Rapid diagnostic and assessment pathways

Implementing a timed prostate cancer diagnostic pathway

A handbook for local health and care systems

April 2018
Information Governance Statement

Organisations need to be mindful of the need to comply with the Data Protection Act 1998, the Common Law Duty of Confidence and Human Rights Act 1998 (Article 8 – right to family life and privacy).

Equalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England’s values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request.

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Rapid diagnostic and assessment pathways

Rapid diagnostic and assessment pathways illustrate how timely and effective care can be provided to patients presenting with cancer symptoms. Delivery of the pathways will support us to provide the highest quality care to our patients, and reduce variation in patient access to diagnostic and treatment options.

This handbook sets out how diagnosis within 14 days and diagnosis within 28 days can be achieved for the prostate cancer pathway.

We have identified useful resources that can support you with implementation, and have highlighted the key role of cancer alliances in delivering large scale transformation across whole systems.

The National Cancer Vanguard has been a leader in the development of these timed prostate cancer pathways. The Vanguard includes Greater Manchester Cancer, RM Partners, and the University College London Hospitals Cancer Collaborative.

The ‘faster pathway’ outlined in this document has been drawn from pathway redesign within RM Partners and at University College London Hospitals Cancer Collaborative.

The pathways in this document have also been shaped and approved by the NHS England Clinical Expert Group for Prostate Cancer.

Clinical Expert Groups (CEGs) bring together clinical leaders who provide tumour specific clinical expertise. Their role includes ensuring that advice on best practice cancer pathways is evidence-based and is available for anyone involved in the improvement of cancer services. This includes cancer alliances, commissioners, clinicians, managers, and patients.

This guidance complements existing resources such as NICE Guidelines (including NG12) and should therefore be read alongside such guidance.

For any questions about this document please email the NHS Cancer Programme at england.cancerpolicy@nhs.net.

Professor Chris Harrison
National Clinical Director for Cancer

Professor Hashim Ahmed
NHS England Clinical Expert Group for Prostate Cancer

Mr David Shackley
Medical Director, National Cancer Vanguard
## World class cancer care in England

The [national cancer strategy](#) sets out an ambitious aim for the NHS to make significant progress in reducing preventable cancers, increasing cancer survival and improving patient experience and quality of life by 2020.

Survival rates for cancer in England have never been higher, and overall patients report a very good experience of care. However, we know there is more we can do to ensure patients are diagnosed early and quickly, and this will have a major impact on survival. We also know that patients continue to experience variation in their access to care, which needs to be addressed.

Early diagnosis, fast diagnosis, and equity of access to treatment and care are central to the National Cancer Programme and the transformation of services we want to achieve by 2020/21.

### Faster Diagnosis Standard (FDS)

We are implementing a new diagnostic standard for cancer that emphasises the importance of receiving a diagnosis or ruling out of cancer within 28 days. For patients who are diagnosed with cancer, this means treatment can be offered earlier. For those who are not diagnosed with cancer, this communication of an ‘all clear’ reduces the anxiety felt at a very stressful time.

Cancer alliances are leading their local commissioners and providers to drive earlier and faster diagnosis. The rapid diagnosis and assessment interventions they are putting in place now will help to ensure the Faster Diagnosis Standard is met for patients when fully introduced from April 2020.

The new Cancer Waiting Times system should be used to support the collection of the new faster diagnosis data items. This data can be used to audit how long it takes for patients to have their diagnosis communicated to them, and understand where to make improvements to shorten pathways. The focus is on reducing variation for patients and providing a consistent timed pathway.

Teams may improve beyond the pathways in this handbook, radically shorten the diagnostic time period further, building on local innovation to deliver sustainable pathways. The aim is to enable patients to have their diagnosis communicated to them in the shortest time possible, having experienced high quality care.

### E-referrals service (eRS)

The NHS e-Referral Service is the process for referring all consultant-led first outpatient appointments from 1 October 2018. Resources for implementation are available on the NHS Digital website.
System transformation

How to achieve success:

- **Engage with patients** throughout the pathway redesign and implementation stages to ensure that changes will benefit your patients in terms of clinical outcomes and patient experience.

- **Ensure board or executive level sponsorship** in each organisation to ensure prioritisation of pathway implementation (board-level reporting of progress and diagnostic performance).

- **Establish a cross-system implementation team** to enable access to limited resources, implement changes, overcome organisational divisions and structures, and avoid ‘silo’ working. This could include GPs, consultants, clinical nurse specialists, pathway navigators, cancer alliance leads, and CCG and Acute trust leads (e.g. contracts, IT).

- **Identify clinical champions across the pathway**, across disciplines and departments, to ensure clinical leadership and endorsement on the ground. This can help you to quickly resolve problems, and develop and implement additional solutions to service challenges throughout implementation.

- **Engage and communicate regularly with key stakeholders** throughout the implementation process. Use local networks for communication, such as newsletters and GP events, to build awareness. Sharing positive feedback can be powerful.

- **Establish workforce development for teams** in order to support new ways of working across the whole pathway (e.g. network radiologists with buddying between individuals with different levels of experience, joint masterclasses on the pathway).

Your cancer alliance

Cancer alliances are the local strategic leaders for cancer, driving the change needed across the country to achieve world class cancer care in England. There are 19 cancer alliances across the country, and these organisations bring together local leaders to implement the cancer strategy at a local level.

NHS England provides support, funding and guidance to help cancer alliances improve outcomes and reduce variation for their populations.

Your cancer alliance will work across the local system to ensure:
- Senior stakeholder prioritisation of pathway implementation
- Development of clinical leadership (e.g. pathway transformation leads)
- Successful coordination of cancer services
- Access to national learning and resources by local organisations
- Provision of transformation and change management expertise to support improvement
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mpMRI before biopsy:

- Conducting mpMRI before first prostate biopsy improves the detection accuracy of clinically significant cancer (PROMIS trial).
- Approximately 25% of patients with suspected prostate cancer had a non-suspicious mpMRI and avoided the need for immediate biopsy (PROMIS). This change in practice will lead to a reduction in biopsy-associated risks such as infection.
- Using mpMRI before biopsy has the potential to dramatically improve patient experience with a potential ‘rule-out’ of prostate cancer without the need for an invasive procedure.
- In 2015-16, only 51% of men underwent an mpMRI for suspected prostate cancer, of which 73% were performed before biopsy.

Prostate cancer is the second most common diagnosed cancer in England, and the most common cancer diagnosed in men.

- For prostate cancer patients in England diagnosed 2011 to 2015, one-year survival was 96.3%.
- In 2016, 49.1% of all prostate cancers were diagnosed at an early stage. This varied by cancer alliance with a range of 39.7-54.5%.
- Prostate cancer is one of only two cancer types to have seen a fall in the rate of early diagnosis (and total number of patients diagnosed at stage 1 and 2) over the last 2 years. With relatively high survival of prostate cancer the impact of late diagnosis is less severe than for other cancers (almost 100% one-year survival for stage 3 diagnoses, over 80% for stage 4).
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"We need to change the manner in which we diagnose prostate cancer. We are seeing rising incidence of prostate cancer, but very little change in the mortality rate. Our current diagnostic pathway for prostate cancer needs urgent change. The PROMIS trial has shown us that transrectal ultrasound-guided prostate biopsies are inaccurate. They miss significant cancer, over-diagnose insignificant cancers which leads to over-treatment harms and costs, and biopsies carry risk. PROMIS has also shown that by using pre-biopsy multi-parametric MRI we are able to a) triage men towards a biopsy so at least 25% can avoid it, b) diagnose over 90% of significant cancers and c) diagnose fewer insignificant cancers. This is a watershed moment for those of us involved in looking after men with suspected prostate cancer. I trust all of us will fully embrace the change."

Professor Hashim Ahmed
NHS England Clinical Expert Group for Prostate Cancer

Timed pathways

28 day

21 Day

14 day

Features of a faster pathway

Patient information

Provided at point of referral, information resources can empower patients and help to manage anxiety by setting out what can be expected from the diagnostic process (e.g. tests, timings and communications). This information can benefit patient experience and also encourage compliance, which will reduce delays along the pathway (i.e. reduced DNAs and re-booking of appointments). Best when co-produced with patients as part of a pathway improvement programme.

Service models

Implementing the following service models can support services to reduce variation and make improvements to patient flow:

- Clinical triage to optimise direct access diagnostics, ensure patients in the ‘right place, first time’
- One stop models for a faster diagnostic pathway, particularly effective alongside hot reporting
- Clinical decision protocols that facilitate effective triage
- Networking (e.g. hub and spoke) to optimise use of existing resources and expertise, particularly useful for improving radiology reporting turnaround times and access to specialist investigations.

Workforce utilisation

- Workforce development for teams to support new ways of working across the whole pathway
- Co-location of medical, nursing, navigator and support staff to improve communication, aid business intelligence, reinforce team integration, and enable effective day-to-day working
- Patient navigators for administrative support and value in tracking patients for improved flow
The benefits

For patients:
- Empowerment from information about the diagnostic process provided at point of referral
- Reduced anxiety and uncertainty of a possible cancer diagnosis, with less time between referral and hearing the outcome of diagnostic tests
- Improved patient experience from fewer visits to the hospital, particularly with ‘one stop’ services
- Potential to avoid invasive investigations and biopsy-associated risks such as infection
- Potential for improved survival by using mpMRI for early detection of clinically significant cancers (and reduction in over-treatment of clinically insignificant cancers)

For clinicians:
- Using a nationally agreed and clinically endorsed pathway to support quality improvement and reconfiguration of prostate cancer diagnostic services
- Working across primary and secondary care to ensure high quality referrals into a streamlined service that gets the patient to the right place, first time
- Improved ability to meet increasing demand and ensure best utilisation of highly skilled workforce
- Training and development opportunities for radiographers, radiologists, and urologists in performing, reporting, and interpreting mpMRI

For systems:
- Reduce demand in outpatient clinics
- Improved performance against national standards (particularly 62 day performance and the new 28 day faster diagnosis standard)
- Improved quality, safety, and effectiveness of care with reduced variation and improvement in outcomes
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28 day pathway

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<th>Day 0 to 3</th>
<th>Day 3 to 14</th>
<th>Day 21</th>
<th>Day 28</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Urgent GP referral</strong> Including locally mandated information¹</td>
<td><strong>mpMRI before biopsy</strong></td>
<td><strong>Prostate biopsy (by day 9)</strong></td>
<td>sMDT⁵</td>
<td>Communication to patient on outcome (cancer confirmed or all-clear provided)</td>
</tr>
<tr>
<td><strong>Clinical triage</strong> Based on local protocol</td>
<td><strong>Further investigations</strong> If required for staging</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient information</strong> Provided in primary care</td>
<td><strong>Outpatient clinic</strong> Review mpMRI and plan investigations</td>
<td><strong>Outpatient clinic</strong> Review biopsy and plan further management</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Unsuitable for cancer pathway</strong> Men with UTI / positive MSU to be investigated off pathway</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>No suspicious lesions reported</strong> Some cases may be removed from pathway²</td>
<td><strong>Negative biopsy</strong> Imaging review meeting (radiology and urology)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Maximum target times provided

This is a straight to test pathway using mpMRI. The 21 day pathway should be used when an immediate MRI is not required or is contraindicated.

See footnotes on page 11
### Rapid diagnostic and assessment pathways

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#### System transformation

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| Timed pathways | 28 day | 21 Day | 14 day |

#### The case for change

- **The request**
- **The benefits**

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| 21 day pathway |

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<th>Day 21</th>
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</thead>
<tbody>
<tr>
<td>Urgent GP referral</td>
<td>Clinical triage</td>
<td>Outpatient clinic</td>
<td>Communication to patient on outcome</td>
</tr>
<tr>
<td>Including locally mandated information</td>
<td>Based on local protocol</td>
<td>Stratify risk (incl. PSAD) and plan investigations</td>
<td>(e.g. CT/ bone scan)</td>
</tr>
</tbody>
</table>

#### Unsuitable for cancer pathway

- Men with UTI / positive MSU to be investigated off pathway

#### Patient information

- Provided in primary care

#### Prostate biopsy

- If indicated

### Maximum target times provided

This pathway ensures diagnosis is reached within 28 days (in this case by day 21) for the subset of patients where MRI may not be required or is contraindicated:

- **Unsuitable for active treatment options in which local staging with mpMRI is not required**
- **Upper limit threshold for PSA may be agreed locally (e.g. PSA >30) to indicate likely metastatic disease at presentation**
- **Contraindications to MRI (dependent on local protocols)**

See footnotes on page 11
Pathway footnotes

28 day pathway
1. Locally mandated information is determined with commissioners but should include demographics, investigation results (PSA, U&E/ eGFR, urine dipstick (+ MSU result if dipstick positive), and DRE), performance status, weight and BMI, medication, anti-coagulant history, and MRI scanning exclusion criteria. A PSA of >3ng/ml should be used as referral rate for men aged 50-69. A rectal swab may also be required.
2. Likert or PIRADS 1/2 or Likert or PIRADS 3 with PSA density <0.15 or <0.12 depending on local clinical choice for threshold (currently in literature both are reported). Also consider risk factors (e.g. Family History). Dependent on local expertise in mpMRI reporting, mpMRI patients may be offered shared-decision making around biopsy or PSA observation.
3. Prostate biopsy: This could be transrectal, transperineal targeted (visual-estimation or image-fusion) depending on local expertise, protocols and availability of equipment. Transperineal template sectoral or mapping biopsies should only be used in select cases.
4. Consider re-biopsy, surveillance or discharge depending on mpMRI and histology findings. Likert or PIRADS 4/5 with no atrophy or inflammation might be a ‘miss’ so should consider re-biopsy/surveillance. Likert or PIRADS 1-3 can be discharged to GP with personalised PSA threshold for re-referral.
5. It is envisaged that when the new guidance on multidisciplinary team meetings is published in summer 2018, there will be a recommendation that some patients on clear and agreed cancer pathways may be discussed more briefly either at the beginning, or end, of the MDT.

21 day pathway
1. Locally mandated information is determined with commissioners but should include demographics, investigation results (PSA, U&E/ eGFR, urine dipstick (+ MSU result if dipstick positive), and DRE), performance status, weight and BMI, medication, anti-coagulant history, and MRI scanning exclusion criteria. A PSA of >3ng/ml should be used as referral rate for men aged 50-69. A rectal swab may also be required.
2. Prostate biopsy: This could be transrectal, transperineal targeted (visual-estimation or image-fusion) depending on local expertise, protocols and availability of equipment. Transperineal template sectoral or mapping biopsies should only be used in select cases.
3. It is envisaged that when the new guidance on multidisciplinary team meetings is published in summer 2018, there will be a recommendation that some patients on clear and agreed cancer pathways may be discussed more briefly either at the beginning, or end, of the MDT.
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#### Timed pathways

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**21 Day**

**14 day**

#### Additional information

- Audit tool
- Resources

### 14 day pathway

<table>
<thead>
<tr>
<th>Day 0</th>
<th>Day 0 to 1</th>
<th>Day 2 to 7</th>
<th>Day 14</th>
</tr>
</thead>
</table>
| **Urgent GP referral** Including locally mandated information | **Clinical triage** Based on local protocol | **One-stop diagnostics clinic (consultant led), including:**
  - mpMRI before biopsy
  - Targeted biopsy +/- systematic biopsies (if MRI clinically suspicious) | sMDT³ |

#### Communication to patient on outcome

(cancer confirmed or all-clear provided)

#### Unsuitable for cancer pathway

Men with UTI / positive MSU to be investigated off pathway

#### Patient information

Provided in primary care

#### No suspicious lesions reported

Some cases may be removed from pathway²

#### Maximum target times provided

1. Locally mandated information is determined with commissioners but should include demographics, investigation results (PSA, U&E/ eGFR, urine dipstick (+ MSU result if dipstick positive), and DRE), performance status, weight and BMI, medication, anti-coagulant history, and MRI scanning exclusion criteria. A PSA of >3ng/ml should be used as referral rate for men aged 50-69. A rectal swab may also be required.

2. Likert or PIRADS 1/2 or Likert or PIRADS 3 with PSA density <0.15 or <0.12 depending on local clinical choice for threshold (currently in literature both are reported). Also consider risk factors (e.g. Family History). Dependent on local expertise in mpMRI reporting, mpMRI patients may be offered shared-decision making around biopsy or PSA observation.

3. It is envisaged that when the new guidance on multidisciplinary team meetings is published in summer 2018, there will be a recommendation that some patients on clear and agreed cancer pathways may be discussed more briefly either at the beginning, or end, of the MDT.
### Audit tool

This tool can be used to undertake a baseline audit, identify areas for improvement, select measurements for improvement, and then conduct re-audits as part of continuous improvement.

<table>
<thead>
<tr>
<th>Day</th>
<th>Pathway step</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>GP Referral – develop local referral pathway with agreed minimum dataset to facilitate triage and mpMRI before clinic review (where appropriate)</td>
</tr>
<tr>
<td></td>
<td>Patient information resources developed – ensure patient engagement and empowerment</td>
</tr>
<tr>
<td>0-3</td>
<td>Clinical triage following GP referral – should be consultant supervised and delivered by appropriately trained clinician (e.g. CNS) – ensure local clinical decision protocols in place to facilitate this.</td>
</tr>
<tr>
<td>3-9</td>
<td>Straight to test mpMRI for appropriate patients - scanner optimisation, radiologist and radiographer training may be required, consider quality assurance (double reporting) and networking radiology to meet local capacity and demand requirements.</td>
</tr>
<tr>
<td></td>
<td>Clinic review with mpMRI result to determine if further investigation with biopsy is required</td>
</tr>
<tr>
<td></td>
<td>Prostate Biopsy after mpMRI (if appropriate) with additional targeting of suspicious lesions. Target of five day turnaround for reported pathology should be agreed as a minimum standard.</td>
</tr>
<tr>
<td>14</td>
<td>Outpatient clinic review for review of biopsy results and further investigative planning if required. Patients with negative biopsy may be removed off the pathway at this stage if imaging is low risk (see detail in pathway). Those with positive biopsy will need appropriate staging investigations and referral to sMDT.</td>
</tr>
<tr>
<td>21</td>
<td>sMDT for review and planning (It is envisaged that when the new guidance on multidisciplinary team meetings is published in summer 2018, there will be a recommendation that some patients on clear and agreed cancer pathways may be discussed more briefly either at the beginning, or end, of the MDT).</td>
</tr>
<tr>
<td>28</td>
<td>Cancer confirmed and treatment options discussed; if no cancer diagnosis or low risk of cancer not requiring biopsy after mpMRI, patient should be told as soon as possible and relevant follow up plans made.</td>
</tr>
</tbody>
</table>
Resources

Resources for implementation of mpMRI:
The PROMIS Trial validated the move to pre-biopsy mpMRI, demonstrating the potential to:
- Better identify clinically significant cancer
- Reduce the diagnosis of clinically insignificant cancer and resulting overtreatment
- Reduce the number of men who need immediate biopsies

- **Prostate Cancer UK Case Studies** highlight how different trusts across the country have implemented mpMRI before biopsy (including the challenges they faced and overcame)

- **Prostate Cancer UK ‘mpMRI before biopsy’ e-learning** is a preliminary course for radiology professionals providing an overview of the requirements for undertaking prostate MRI before biopsy (3 learning hours)

Other resources for prostate pathway redesign:
- **Implementation guide for the Cancer Vanguard (UCLCC) ‘one stop’ pathway**, with practical advice on service reconfiguration for faster pathways

- **Prostate Cancer UK full best practice pathway** (diagnostics, treatment and support)

NHS England Change Model:
- **The Change Model** is a framework for any project or programme seeking to achieve transformational, sustainable change (refreshed on 4 April 2018).

Resources from NHS Improvement:
- **The Improvement Hub** provides a number of useful resources that can support service improvement including guidance, modelling tools, and webinars.

- **The Rapid Improvement Guide: Sustainable Delivery of the 62 Day Cancer Standard** sets out how these resources can be used to reduce waiting times and improve performance against the 62 day standard, with a focus on three elements:
  - Reducing the time to first appointment
  - Reducing the number of pathway steps
  - Reducing the overall size of the patient tracking list (PTL)

Acknowledgements: This handbook was developed by the NHS Cancer Programme (with Mr Arun Takhar as Clinical Fellow) and builds on experience and expertise provided by the Clinical Expert Group for Prostate Cancer (with Prof Hashim Ahmed as Chair, Prof Freddie Hamdy as Vice Chair, and Prostate Cancer UK as secretariat), the National Cancer Vanguard (Prof Noel Clarke, Jacob Goodman, Mr John Hines, Netty Kinsella, Mr Satish Maddineni, Mrs Caroline Moore, Nicola Hunt, James Leighton, Prof Kathy Pritchard Jones, Liz Rippon, Mr David Shackley, and Dr Nicholas van As), and Prostate Cancer UK (Karen Stalbow).