National Cancer Recovery Group
National Cancer Quality Steering Group

Prostate Cancer
Clinical Quality Performance Indicators

First Published: **May 2012**
Version 5.0 **April 2023**

Published by:
Healthcare Improvement Scotland

Revision History

Version	Date	Summary of Changes
V1.0	May 2012	Initial publication
V2.0	November 2013	Addition of QPI 4 – Multidisciplinary Team (MDT) Meeting
V2.1	December 2014	Baseline review changes
V3.0	July 2016	Formal review changes (1st cycle)
V4.0	January 2020	Formal review changes (2nd Cycle)
V4.1	October 2020	Amendment QPI 6 – Volume of Cases per Surgeon
V5.0	April 2023	Formal Review Changes (3rd Cycle)

Contents Update Record

April 2023 (v5.0)
This document was updated following formal review (3rd cycle) of the Prostate Cancer Quality Performance Indicators (QPIs) which took place following analysis of year 9 of the prostate cancer QPI data.

The following QPIs have been updated:

- QPI 7: Androgen Deprivation Therapy (ADT) with Additional Systemic Therapy
- QPI 8: Assessment of Post Treatment Patient Reported Outcome Measures
- QPI 11: Management of Active Surveillance
- QPI 15: Low Burden Metastatic Disease

The following QPI has been archived:

- QPI 2: Radiological Staging
- QPI 12: 30 Day Mortality following Systemic Anti-Cancer Therapy*
- QPI 13: Clinical Trial and Research Study Access*

* These important indicators will continue to be monitored via other national reporting systems rather than through the QPI process.

As a result of the changes above, the contents page and page numbering differ from earlier versions of this document. Sections 1-11 and the appendices have also been updated.

Please note that this version of the Prostate Cancer QPI Documents applies to cases diagnosed from 1st July 2022.

Previous Updates

October 2020 (v4.1)
The document has been updated to detail reporting requirements for QPI 6 – Volume of Cases per Surgeon. This will now be measured using audit data therefore the statement on the use of SMR01 data for reporting has been removed. A statement has been added to confirm reporting of all radical prostatectomies during the audit period.

January 2020 (v4.0)
This document was updated following formal review (2nd cycle) of the Prostate Cancer Quality Performance Indicators (QPIs) which took place following analysis of year 6 of the prostate cancer QPI data.

The following QPIs have been updated:

- QPI 2: Radiological Staging
- QPI 4: MDT
- QPI 7: Hormone Therapy and Docetaxel Chemotherapy
- QPI 8: Post Surgical Incontinence
- QPI 11: Management of Active Surveillance
- QPI 12: 30 Day Mortality following Systemic Anti-Cancer Therapy (SACT)

The following QPIs have been archived:

- QPI 1: Biopsy Procedure
- QPI 3: Pathology Reporting

The following new QPIs have been added:

- QPI 14: Diagnostic Pre-Biopsy MRI
- QPI 15: Low Burden Metastatic Disease

Please note the revised Clinical Trials and Research Study Access QPI has also been added (see QPI 13: Clinical Trials & Research Study Access).

As a result of the changes above, the contents page and page numbering differ from earlier versions of this document. Sections 1 - 11 and the appendices have also been updated.

Please note that this version of the Prostate Cancer QPI Document applies to cases diagnosed from 1st July 2018 onwards. Where amended or new QPIs require new data items for measurement, this will apply for patients diagnosed from 1st July 2019.

July 2016 (v3.0)
This document was updated following formal review of the Prostate Cancer Quality Performance Indicators (QPIs) which took place 3 years following implementation of the indicators.

The following QPIs have been updated:

- QPI 1 – Biopsy Procedure
- QPI 2 – Radiological Staging
- QPI 4 – Multi-Disciplinary Team (MDT) Meeting
- QPI 5 – Surgical Margins
- QPI 6 – Volume of Cases per Surgeon
- QPI 7 – Hormone Therapy and Docetaxel Chemotherapy
- QPI 8 – Post Surgical Incontinence

The following QPIs have been archived:

- QPI 9 - Post Radiotherapy Toxicity
- QPI 10 - PSA Relapse Rate

The following new QPIs have been added:

- QPI 11 – Early Management of Active Surveillance
- QPI 12 – 30 Day Mortality following Chemotherapy

Please note the extant Clinical Trials QPI has now been added into each tumour specific QPI document (see QPI 13 – Clinical Trials).

As a result of the changes above, the contents page and page numbering differ from earlier versions of this document. Sections 1 - 11 and the appendices have also been updated.

Please note that this version of the Prostate Cancer QPI Document applies to cases diagnosed from 1st July 2015 onwards.

December 2014 (v2.1)
This document was updated following baseline review of the Prostate Cancer QPIs which took place following analysis of year 1 of the prostate cancer QPI data. As a result, the below QPIs have been updated:

- QPI 2 – Radiological Staging
- QPI 7 – Hormone Therapy

Please note that v2.1of the Prostate Cancer QPI Document applies to cases diagnosed from 1st July 2014 onwards.

November 2013 (v2.0)
Please note that this document has been updated to include QPI 4 – Multi-Disciplinary Team (MDT) Meeting.

The overall QPI numbering, contents page and the page numbering have been amended as a result and therefore differ from earlier versions of this document.

Contents Page

1. National Cancer Quality Programme

Better Cancer: Ambition and Action (2016)[1] details a commitment to delivering the National Cancer Quality Programme across NHS Scotland, with a recognised need for national cancer QPIs to support a culture of continuous quality improvement. Addressing variation in the quality of cancer services is pivotal to delivering improvements in quality of care. This is best achieved if there is consensus and clear indicators of what good cancer care looks like.

Small sets of cancer specific outcome focussed, evidence based indicators are in place for 19 different tumour types. These QPIs ensure that activity is focused on those areas that are most important in terms of improving survival and individual care experience whilst reducing variation and supporting the most effective and efficient delivery of care for people with cancer. QPIs are kept under regular review and are responsive to changes in clinical practice and emerging evidence.

A programme to review and update the QPIs in line with evolving evidence is in place as well as a robust mechanism by which additional QPIs will be developed over the coming years.

1.1 Quality Assurance and Continuous Quality Improvement

The ultimate aim of the programme is to develop a framework, and foster a culture of continuous quality improvement, whereby real time data is reviewed regularly at an individual Multidisciplinary Team (MDT)/Unit level and findings actioned to deliver continual improvements in the quality of cancer care. This is underpinned and supported by a programme of regional and national comparative reporting and review.

NHS Boards are required to report against QPIs as part of a mandatory, publicly reported, programme at a national level. A rolling programme of reporting is in place, with approximately three national tumour specific summary reports published annually. These reports highlight the publication of performance data in the Cancer QPI dashboard held within the Scottish Cancer Registry and Intelligence Service (SCRIS). The dashboard includes comparative reporting of performance against QPIs at MDT/Unit level across NHS Scotland, trend analysis and survival. This approach helps to overcome existing issues relating to the reporting of small volumes in any one year.

In the intervening years, tumour specific QPIs are monitored on an annual basis through established Regional Cancer Network and local governance processes, with analysed data submitted to Public Health Scotland (PHS) for inclusion in the Cancer QPI Dashboard and subsequent national summary reports. This ensures that timely action is taken in response to any issues that may be identified through comparative reporting and systematic review.

2. Quality Performance Indicator Development Process

The QPI development process was designed to ensure that indicators are developed in an open, transparent and timely way. The development process can be found in appendix 1.

The Prostate Cancer QPI Development Group was convened in October 2010, chaired by Professor Robert Masterton (Executive Medical Director, NHS Ayrshire and Arran). Membership of this group included clinical representatives drawn from the three regional cancer networks, Healthcare Improvement Scotland, ISD and patient/carer representatives.

The development process and membership of the development group can be found in appendix 1.

3. QPI Formal Review Process

As part of the National Cancer Quality Programme, a systematic rolling programme of national review has been developed. This ensures all tumour specific QPIs are subject to formal review following every 3rd year of comparative QPI data analysis.

The formal review process is clinically driven with proposals for change sought from specialty specific representatives in each of the Regional Cancer Networks. It is designed to be flexible in terms of the extent of review required with tumour specific Regional Clinical Leads undertaking a key role in this decision making. Formal review meetings to further discuss proposals are arranged where deemed necessary. The review builds on existing evidence using expert clinical opinion to identify where new evidence is available, and a full public engagement exercise will take place where significant revisions have been made or new QPIs developed.

During formal review QPIs may be archived and replaced with new QPIs. Triggers for doing so include significant change to clinical practice, targets being consistently met by all Boards, and publication of new evidence. Where QPIs have been archived, associated data items will continue to be collected where these are utilised for other indicators, or measures such as survival analysis.

Any new QPIs have been developed in line with the following criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

Three formal reviews of the Prostate Cancer QPIs have been undertaken to date. Further information can be found in appendix 2.

4. Format of the Quality Performance Indicators

QPIs are designed to be clear and measurable, based on sound clinical evidence whilst also taking into account other recognised standards and guidelines.

- Each QPI has a **short title** which will be utilised in reports as well as a fuller **description** which explains exactly what the indicator is measuring.
- This is followed by a brief overview of the **evidence base and rationale** which explains why the development of this indicator was important.
- The measurability **specifications** are then detailed; these highlight how the indicator will actually be measured in practice to allow for comparison across NHSScotland.
- Finally a **target** is indicated, which dictates the level each unit should be aiming to achieve against each indicator.

In order to ensure that the chosen target levels are the most appropriate and drive continuous quality improvement as intended they are kept under review and revised as necessary, if further evidence or data becomes available.

Rather than utilising multiple exclusions, a tolerance level has been built into the QPIs. It is very difficult to accurately measure patient choice, co-morbidities and patient fitness therefore target levels have been set to account for these factors. Further detail is noted within QPIs where there are other factors which influenced the target level.

Where ‘less than’ (<) target levels have been set the rationale has been detailed within the relevant QPI. All other target levels should be interpreted as ‘greater than’ (>) levels.

5. Supporting Documentation

A national minimum core dataset and a measurability specification document have been developed in parallel with the indicators to support the monitoring and reporting of Prostate Cancer QPIs. The latest version of these documents can be found at:

Public Health Scotland Cancer Audit

6. Quality Performance Indicators for Prostate Cancer

QPI 4: Multi-Disciplinary Team (MDT) Meeting

QPI Title:	Patients should be discussed by a multidisciplinary team prior to definitive treatment.	
Description:	Proportion of patients with prostate cancer who are discussed at MDT meeting before definitive treatment. **Please note:** The specifications of this QPI are separated to ensure clear measurement of patients with: (i) Non-metastatic prostate cancer (TanyNanyM0); and (ii) Metastatic prostate cancer (TanyNanyM1).	
Rationale and Evidence:	Evidence suggests that patients with cancer managed by a multi-disciplinary team have a better outcome. There is also evidence that the multidisciplinary management of patients increases their overall satisfaction with their care[2]. Discussion prior to definitive treatment decisions being made provides reassurance that patients are being managed appropriately. For patients presenting with metastatic disease it is often clinically appropriate to commence hormone therapy immediately, i.e. prior to MDT discussion, therefore specification (ii) has been developed to account for this cohort of patients.	
Specification (i):	**Numerator:**	Number of patients with non-metastatic prostate cancer (TanyNanyM0) discussed at the MDT before definitive treatment.
	Denominator:	All patients with non-metastatic prostate cancer (TanyNanyM0).
	Exclusions:	• Patients who died before first treatment.
Specification (ii):	**Numerator:**	Number of patients with metastatic prostate cancer (TanyNanyM1) discussed at the MDT within 6 weeks of commencing treatment.
	Denominator:	All patients with metastatic prostate cancer (TanyNanyM1).
	Exclusions:	• Patients who died before first treatment.
Target:	95% The tolerance within this target accounts for situations where patients require treatment urgently, or where prostate cancer is an incidental finding at surgery.	

QPI 5: Surgical Margins

QPI Title:	Organ confined prostate cancers which are surgically treated with radical prostatectomy should be completely excised.	
Description:	Proportion of patients with pathologically confirmed, organ confined (stage pT2) prostate cancer who undergo radical prostatectomy in which tumour is present at the margin, i.e. positive surgical margin.	
Rationale and Evidence:	Positive surgical margin is an independent prognostic factor in adversely impacting biochemical recurrence free (PSA failure) period and progression free survival[3].	
Specifications:	**Numerator:**	Number of patients with stage pT2 prostate cancer who underwent radical prostatectomy in which tumour is present at the margin.
	Denominator:	All patients with stage pT2 prostate cancer who underwent radical prostatectomy.
	Exclusions:	• No exclusions.
Target:	<20% **Please Note:** Varying evidence exists regarding the most appropriate target level therefore this may need redefined in the future, to take account of new evidence.	

Please note:
This QPI will report on all patients undergoing surgery during the audit period. Where patients have been diagnosed during a previous audit period, surgical records will continue to be updated for inclusion within the measure. This will ensure that patients who undergo active surveillance and proceed to surgery at a later date are captured within the QPI.

QPI 6: Volume of Cases per Surgeon

QPI Title:	Surgery should be performed by surgeons who perform the procedure routinely.
Description:	Number of radical prostatectomy procedures performed by a surgeon over a 1 year period.
Rationale and Evidence:	Radical prostatectomy should be performed by surgeons who work in high-volume hospitals, with outcomes audited regularly[3,4]. The European and North American literature supports the view that there is a relationship between increasing surgeon volume and improved patient outcomes, for example, rates of post-operative and late urinary complications and positive surgical margin rates[3]. Studies have shown that there is a clear link between surgeon experience and improved clinical outcomes and this continues to increase with the number of cases undertaken[5,6,7]. For robotic assisted radical prostatectomy it has been suggested that individual surgeons should undertake a minimum of 50-100 cases per annum[8].
Specifications:	Number of radical prostatectomies performed by each surgeon in a given year. **Exclusions:** • No exclusions
Target:	Minimum 50 procedures per surgeon in a 1 year period. This is a minimum target level and is designed to ensure that all surgeons performing radical prostatectomy perform **a minimum of 50** procedures per year. **Please Note:** It is recommended that where two consultants operate together on the same patient the case should be counted under the Lead Surgeon.

Please note:
This QPI will report on all radical prostatectomy procedures undertaken during the audit period. Where patients have been diagnosed during a previous audit period, surgical records will continue to be updated for inclusion within the measure. This will ensure that all relevant procedures are captured within the QPI.

QPI 7: Androgen Deprivation Therapy (ADT) with Additional Systemic Therapy

QPI Title:	Patients with metastatic prostate cancer should undergo immediate* androgen deprivation therapy (ADT)†, with additional systemic therapy where appropriate‡.
Description:	Proportion of patients with metastatic prostate cancer (TanyNanyM1) who undergo immediate management with ADT, plus additional systemic therapy. **Please note:** The specifications of this QPI are separated to ensure clear measurement of patients who undergo: (i) Immediate ADT; and (ii) Immediate ADT plus additional systemic therapy.
Rationale and Evidence:	Luteinizing hormone-releasing hormone (LHRH) agonist / antagonist monotherapy or Dual Androgen Blockade (LHRH agonist plus anti-androgen combined therapy) or bilateral orchidectomy should be offered as immediate therapy to all patients with metastatic prostate cancer[3,4,9]. Addition of further systemic therapy to androgen deprivation therapy (ADT) has been shown to improve progression free, and overall survival and should be considered in all suitable patients with newly diagnosed metastatic prostate cancer. Examples of this include abiraterone, enzalutamide, apalutamide and darolutamide with or without chemotherapy[10-16]. LHRH agonists / antagonists should be any that are licensed in this indication as monotherapy or in combination with an anti-androgen for dual androgen blockade. Bilateral orchidectomy is also an acceptable form of hormone therapy in this context.
Specification (i):	**Numerator:** Number of patients presenting with metastatic prostate cancer (TanyNanyM1) treated with immediate ADT. **Denominator:** All patients presenting with metastatic prostate cancer (TanyNanyM1). **Exclusions:** • Patients documented to have declined immediate ADT. • Patients enrolled in clinical trials.
Target:	95% The tolerance within this target is to account for the fact that due to co-morbidities and fitness not all patients will be suitable for treatment.

Continued overleaf……..

* Immediate ADT would be within 31 days of MDT meeting (pre-treatment).

† ADT is defined as LHRH agonist / antagonist monotherapy, dual androgen blockade or bilateral orchidectomy.

‡Additional systemic therapy includes any one or more of the following: docetaxel, abiraterone, enzalutamide, apalutamide or darolutamide. This should be started within 100 days of the first dose of ADT.

QPI 7: Androgen Deprivation Therapy (ADT) with Additional Systemic Therapy……continued

Specification (ii):	**Numerator:**	Number of patients presenting with metastatic prostate cancer (TanyNanyM1) treated with immediate ADT plus additional systemic therapy.
	Denominator:	All patients presenting with metastatic prostate cancer (TanyNanyM1).
	Exclusions:	• Patients documented to have declined immediate ADT. • Patients documented to have declined systemic therapy. • Patients enrolled in clinical trials.
Target:	60% The tolerance within this target is to account for the fact that due to co-morbidities and fitness not all patients will be suitable for treatment.	

QPI 8: Assessment of Post-Treatment Patient Reported Outcome Measures (PROMs)

QPI Title:	Post-treatment outcomes for patients with prostate cancer should be assessed using a validated PROMs (Patient Reported Outcome Measures) tool[§].	
Description:	Proportion of patients with prostate cancer who undergo radical treatment that have returned a PROMs tool both pre and post treatment[**] for assessment of quality of life issues[††]. **Please note:** The specifications of this QPI are separated to ensure clear measurement of patients who undergo: (i) Radical prostatectomy; (ii) Radical external beam radiotherapy; and (iii) Brachytherapy	
Rationale and Evidence:	Urinary, sexual, bowel and hormonal dysfunction, especially over the long-term, is significant and is associated with poor quality of life, therefore requires to be minimised in men undergoing radical treatment for prostate cancer[17,3]. Patient reported outcome measures (PROMs) are used to establish patient views on quality of life issues at various points within the care experience. Many men with prostate cancer experience significant quality of life issues post radical treatment including incontinence, sexual function, and bowel function. The use of a validated PROMs tool provides a reliable measure of health quality for these patients.	
Specification (i):	**Numerator:**	Number of patients with prostate cancer undergoing radical prostatectomy that have returned a PROMs tool both pre and post-treatment** for assessment of quality of life issues (urinary, bowel, sexual and hormonal function).
	Denominator:	All patients with prostate cancer undergoing radical prostatectomy.
	Exclusions:	• Patients who undergo salvage prostatectomy. • Patients who receive adjuvant radiotherapy within 12 months of surgery. • Patients who die within 12 months of surgical treatment.

(Continued overleaf……)

[§] The validated PROMs tool appropriate for this measurement is as follows: The Expanded Prostate Cancer Index Composite (EPIC26).

[**] Post-treatment is defined as between 10-18 months following surgery, radiotherapy or brachytherapy.

[††] The quality of life issues covered by the PROMs tool are urinary incontinence, urinary obstructive/irritative, bowel function, sexual function and hormonal function.

QPI 8: Assessment of Post-Treatment Patient Reported Outcome Measures (PROMS)……continued

Specification (ii):	**Numerator:**	Number of patients with prostate cancer undergoing radical external beam radiotherapy that have returned a PROMs tool both pre and post treatment** for the assessment of quality of life issues.
	Denominator:	All patients with prostate cancer undergoing radical external beam radiotherapy.
	Exclusions:	• Patients who undergo radical prostatectomy within 12 months of radical radiotherapy. • Patients who die within 12 months of radiotherapy treatment.
Specification (iii):	**Numerator:**	Number of patients with prostate cancer undergoing low dose rate (LDR) brachytherapy as monotherapy that have returned a PROMs tool both pre and post treatment** for assessment of quality of life issues.
	Denominator:	All patients with prostate cancer undergoing low dose rate (LDR) brachytherapy as monotherapy.
	Exclusions:	• Patients who undergo radical prostatectomy within 12 months of brachytherapy. • Patients who die within 12 months of brachytherapy treatment.
Target:	50% **Please note:** The measurement of this QPI is the initial approach to achieving accurate and reliable data in order to measure post-treatment outcomes. In addition to this, the relevant data for all quality of life domains from the PROMs tool will be collected and analysed locally within each centre. This will be tested across all NHS Boards to determine reliability and validity of data collection with a view to introducing this within a future QPI.	

QPI 11: Management of Active Surveillance

QPI Title:	Men under active surveillance for prostate cancer should undergo MRI or prostate biopsy within 18 months‡‡ of diagnosis.
Description:	Proportion of men with prostate cancer under active surveillance who undergo MRI (biparametric (bpMRI) or multiparametric (mpMRI)) or prostate biopsy within 18 months of diagnosis.
Rationale and Evidence:	Different treatment options are available for men with low risk prostate cancer including surgery, radiotherapy and also active surveillance. Active surveillance as a treatment option can reduce overtreatment and therefore reduce potential adverse effects from radical treatments as well as being beneficial in terms of healthcare costs[18,19]. Active surveillance involves monitoring based on digital rectal examinations, PSA testing, prostate biopsy and MRI. Prostate biopsy may only be necessary where there are radiological changes on MRI or rising PSA levels[20]. It is recommended that men who are undergoing active surveillance should have a multiparametric MRI (mpMRI) performed at the outset if not had one previously. Evidence suggests that a further mpMRI should also be undertaken 12 – 18 months later in order to identify any clinically significant cancer or re-stage prostate cancer after diagnosis[17]. Recent meta-analysis of bpMRI versus mpMRI suggests similar efficacy in diagnosing prostate cancer[21].

Specifications:	**Numerator:** Number of patients with prostate cancer under active surveillance who undergo MRI (bpMRI or mpMRI) or prostate biopsy within 18 months of diagnosis.
	
	Denominator: All patients with prostate cancer under active surveillance.
	
	Exclusions:
	• Patients unable to undergo an MRI scan:
	  ○ Pacemaker or other MRI incompatible implanted device.
	  ○ Cerebral aneurysm clip.
	  ○ Metal in eye.
	  ○ Claustrophobia.
	  ○ Unable to fit bore of scanner.
	  ○ Too heavy for MRI table.
	• Patients who decline MRI.
	• Patients who undergo radical treatment within 12 months.

Target:	95% The tolerance within this target is to account for other situations where patients are deemed clinically unsuitable or unfit to undergo MRI or prostate biopsy.

‡‡ MRI / prostate biopsy should not be performed any earlier than 11 months following the date of diagnosis.

QPI 14: Diagnostic Pre-biopsy MRI

QPI Title:	Patients with prostate cancer who undergo biopsy should be evaluated initially with a pre-biopsy biparametric MRI (bpMRI) or multiparametric MRI (mpMRI) and reported using a PI-RADS/Likert system of grading[§§].	
Description:	Proportion of patients with prostate cancer who undergo biopsy and have a pre-biopsy bpMRI or mp MRI as their first line diagnostic investigation, with imaging reported using a PI-RADS/Likert system of grading. **Please note:** This QPI measures 2 distinct elements. The specifications are separated to ensure clear measurement of: (i) Patients with prostate cancer who undergo biopsy that have a pre-biopsy bpMRI or mpMRI as their first line diagnostic investigation; and (ii) Patients with prostate cancer who undergo biopsy that have a pre-biopsy bpMRI or mpMRI as their first line diagnostic investigation with imaging reported using a PI-RADS/ Likert system of grading.	
Rationale and Evidence:	Evidence from the PROMIS trial suggests that performing multi-parametric MRI as a triage investigation can reduce the number of patients undergoing unnecessary biopsy by approximately one quarter. In addition, it can also improve the detection of clinically significant cancers compared with the standard TRUS (transrectal ultrasound) biopsy whilst reducing the over-diagnosis of insignificant cancers[22]. Recent meta-analysis of bpMRI versus mpMRI suggests similar efficacy in diagnosing prostate cancer[21]. In line with recommendations, patients with suspected clinically localised prostate cancer should be offered multi-parametric MRI as first line investigation, with results reported using a Likert scale. Use of a standardised Likert scoring system to detect clinically significant cancer provides guidance on whether a biopsy is recommended[17].	
Specification (i):	**Numerator:**	Number of patients with prostate cancer who undergo biopsy that have a pre-biopsy bpMRI or mpMRI as their first line diagnostic investigation.
	Denominator:	All patients with prostate cancer who undergo biopsy.

	Exclusions:	• Patients unable to undergo an MRI scan:
		  ○ Pacemaker or other MRI incompatible implanted device.
		  ○ Cerebral aneurysm clip; Metal in eye.
		  ○ Claustrophobia; Unable to fit bore of scanner; Too heavy for MRI table.
		• Patients who decline MRI.
		• Patients who have undergone TURP.
		• Patients who have undergone laser enucleation.
		• Patients with locally advanced (Clinical T3 and above) and / or M1 disease.

Target:	95% The tolerance within this target is to account for other situations where patients are deemed clinically unsuitable or unfit to undergo MRI.	

[§§] PI-RADS (Prostate Imaging – Reporting and Data System) v2 or Likert Scoring systems may be used for the measurement of this QPI.

QPI 14: Diagnostic Pre-biopsy MRI …….continued

Specification (ii):	**Numerator:**	Number of patients with prostate cancer who undergo biopsy that have a pre-biopsy bpMRI or mpMRI as their first line diagnostic investigation with imaging reported using a PI-RADS/Likert system of grading.
	Denominator:	All patients with prostate cancer who undergo biopsy that have a pre-biopsy bpMRI or mpMRI as their first line diagnostic investigation.
	Exclusions:	• No exclusions.
Target:	95%	

QPI 15: Low Burden Metastatic Disease

QPI Title:	Patients presenting with metastatic prostate cancer should have their burden of disease assessed[***], and undergo radiotherapy[†††] where appropriate.
Description:	Proportion of patients presenting with metastatic prostate cancer who have their burden of disease assessed, and undergo radiotherapy if metastatic burden is low. **Please note:** This QPI measures 2 distinct elements. The specifications are separated to ensure clear measurement of: (i) Patients presenting with metastatic prostate cancer in whom burden of disease is assessed; and (ii) Patients presenting with metastatic prostate cancer who have a low metastatic burden that receive radiotherapy.
Rationale and Evidence:	Metastatic burden of disease should be assessed in order to guide treatment decisions in men with newly diagnosed metastatic prostate cancer. There is evidence to suggest that prostate radiotherapy treatment provides an overall survival benefit when given to men with newly diagnosed metastatic prostate cancer who have a low metastatic disease burden. High burden metastatic disease is defined as: more than four bone metastases where at least one lies outside the pelvis or spine AND/OR visceral metastases confirmed on bone scintigraphy and standard axial imaging (using either CT or MRI). Other assessable patients are considered to have low burden metastatic disease[23,24].
Specification (i):	**Numerator:** Number of patients presenting with metastatic prostate cancer in whom burden of disease is assessed. **Denominator:** All patients presenting with metastatic prostate cancer. **Exclusions:** • No exclusions
Target:	95% The tolerance within this target is to account for those patients with very advanced disease who may not be fully assessed with all staging modalities.

Continued overleaf……..

[***] MRI, Bone Scan or CT are the current methods routinely used within NHSScotland to assess metastatic burden of disease.

[†††] Radiotherapy regimes included in the measurement of this QPI are 36Gy (6 fractions) or a minimum of 50Gy (20 fractions).

QPI 15: Low Burden Metastatic Disease……continued

Specification (ii):	**Numerator:**	Number of patients presenting with metastatic prostate cancer who have a low metastatic burden that receive radiotherapy.
	Denominator:	All patients presenting with metastatic prostate cancer who have a low metastatic burden.
	Exclusions:	• Patients documented to have declined radiotherapy treatment.
Target:	60% The tolerance within this target is designed to account for situations where patients are deemed clinically unsuitable or unfit to undergo radiotherapy, for example due to co-morbid illness, Inflammatory bowel disease, or previous pelvic radiotherapy.	

7. Survival

Improving survival forms an integral part of the national cancer quality improvement programme. Prostate cancer survival analysis will be reported and analysed on a 3 yearly basis by Public Health Scotland (PHS). The specific issues which will be addressed will be identified by an expert group ahead of any analysis being undertaken, as per the agreed national cancer quality governance and improvement framework.

The Prostate Cancer QPI Group has identified, during the QPI development process, the following issues for survival analysis:

- 5 and 10 year overall survival

To ensure consistent application of survival analysis, it has been agreed that a single analyst on behalf of all three regional cancer networks undertakes this work. Survival analysis is scheduled as per the national survival analysis and reporting timetable, agreed with the National Cancer Quality Steering Group and National Cancer Recovery Group. This reflects the requirement for record linkage and the more technical requirements of survival analyses which makes it difficult for individual Boards to undertake routinely and in a nationally consistent manner.

8. Areas for Future Consideration

The Prostate Cancer QPI Groups have not been able to identify sufficient evidence, or determine appropriate measurability specifications, to address all areas felt to be of key importance in the treatment of prostate cancer, and therefore in improving the quality of care for patients affected by prostate cancer.

The following areas for future consideration have been raised across the lifetime of the Prostate Cancer QPIs:

- Multi-disciplinary team management of patients with castrate-resistant metastatic prostate cancer.
- Post radiotherapy toxicity.
- PSMA-PET scanning after radical treatment.
- Metastatic prostate cancer and bone health.
- BRCA testing in patients with hormone sensitive metastatic prostate cancer.

8.1 Post Radiotherapy Toxicity

The Post Radiotherapy Toxicity QPI (previously QPI 9) was piloted over a 3 year period and, despite extensive efforts, consistent and comparable data recording and measurement has not been successful to date.

The QPI Formal Review Group agreed that this is an area of high importance and that Regional Cancer Networks should continue to strive to collect this data and implement suitable ways of recording this in a consistent manner. This information will continue to be included within the Prostate Cancer National Minimum Core Dataset across NHSScotland.

9. Governance and Scrutiny

A national and regional governance framework to assure the quality of cancer services in NHSScotland has been developed; key roles and responsibilities within this are set out below. Appendices 3 and 4 provide an overview of these governance arrangements diagrammatically. The importance of ensuring robust local governance processes are in place is recognised and it is essential that NHS Boards ensure that cancer clinical audit is fully embedded within established processes.

9.1 National

- National Cancer Recovery Group
    - Accountable for overall national cancer quality programme and overseeing the quality of cancer care across NHSScotland.
    - Advise Scottish Government Health and Social Care Directorate (SGHSCD) if escalation required.

- Healthcare Improvement Scotland
    - Proportionate scrutiny of performance.
    - Support performance improvement.
    - Quality assurance: ensure robust action plans are in place and being progressed via regions/Boards to address any issues identified.

- Public Health Scotland (PHS)
    - Publish national comparative report on tumour specific QPIs and survival for approximately three tumour types per annum as part of the rolling programme of reporting.

9.2 Regional – Regional Cancer Networks

- Annual regional comparative analysis and reporting against tumour specific QPIs.
- Support national comparative reporting of specified generic QPIs.
- Identify and share good practice.
- In conjunction with constituent NHS Boards identify regional and local actions required to develop an action plan to address regional issues identified.
- Review and monitor progress against agreed actions.
- Provide assurance to NHS Board Chief Executive Officers and National Cancer Recovery Group that any issues identified have been adequately and timeously progressed.

9.3 Local – NHS Boards

- Collect and submit data for regional comparative analysis and reporting in line with agreed measurability and reporting schedule (generic and tumour specific QPIs).
- Utilise local governance structures to review performance, develop local action plans and monitor delivery.
- Demonstrate continual improvements in quality of care through on-going review, analysis and feedback of clinical audit data at an individual multidisciplinary team (MDT) or unit level.

10. References

1. Scottish Government (2016). . Beating Cancer: Ambition and Action Available from: http://www.gov.scot/Resource/0049/00496709.pdf.
2. NHS Quality Improvement Scotland (2008). Management of Core Cancer Services Standards [online]. (accessed August 2013).
3. EAU (2010). European Association of Urology. Guidelines on prostate cancer [online]. Available from: http://www.uroweb.org/?id=218&gid=3 (accessed August 2013).
4. ACCC (2007) Association of Comprehensive Cancer Centres / Dutch Urological Association. Prostate cancer [online]. (accessed August 2013).
5. Vickers AJ, Savage CJ, Hruza M, Tuerk I, Koenig P, Martinez-Pineiro L, et al. (2009) The surgical learning curve for laparoscopic radical prostatectomy: a retrospective cohort study. *Lancet Oncol* 2009;10(5):475-80
6. Vickers AJ, Bianco FJ, Serio AM, Eastham JA, Schrag D, Klein EA, et al. (2007) The surgical learning curve for prostate cancer control after radical prostatectomy. *J Natl Cancer Inst* 2007;99(15):1171-7.
7. UK radical prostatectomy outcomes and surgeon case volume: based on an analysis of the British Association of Urological Surgeons Complex Operations Database.
8. Anderson JB, Clarke NC, Gillatt D, Dasgupta P, Neal DE, Pickard RS (2012). Advice on the Development of Robotic Assisted Radical Prostatectomy in England – Prostate Cancer Advisory Group.
9. Loblaw DA, Virgo KS, Nam R, Somerfield MR, Ben-Josef E, et al. for the American Society of Clinical Oncology (2007). Initial hormonal management of androgen-sensitive metastatic, recurrent, or progressive prostate cancer: 2006 update of an American Society of Clinical Oncology practice guideline. Journal of Clinical Oncology. 25(12), 1596-605.
10. James ND, De Bono JS, Spears MR, Clarke NW, Mason MD, Dearnaley DP et al. (2017) Abiraterone for prostate cancer not previously treated with hormone therapy N Engl J Med 2017; 377:338-351 [online] Available from: https://pubmed.ncbi.nlm.nih.gov/28578639/ (accessed February 2023)
11. Chi KN, Agarwal N, Bjartell A, Chung BH, Pereira de Santana Gomes AJ, Given R et al. (2019) Apalutamide for metastatic castration-sensitive prostate cancer N Engl J Med 2019; 381:13-24 [online] Available from: https://pubmed.ncbi.nlm.nih.gov/31150574/ (accessed February 2023)
12. Armstrong AJ, Szmulewitz, RZ, Petrylak DP, Holzbeierlein J, Villers A, Azad A et al. (2019) ARCHES: A Randomized, Phase III Study of Androgen Deprivation Therapy With Enzalutamide or Placebo in Men With Metastatic Hormone-Sensitive Prostate Cancer Journal of Clinical Oncology 37, no. 32 (November 10, 2019) 2974-2986.[online] Available from: https://pubmed.ncbi.nlm.nih.gov/31329516/ (accessed February 2023)
13. James ND et al. (2022) Abiraterone acetate plus prednisolone for metastatic patients starting hormone therapy: 5-year follow-up results from the STAMPEDE randomised trial (NCT00268476). Int J Cancer. Aug 1;151(3):422-434. [online] Available from: https://pubmed.ncbi.nlm.nih.gov/35411939/ (access February 2023).
14. Davis ID et al. (2019) Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer. N Engl J Med. 2019 Jul 11;381(2):121-131. [online] Available from: https://pubmed.ncbi.nlm.nih.gov/31157964/ (accessed February 2023)
15. Chi KN et al. (2021) Apalutamide in Patients With Metastatic Castration-Sensitive Prostate Cancer: Final Survival Analysis of the Randomized, Double-Blind, Phase III TITAN Study. J Clin Oncol. 2021 Jul 10;39(20):2294-2303. [online] Available from: https://pubmed.ncbi.nlm.nih.gov/33914595/ (accessed February 2023).

16. Smith MR et al. (2022) Darolutamide and Survival in Metastatic, Hormone-Sensitive Prostate Cancer. N Engl J Med. 2022 Mar 24;386(12):1132-1142. [online] Available from: https://pubmed.ncbi.nlm.nih.gov/35179323/ (accessed February 2023)
17. Nice (2019): Prostate Cancer: Diagnosis and Management. Available from: https://www.nice.org.uk/guidance/ng131 (accessed October 2019).
18. NICE (2015). Prostate Cancer [online]. Available from: https://www.nice.org.uk/guidance/qs91 (accessed February 2016).
19. Bul et al (2013). Active Surveillance for Low-Risk Prostate Cancer Worldwide: The PRIAS Study. European Urology. 63 (4), 597 – 603.
20. Giganti F, Stavrinides V, Moore C. (2022) Magnetic resonance imaging– guided active surveillance of prostate cancer: time to say goodbye to protocol-based biopsies. Eur Urol Open Sci 2022;38:40–3 [online] Available from: https://pubmed.ncbi.nlm.nih.gov/35243397/
21. Kang Z, Min X, Weinreb J, Li Q, Feng Z, Wang L (2019). Abbreviated biparametric versus standard multiparametric MRI for diagnosis of prostate cancer: a systematic review and meta-analysis. AJR Am J Roentgenol. 2019 Feb;212(2):357–365. Available from: https://www.ncbi.nlm.nih.gov/pubmed/30512996 (accessed January 2020).
22. Ahmed HU et al (2017). Diagnostic Accuracy of multi-parametric MRI and TRUS biopsy in Prostate Cancer (PROMIS): a paired validating confirmatory study. The Lancet 389 (10079), 815-822. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28110982 (accessed September 2019).
23. Parker CC et al (2018). Radiotherapy to the primary tumour for newly diagnosed metastatic prostate cancer (STAMPEDE): a randomised controlled phase III trial. The Lancet 392 (10162), 2353-2366. Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32486-3/fulltext (accessed September 2019).
24. NHS England (2020) Clinical Commissioning Policy: External beam radiotherapy for patients presenting with hormone sensitive, low volume metastatic prostate cancer at the time of diagnosis. Available from: https://www.england.nhs.uk/wp-content/uploads/2020/11/1901-external-beam-radiotherapy-for-patients-presenting-with-hormone-sensitive-low-volume-metastatic-prostate-.pdf (accessed February 2023)
25. Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium (2010). AGREE II: Advancing guideline development, reporting and evaluation in healthcare. Can Med Assoc J. 182(18), E839-E842 (accessed August 2013). Available online from: http://www.cmaj.ca/content/182/18/E839.full.pdf+html?maxtoshow=&hits=10&RESU%20LTFORMAT=&fulltext=brouwers&searchid=1&FIRSTINDEX=0&volume=182&issue=%2018&resourcetype=HWCIT%2520%2520%2520

11. Appendices

Appendix 1: QPI Development Process

Preparatory Work and Scoping

The preparatory work involved the development of a structured briefing paper by Healthcare Improvement Scotland. This paper took account of existing, high quality, clinical guidance and provided a basis for the development of QPIs.

The scope for development of prostate cancer QPIs and a search narrative were defined and agreed by the Prostate Cancer QPI Development Group. The table below shows the final search criteria used in the literature search.

Inclusion	Exclusion
Prostate carcinomas Adults only *Date:* 2005 or later *Topics:* diagnosis, staging, management of non-metastatic (organ confined or locally advanced) and metastatic (advanced) disease, follow up	Prostate sarcomas *Topics:* prevention, screening, palliative/end of life care

Table 1 – Prostate Cancer Search Criteria

A systematic search was carried out by Healthcare Improvement Scotland using selected websites and two primary medical databases to identify national and international guidelines.

Thirty-four guidelines were appraised for quality using the AGREE II instrument[25]. The instrument assesses the methodological rigour and precision used when developing a guideline. Seventeen of the guidelines were not recommended for use. Five of the guidelines were recommended for use and six recommended for use with modifications.

Indicator Development

The Prostate Cancer QPI Development Group defined evidence based, measurable indicators with a clear focus on improving the quality and outcome of care provided.

The Group developed QPIs using the clinical recommendations set out in the briefing paper as a base, ensuring all indicators met the following criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

Engagement Process

A wide clinical and public engagement exercise was undertaken as part of development in 2011 where the Prostate Cancer QPIs, along with accompanying draft minimum core dataset and measurability specifications, were made available on the Scottish Government website.

During the engagement period clinical and management colleagues from across NHSScotland, patients affected by prostate cancer and the wider public were given the opportunity to influence the development of Prostate Cancer QPIs. Several different methods of engagement were utilised:

Professional groups, health service staff, voluntary organisations and individuals:

• Wide circulation of the draft documentation for comment and feedback.

Patient representative groups:

• Organised patient focus group sessions were held in conjunction with the Urological Cancer Charity (UCAN) and The Prostate Cancer Charity.

Following the engagement period all comments and responses received were reviewed by the Prostate Cancer QPI Development Group and used to produce and refine the final indicators.

Prostate Cancer QPI Development Group Membership (2012)

Name	Designation	Cancer Network/Base
Robert Masterton	Executive Medical Director (CHAIR)	NHS Ayrshire and Arran
Prasad Bollina	Consultant Urologist	SCAN (Western General Hospital)
Sudhir Borgaonkar	Consultant Urologist	NOSCAN (Raigmore Hospital)
Brian Corr	Clinical Nurse Specialist	NOSCAN (Raigmore Hospital)
Iain Dickson	Patient Representative	
Clare Echlin	Acting Head of Standards Development	Healthcare Improvement Scotland
Jenny Fleming	Service Manager	SCAN (Western General Hospital)
Lesley Frew	Clinical Nurse Specialist	SCAN (Victoria Hospital)
Rob Jones	Consultant Oncologist	WoSCAN (Beatson West of Scotland Cancer Centre)
Julian Keanie	Consultant Radiologist	SCAN (Western General Hospital)
Hing Leung	Consultant Urologist	WoSCAN (Gartnavel General Hospital)
Peter McAlear	Patient Representative	
Alex McGuire	Cancer Services Manager	WoSCAN (Crosshouse Hospital)
Chris McIntosh	Network Manager	NOSCAN
Duncan McLaren	Consultant Oncologist	SCAN (Western General Hospital)
Fiona Muirhead	Clinical Nurse Specialist	WoSCAN (Gartnavel General Hospital)
Brian Murray	National Cancer Information Coordinator	Information Services Division

Name	Designation	Cancer Network/Base
Bob Nairn	Consultant Pathologist	WoSCAN (Crosshouse Hospital)
Peter Phillips	Patient Representative	
Iona Scott	Project Manager	WoSCAN
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN
Phyllis Windsor	Consultant Oncologist	NOSCAN (Ninewells Hospital)

NOSCAN - North of Scotland Cancer Network
SCAN - South East Scotland Cancer Network
WoSCAN - West of Scotland Cancer Network

Appendix 2: Prostate Cancer QPI Formal Reviews

Formal review of the Prostate Cancer QPIs was undertaken for the first time in December 2015. A Formal Review Group was convened, chaired by Dr Hilary Dobson (former Chair, National Cancer Quality Steering Group). Membership of this group included Clinical Leads from the three Regional Cancer Networks. Membership of this group is outlined below:

Prostate Cancer QPI Formal Review Group Membership (2016)

Name	Designation	Cancer Network/Base
Hilary Dobson	Chair, National Cancer Quality Steering Group	WoSCAN
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN
Grenville Oades	Clinical Lead Urological Cancers MCN	WoSCAN / NHS Greater Glasgow and Clyde
Prasad Bollina	Clinical Lead Urological Cancers MCN	SCAN / NHS Lothian
Chris Goodman *(until May 2016)*	Clinical Lead Urological Cancers MCN	NOSCAN / NHS Tayside
Alan McNeil	Consultant Urological Surgeon	NOSCAN / NHS Lothian
Hasan Qazi	Consultant Urological Surgeon	WoSCAN / NHS Greater Glasgow and Clyde
Justine Royle	Consultant Urological Surgeon	NOSCAN / NHS Grampian
Ghulam Nabi	Consultant Urological Surgeon	NOSCAN / NHS Tayside
Thomas Lam	Consultant Urological Surgeon	NOSCAN / NHS Grampian
Jaimin Bhatt	Consultant Urological Surgeon	WoSCAN / NHS Ayrshire and Arran
Carol Marshall *(until Feb 16)*	Information Manager	WoSCAN
Iona Scott *(from Feb 16)*	Quality & Service Improvement Manager	WoSCAN
Jen Doherty	National Cancer Quality Programme Co-ordinator	National Cancer Quality Programme

Formal review of the Prostate Cancer QPIs has been undertaken in consultation with various other clinical specialties e.g. Oncology and Pathology

NOSCAN - North of Scotland Caner Network
SCAN - South East Scotland Cancer Network
WoSCAN - West of Scotland Cancer Network

2nd Cycle Formal Review

The 2nd cycle of formal review commenced in May 2019. This cycle of review was more selective and focussed on ensuring the ongoing clinical relevance of the QPIs. A Formal Review Group was convened in September 2019, with Mr James Mander, Consultant General & Colorectal Surgeon, SCAN and Chair of the National Cancer Quality Steering Group appointed as Clinical Advisor/Chair to the group. Membership of this group is outlined below:

Prostate Cancer QPI Formal Review Group Membership (2019)

Name	Designation	Cancer Network/Base
James Mander	Consultant General & Colorectal Surgeon and SCAN Regional Clinical Lead	SCAN
Imran Ahmad	Consultant Urological and Robotic Surgeon, WoSCAN	WoSCAN
Jaimin Bhatt	Consultant Urological Surgeon	WoSCAN
Karen Connor	MCN and Improvement Manager	WoSCAN
Jen Doherty	National Cancer Quality Programme Co-ordinator	National
David Douglas	Consultant Urological Surgeon and Clinical Lead	NCA
Rob Jones	Consultant Medical Oncologist	WoSCAN
Carol Marshall	Information Manger	WoSCAN
Bryan McKellar	Programme Coordinator	NCA
Duncan McLaren	Consultant Clinical Oncologist	SCAN
Alan McNeil	Consultant Urological Surgeon and Clinical Lead	SCAN
Paddy Niblock	Consultant Clinical Oncologist	NCA
Lorraine Stirling	Project Officer, National Cancer Quality Programme	National
Nkem Umez-Eronini	Consultant Urological Surgeon and Clinical Lead	WoSCAN
Feng Yi Soh	Consultant Clinical Oncologist	NCA

3rd Cycle Formal Review

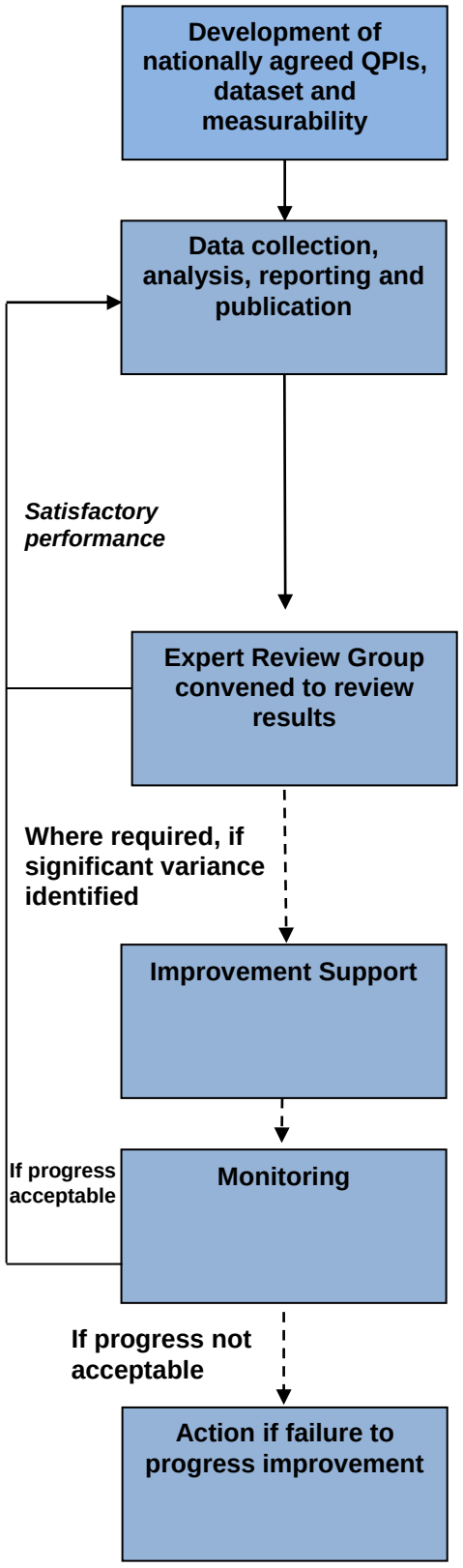
The 3rd cycle of formal review commenced in May 2022. Mr James Mander, Consultant General & Colorectal Surgeon, SCAN and Chair of the National Cancer Quality Steering Group was appointed as Clinical Advisor/Chair to the Formal Review Group. Membership of this group is outlined below:

Prostate Cancer QPI Formal Review Group Membership – 3rd Cycle (2022)

Name	Designation	Cancer Network
James Mander	Consultant General & Colorectal Surgeon	SCAN
Imran Ahmad	Consultant Urological Surgeon	WoSCAN
Jaimin Bhatt	Consultant Urological Surgeon	WoSCAN
Jen Doherty	National Cancer Quality Programme Co-ordinator	National
David Douglas	Consultant Urological Surgeon	NCA
Kevin Gallagher	PHS Clinical Fellow for Data Driven Innovation, Specialist Trainee in Urology	SCAN
Hilary Glen	Consultant Medical Oncologist	WoSCAN
Daniel Good	Consultant Urological Surgeon	SCAN
Rob Jones	Consultant Medical Oncologist	WoSCAN
Andrew Martindale	Consultant Urological Surgeon & Clinical Lead	NCA
Alan McNeil	Consultant Urological Surgeon & Clinical Lead	SCAN
Bryan McKellar	Regional Manager (Cancer)	NCA
Duncan McLaren	Professor & Consultant Clinical Oncologist	SCAN
Lorraine Stirling	Project Officer, National Cancer Quality Programme	National
Aravindhan Sundaramurthy	Consultant Clinical Oncologist	SCAN
Nkem Umez-Eronini	Consultant Urological Surgeon & Clinical Lead	WoSCAN
Christine Urquhart	Information Analyst	WoSCAN

Appendix 3: 3 Yearly National Governance Process & Improvement Framework for Cancer Care

This process is underpinned by the annual regional reporting and governance framework (see appendix 4).



1. National QPI Development Stage

- QPIs developed by QPI development groups, which include representation from Regional Cancer Networks, Healthcare Improvement Scotland, PHS, patient representatives and the Cancer Coalition.

2. Data Analysis Stage:

- NHS Boards and Regional Cancer Advisory Groups (RCAGs)* collect data and analyse on yearly basis using nationally agreed measurability criteria and produce action plans to address areas of variance, see appendix 4.
- Submit yearly reports to PHS for collation and publication every 3 years.
- National comparative report approved by NHS Boards and RCAGs.
- PHS produce comparative, publicly available, national report consisting of trend analysis of 3 years data and survival analysis.

3. Expert Review Group Stage (for 3 tumour types per year):

- Expert group, hosted by Healthcare Improvement Scotland, review comparative national results.
- Write to RCAGs highlighting areas of good practice and variances.
- Where required NHS Boards requested to submit improvement plans for any outstanding unresolved issues with timescales for improvement to expert group.
- Improvement plans ratified by expert group and National Cancer Recovery Group.

4. Improvement Support Stage:

- Where required Healthcare Improvement Scotland provide expertise on improvement methodologies and support.

5. Monitoring Stage:

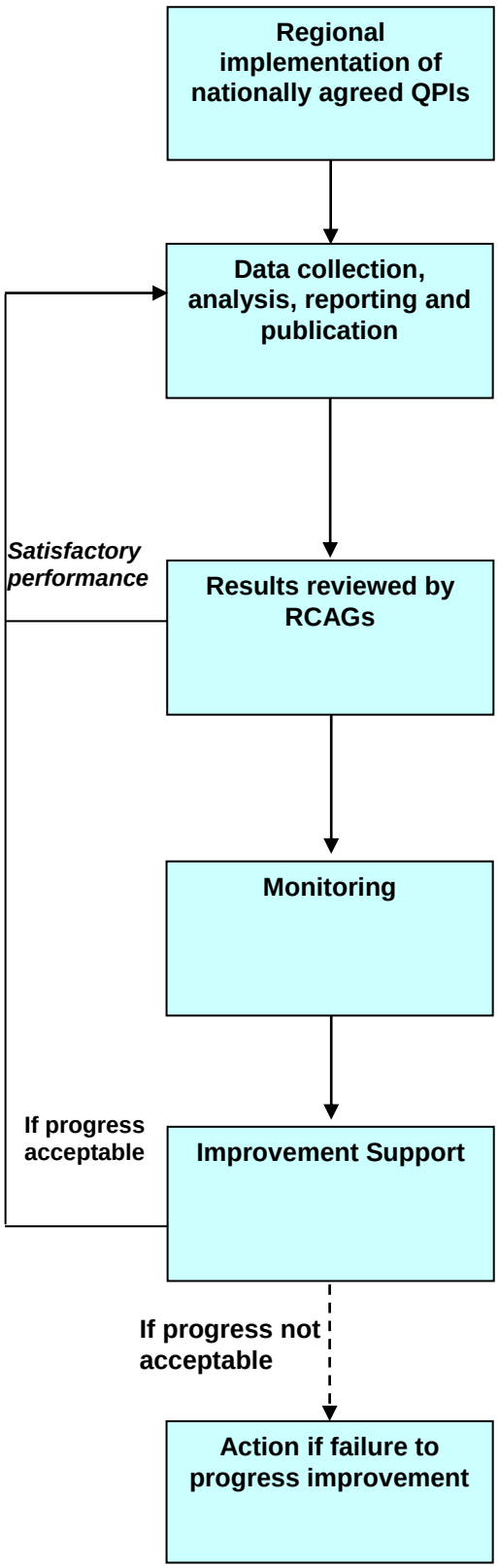
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to National Cancer Recovery Group as to whether progress is acceptable**.**

6. Escalation Stage:

- If progress not acceptable, Healthcare Improvement Scotland will visit the service concerned and work with the RCAG and Board to address issues.
- Report submitted to National Cancer Recovery Group and escalation with a proposal to take forward to Scottish Government Health Department.

**The Regional Cancer Planning Group (South and East of Scotland) and the North Cancer Clinical Leadership Group (North Cancer Alliance) are equivalent to the Regional Cancer Advisory Group (RCAG) in the West of Scotland.*

Appendix 4: Regional Annual Governance Process and Improvement Framework for Cancer Care



1. Regional QPI Implementation Stage:

- National cancer QPIs and associated national minimum core dataset and measurability specifications, developed by QPI development groups.
- Regional implementation of nationally agreed dataset to enable reporting of QPIs.

2. Data Analysis Stage:

- NHS Boards collect data and data is analysed on a yearly basis using nationally agreed measurability criteria at local/ regional level.
- Data/results validated by Boards and annual regional comparative report produced by Regional Networks.
- Areas of best practice and variance across the region highlighted.
- Yearly regional reports submitted to PHS for collation and presentation in national report every 3 years.

3. Regional Performance Review Stage:

- RCAGs* review regional comparative report.
- Regional or local NHS Board action plans to address areas of variance developed.
- Appropriate leads identified to progress each action.
- Action plans ratified by RCAGs.

4. Monitoring Stage:

- Where required, NHS Boards monitor progress with action plans and submit progress reports to RCAGs.
- RCAGs review and monitor regional improvement.

5. Improvement Support Stage:

- Where required Healthcare Improvement Scotland maybe requested to provide expertise to NHS Boards/RCAGs on improvement methodologies and support.

6. Escalation Stage:

- If progress not acceptable, RCAGs will escalate any issues to relevant Board Chief Executives. If progress remains unacceptable RCAGs will escalate any relevant issues to Healthcare Improvement Scotland.

**The Regional Cancer Planning Group (South and East of Scotland) and the North Cancer Clinical Leadership Group (North Cancer Alliance) are equivalent to the Regional Cancer Advisory Group (RCAG) in the West of* Scotland.

Appendix 5: Glossary of Terms

Adenocarcinoma	Cancer that begins in cells that line certain internal organs and that have gland-like (secretory) properties.
Adjuvant	Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.
Androgen	A type of hormone that promotes the development and maintenance of male sex characteristics.
Anterior	In human anatomy, has to do with the front of a structure, or a structure found toward the front of the body.
Anti-Androgen	A compound (usually a synthetic pharmaceutical) that blocks or otherwise interferes with the normal action of androgens at cellular receptor sites.
Asymptomatic	Having no symptoms. You are considered asymptomatic if you: • Have recovered from an illness or condition and no longer have symptoms • Have an illness or condition (such as early stage high blood pressure or glaucoma) but do not have symptoms
Bilateral	Affecting both the right and left sides of the body.
Biochemical recurrence	Rise in the blood level of PSA (prostate-specific antigen) in prostate cancer patients after treatment with surgery or radiation. Biochemical recurrence may occur in patients who do not have symptoms. It may mean that the cancer has come back. Also called biochemical relapse and PSA relapse.
Biopsy	Removal of a sample of tissue from the body to assist in diagnosis of a disease.
Bladder	The organ which stores urine.
Bone scan	A technique to create images of bones on a computer screen or on film.
Bowel	The long, tube-shaped organ in the abdomen that completes the process of digestion. The bowel has two parts, the small bowel and the large bowel.
Brachytherapy	A type of radiation therapy in which radioactive material sealed in needles, seeds, wires, or catheters is placed directly into or near a tumour. Also called implant radiation therapy, internal radiation therapy, and radiation brachytherapy.
Capsular	In medicine, a sac of tissue and blood vessels that surrounds an organ, joint, or tumour. A capsule is also a form for medicine that is taken by mouth. It usually has a shell made of gelatine with the medicine inside.
Carcinoma	Cancer that begins in the skin or in tissues that line or cover internal organs.
Cause-specific survival	A method of estimating net survival. Only deaths attributable to the cancer of diagnosis are counted as deaths, giving the probability of survival in the absence of other causes of death.
Chemotherapy	The use of drugs that kill cancer cells, or prevent or slow their growth.
Claustrophobia	Fear of enclosed spaces.

Clinical trials	Type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease.
Computed Tomography (CT)	An x-ray imaging technique, which allows detailed investigation of the internal organ of the body.
Contraindication	A symptom or medical condition that makes a particular treatment or procedure inadvisable because a person is likely to have a bad reaction.
Core	A piece of prostate tissue.
Curative intent	Treatment which is given with the aim of curing the cancer.
Cystoscopy	Examination of the bladder and urethra using a cystoscope, inserted into the urethra. A cystoscope is a thin, tube-like instrument with a light and a lens for viewing. It may also have a tool to remove tissue to be checked under a microscope for signs of disease.
Diagnosis	The process of identifying a disease, such as cancer, from its signs and symptoms.
Digital Rectal Examination (DRE)	An examination in which a doctor inserts a lubricated, gloved finger into the rectum to feel for abnormalities.
EMEA	European Medicines Agency
Enemas	The injection of a liquid through the anus into the large bowel.
External Beam Radiotherapy (EBRT)	A type of radiotherapy that uses a machine to aim high-energy rays at the cancer from outside of the body.
Gleason Score	A system of grading prostate cancer tissue based on how it looks under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a tumour will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumour is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumour is more likely to spread.
Histological / Histopathogical	The study of the structure, composition and function of tissues under the microscope, and their abnormalities.
Hormone therapy	Treating a disease with hormones, or by blocking the action of hormones.
Incontinence	Inability to control the flow of urine from the bladder (urinary incontinence) or the escape of stool from the rectum (faecal incontinence).
Information Services Division (ISD)	A division of National Services Scotland, part of NHS Scotland. ISD provides health information, health intelligence, statistical services and advice that support the NHS in progressing quality improvement in health and care and facilitates robust planning and decision making.
Intervention	A treatment or action taken to prevent or treat disease, or improve health in other ways.
Laser coagulation	The coagulation (clotting) of tissue using a laser.
Local anaesthetic	Drug which reduces or abolishes sensation from a specific area, to numb it.
Locally advanced	Cancer that has spread from where it started to nearby tissue or lymph nodes.
Luteinizing-hormone-releasing hormone	A hormonal therapy for prostate cancer.

(LHRH) agonist	
Magnetic Resonance Imaging (MRI)	A procedure in which radio waves and a powerful magnet linked to a computer are used to create detailed pictures of areas inside the body. These pictures can show the difference between normal and diseased tissue.
Multiparametric MRI (mpMRI)	A particular type of MRI investigation which creates a more detailed picture by using a number of different types of images including the use of dynamic contrast-enhanced sequences (DCE).
Biparametric MRI (bpMRI)	As above without the use of dynamic contrast-enhanced sequences (DCE).
Margin	See *Resection Margins*
Metastases/ Metastatic disease	Spread of cancer away from the primary site to somewhere else via the bloodstream or the lymphatic system.
MHRA	Medicines and Healthcare products Regulatory Committee.
Monotherapy	Treatment of a condition by means of a single drug.
Mortality	Either (1) the condition of being subject to death; or (2) the death rate, which reflects the number of deaths per unit of population in any specific region, age group, disease or other classification, usually expressed as deaths per 1000, 10,000 or 100,000.
Multi-disciplinary team meeting (MDT)	A meeting which is held on a regular basis, which is made up of participants from various disciplines appropriate to the disease area, where diagnosis, management, and appropriate treatment of patients is discussed and decided.
Nadir level	Lowest point.
NCA	North Cancer Alliance
Nodal	Affecting the cells that form small lumps near the joints in your body.
Orchidectomy	Surgery to remove one or both testicles.
Organ confined disease	Cancer which is confined to the prostate and has not spread to any other organ.
Pacemaker	Artificial device implanted into the body to monitor heart rate.
Palliative/Palliation	Anything which serves to alleviate symptoms due to the underlying cancer but is not expected to cure it.
Palpable disease	Cancer which can be felt by touch.
Pathology	The study of disease processes with the aim of understanding their nature and causes. This is achieved by observing samples of fluid and tissues obtained from the living patient by various methods, or at post mortem.
Pelvic	Having to do with the pelvis (the lower part of the abdomen located between the hip bones).
Performance status	A measure of how well a patient is able to perform ordinary tasks and carry out daily activities. (PS WHO score of 0=asymptomatic, 4=bedridden).
Prognosis/Prognostic	An assessment of the expected future course and outcome of a person's disease.
Progression	In medicine, the course of a disease, such as cancer, as it becomes

	worse or spreads in the body.
Prostate	A gland in the male reproductive system. The prostate surrounds the part of the urethra (the tube that empties the bladder) just below the bladder, and produces a fluid that forms part of the semen.
Prostate Specific Antigen (PSA)	A protein made by the prostate gland and found in the blood. Prostate-specific antigen blood levels may be higher than normal in men who have prostate cancer, benign prostatic hyperplasia (BPH), or infection or inflammation of the prostate gland.
PSA bounce	A brief rise and then fall in the blood level of PSA (prostate-specific antigen) that occurs in some patients 1-3 years after receiving radiation treatment for prostate cancer. PSA bounce does not mean that the cancer has come back. It may be caused by the release of PSA from destroyed cancer cells or from normal prostate tissue exposed to the radiation treatment.
Quality Performance Indicator (QPI)	A proxy measure of quality patient care.
Radiation Therapy Oncology Group (RTOG)	A clinical cooperative group founded to increase the survival and quality of life of patients diagnosed with cancer.
Radical Prostatectomy	Surgery to remove the entire prostate. The two types of radical prostatectomy are retropubic prostatectomy (surgery through an incision in the wall of the abdomen) and perineal prostatectomy (surgery through an incision between the scrotum and the anus).
Radical Treatment	Treatment that aims to get to completely get rid of a cancer.
Radiotherapy	The use of radiation, usually X-rays or gamma rays, to kill tumour cells.
Rectal	By or having to do with the rectum. The rectum is the last several inches of the large bowel closest to the anus.
Recurrence	When new cancer cells are detected at the site of the original tumour, following treatment.
Relapse	The return of a disease or the signs and symptoms of a disease after a period of improvement.
Resection margins	The edge or border of the tissue removed in surgery.
Salvage	Treatment that is given after the cancer has not responded to other treatments.
Sarcoma	A cancer of the bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue.
SCAN	South and East Scotland Cancer Network
Scottish Medicines Consortium (SMC)	The purpose of the SMC is to accept for use those newly licensed drugs that clearly represent good value for money to NHSScotland. SMC analyses information supplied by the drug manufacturer on the health benefits of the drug and justification of its price.
Seminal Vesicle	A gland that helps produce semen.
Sigmoidoscopy	Examination of the lower bowel using a sigmoidoscope, inserted into the rectum. A sigmoidoscope is a thin, tube-like instrument with a light and a lens for viewing. It may also have a tool to remove tissue to be checked under a microscope for signs of disease.
Staging	Process of describing to what degree cancer has spread from its original site to another part of the body. Staging involves clinical, surgical and pathology assessments.

Surgical margins	See *Resection Margins*
Surgical resection	Surgical removal of the tumour/lesion.
Survival	The percentage of people in a study or treatment group who are alive for a certain period of time after they were diagnosed with or treated for a disease, such as cancer.
Symptomatic	Having to do with symptoms, which are signs of a condition or disease.
TNM staging system	TNM classification provides a system for staging the extent of cancer. T refers to the size of the primary tumour. N refers to the involvement of the lymph nodes. M refers to the presence of metastases or distant spread of the disease.
Toxicity	The extent to which something is poisonous or harmful.
Trans Rectal Ultrasound (TRUS) Guided Biopsy	A procedure that takes small samples of tissue from the prostate gland.
Tumour	A lump or mass of cells which can be either benign (not cancerous) or malignant.
Tumour volume	The size of a cancer measured by the amount of space taken up by the tumour.
ug/l	Micrograms per litre.
Urinary	Having to do with urine or the organs of the body that produce and get rid of urine.
WoSCAN	West of Scotland Cancer Network.