apparent that there were patterns for the reasons for re-admission. As noted above the largest group were patients who attended for urinary tract infections. Our protocol requires that patients have MSUs performed routinely at pre-assessment and the results are checked by the operating surgeon. Unfortunately this was not strictly implemented at the time, with reliance on patient symptoms and a urine dipstick in the morning of surgery.

Now the team are aware that pre-operative MSUs should be performed in every case. Our peri-operative antibiotic prophylaxis has also since been modified following discussion with the microbiologist to replace gentamycin and metronidazole with gentamycin and co-amoxiclav as a single dose. The ward staff are asked to give gentamycin at TWOC. In most patients a clear cystogram results in TWOC on the same day but occasionally due to the late timing of the cystogram these may be on different days. We have informed the TWOC team that antibiotic cover should be routinely prescribed to prevent any sepsis.

Response from Bradford Teaching Hospitals NHS Foundation Trust

<u>Performance indicator 8:</u> Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery.

The serious bowel complications were due to pre-existing conditions and it is not entirely clear if these were a direct consequence of the radical prostatectomy itself. Severe diverticulitis in one case and an incidental diverticular perforation resulted in laparotomy and colostomy in both these cases. The colorectal surgeon specifically noted that these were not related to any direct injury inflicted during the prostatectomy. A third patient developed high intestinal obstruction due to efferent loop obstruction of a gastro-jejunostomy due to adhesions and a kinking. Although not directly due to a surgical injury in all 3 cases the time-line suggests that these were possibly precipitated by the recent surgery. None of these patients had symptoms or signs on pre-operative imaging to suggest these issues were manifest at the time or were likely to occur.

The next group of complications relates to pelvic haematomas post prostatectomy. The surgery is performed at Intra-abdominal pressures of 10-12mm. All 3 surgeons routinely lower the intra-abdominal pressure to 6mm towards the end of the surgery to ensure no oozing. Operative notes for all these cases suggested difficult dissections, high BMIs and no "Rocco" stitches were placed. All 3 surgeons now routinely perform "Rocco" stitches and this practise will hopefully decrease the risk of this complication.

Five patients developed symptomatic lymphocoeles necessitating drainage. Our templates for lymph-node dissection were similar for bladder and prostate cancer in this period. There is some suggestion that dissection lateral to the iliac vessels may not be beneficial in prostate cancer dissections and results in a higher incidence of lymphocoeles. We have now altered our templates and will be auditing our practise to assess a decrease.

One patient had a Hemolock placed across the lower end on the left ureter whilst performing a posterior approach for the release of seminal vesicles. The surgeon clearly applied the Hemolock more laterally than intended assuming it was being placed at the tip of the vesicle. Particular care is taken to avoid a similar complication by staying close to the surface of the tip of the vesicle.

In our practise we encourage patients to have a low threshold for seeking advice and attending for a review by the urology team. This is to avoid review by less experienced staff in primary care or district nursing teams which are often considered the first port of call by patients. This has resulted in rapid experienced reviews and often simple reassurances which can allay anxiety for patients - particularly concerns about wounds or catheters.

The prompt review does sometimes result in the event being registered as an admission but we do not regard these as complications. If we exclude these 20 cases where either no admission was recorded (3), drain reviews were performed (5) or review and reassurance provided without overnight admission (12) our 90 day re-admission rates are 34 of 223 (15.2%) cases that we have recorded for this period. This is very similar to the average of 14% 90-days re-admission rates recorded nationally and this is despite having an 8% higher rate of locally advanced prostate cancers (56% v 48% nationally) in our patient population.

In conclusion we appreciate the NPCA providing us an opportunity to clarify the reasons for a higher 90d re-admission rate reported. We have identified several issues for which remedial actions have been initiated to mitigate these risks. We also feel that if account is taken of the day reviews for patients the risks are in keeping with the national average.

We are happy to provide any further clarifications and will continue to engage constructively with the NPCA.

Response 2

Thank you for your letter highlighting our potential outlier status for re-admissions after radical prostatectomy. We welcome the review and the opportunity to re-examine our outcomes after robotic prostatectomy.

We acknowledge and accept the results of the audit. We feel many of the reported re-admissions are a result of recording errors, with patients presenting (often as a planned attendance) for clinical review. We are working with our data teams to address this

Our Urology department has also made some changes to reduce the incidence of some complications that have led to some 'real' readmissions, including a change in our peri-operative antibiotic prophylaxis and the use of reinforcing sutures ('Rocco' stitch). We are continuing to monitor the outcomes to confirm this is reducing post-operative infections and haematomas.

Response from East Lancashire Hospitals NHS Trust

<u>Performance indicator 9:</u> Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy.

Thank you for informing us that ELHT is an outlier in the NPCA with respect to patients experiencing at least one severe genitourinary tract complication within 2 years of radical prostatectomy.

This was clearly very disappointing for us to discover as a Trust and consequently we have looked in detail into our data. We were aware of some complications as a result of our ongoing internal audit process. Changes to practice have already been made in terms of use and positioning of clips and bladder neck anastomosis.

Having reviewed our internal audit data with that of the NPCA there were 83 cases recorded locally, compared to, 64 with the NPCA. We assume this is down to a coding / data issue with HES and we are in the process of looking into this internally. Incorporating these extra cases into the total number of procedures will make a difference when calculating complication rates.

On reviewing all the cases that were recorded as having a complication we felt that some of these should be excluded from the analysis. We have commented the reason for exclusion against each case number.

Patient A² – From our information this patient was admitted with constipation and bladder spasm but did not have any significant intervention.

Patient B - From our information this patient was diagnosed with an overactive bladder and was treated with Botox.

Patient C - This patient had difficulty with catheter removal. This fell out shortly after attempted removal with no intervention required.

Patient D – This patient had complex pre-existing urological problems associated with previous stricture and urethroplasty, he therefore should not be included as a post op complication.

Patient E – This patient had an episode of epididymo orchitis following surgery and does not fit the criteria of a major complication.

When we look at the additional patient data and take into account the above suggested exclusions we feel our complication rate is much lower at 14 percent. We did not have access to HES data to double check for admission but did view our hospital admissions and cross checked with our neighbouring hospitals that we provide the radical prostatectomy service for. Local agreement is that any complications occurring post-surgery are referred back to ELHT to manage so we would expect to have picked up most of the significant complications.

We accept that our bladder neck stenosis rate is slightly higher than we would like and as mentioned above have already picked this up with our internal audit process and have changed our practice. An audit of 2018 patient has started which has demonstrated 171 patients treated with a complication rate of 9%, suggesting that there has been a successful change in practice. We are in the process of going through this data and validating it further.

² Patient ID numbers have been replaced

Response from Gloucestershire Hospitals NHS Foundation Trust

Performance indicator 9: Proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy.

I am writing in response to your letter written on 1st December 2020. You highlighted that our Trust was an outlier for the following performance indicator:-

The proportion of patients experiencing at least one genitourinary (GU) complication requiring a procedural/surgical intervention within 2 years of radical prostatectomy (men undergoing RP between 1st January 2017 and 31st December 2017).

The raw data suggests 36 out of 112 patients that were affected. The Trust was an outlier in the same performance indicator in last year's report (1st January 2016 to 31st December 2016). As a department, we identified that during this time period we experienced an increased rate of development of urethral stricture post-operatively. This increase resulted in the complication rate highlighted. This was highlighted to you last year.

The strictures occurred across all 4 surgeons performing the operation. We reviewed the entire process of surgery to try and identify any causative factors. Discussion with other departments highlighted similar problems in the units. Following our review we have changed the skin prep used at surgery, we have also shortened the time a catheter may be put on gentle traction during surgery.

The actions described were put in place in 2018/19 and therefore would not have been in place to support the patients captured in this reports timeframe. I am pleased to inform you that the clinical team have completed an audit on patients treated from January 2018 to April 2019 and the review included all patients who had a follow up to December 2020. The scope of the audit includes 172 procedures, of this cohort only 2 patients (1.16%) experienced genitourinary complications requiring a procedure/surgical intervention. One patient was diagnosed with urine leak requiring drain insertion post op whilst an inpatient, whilst the other patient was diagnosed with bladder neck stricture requiring readmitting and dilatation.

Response from Norfolk & Norwich University Hospitals NHS Foundation Trust

Performance indicator 10: Proportion of patients experiencing at least one severe gastrointestinal (GI) complication within 2 years of radical external beam radiotherapy.

Thank you for informing us that we remain a significant outlier for radiation proctitis for the 2017 patient cohort. We would like to thank you for recognising our engagement in improving our outcomes and willingness to share our experience to date. We expect this relationship to continue until we see significant improvements in our outcomes.

We have reviewed the patient dataset and agree that we remain a significant outlier triggering your alarm limits with a radiation proctitis

We would like to summarise all of the changes that we have made over the last two years since the last report and our presentation to the NPCA. The following is a timeline of all of those changes.

Feb 2018	Moved from Bony matching to Soft tissue matching		
May 2018	Reduced prostate margin from 1cm (0.5cm) sv margin 1cm		
Aug 2018	Weekly Prostate Peer review meeting initiated		
Oct 2018	First identified as outlier Radiation Proctitis 2015 Cohort		
Dec 2018	Seminal vesicle dose dropped to 52.5Gy (60Gy prostates) and 60Gy (74Gy Prostates)		
June 2019	Imaging study for IGRT showed with bony matching dose to rectum higher than planned		
Oct 2019	Alarm Outlier for Radiation Proctitis 2016 Cohort		
Dec 2019	Presentation of our proctitis rates at NPCA study day Guys Hospital Outside review Prostate protocols		
Jan 2020	Dropped seminal vesicle dose to 48Gy for 6oGy prostates. GTV delineated Undertook Proknow national prostate planning benchmark study national prostate planning benchmark study		
July 2020	Adopted CHHIP planning for P and SV patients		

It is a significant frustration that as it takes two years for radiation proctitis to develop it takes a long time to know whether the changes we have made have been successful. We have prospectively looked at our outcome data for 2018 and for 2019. We will remain a significant outlier for 2018 but are confident that from 2019 we will start to see significant improvements in our radiation proctitis rate as all of the changes we have made to our processes kick in. The numbers for 2019 look significantly lower so far but it is still early.

The most significant changes performed over the last year were to ask a radiation oncology centre with a much lower radiation proctitis rate to review our process after the 2019 round. We adopted all of the suggested planning changes. The changes suggested were as outlined above ie dropping SV dose to 48Gy in 20 fractions, outlining a tumour volume and optimising our plans to achieve the best rectal dose level we can achieve rather than stopping when mandatory constraints were met.

We have also, since the last report, taken part in the Proknow benchmarking study. We found that although our earlier changes put us on a par dosimetrically with other centres, the adoption of the CHHIP planning technique improved our rectal dosimetry significantly. We now plan all of our Prostate and seminal vesicle patients using the CHHIP protocol.