

**Scottish Cancer Taskforce
National Cancer Quality Steering Group**

**Prostate Cancer
Clinical Quality
Performance Indicators
Engagement Document**



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1. National Cancer Quality Programme

Better Cancer Care¹ states that a wide ranging approach to quality improvement is required to ensure that services improve performance across all dimensions of quality. The NHS Scotland Healthcare Quality Strategy² (launched in May 2010) further expands upon this by articulating three quality ambitions:

- Mutually beneficial partnerships between patients, their families and those delivering healthcare services which respect individual needs and values and which demonstrate compassion, continuity, clear communication and shared decision-making.
- No avoidable injury or harm from the healthcare they receive, and that they are cared for in an appropriate, clean and safe environment at all times.
- The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, with no wasteful or harmful variation.

The quality strategy aims to put quality at the very heart of the NHS, building upon the excellent foundations already in place. A quality measurement framework has been developed which sets out measures and targets which will be used to monitor, challenge, manage and report progress towards the three quality ambitions. This framework also allows for supplementary national indicators that will underpin progress towards the quality ambitions².

Under the auspices of the Scottish Cancer Taskforce, National Cancer Quality Performance Indicators (QPIs) have been developed to drive continuous quality improvement in cancer care across NHSScotland. The QPIs are small sets of cancer-specific outcome focussed, evidence based indicators. These are underpinned by Patient Experience QPIs that are applicable to all, irrespective of cancer type. QPI implementation ensures that activity is focussed on those areas that are most important in terms of improving survival and patient experience whilst reducing variance and ensuring the most effective and efficient delivery of care.

A QPI is defined as a proxy measure of quality care. QPIs are kept under regular review and are responsive to changes in clinical practice and emerging evidence.

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 Multi Disciplinary Team/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 reports published annually. National reports include comparative reporting of performance against QPIs at Board/Multi Disciplinary Team level across NHSScotland, 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 Information Services Division (ISD) for inclusion in subsequent national reports.

This approach 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. Membership of the development group can be found in appendix 2.

3. QPI Formal Review Process

As part of the National Cancer Quality Programme a systematic national review process has been developed, whereby all tumour specific QPIs published are subject to formal review following 3 years analysis of comparative QPI data.

Formal review of the Prostate Cancer QPIs was undertaken in December 2015. This was brought forward to align with the introduction of robotic assisted surgery and the impact this may have on the indicators.

A formal review group was convened, chaired by Dr Hilary Dobson (Chair, National Cancer Quality Steering Group). Membership of this group included Clinical Leads from the three Regional Cancer Networks. Membership of this group can be found in appendix 3.

The formal review process is clinically driven with comments sought from specialty specific representatives in each of the Regional Cancer Networks for discussion at the initial meeting. This review builds on existing evidence using expert clinical opinion to identify where new evidence is available.

During formal review QPIs may be removed 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.

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?

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. These were implemented for all patients diagnosed with prostate cancer on, or after, 1st July 2012. All relevant updates have been made to the supporting documentation following formal review of the QPIs.

6. Prostate Cancer Risk Categorisation

Several factors are known to predict the risk of recurrence of prostate cancer; these factors are used to classify localised prostate cancer into risk categories⁴. Some of the Prostate Cancer QPIs (section 7) refer to specific risk categories which are detailed in the table below.

Low Risk	Clinical Stage T1 – T2a* and Gleason score ≤ 6 and PSA [†] at diagnosis <10 ug/l
Intermediate Risk	Clinical Stage T2b or T2c or Gleason score 7 or PSA at diagnosis 10-20 ug/l
High Risk	Clinical Stage T3 – T4 or Gleason score 8-10 or PSA at diagnosis >20 ug/l

Table 1: Localised Prostate Cancer Risk Categories

(adapted from NICE Prostate Cancer: Diagnosis and Treatment Guideline)⁴

* TNM classification is a system for staging the extent of cancer. T describes the size of the tumour. N refers to the involvement of the lymph nodes. M refers to the presence of metastatic disease.

† Prostate Specific Antigen (PSA) is a protein made by the prostate gland and found in the blood. Prostate cancer, and other benign conditions, can increase PSA levels in the blood.

7. Quality Performance Indicators for Prostate Cancer

QPI 1: Biopsy Procedure

QPI Title:	Procedure for performing prostate biopsy should be optimised.
Description:	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.
Rationale and Evidence:	<p>Where biopsy is being undertaken to diagnose prostate cancer a minimum of ten cores of tissue should be taken to ensure adequate sampling^{3,4,5}</p> <p>In line with recommended best practice local anaesthetic should be given to patients undergoing TRUS prostate biopsy⁶.</p>
Specifications:	<p>Numerator: Number of patients with prostate cancer who undergo TRUS biopsy where a minimum of 10 cores are received by pathology.</p> <p>Denominator: All patients with prostate cancer who undergo TRUS biopsy of the prostate.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients enrolled in clinical trials • Patients with advanced (T4NanyMany) or metastatic disease (TanyNanyM1)
Target:	<p>90%</p> <p>The tolerance within this target is designed to account for situations where, due to clinical suspicion, a smaller number of cores will suffice if the biopsy operator is satisfied they have taken sufficient tissue to make a histological diagnosis.</p> <p>In addition, some patients may become unwell during the procedure, meaning that the procedure may have to be abandoned.</p>

QPI 2: Radiological Staging

QPI Title:	Patients with intermediate or high risk prostate cancer, who are suitable for radical treatment, should be evaluated for locally advanced, nodal or bony metastatic disease.
Description:	<p>Proportion of patients with intermediate or high risk prostate cancer undergoing radical treatment who have had Magnetic Resonance Imaging (MRI) and bone scan staging.*</p> <p>Please note that this QPI measures two distinct elements:</p> <ul style="list-style-type: none"> (i) Patients with intermediate prostate cancer who undergo MRI. (ii) Patients with high risk prostate cancer who undergo MRI and bone scan.
Rationale and Evidence:	<p>Local staging is of importance in helping guide both patient and clinician towards a treatment decision. Whilst digital rectal examination, Prostate Specific Androgen (PSA) level and needle biopsy histology together help predict the likelihood of organ-confined disease, this is on a population rather than individual patient basis. In addition, needle biopsies are prone to sampling error. Therefore the management of a patient predicted to have organ confined disease by the above parameters who unexpectedly on MRI has definite capsular, seminal vesicle, nodal or bony involvement (or a predominant anterior tumour not palpable or reached by biopsy) may be radically changed by that MRI result. Similarly, patients predicted to have significant risk of locally advanced disease may be considered suitable for radical treatment if the MRI shows organ-confined disease. Clearly patients found to have bone metastases are by definition not suitable for radical treatment^{7,8,9}.</p> <p>Patients with high-risk prostate cancer should have MRI to assess the extent of disease ahead of radical treatment⁴.</p> <p>* For patients with intermediate risk prostate cancer with PSA <10 at diagnosis a bone scan is not routinely recommended⁴.</p>
Specification (i):	<p>Numerator: Number of patients with intermediate risk prostate cancer undergoing radical treatment who have an MRI of the prostate.</p> <p>Denominator: All patients with intermediate risk prostate cancer undergoing radical treatment.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients unable to undergo an MRI scan: <ul style="list-style-type: none"> ○ 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 refuse MRI.
Target:	<p>95%</p> <p>The tolerance within this target is to account for situations where patients are deemed clinically unsuitable or unfit to undergo MRI.</p>

QPI 2: Radiological Staging (cont...)

Specification (ii):	<p>Numerator: Number of patients with high risk prostate cancer undergoing radical treatment who have an MRI of the prostate and isotope bone scan (or alternative whole body MRI evaluation).</p> <p>Denominator: All patients with high risk prostate cancer undergoing radical treatment.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients unable to undergo an MRI scan: <ul style="list-style-type: none"> ○ 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 refuse MRI.
Target:	<p>95%</p> <p>The tolerance within this target is to account for situations where patients are deemed clinically unsuitable or unfit to undergo MRI.</p>

QPI 3: Pathology Reporting

QPI Title:	All surgical pathology reports for prostate needle biopsies should contain full pathology information to inform treatment decision making.
Description:	Proportion of patients who undergo needle biopsy where the pathology report contains a full set of data items (defined by the Scottish Urological Pathologists dataset – see appendix 4).
Rationale and Evidence:	To help plan treatment for men diagnosed with prostate cancer, prognostic information from the needle biopsy is necessary. The use of datasets improves the completeness of data in pathology reports and a minimum prostate cancer dataset has been agreed for Scotland based on the Royal College of Pathologists most recent Standard and Guideline for Prostate Cancer ^{10,11} .
Specifications:	<p>Numerator: Number of patients with prostate adenocarcinoma who undergo prostate needle biopsy where needle biopsy pathology report contains all data items (as defined in the Scottish Urological Pathologists dataset – see appendix 4).</p> <p>Denominator: All patients with prostate adenocarcinoma who undergo prostate needle biopsy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Target:	<p>90%</p> <p>The tolerance within this target is designed to account for situations where it is not possible to report all components of the dataset due to specimen size.</p>

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.
Rationale and Evidence:	<p>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 care¹².</p> <p>Discussion prior to definitive treatment decisions being made provides reassurance that patients are being managed appropriately.</p>
Specifications:	<p>Numerator: Number of patients with prostate cancer discussed at the MDT before definitive treatment.</p> <p>Denominator: All patients with prostate cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who died before first treatment.
Target:	<p>95%</p> <p>The tolerance within this target accounts for situations where patients require treatment urgently.</p>

QPI 5: Early Management of Active Surveillance

QPI Title:	Men under active surveillance for prostate cancer should undergo appropriate investigations at the clinically relevant timings.
Description:	<p>Proportion of men under active surveillance for prostate cancer who undergo multiparametric MRI within 6 months, and prostate re-biopsy within 14 months of diagnosis</p> <p>Please Note: the specifications of this QPI are separated to ensure clear measurement of patients who have undergone:</p> <ul style="list-style-type: none"> (i) Multiparametric MRI within 6 months of diagnosis (ii) Prostate re-biopsy within 14 months of diagnosis
Rationale and Evidence:	<p>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. ^{13, 14}</p> <p>It is recommended that men who are undergoing active surveillance should have a multiparametric MRI performed at enrolment of active surveillance if not previously performed. A prostate re-biopsy should also be performed at the Year 1 end of active surveillance. ¹⁵</p>
Specification (i):	<p>Numerator: Number of patients undergoing multiparametric MRI within 6 months of diagnosis</p> <p>Denominator: All patients under active surveillance</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients unable to undergo an MRI scan: <ul style="list-style-type: none"> ○ 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 refuse MRI.
Target:	<p>75%</p> <p>The tolerance within this target is to account for situations where patients are deemed clinically unsuitable or unfit to undergo MRI.</p> <p>Please note: In order to ensure that the chosen target level is the most appropriate and drives continuous quality improvement as intended it will be kept under review and revised as necessary, once baseline data or further evidence becomes available.</p>

QPI 5: Early Management of Active Surveillance (cont...)

<p>Specification (ii):</p>	<p>Numerator: Number of patients undergoing trans-rectal ultrasound guided (TRUS) prostate re-biopsy within 14 months of diagnosis</p> <p>Denominator: All patients under active surveillance</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who undergo radical treatment within 14 months of diagnosis
<p>Target:</p>	<p>75%</p> <p>The tolerance within this target is to account for situations where patients are deemed clinically unsuitable to undergo re-biopsy as well as factors relating to patient choice.</p> <p>Please note: In order to ensure that the chosen target level is the most appropriate and drives continuous quality improvement as intended it will be kept under review and revised as necessary, once baseline data or further evidence becomes available.</p>

QPI 6: 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 ⁶ .
Specifications:	<p>Numerator: Number of patients with stage pT2 prostate cancer who underwent radical prostatectomy in which tumour is present at the margin.</p> <p>Denominator: All patients with stage pT2 prostate cancer who underwent radical prostatectomy.</p> <p>Exclusions: • None</p>
Target:	<p><20%</p> <p>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.</p>

QPI 7: 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:	<p>Radical prostatectomy should be performed by surgeons who work in high-volume hospitals, with outcomes audited regularly^{3,6}.</p> <p>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 rates⁶.</p> <p>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.^{16, 17, 18}</p> <p>For robotic assisted radical prostatectomy it has been suggested that individual surgeons should undertake a minimum of 50-100 cases per annum.¹⁹</p>
Specifications:	<p>Number of radical prostatectomies performed by each surgeon in a given year.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • None
Target:	<p>Minimum 50 procedures per surgeon in a 1 year period.</p> <p>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.</p> <p>Please Note: It is recommended that where two consultants operate together on the same patient the case should be counted under the Lead Surgeon.</p>

Please note:

SMR01 data will be utilised to support reporting and monitoring of this QPI rather than clinical audit. This will maximise the use of data which are already collected and remove the need for any duplication of data collection. Standard reports are currently being specified and direct access for each Board to run these reports is being investigated to ensure nationally consistent analysis and reporting.

QPI 8: Hormone Therapy and Docetaxel Chemotherapy

QPI Title:	Patients with metastatic prostate cancer should undergo immediate hormone therapy [‡] , and chemotherapy where appropriate [§] .
Description:	<p>Proportion of patients with metastatic prostate cancer (TanyNanyM1) who undergo immediate management with hormone therapy, and docetaxel chemotherapy.</p> <p>Please note: The specifications of this QPI are separated to ensure clear measurement of both patients who receive:</p> <ul style="list-style-type: none"> (i) Immediate hormone therapy; and (ii) Immediate hormone therapy and docetaxel chemotherapy
Rationale and Evidence:	<p>There is evidence for symptom palliation and possible survival benefit in symptomatic metastatic patients, and for prolonged progression-free survival in asymptomatic patients with metastatic prostate cancer^{4,6}.</p> <p>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^{3,6,20}.</p> <p>Docetaxel chemotherapy has shown evidence of improved survival when given in conjunction with hormone therapy and should be offered to men who are suitably fit as part of their care²¹.</p> <p>The hormone therapy should be licensed in this indication as monotherapy or in combination with an anti-androgen for dual androgen blockade. Bilateral orchidectomy is an acceptable form of hormone therapy in this context.</p>
Specification (i):	<p>Numerator: Number of patients presenting with metastatic prostate cancer (TanyNanyM1) treated with immediate hormone therapy</p> <p>Denominator: All patients presenting with metastatic prostate cancer (TanyNanyM1).</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients documented to have refused immediate hormone therapy. • Patients enrolled in clinical trials.
Target:	<p>95%</p> <p>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.</p>

[‡] Immediate therapy would be within 31 days of MDT meeting (pre treatment)

[§] Docetaxel should be started within 90 days of first dose of hormone therapy.

QPI 8: Hormone Therapy and Docetaxel Chemotherapy (cont...)

Specification (ii):	<p>Numerator: Number of patients presenting with metastatic prostate cancer (TanyNanyM1) treated with immediate hormone therapy (LHRH agonist/ antagonist monotherapy, dual androgen blockade or bilateral orchidectomy) and docetaxel chemotherapy.</p> <p>Denominator: All patients presenting with metastatic prostate cancer (TanyNanyM1).</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients documented to have refused immediate hormone therapy. • Patients documented to have refused chemotherapy • Patients with performance status 2 or worse • Patients enrolled in clinical trials.
Target:	<p>70%</p> <p>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.</p> <p>Please note: In order to ensure that the chosen target level is the most appropriate and drives continuous quality improvement as intended it will be kept under review and revised as necessary, once baseline data or further evidence becomes available.</p>

QPI 9: Post Surgical Incontinence

QPI Title:	Post surgical incontinence for patients with prostate cancer should be minimised.
Description:	Proportion of prostate cancer patients who undergo radical prostatectomy with post surgical incontinence approximately 1 year (between 10 and 14 months) after surgery.
Rationale and Evidence:	Urinary incontinence, especially over the long-term, is significant and is associated with poor quality of life, this therefore requires to be minimised in men undergoing surgery for prostate cancer ^{4,6} .
Specification (i)	<p>Numerator: Number of patients with prostate cancer undergoing radical prostatectomy with post surgical incontinence (>0 pads per day measured using a validated tool^{**}) at 1 year (10-14 months) post radical prostatectomy.</p> <p>Denominator: All patients with prostate cancer undergoing radical prostatectomy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who undergo salvage prostatectomy. • Patients who receive adjuvant radiotherapy within 6 months of surgery.
Target	<20%
Specification (ii):	<p>Numerator: Number of patients with prostate cancer undergoing radical prostatectomy with post surgical incontinence (greater than 1 pad per day measured using a validated tool) at 1 year (10-14 months) post radical prostatectomy.</p> <p>Denominator: All patients with prostate cancer undergoing radical prostatectomy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who undergo salvage prostatectomy. • Patients who receive adjuvant radiotherapy within 6 months of surgery.
Target:	<10%

^{**} Validated tools appropriate for this measurement would be:

- The Expanded Prostate Cancer Index Composite (EPIC) Urinary Assessment
- Incontinence Questionnaire (ICIQ)

Please Note:

Due to the difficulty in reaching an appropriate definition of incontinence and a lack of clear evidence to determine this, two distinct targets based on the use of incontinence pads are detailed.

These two distinct target levels have been chosen as they account for differences in patient perceptions of the severity of symptoms following surgery. Evidence suggests that the degree to which these symptoms bother individuals is very variable⁴.

QPI 10: 30 Day Mortality for Systemic Anti-Cancer Treatment (SACT)

QPI Title:	30 day mortality following systemic anti-cancer treatment for prostate cancer.
Description:	Proportion of patients with prostate cancer who die within 30 days of systemic anti-cancer treatment.
Rationale and Evidence:	<p>Outcomes of treatment, including treatment related morbidity and mortality should be regularly assessed.²²</p> <p>Treatment should only be undertaken in individuals that may benefit from that treatment, that is, treatments should not be undertaken in futile situations. This QPI is intended to ensure treatment is given appropriately, and the outcome reported on and reviewed.</p>
Specifications:	<p>Numerator: Number of patients with prostate cancer who receive systemic anti-cancer treatment that die within 30 days of treatment.</p> <p>Denominator: All patients with prostate cancer who receive systemic anti-cancer treatment.</p> <p>Exclusions:</p> <ul style="list-style-type: none">• No exclusions
Target:	<5%

8. Survival

Improving survival forms an integral part of the national cancer quality improvement programme. Prostate cancer survival analysis is reported and analysed on a 3 yearly basis by ISD. The specific issues which will be addressed, for example 1 year or 5 year survival rates, will be identified by an expert group ahead of any analysis being undertaken, as per the agreed national cancer quality governance and improvement framework.

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 Scottish Cancer Taskforce. 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.

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 5 and 6 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

- Scottish Cancer Taskforce
 - Accountable for overall national cancer quality programme and overseeing the quality of cancer care across NHSScotland.
 - Advising 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.
- Information Services Division (ISD)
 - 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 monitoring of progress against agreed actions.

- Provide assurance to NHS Board Chief Executive Officers and Scottish Cancer Taskforce 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. 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.
- Erectile dysfunction following treatment for prostate cancer.
- Active surveillance and watchful waiting.
- Multi parametric (MP) MRI Screening for targeted TRUS biopsies

11. How to participate in the engagement process

In order to ensure wide inclusiveness of clinical and management colleagues from across NHS Scotland, patients affected by prostate cancer and the wider public, several different methods of engagement are being pursued:

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 to be held.

11.1 Submitting your comments

You can submit your comments on the prostate cancer QPIs via the Scottish Government Consultation Hub (website link below):

<https://consult.scotland.gov.uk/nhs/prostate-cancer-qpi>

All responses should be submitted by **Friday 3rd June 2016**.

If you require any further information regarding the engagement process please use the email address below.

Email: ProstateQIPublicEngagement@gov.scot

11.2 Engagement feedback

At the end of the engagement period, all comments and responses will be collated for review by the Prostate Cancer QPI Formal Review Group. Those who have participated in the engagement process will receive an overview of the changes made and a copy of the final Prostate Cancer QPI document.

12. References

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13. 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	Prostate sarcomas
Adults only	
<i>Date:</i> 2005 or later	
<i>Topics:</i> diagnosis, staging, management of non-metastatic (organ confined or locally advanced) and metastatic (advanced) disease, follow up	<i>Topics:</i> 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. 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.

Appendix 2: Prostate Cancer QPI Development Group Membership

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
Bob Nairn	Consultant Pathologist	WoSCAN (Crosshouse Hospital)
Peter Phillips	Patient Representative	
Iona Scott	Project Manager	
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 3: Prostate Cancer QPI Formal Review Group Membership

Name	Designation	Cancer Network/Base
Hilary Dobson	Chair, National Cancer Quality Steering Group	WoSCAN
Evelyn Thomson	Regional Cancer Manager	WoSCAN
Grenville Oades	Clinical Lead Urological Cancers MCN	WoSCAN / NHS Greater Glasgow & Clyde
Prasad Bollina	Clinical Lead Urological Cancers MCN	SCAN / NHS Lothian
Chris Goodman	Clinical Lead Urological Cancers MCN	NOSCAN / NHS Tayside
Alan McNeil	Consultant Urological Surgeon	SCAN / NHS Lothian
Hasan Qazi	Consultant Urological Surgeon	WoSCAN / NHS Greater Glasgow & 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 & Arran
Carol Marshall	Information Manager	WoSCAN
Jen Doherty	Project Co-ordinator	National Cancer Quality Programme

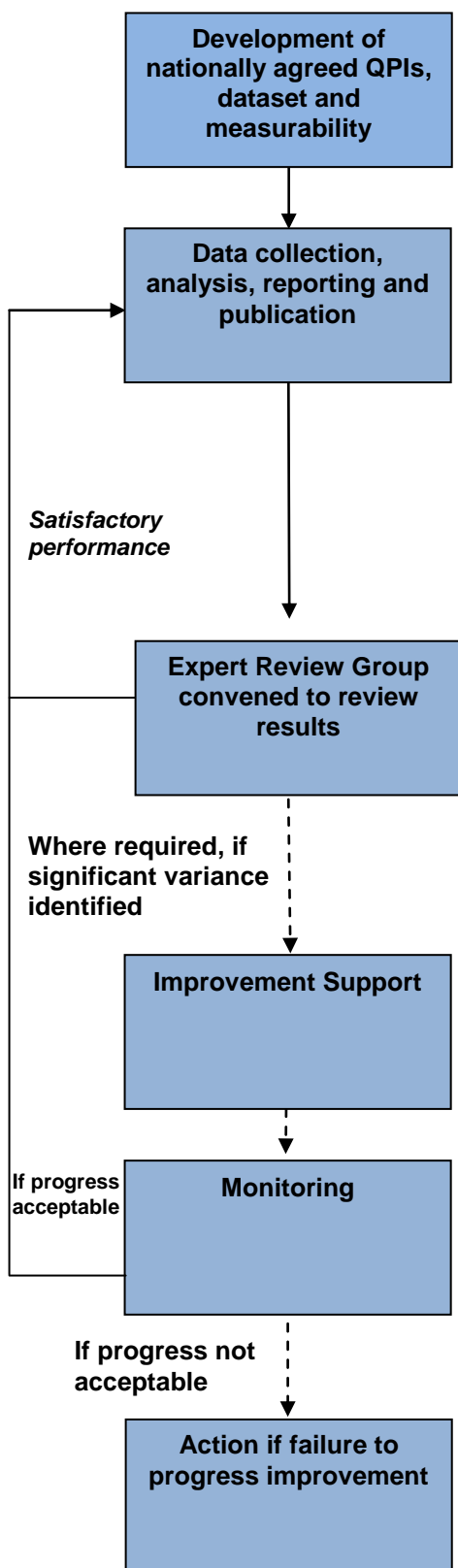
Appendix 4: Scottish Prostate Needle Biopsy Dataset

This dataset has been approved by the Scottish Pathology Network (SPAN). The following data collection form is included as a template to assist with reporting of prostate cancer needle biopsies.

Specimen Details	
PSA (if known) µg/l	
Needle biopsy <input type="checkbox"/>	Number of needle cores Right <input type="checkbox"/>Left
TURP <input type="checkbox"/>	TURP weight gms
Other <input type="checkbox"/>	Specify
Histology	
Tumour type	
Microacinar <input type="checkbox"/>	Other <input type="checkbox"/> Specify
Number of cores invaded by tumourRight <input type="checkbox"/> Left <input type="checkbox"/>	
Primary Gleason <input type="checkbox"/> Secondary Gleason <input type="checkbox"/> Gleason score <input type="checkbox"/>	
% Cancer involvement <input type="checkbox"/> (N.B. Specify in comments: if Total percentage of cancer or Greatest Percent in one core)	
Adipose tissue invasion seen Yes <input type="checkbox"/> No <input type="checkbox"/>	
Perineural invasion seen Yes <input type="checkbox"/> No <input type="checkbox"/>	
Comments (Indicate which core if focal disease; indicate if vascular invasion seen, * indicate if Tertiary Gleason score)	
<p>N.B. 1) * A tertiary grade is very rare in biopsy material. 2) It is recommended that where there is a small area of high grade tumour, it is reported as the “Secondary” grade. 3) Both the Primary pattern and the highest grade should be reported. (If small amount of tumour i.e. < 3mm give total length)</p>	

Appendix 5: 3 Yearly National Governance Process & Improvement Framework for Cancer Care

This process is underpinned by the annual regional reporting and governance framework (see appendix 6).



1. National QPI Development Stage

- QPIs developed by QPI development groups, which include representation from Regional Cancer Networks, Healthcare Improvement Scotland, ISD, 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 6.
- Submit yearly reports to ISD for collation and publication every 3 years.
- National comparative report approved by NHS Boards and RCAGs.
- ISD 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 Scottish Cancer Taskforce.

4. Improvement Support Stage:

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

5. Monitoring Stage:

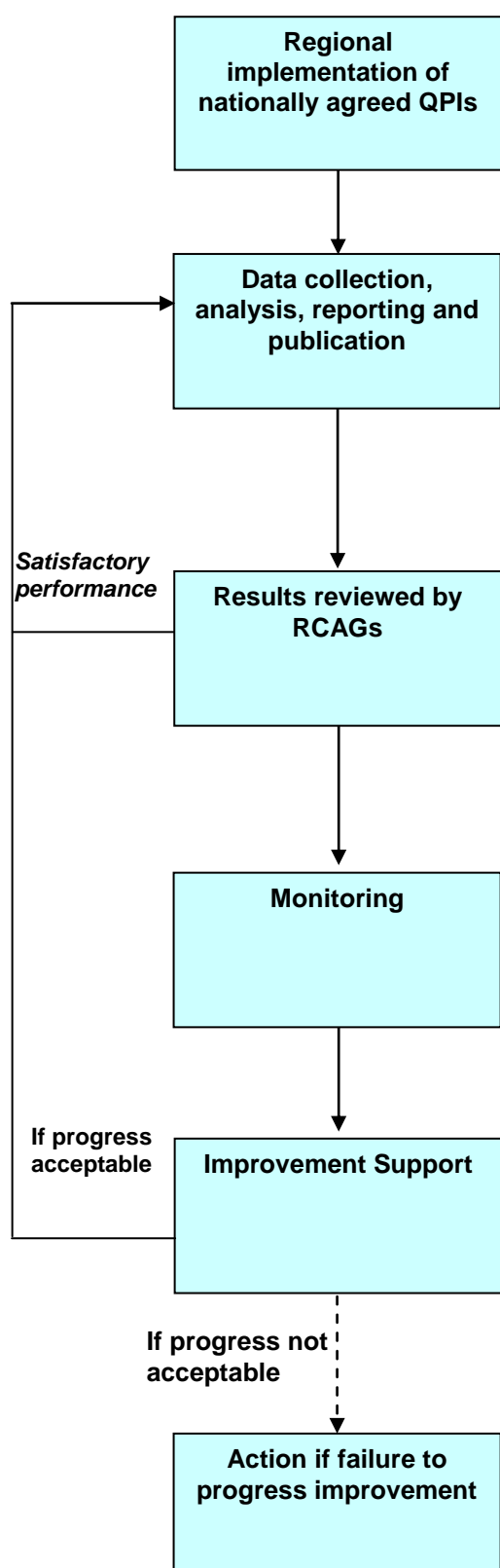
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable.

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 Scottish Cancer Taskforce and escalation with a proposal to take forward to Scottish Government Health Department.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).

Appendix 6: 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 ISD 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.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).

Appendix 7: 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: <ul style="list-style-type: none">• 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 / Histopathological	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 (LHRH) agonist	A hormonal therapy for prostate cancer.
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.
Margin	See <i>Resection Margins</i>
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.
Nodal	Affecting the cells that form small lumps near the joints in your body.
NoSCAN	North of Scotland Cancer Network
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	A protein made by the prostate gland and found in the blood.

Antigen (PSA)	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 <i>Resection Margins</i>
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	Is 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.



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