Quality Performance Indicators Audit Report

Tumour Area:	Prostate Cancer
Patients Diagnosed:	1 st July 2016 to 30 th June 2017
Published Date:	26 th March 2019
Clinical Commentary:	Mr. David Douglas
	Consultant Surgeon, NHS Highland



1. Prostate Cancer in Scotland

With over 3,000 cases diagnosed in Scotland in 2016, prostate cancer is ranked as the most commonly diagnosed cancer in male patients in Scotland and the fourth most commonly diagnosed cancer in males after lung, breast and colorectal cancers¹.

Following a previous trend for increasing incidence rates for prostate cancer in Scotland, the incidence of prostate cancer has in fact decreased in the past ten years by $3.5\%^1$. While part of the historic increase in incidence of prostate cancer may reflect a genuine increase in risk, much of the increase since the mid-1990s seems likely to reflect increased detection of latent disease through increasing use of the prostate-specific antigen (PSA) test². However, it is now suggested that this increased use of PSA testing may have resulted in prostate cancer diagnoses which otherwise might not have been detected within the patient's lifetime (i.e. overdiagnosis) and thereby the overtreatment of prostate cancer³.

Relative survival of patients diagnosed with prostate cancer in Scotland is increasing⁴. The table below shows the percentage change in one-year and five-year age-standardised survival rates for patients diagnosed in 1987-1991 compared to those diagnosed in 2007-2011.

Relative age-standardised survival for prostate cancer in Scotland at 1 year and 5 years showing percentage change from 1987-1991 to 2007-2011⁴.

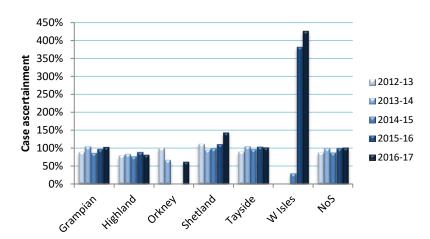
	Relative surviv	al at 1 year (%)	Relative surviva	l at 5 years (%)
	2007-2011	% change	2007-2011	% change
Prostate Cancer	96.0 %	+ 11.3 %	84.0%	+ 31.0 %

The significant increase in five-year survival rates may in part be due to the increased use of PSA testing in Scotland since 1990s. As the PSA test enables some invasive prostate cancers to be detected earlier, this leads to an increase in survival time even in cases where a patient's life is not necessarily extended by treatment.

A recent study in the USA by the National Cancer Institute found that men who underwent annual prostate cancer screening had a higher incidence of prostate cancer than the control group but had the same rate of deaths from the disease. Another European study, the European Randomised Study of Screening for Prostate Cancer (ERSPC), also showed that men in the screening group had a higher incidence of prostate cancer but, in contrast, this study showed that the men who were screened had a lower rate of death from prostate cancer⁵. However, the study showed that screening had no effect on all-cause mortality and concluded that more evidence was required on the balance of benefits and risks of prostate-cancer screening before recommendations could be made⁶.

2. Patient Numbers and Case Ascertainment in the North of Scotland

A total of 842 cases of prostate cancer were recorded through audit as diagnosed in the North of Scotland between 1st July 2016 and 30th June 2017. Case ascertainment for the period reported in the North of Scotland was high at 101.8%, an increase from the 2015-16 figure of 99.2%. Case ascertainment for each Board across the North of Scotland is illustrated below. Fluctuations in case ascertainment are expected in the island boards as a result of chance variation due to the small numbers of patients diagnosed.

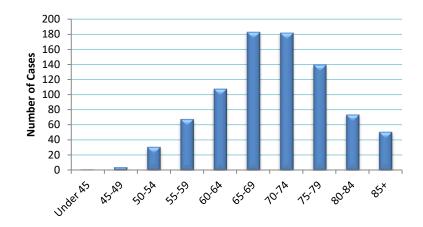


	Grampian	Highland	Orkney	Shetland	Tayside	W Isles	NoS
Number of Patients 2016-2017	370	146	1	29	267	29	842
ISD Cases 2012-2016	357.8	178.8	1.6	20.2	261.8	6.8	827.0
% Case ascertainment 2016-17	103.4%	81.7%	62.5%	143.6%	102.0%	426.5%	101.8%

Audit data were considered sufficiently complete to allow QPI calculations. While difficulties with recording of clinical TNM in NHS Tayside and NHS Grampian resulted in incomplete datasets there have been significant improvements in the collection of these data in recent years. For QPIs 2, 3, 4 and 7 clinical TNM staging data is required to derive results. The absence of these data for some patients has resulted in QPI results not being calculated from information on all patients. In addition, data on continence was missing for some NHS Tayside and NHS Grampian patients, while data on early management of active surveillance was not collected for any patients in NHS Tayside, affecting the results for QPI 8 and QPI 11.

3. Age Distribution

The age distribution of patients diagnosed with prostate cancer in the North of Scotland in 2016-17 is shown below. Incidences of prostate cancer peak in the 65-69 age group.



4. Performance against Quality Performance Indicators (QPIs)

Definitions for the QPIs reported in this section are published by Health Improvement Scotland⁷, while further information on datasets and measurability used are available from Information Services Division⁸. Data for most QPIs are presented by Board of diagnosis, however QPIs 5 and 8 are presented by Hospital of Surgery and QPI 6 is presented by surgeon. Further, QPI 13, clinical trials and research access, is reported by patients NHS Board of residence. Please note that where QPI definitions have been amended, results are not compared with those from previous years.

5. Governance and Risk

Governance is defined as the combination of structures and processes at all levels to lead on North quality performance including:

- Ensuring accountability for quality and required standards
- Investigating and taking action on sub-standard performance
- Identifying, sharing and ensuring delivery of best-practice
- Identifying and managing risks to ensure quality of care
- Driving continuous improvement

Our current governance structure provides assurance to the boards that risks associated QPIs are being addressed as an alliance. Clinical risks are discussed at the North Cancer Urology Pathway Board (NCUPB) and North Cancer Clinical Leadership Group (NCCLG). Risk levels are jointly agreed. The NCCLG are presented with all available evidence and actions so they have all the information to define the risk in a collaborative way.

- **Tolerate** Accept the risk at its current level
- **Mitigate** Reduce or mitigate the risk, in terms of reducing the likelihood of its occurrence or reducing the severity of impact if it does occur. This can be assessed through the action plans provided or the information provided is appropriate to prevent reoccurrence.
- **Escalate** Escalate the risk to the appropriate committee and/or take further action as the mitigations were not suitable or there are no actions identified to mitigate the risk. This will be revisited by the RCCLG for further risk discussion.
- **Immediate** Immediate action is required to prevent the risk reoccurring. This risk will have major impact on patient care delivery and the consequences thereafter. Very few risks should occur in this level.

The full governance document on risk should be referred to in conjunction with this summary, which is available on the NCA website⁹.

Biopsy Procedure

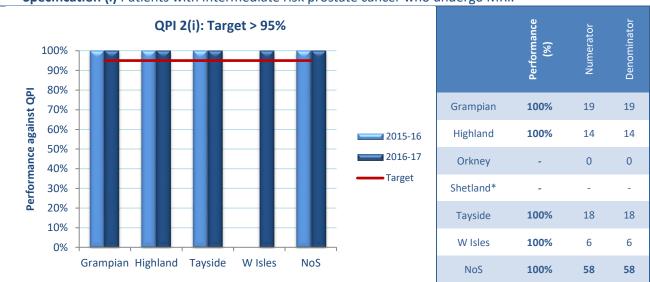
Proportion of patients with prostate cancer who undergo trans-rectal ultrasound guided (TRUS) prostate biopsy for histological diagnosis where a minimum of 10 cores are received by pathology.



Clinical Commentary	This QPI should exclude patients with advanced or metastatic disease. The absence of clinical TNM data for approximately 9% of patients included within this QPI measurement will likely have resulted in some patients with advanced or metastatic disease having been erroneously included within calculations, thereby potentially lowering results. QPI 1 was achieved throughout the North of Scotland with the exception of the Western Isles; however the diagnosis of prostate cancer in the Western Isles is delivered by NHS Highland, where the QPI was met. Older men with high PSA's and clinically advanced prostate cancer do not need 10 or more cores from their prostates to get a diagnosis. This is the reason why the target wasn't met in the Western Isles.
Actions	No action required
Risk Status	Tolerate

Radiological Staging

Proportion of patients with intermediate or high risk prostate cancer undergoing radical treatment who have had Magnetic Resonance Imaging (MRI) and bone scan staging.



Specification (i) Patients with intermediate risk prostate cancer who undergo MRI.

*Where the number of cases per Board is between one and four, this is excluded from charts and tables to minimise the risk of disclosure. However, these excluded Board numbers are included within the total for the North of Scotland.



Specification (ii) Patients with high risk prostate cancer who undergo MRI and bone scan.

Clinical Commentary	This QPI was met for all patients with intermediate risk prostate cancer. However the target was not met for patients with high risk prostate cancer in any NHS Board except NHS Tayside. This is due to a fundamental difference in the interpretation of intermediate and high risk prostate cancer, specifically the difference is the stratification of cT2c prostate cancer. Some class it as intermediate risk where as other classifications put cT2c disease in the high risk category. The QPI definition now classes this as high risk, therefore requiring MR and bone scan. In the North cT2c disease is considered to be intermediate risk and therefore most patients don't get a bone scan. Until there are amendments to the QPI definition then it is likely to continue to fail the second specification for this QPI. Performance against this specification is lower than in other regions of Scotland.
Actions	1. NCUPB to ensure that the classification of high risk and intermediate risk prostate cancer, and its implications for the reporting of QPI 2, are raised at the next formal review of Prostate Cancer QPIs.
Risk Status	Mitigate

Pathology Reporting

Proportion of patients who undergo needle biopsy where the pathology report contains a full set of data.



Clinical	This QPI was met by all NHS Boards in the North of Scotland except NHS Highland and
Commentary	NHS Western Isles. These boards should be considered together as all Western Isles prostate biopsies are performed by NHS Highland. The pathology department in NHS
	Highland has already made changes to the way pathology reports are worded to improve performance against this QPI. However, as changes were made in 2017, there are numerous patients from 2016 who have failed this QPI. The majority of failures were due to a lack of clarification of whether adipose tissue was involved. All NHS Highland pathology reports for prostate biopsy now include this information and therefore performance against this indicator is expected to improve for the next reporting cycle.
Actions	 NHS Highland has taken action to address their pathology report to ensure compliance.
Risk Status	Mitigate

Multi-Disciplinary Team (MDT) Meeting

Proportion of patients with prostate cancer who are discussed at MDT meeting before definitive treatment.



Specification (i) Patients with non-metastatic prostate cancer discussed before treatment

Specification (ii) Patients with metastatic prostate cancer discussed within 4 weeks of commencing treatment



Clinical	Most boards did not achieve the target for specification (ii) due to two main reasons.
Commentary	Firstly, several patients were not formally discussed at MDT. Even if the patient is appropriately treated then this QPI would be failed due to the lack of MDT discussion. This should be easily rectified by remembering to discuss all new prostate cancers in MDT in a timely fashion. The second reason is that some patients are started on treatment long before they are discussed at MDT, especially in patients with metastatic disease where delay in treatment while waiting on an MDT discussion could be detrimental. It would be hard to justify changing this, however the target is still achievable if patients are discussed at MDT within 4 weeks of commencing androgen ablation therapy. If this QPI result doesn't improve in subsequent years then the reasons for not adding patients to MDT in a timely manner need to be explored, for example to establish if there is sufficient availability of MDT resource across the region.
Actions	 NCUPB to highlight that timely discussion at MDT is essential to achieve QPI 4 and note that for patients with metastatic disease this QPI will be met if discussion can take place within the 4 weeks of treatment. All NHS Boards to circulate this NOS Audit Report to all MDT members to stress the importance of timely MDT discussion of all patients. NCUPB to undertake review of timelines for treatment. NCUPB to map MDT resource availability.
Risk Status	Mitigate

Surgical Margins

Proportion of patients with pathologically confirmed, organ confined (stage pT2) prostate cancer who undergo radical prostatectomy in which tumour is present at the margin.



Clinical Commentary	The North of Scotland achieved this QPI as a whole. NHS Tayside was marginally outside the 20% target, however small variations like this are common with the relatively small numbers of patients included within the indicators and one year's results should not be seen as a cause of concern. There is a difference in surgical approach between Tayside and Grampian, with laparoscopic surgery undertaken in NHS Tayside and robotically assisted surgery undertaken in NHS Grampian. However as both NHS Boards have a similar proportion of patients with positive surgical margins, at around 20%, there is no suggestion at present of a difference in QPI outcomes due to surgical approaches. Performance against this indicator should be monitored over a few years.
Actions	No action required
Risk Status	Tolerate

Volume of Cases per Surgeon

Number of radical prostatectomy procedures performed by each surgeon over a 1 year period.

Target: > 50	Surgeon	Number of Prostatectomy Procedures		
procedures	Juigeon	2015-16	2016-17	
	А	52	69	
NHS Grampian	В	16	30	
	С	0	24	
	D	3	4	
NHS Tayside	E	50	66	

Clinical	Data used to measure performance against this QPI comes from in patients records	
Commentary	(SMR01) rather than the Cancer Audit data specifically collected to report other QPIs.	
	There are some concerns about the accuracy of recording of these data and NHS Boards	
	should check the accuracy of these data against surgeons own records.	
Actions	 NHS Boards to ensure that they check SMR01 figures for surgical volumes against surgeons own figures and discuss any discrepancies with the teams collecting the SMR01 data. QPI results to be monitored in light of changed practice due to the use of robot technology for surgery and input as part of national Robotics group. Ensure QPI is reviewed as part of next formal QPI review. Benchmarking exercise to be undertaken by NCUPB to understand comparison to other regions. 	
Risk Status	Escalate	

Hormone Therapy and Docetaxel Chemotherapy

Proportion of patients with metastatic prostate cancer (TanyNanyM1) who undergo immediate management with hormone therapy, and docetaxel chemotherapy.



Specification (i) Patients who receive immediate hormone therapy

*Where the number of cases per Board is between one and four, this is excluded from charts and tables to minimise the risk of disclosure. However, these excluded Board numbers are included within the total for the North of Scotland.

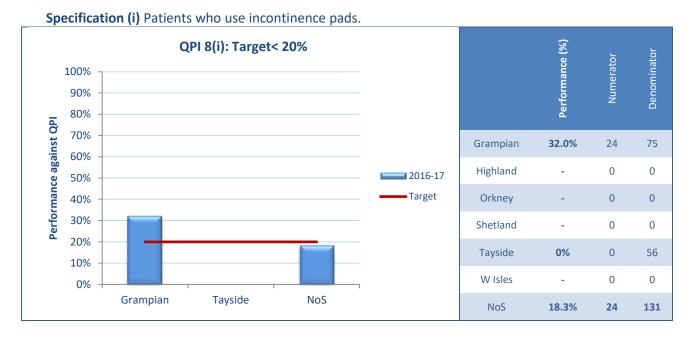


Specification (ii) Patients who receive immediate hormone therapy and docetaxel chemotherapy.

Clinical	Specification (i) – Some patients did not meet the QPI as they were not discussed at	
Commentary	MDT, others due to delays in starting treatment, however results are similar to other	
	regions.	
	Specification (ii) – This is a new quality indicator. Some concerns have been raised that	
	not all patients with metastatic disease are eligible for chemotherapy and a 70% target is unrealistic. NHS Tayside have implemented a policy of immediate hormone and	
	chemotherapy specifically due to this QPI and therefore results in Tayside should	
	improve in future years.	
Actions	1. All NHS Boards to encourage the use of chemotherapy in patients with new	
	metastatic prostate cancer as stated in Prostate Cancer CMG.	
	2. The North Cancer Alliance to undertake interim audit to look at issues with hormone	
	therapy treatments for prostate cancer in the North.	
	3. The North Cancer Alliance to benchmark performance of QPI 7 (ii) with other NHS	
	boards.	
Risk Status	Escalate – further action required	

QPI 8	Post Surgical Incontinence
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Proportion of prostate cancer patients who undergo radical prostatectomy with post surgical incontinence approximately 1 year after surgery. This QPI is reporting one year in arrears and as such results presented below are for patients diagnosed in 2015-16.



Specification (ii) Patients who use more that 1 incontinence pad per day.



Clinical	Radical prostatectomies are now only undertaken at two surgical centres in the North of
Commentary	Scotland, Aberdeen Royal Infirmary (ARI), NHS Grampian, and Ninewells Hospital, NHS
	Tayside. While reported incontinence levels in NHS Tayside were very low, the lack of
	recording of whether pads were used by patients for 37.5% of patients will have
	underestimated incontinence in this NHS Board. Incontinence rates in NHS Grampian
	were higher and did not meet the target level for either measure, lack of recording of
	pad use for 26.7% of patients here will also have affected reported incontinence levels in
	NHS Grampian.

	Although numbers of pads (especially wearing no pads) is a direct reflection of urinary continence, it is difficult to interpret these data when one third of the data is missing. Generally PROMs are recommended now and these should be collated as part of the BAUS complex operations database. Hopefully this matter will be address in the upcoming review of robotic prostatectomy in Scotland.		
Actions	 The North Clinical Lead for prostate cancer to facilitate a discussion on post- operative data collection, including defining data to be collected and resourcing of data collection, at the next national review of robotic surgery on 1st October 2018. The North Cancer team to escalate nursing issues with regards to incontinence to nurse consultants as part of North Urology collaborative. The North Cancer team to undertake further analysis of data in terms of surgical volumes and incontinence. 		
Risk Status	Escalate		

Early Management of Active Surveillance

Proportion of men with prostate cancer under active surveillance who undergo multiparametric MRI within 6 months, and prostate re-biopsy within 14 months of diagnosis. This QPI is reporting one year in arrears and as such figures reported here are for patients diagnosed in 2015-16.



Specification (i) Patients who have undergone multi-parametric MRI within 6 months of diagnosis.

*Where the number of cases per Board is between one and four, this is excluded from charts and tables to minimise the risk of disclosure. However, these excluded Board numbers are included within the total for the North of Scotland.



Specification (ii) Patients who have undergone prostate re-biopsy within 14 months of diagnosis.

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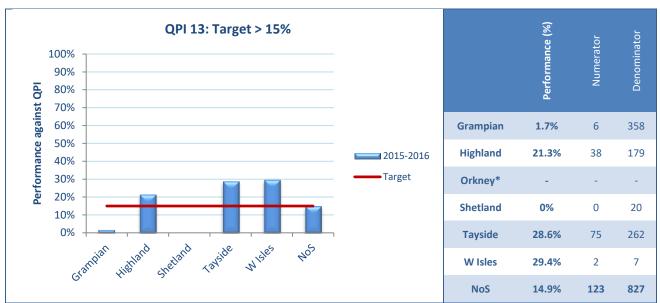
ClinicalThe way QPI 11(i) is currently defined is not clinically meaningful as it does not take into
account the recent move towards pre-biopsy multiparametric MRI. If the MRI occurs
before the biopsy then this QPI will be failed under the current definition. However the
way this indicator is measured will be amended in future years so patient having a pre-
biopsy MRI will meet this indicator, making the indicator a more clinically meaningful
indicator of quality.

	QPI 11(ii) was not achieved across the North for several reasons. Firstly, some patients not on active surveillance are being included in the figures. The distinction between active surveillance and watchful waiting needs particular attention. There are also some patients having repeat biopsies beyond the 14 month cut off. This suggests an issue with space for prostate biopsy, and possibly new diagnosis biopsies being given priority over surveillance biopsies. Results reported here are for patient diagnosed in 2015-16, a significant improvement in performance is anticipated for patients diagnosed in 2016 - 17. At the time of reporting NHS Tayside did not record the information required to report this QPI for any patients on active surveillance. Audit procedures have now been implemented to ensure data is being entered so performance will be reported in future years
Actions	1. All NHS Boards need to ensure that surveillance biopsies are performed in a timely fashion, this should be an action on the NCUPB to take this forward.
Risk Status	2. NHS Tayside change audit procedure to ensure active surveillance data are recorded. Mitigate

30 Day Mortality following Chemotherapy

Target < 5%	Performance (%)	Numerator	Denominator
Grampian	0%	0	21
Highland	0%	0	27
Orkney*	-	-	-
Shetland	-	0	0
Tayside	0%	0	20
W Isles*	-	-	-
NoS	0%	0	72

Clinical Commentary	Of the 72 patients diagnosed with prostate cancer in 2016-17 and undergoing chemotherapy, none (0%) died within 30 days of chemotherapy treatment, well within the target of <5%. As this is a new QPI there are no comparable figures from previous years.	
Actions	No action required	
Risk Status	None	



Clinical Commentary	All cancer patients that pass through each of the three cancer centres in the North are considered for potential participation in the open trials currently available. However, as with other cancer specific studies, consequent to the demise of larger general trials and the advent of genetically selective trials that only target small populations of patients, many of the prostate cancer trials that are currently open to recruitment in the North of Scotland have very select eligibility criteria. Consequently they will only be available to a small percentage of the total number of people who were diagnosed with prostate cancer. During 2017 there were 11 trials open to recruitment in the North with 5 of the trials recruiting patients. In addition some patients from the North of Scotland were entered in to other trials outwith the region. This offered patients with prostate cancer diagnosis the opportunity to participate in a range of different prostate cancer trials. Furthermore, all the prostate cancer patients passing through the cancer centres in the North will have been assessed for eligibility for clinical trials. Due to the increasing complexity of trials and time burden needed to run them effectively, and a lack of clinical and research support to run such further trials, it is not currently possible to open a greater number of available trials in the North of Scotland. Constraints imposed by the commercial trial sponsors also limit the number of trials it is possible to open in smaller cancer centres such as those in the North region. However a large number of feasibility requests for trials are continually being reviewed by all consultants and if an expression of interest is submitted, the chances that the site will be selected for running the trial are high.
Actions	 All clinicians should consider opening relevant clinical trials in their tumour areas. When this is not possible patient referrals to other sites for access to clinical trials should be considered.
Risk Status	Mitigate

References

- 1. Information Services Division. Cancer Incidence in Scotland (2016). Available at: <u>https://www.isdscotland.org/Health-Topics/Cancer/Publications/2018-04-24/2018-04-24-</u> <u>Cancer-Incidence-Report.pdf?27306765318</u>
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- 8. <u>http://www.isdscotland.org/Health-Topics/Cancer/Cancer-Audit/</u>
- 9. <u>https://www.nrhcc.scot/uploads/tinymce/NCA/NCA%20Governance/NCA-GOV-QPI-Process-</u> <u>Explained.pdf</u>

Trial	Principle Investigator	Patients consented into trial in 2017
ADD ASPIRIN	Dr Russell Mullen (Highland)	Y
ATLAS: JNJ56021927 (ARN509)	Dr Judith Grant (Grampian)	Y
MULTIPROS study	Prof Ghulam Nabi (Tayside)	Y
STAMPEDE	Dr Neil McPhail (Highland)	Y
TITAN JNJ-56021927	Prof Ghulam Nabi (Tayside)	Y
Open Label Study of Relugolix in Men	Dr Graham MacDonald	
with Advanced Prostate Cancer	(Grampian)	
PR.17 (ANZUP 1304)	Dr Graham MacDonald	
	(Grampian)	
PROMPTS	Dr Asa Dahle-Smith	
	(Highland)	
Shear wave elastosonography (SWE) in the detection of prostate cancer	Prof Ghulam Nabi (Tayside)	
TriCREST	Dr Neil McPhail (Highland)	
	Mr Nicholas Cohen	
UK Genetic Prostate Cancer Study	(Grampian)	
	Prof Ghulam Nabi (Tayside)	

Appendix 1: Clinical trials and research studies open within the North of Scotland in 2017.