Classification: Official

Publication approval reference: PAR1348



# Faster diagnostic pathways

# Implementing a timed prostate cancer diagnostic pathway

Guidance for local health and care systems

21 October 2022

# **Contents**

| Best practice timed diagnostic pathways | 2    |
|---|------|
| The Faster Diagnosis Standard           | 3    |
| The case for change                     | 4    |
| Actions for cancer alliances            | 6    |
| Benefits of pathway change              | 7    |
| 28-day best practice timed pathway      | 9    |
| 21-day best practice timed pathway      | . 10 |
| 14-day best practice timed pathway      | . 11 |
| Additional information                  | . 15 |

# Best practice timed diagnostic pathways

Best practice timed pathways support the on-going improvement effort to shorten diagnosis pathways, reduce variation, improve experience of care, and meet the Faster Diagnosis Standard (FDS). The guidance will support cancer alliances and constituent organisations to adopt consistent, system-wide approaches to managing this diagnosis pathway.

This guidance sets out how diagnosis within 28 days can be achieved for the suspected prostate cancer pathway. Alongside the pathway itself, resources are highlighted to support implementation of the pathways.

This prostate pathway is part of a series, published since April 2018. From previous pathways implemented by cancer alliances, implementation guidance was shared in June 2021, identifying areas that are key to success, such as setting up with clinical and operational engagement, auditing pathways, allocating project management resources, ensuring leadership, analysing data, and sharing successes.

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

The former National Cancer Vanguard was a leader in the development of these timed prostate cancer pathways. The Vanguard included Greater Manchester Cancer, Royal Marsden Partners, and the University College London Hospitals Cancer Collaborative. The '21-Day Pathway' outlined in this document has been drawn from pathway redesign within Royal Marsden Partners and at University College London Hospitals Cancer Collaborative.

The pathways in this document were shaped 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 included ensuring that advice on best practice cancer pathways was evidence-based and available for anyone involved in the improvement of cancer services, including cancer alliances, commissioners, clinicians, managers, and patients.

In line with available evidence and PI-RADS Committee Position, we are unable to currently endorse bi-parametric MRI before biopsy as national best practice. We will keep this decision under review as further studies are reported.

For any questions about this document please email england.cancerpolicy@nhs.net.

#### **Professor Peter Johnson**

National Clinical Director for Cancer NHS England

#### Professor Vijay K Sangar

Clinical Advisory Group NHS Cancer Programme

### The Faster Diagnosis Standard

We committed in the NHS Long Term Plan to provide a faster diagnosis for people through the introduction of the Faster Diagnosis Standard (FDS). This standard will ensure people are told they have cancer, or that cancer is excluded, within a maximum of 28 days from referral. The new standard is intended to:

- reduce the time between referral and diagnosis of cancer
- reduce anxiety for the cohort of people who will be diagnosed with cancer or receive an 'all clear'
- reduce unwarranted variation in England by understanding how long it is taking people to receive a diagnosis or 'all clear' for cancer
- represent a significant improvement on the current two-week wait to first appointment target, and a more person-centred performance standard.

FDS performance data, including a breakdown by suspected cancer pathway, has been published since June 2021, and faster, more streamlined pathways will be a priority.

As the key system-wide organisations for cancer services, cancer alliances will need to work across the local system to ensure that implementation is prioritised by senior stakeholders, clinical leaders, and operational colleagues, and that capacity is prioritised to enable the standard to be delivered.

The FDS has been formally performance managed since October 2021 activity, in line with cancer services recovery, with an initial threshold of 75%. Cancer alliances will need to ensure that they have plans to meet the threshold, which will need to be increased in subsequent years if we are to contribute to achieving the early diagnosis ambitions in the NHS Long Term Plan.

### The case for change

- Prostate cancer is the second most common diagnosed cancer in England.
- It is the most common cancer diagnosed in men.
- In 2019, only 42% of all prostate cancers were diagnosed at an early **stage**. This varied by CCG with a range of 23% to 66%.
- 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 and over 80% for stage 4); identifying high and intermediate risk cases is important.

### MpMRI before biopsy

- Conducting mpMRI before first prostate biopsy may improve the detection accuracy of clinically significant cancer (PROMIS trial).
- In 2015-16, only 51% of men underwent an mpMRI for suspected prostate cancer, of which 73% were performed before biopsy.
- Approximately 25% of patients with suspected prostate cancer had a nonsuspicious mpMRI and avoided the need for immediate biopsy (PROMIS), with approximately 45% avoiding the need for immediate biopsy in the RAPID programme. 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 significant prostate cancer without the need for an invasive procedure.

Figure 1: Prostate cancers diagnosed at stage 1 and 2, stage 3 and 4, and unknown, as a proportion of prostate cancers

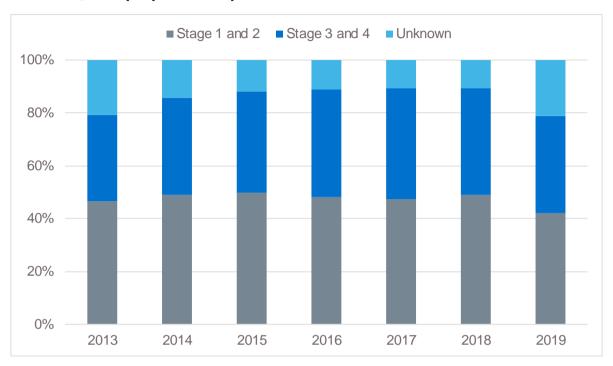
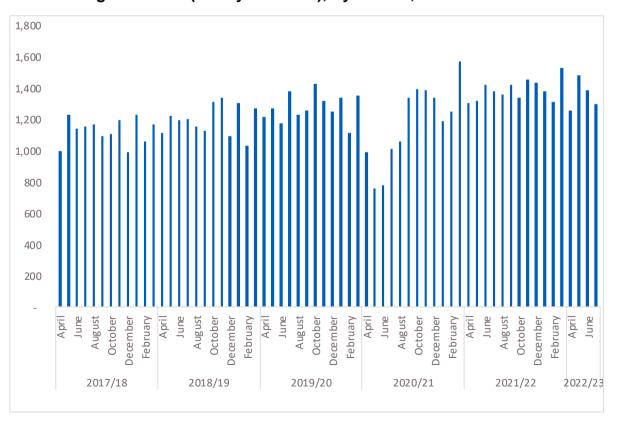


Figure 2: Prostate cancers referred for urgent suspected cancer and commencing treatment (62-day standard), by volume, 2016/17 to 2022/23



### Actions for cancer alliances

Cancer alliances, on behalf of integrated care systems (ICSs), are asked to:

- complete any outstanding work on the cancer recovery objectives
- ensure there is sufficient diagnostic and treatment capacity to meet recovering levels of demand, including increasing diagnostic activity to a minimum of 120% of pre-pandemic levels
- improve performance against all cancer standards
- make progress against the ambition in the NHS Long Term Plan to diagnose more people with cancer at an earlier stage, with a particular focus on disadvantaged areas where rates of early diagnosis are lower
- ensure at least 65% of urgent cancer referrals for suspected prostate, colorectal, lung, oesophago-gastric, gynaecology and head and neck cancer meet timed pathway milestones
- increase the recruitment and retention of clinical nurse specialists (CNSs), cancer support workers and pathway navigators, and promote take up of clinical training opportunities for the cancer workforce.

NHS England provides support, funding and guidance to help cancer alliances improve outcomes and reduce variation. The following support is available:

- Funding and programme management to support delivery to achieve the FDS and best practice timed pathway milestones.
- Implementation guidance for achieving pathways.
- Collaboration and networking events to share best practice.

"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 trials have shown that by using pre-biopsy multi-parametric MRI we are able to a) triage patients towards a biopsy so at least 25% can avoid it with recent data showing 45% can avoid a biopsy in the RAPID programme, b) diagnose over 90% of significant cancers and c) diagnose fewer insignificant cancers. 2017 was a watershed moment for those of us involved in looking after patients with

suspected prostate cancer. Many of us in the UK fully embraced that change over the last five years. I am confident that we will all continue to improve the pathway for the benefit of our patients and the NHS."

#### **Professor Hashim Ahmed**

Chair of Urology at Imperial College London

# Benefits of pathway change

#### For patients and unpaid carers

- Reduced anxiety and uncertainty of a possible cancer diagnosis, with less time between referral and receiving the outcome of diagnostic tests.
- Improved patient experience from fewer visits to the hospital, particularly to specialist centres if possible, and avoiding emergency admission.
- Potential for earlier recognition and initiation of pre-optimisation for treatment that could reduce complications and adverse outcomes.

#### For systems

- Reduced demand in outpatient clinics with increased straight to test provision and use of pathway navigators.
- Allow resources to be targeted at patients with cancer by removing noncancer patients earlier in the pathway.
- Improved quality, safety, and effectiveness of care with reduced variation and improvement in outcomes.

#### **Experience of care**

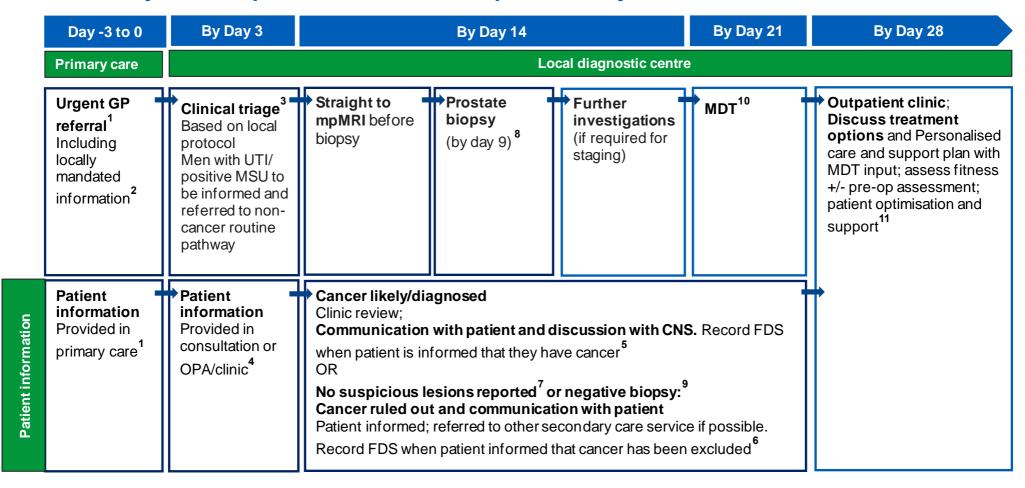
- Patients and carers know they are urgently referred for investigation of suspected cancer and should expect diagnosis within 28 days.
- Ensure that patients and carers' ability to attend appointments is taken into account and additional support is offered, where necessary.
- Patients are communicated with clearly, understand the information provided, and are given additional support, such as access to a CNS or navigator, psychological support, buddy system, where necessary.

#### For clinicians

- Using a nationally agreed and clinically endorsed pathway to support quality improvement and reconfiguration of prostate cancer diagnostic services.
- The use of predetermined diagnostic algorithms and standards of care to streamline clinical decision-making and reduce delays for multidisciplinary team (MDT) discussion.
- · Improved ability to meet increasing demand and ensure best utilisation of the highly skilled workforce.

### 28-day best practice timed pathway

This is a straight to test pathway using mpMRI.

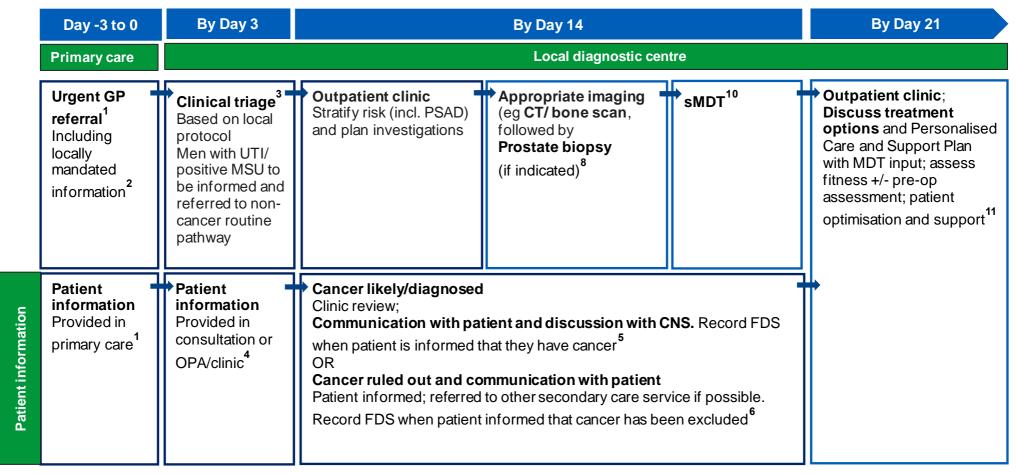


This is a straight to test pathway using mpMRI. The 21-day pathway should be used when an immediate MRI is not required or is contra-indicated.

See detailed information on pages 12 to 15

# 21-day best practice timed pathway

This pathway ensures diagnosis is reached by day 14 for the subset of patients where MRI may not be required or is contraindicated (this should be the exception)



This pathway ensures diagnosis is reached by day 14 for the subset of patients where MRI may not be required or is contraindicated (this should be the exception):

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

See detailed information on pages 12 to 15

# 14-day best practice timed pathway

This is a straight to one-stop clinic pathway using mpMRI.

|                    | Day -3 to 0   | By Day 3   | By Day 7  | By Day 14  |
|--------------------|---|--|---|--|
|                    | Primary care  |  |   |  |
|                    | Urgent GP referral <sup>1</sup> Including locally mandated information <sup>2</sup> | Clinical triage <sup>3</sup> Based on local protocol Men with UTI / positive MSU to be informed and referred to non-cancer routine | One-stop diagnostics clinic (consultant led)  MpMRI before biopsy, followed by  Targeted biopsy <sup>8</sup> +/- systematic biopsies if MRI clinically suspicious   | sMDT <sup>10</sup> ; Outpatient Clinic; Discuss treatment options and Personalised Care and Support Plan with MDT input; assess fitness +/- pre-op assessment; Patient |
| Patientinformation | Patient information Provided in primary care  | Patient information Provided in consultation or OPA / clinic   | Cancer likely / diagnosed Clinic review; Communication with patient and discussion with CNS. Record FDS when patient is informed that they have cancer 6 OR No suspicious lesions reported 7 or negative biopsy: Cancer ruled out and communication with patient Patient informed; referred to other secondary care service if possible. Record FDS when patient informed that cancer has been excluded 6 | optimisation and support <sup>11</sup>   |

See detailed information on pages 12 to 15

#### **Detailed information**

- 1. Urgent GP referral pathway should be used for patients who meet NG12 criteria for suspected cancer pathway referrals. The National Cancer Waiting Times Monitoring Dataset Guidance v11.0 sets out consultant upgrade rules, including from non-GP scenarios such as A&E and acute settings. cancer alliances may agree local arrangements to facilitate patient self-referral, community diagnostic centres and other referral routes, to access this pathway.
  - It is noted with the implementation of community diagnostic hubs that referral pathways may be subject to change. Primary care should inform the patient that they are being referred for an urgent suspected cancer pathway, although stating that vast majority of referrals result in non-cancer diagnoses. Primary care should also make the patient aware of their responsibilities to make themselves available for the first two weeks for full diagnostic testing.
- 2. A minimum dataset should be agreed locally with GPs, to accompany the referral and facilitate straight to clinic and diagnostic testing, which includes:
  - patient symptoms in line with NG12
  - patient demographics
  - anticoagulant status
  - WHO performance status
  - co-morbidity
  - weight and BMI
  - smoking status and alcohol intake

- prescribed medication (when autopopulated, if possible, in practice IT system)
- investigation results (PSA, U&E/eGFR, urine dipstick [+ MSU result if dipstick positive], and DRE)
- need for interpreter
- mental capacity to consent
- MRI scanning exclusion criteria.

A rectal swab may also be required. Capacity will need to be considered for completing missing dataset tests in the first OPA or clinic, following referral from primary care. A PSA of >3ng/ml should be used as referral rate for men aged 50-69.

3. Clinical triage, according to NICE Prostate Cancer Guidelines (NG131), can be done by a suitably experienced urologist physician or cancer CNS. If deemed medically fit, the appropriate first line investigations should be performed and reported within three days of triage so that this cohort can progress on the pathway in the same timeframes.

Patients should have same-day investigations to reduce repeat visits and improve patient experience. Telephone or video consultation could be used to determine suitability for straight to test and pre-assessment. Preparation for any tests can be communicated to patients at this stage. If a patient is medically unfit for straight to test, patient should be reviewed in clinic.

4. Patients and care-givers should be asked what information they require about the pathway, provided with standard leaflets about investigations when sending confirmation of appointment, confirmation of next step(s) and any patient needs required to prepare for the day (for example, can they eat and drink before), and whether they have any disabilities or language barriers.

Preferences for amount of information and when it is provided will vary, and therefore it will help to provide caseworker/navigator telephone contact details to provide support throughout the pathway and outside of clinic times, provide signposting to charities and support services, provide information about caregivers attending appointments, and offer follow-up if patients do not receive confirmation of appointment in expected timescale.

Where possible, continuity of caseworker/navigator should be provided to enable familiar contact and to build trust. Patients should also be informed that they may receive one or more procedures and/or diagnostic tests on the same day, at the first face-to-face appointment.

5. Patients should be informed about cancer being ruled out, or diagnosed at the earliest face-to-face opportunity, unless the patient has expressed an alternative preferred method of communication to speed up communication. In this timed pathway, this can be done at a testing clinic, a follow-up testing or results outpatient appointment. Early consideration of patient's fitness for radical therapy and requirements for pre-habilitation should be addressed as soon as possible in the pathway to minimise delays in expediting treatment.

All patients diagnosed with cancer should have a referral to relevant allied health professionals, including a specialist dietitian and speech and language therapist within seven calendar days of diagnosis, and where required, will also be involved during treatment planning. Local protocols and initiatives should be developed in collaboration with perioperative medicine, elderly care and specialist dietitians.

6. Where cancer is ruled out, and specific symptoms suggest further diagnostics are necessary, in some cases it would be appropriate to provide a MRI or CT before onward referral to a non-cancer routine pathway. When prostate cancer is ruled out, but other cancers are not ruled out it may be appropriate to refer the patient on to an alternative tumour site specific pathway, or a pathway where non-specific or vague symptoms can be considered.

Where cancer is excluded or confirmed, the FDS 'clock stop' can be completed at this point of communication with the patient. Cancer waiting time rules (including 'clock start', 'adjustments' and 'clock stop') are set out in the National Cancer Waiting Times Monitoring Dataset Guidance v11.0.

- 7. Where no suspicious lesions are reported the following cases can be downgraded from the urgent cancer pathway: 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 (eg family history). Dependent on local expertise in mpMRI reporting, mpMRI patients may be offered shared-decision making around biopsy or PSA observation.
- 8. Prostate biopsy: This could be transrectal, transperineal targeted (visualestimation 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.
- 9. Where negative biopsy, arrange imaging review meeting (with radiology and urology), and 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 rereferral.
- **10.** The core roles at the full MDT (to be carried out following cancer diagnosis) are lead clinician, radiologist, pathologist, oncologist, CNS and relevant AHP, to review investigation results with a pathway navigator. An oncologist with an interest in urological cancer and a radiologist with an established urology interest should be present at the full MDT. The capacity required to deliver these core roles should be reflected in job plans. National guidance on how to maximise effectiveness of MDT meetings is available.

Locally agreed, clear criteria for referral to sMDT can also support with efficient pathway management. It is unlikely that all necessary management decisions will be made at a single MDT. Some cancer patients require more than one MDT discussion before final diagnosis and treatment options are reached. This can consist of a diagnostic planning meeting or mini-MDT between radiologist, oncologist and referring surgeon and pathologist by day 21. Some cancers may only require one discussion.

MDTs could consider direct referral from pathologists and radiologists, ensuring that a robust process is implemented to ensure the patient's diagnosis is communicated before receiving any subsequent appointments.

11. Personalised care and support planning should be based upon the patient and clinician(s) completing a holistic needs assessment (HNA), usually soon after diagnosis. The HNA ensures conversations focus on what matters to the patient, considering wider health, wellbeing, practical issues and support in addition to clinical needs and fitness. This enables shared decision-making regarding treatment and care options.

### Additional information

### Audit tool

Can be used to undertake a baseline audit of services being delivered and whether sufficient capacity is in place to routinely deliver, identify areas for improvement, select measurements for improvement, and conduct re-audits as part of continuous improvement.

| Day | Pathway step   | Service<br>in<br>place? | Capacity in place? |
|-----|--|-------------------------|--------------------|
| 0   | GP referral – develop local referral pathway with agreed minimum dataset to facilitate triage and mpMRI before clinic review (where appropriate) |                         |                    |
|     | Patient information resources developed – ensure patient engagement and empowerment  |                         |                    |

| Day    | Pathway step   | Service<br>in<br>place? | Capacity in place? |
|--------|--|-------------------------|--------------------|
| 0 to 3 | Clinical triage following GP referral – should be consultant supervised and delivered by appropriately trained clinician (eg CNS) – ensure local clinical decision protocols in place to facilitate this.  |                         |                    |
| 3 to 9 | 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.  |                         |                    |
|        | Clinic review with mpMRI result to determine if further investigation with biopsy is required  |                         |                    |
|        | 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.   |                         |                    |
| 14     | 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. |                         |                    |
| 21     | <u>sMDT</u> for review and planning, with some patients on clear<br>and agreed cancer pathways being discussed more briefly<br>either at the beginning, or end.  |                         |                    |
| 28     | 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.   |                         |                    |

### Resources for implementation of mpMRI

- The PROMIS trial validated the move to pre-biopsy mpMRI, demonstrating the potential to:
  - allow better identification of clinically significant cancer
  - reduce the diagnosis of clinically insignificant cancer and resulting overtreatment

- Reduce the number of men who need immediate biopsies.
- The PRECISION Trial concluded that clinically significant cancer was detected in 38% of people in the MRI-targeted biopsy group, compared with 26% of people in the standard-biopsy group.
- The Cochrane review concluded that the benefits when MRI directly impacted on biopsy decision management, included a reduction in the number of biopsy procedures performed and the frequency of overdiagnosis of grade 1 prostate cancer, combined with an improvement in the detection of grade 2 and higher prostate cancer.
- 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 (three learning hours).

### Other resources for prostate pathway redesign

- Prostate Cancer UK full best practice pathway (three sections: diagnostics, treatment and support)
- Implementation guide for the Cancer Vanguard (UCLH CC) 'one stop' pathway, which provides practical advice on service reconfiguration to enable faster pathways.

#### **NHS England resources**

- The Change Model is a framework for any project or programme seeking to achieve transformational, sustainable change (refreshed on 4 April 2018).
- The Improvement Hub provides several useful resources that can support service improvement including guidance, modelling tools, and webinars.
- The Delivering Cancer Waiting Times A Good Practice Guide sets out good practices to achieve and sustain CWT performance.

#### Cancer alliance workspace

Cancer alliances access this workspace for national guidance, resources, and to share learning. Please use this space to upload materials you have developed

locally and that you think would be useful for colleagues implementing this pathway across the country.

### Acknowledgements

This guidance was developed by the NHS Cancer Programme (with Professor Vijay K. Sangar, Clinical Lead for the Clinical Advisory Group, NHS Cancer Programme and Peter Johnson as National Clinical Director. Mr Arun Takhar as former Clinical Fellow. NHS Cancer Programme and Professor Christopher Harrison as former National Clinical Director) 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).

NHS England Skipton House 80 London Road London SE1 6LH

Contact: enquiries@england.nhs.uk

This publication can be made available in a number of alternative formats on request.