NHS
North Central and East London Cancer Alliance

Guidelines for the Diagnosis of Prostate Cancer

Date Agreed: May 2018
Date Reviewed: June 2019
Date to be Reviewed: June 2020
v.2.0
June 2019

Bringing together hospital trusts, GPs, health service commissioners, local authorities and patients across north and east London to transform cancer care.

Recommendations for prostate cancer diagnostic pathways

These recommendations have been formulated and agreed by the North Central and East London (NCEL) Cancer Alliance Urology Pathway Board. They were first discussed in September 2014, revised in September 2015 and March 2018 and updated in June 2019 by the NCEL Prostate Biopsy Consensus Group, composed of radiologists and urologists representing all of the trusts within the NCEL Cancer Alliance.

The recommendations should be read in conjunction with the UK Prostate Cancer Diagnosis Consensus[1] meeting which is recognised as being the most up to date and NHS relevant prostate cancer guidelines for use in the NHS in England. The place of the 2019 NICE prostate cancer guidelines was also recognised by the group. The place of the START[2] guidelines for reporting MRI targeted biopsies was also recognised, along with the PRECISE guidelines for reporting MRI in active surveillance[3].

The National Prostate Cancer Diagnostic Timed Pathway

There has been a significant amount of work done to identify and agree a best practice pathway for timed referrals for diagnosis and treatment of prostate cancer across the NHS in England. The NCEL Cancer Alliance supported NHS England to establish the new national prostate diagnostic timed pathway in 2018. [4] These guidelines reflect this new agreed pathway.

The timed pathway takes into account the new additional 28 day faster diagnosis target which trusts will be performance managed against from April 2020. This will require trusts to inform patients of their diagnosis 28 days after GP referral.

[1] Consensus meeting: Kirkham, A P S, P Haslam, J Y Keanie, I McCafferty, A R Padhani, S Punwani, J Richenberg, and others. "Prostate MRI: Who, When, and How? Report From a UK Consensus Meeting." Clin Radiol (2013)doi:10.1016/j.crad.2013.03.030.

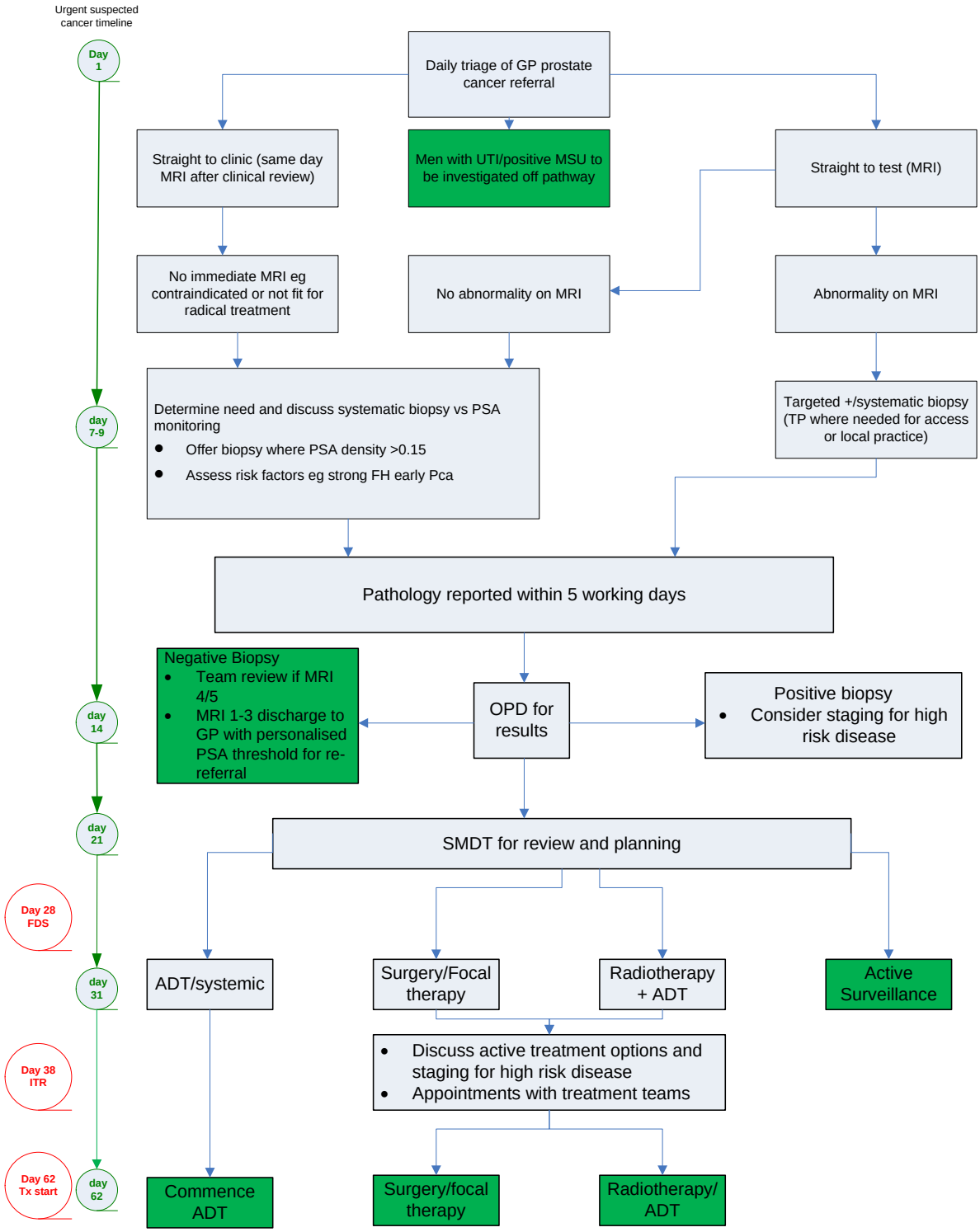
[2] Moore, Caroline M, Veeru Kasivisvanathan, Scott Eggener, Mark Emberton, Jurgen Fütterer, Inderbir S Gill, Robert Grubb, *and others.* "Standards of Reporting for MRI-targeted Biopsy Studies (START) of the Prostate: Recommendations From An International Working Group." *European urology* 64, no. 4 (2013): doi:10.1016/j.eururo.2013.03.030.

[3] Moore, Caroline M, Francesco Giganti, Peter Albertsen, Clare Allen, Chris Bangma, Alberto Briganti, Peter Carroll, *and others.* "Reporting Magnetic Resonance Imaging in Men on Active Surveillance for Prostate Cancer: The PRECISE Recommendations-A Report of a European School of Oncology Task Force." *European urology* (2016)doi:10.1016/j.eururo.2016.06.011.

[4] https://www.england.nhs.uk/wp-content/uploads/2018/04/implementing-timed-prostate-cancer-diagnostic-pathway.pdf

NCEL Prostate Timed Pathway 2018

North Central and East London Cancer Alliance



Specific clarification of each of these guidelines for use across the NCEL Cancer Alliance was discussed and is outlined below:

1. Appropriate patient selection for MRI prior to biopsy

The 2019 NICE guidelines state that trusts should:
Offer multiparametric (mp) MRI as the first-line investigation for people with suspected clinically localised prostate cancer, reporting the results using a 5-point Likert scale.

However, patients who are not going to be able to have radical treatment should not routinely be offered a multiparametric MRI. **(June 2019)**

In light of this NCEL Cancer Alliance has been working towards an mpMRI prior to biopsy for all men except those with proven or suspected metastatic disease on the basis of a positive bone scan or PSA greater than 100 since 2014.

The NCEL Prostate Biopsy Consensus Group support this and agreed that prostate mpMRI scans should be 'hot reported' meaning the report should be available on the same day of the scan. **(June 2019)**

2. Conduct of the MRI scan

a. MRI requirements

It was agreed that a 1.5 T scanner is acceptable for a diagnostic MRI scan providing that it uses a PIRADS v2.1 compliant protocol that has been optimised through the NCEL Cancer Alliance MRI optimisation project. It was also agreed that when a new scanner would be purchased at a Trust that prostate radiologists would share optimised scans on identical machines.

b. Use of dynamic contrast enhancement (DCE)

There is variation across the cancer alliance where not all centres use dynamic contrast enhancement (DCE). NCEL Cancer Alliance is in agreement with the UK consensus stating that DCE is required for an optimal MRI scan. This position has been confirmed by the latest UK Consensus statement on Prostate Cancer diagnosis (2018).

3. Reporting of the MRI scan

a. MRI report must be available for biopsy

For those men that have had an MRI prior to biopsy the result must be available to the person performing the biopsy.

b. It was agreed that a radiologist with a special interest in prostate MRI would report over 50 scans a year and that these radiologists with a special interest would either attend the MDT and/or participate in audit.

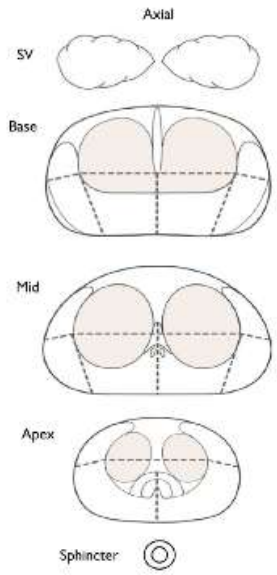
d. Reporting of likelihood of clinical significant cancer

It was agreed that a Likert scale (1-5) would be used to give a likelihood of clinically significant cancer for any lesion and the prostate overall.

e. Anatomical reporting

It was agreed that this could be in the form of an annotation of the images directly onto PACs or hand drawn diagram scanned to the clinical or radiological reporting system OR a colour coded computer generated report showing location of lesions and level of suspicion. It was agreed that the diagram would be the one used by the UK radiologist consensus paper (as below) rather than the European radiologist version (where sectors are annotated with a number and a letter).

Focal lesions should be numbered from most significant up to 4 lesions with diffuse signal change extent and sector involvement



f. Prostate volume on MRI report

It was agreed that prostate volume, according to the formula (length x width x height x .52) would be included on the MRI report to allow calculation of PSA density.

g. Double reporting of MRI scans

The NCEL Prostate Biopsy Consensus Group agreed that it would be beneficial to double report any negative MRI scans. It is recognised that from 2020 Prostate MRI scans will have to be reported by an accredited radiologist and that this may require further collaboration across the network to provide cross trust MRI reporting. Double reporting can either be done in house or from external support via a cloud based solution. **(June 2019)**

4. Conduct and pathological reporting of MRI-targeted biopsies

It was agreed that NCEL Cancer Alliance support the use of the START guidelines for men having standard and targeted biopsies.

A) Standard and targeted cores will be potted and reported separately.
B) A Gleason grade and maximum cancer core length will be recorded for each

5. Biopsy Approach

The NCEL Prostate Biopsy Consensus Group agreed that prostate biopsies can be performed by anyone who has an interest with the relevant training. This includes urologists, radiologists and nurses. Prostate biopsy services should be led by a permanent member of staff, not relying on rotating staff with institutional support available to manage any complications. **(June 2019)**

The 2019 NICE guidelines state that trusts should consider omitting a prostate biopsy for people whose mpMRI LIKERT score is 1 or 2, but only after discussing the risks and benefits with the person. A table outlining the factors to consider when discussing this is outlined in the NICE guidelines **(June 2019)**

The NCEL Prostate Biopsy Consensus Group agreed that the network should adhere to the 2019 NICE guidelines[5] and perform prostate biopsies as follows:

- mpMRI LIKERT 1 or 2 where there is an assurance of diagnostic quality is consider omitting prostate biopsy but only after discussing the risks and benefits with the person. A table outlining the factors to consider when discussing this is outlined in the NICE guidelines **(June 2019)**

- mpMRI LIKERT 3 – Where appropriate, perform biopsy unless reason to defer patient. **(June 2019)**

- mpMRI LIKERT 4 or 5 – Where appropriate, biopsies should be undertaken in cases where the MRI is scored as LIKERT 4/5 and biopsies should be taken from all areas scored LIKERT 3, 4 and 5. **(June 2019)**

Where biopsies are performed it is recommended that:

There is an advantage to using a transperineal approach rather than a transrectal approach to reduce infection rates from 2-4% to 1 in 200. However, this can have significant resource implications, which vary from Trust to Trust. The NCEL Prostate Biopsy Consensus Group agreed that both transrectal and transperineal approaches can be used and that risk factors,

[5] https://www.nice.org.uk/guidance/ng131/chapter/Recommendations

geography of lesion and trust resources should be taken into account when deciding. It is acknowledged that transperineal biopsies will be used more frequently in the future. Each trust should have an antibiotics policy to reduce the sepsis rate.

A minimum of two cores should be taken when performing a targeted biopsy. More cores may need to be taken for smaller lesions or those in more difficult to access areas such as the apex or anterior gland.

When performing a systematic transrectal biopsy 10-12 cores should be taken, a systematic transperineal biopsy should be a maximum of 24 cores for a larger prostate consider omitting the mid zones. The model of template used should be clearly outlined as well as the position of each core taken. **(June 2019)**

If the mpMRI is of high quality systematic sampling may be avoided if the MRI is score LIKERT 4/5 and discrete LIKERT 3. If MRI quality is compromised then systematic sampling is recommended. **(June 2019)**

6. Discussion about order of prostate cancer assessment

The NCEL Prostate Biopsy Consensus Group agreed that prostate biopsies should take place following an mpMRI where appropriate. These scans should be 'hot reported' allowing for trusts to establish one-stop diagnostic services. The radiologist who reports the scan should be available for further consultation if required before the biopsy and this should be included in their job plan. **(June 2019)**

It is recognised that a diagnostic one-stop setting may not be suitable for all patients such as men who require a second MRI report. In this case patients should be provided with a date for their prostate biopsy before leaving their appointment. **(June 2019)**

Adequate patient information should be provided to patients before their one-stop appointment so that they are aware of the commitment on the day and that well informed consent can be given. This has been proven to reduce cancellations. **(June 2019)**

A formal local stage of the disease should be made following MRI and prostate biopsy at the MDT meeting. **(June 2019)**

Men not suitable for an MRI scan

Men in whom an MRI scan is contra-indicated should be offered an alternative diagnostic strategy. This could be a PSMA-PET scan or a standard biopsy, as described above.

7. Follow up for men without a prostate cancer diagnosis

A) Men who have not had a biopsy due to a low risk MRI and men who have a negative biopsy with an equivocal or negative MRI:

a. Men can be discharged to primary care with a personalised PSA threshold set for re-referral to secondary care.
b. The PSA threshold should be determined by a urology practitioner and will be informed by the current PSA density (with PSAD if 0.15 considered a risk factor for clinically significant prostate cancer), and other risk factors.
c. Men who have been discharged following an MRI without a biopsy should have had their MRI double reported. **(June 2019)**
d. Men who have an MRI scored LIKERT 3 and do not have a biopsy consider follow up in secondary care or discharge back to GP with personal PSA threshold. **(June 2019)**
e. Men should be clearly counselled about their PSA threshold and to be provided with a timetable to when they should get their PSA tested.**(June 2019)**

B) Men who have a negative biopsy with an MRI lesion of 4 or 5
   a. The case should be discussed at a joint meeting of urologists and radiologists
   b. If the radiology score of 4 or 5 is unchanged, and there is no atrophy or inflammation on biopsy which would contribute to a suspicious MRI then re-biopsy or close follow up can be considered
   c. If (eg in the case of a small lesion) follow up without immediate biopsy is considered, then the MRI should be repeated at 12 months.

8. Clinical Audit

Trust should keep a rolling audit of their prostate diagnostic service and present this once every six months at specific cancer alliance audit meetings.

The rolling audit should include:

- Number of patients referred to the trust
- PSA
- Demographics
- % of patients referred who have an MRI
- % of patients who are given a LIKERT score of 1/2, 3 and 4/5 with histological correlation when available
- % of MRI scans scored LIKERT 1/2 that were double reported
- **%** if patients who do not have a biopsy **(June 2019)**