National Cancer Control Programme

HSE National Clinical Guideline

Active surveillance for patients with prostate cancer

DRAFT FOR CONSULTATION

HSE National Clinical Guideline:
Active surveillance for patients with prostate cancer
National Policy ☐ National Procedure ☐ National Protocol ☐ National Guideline ☐
National Clinical Guideline ☒

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Evidence-based recommendations on the active surveillance of patients with prostate cancer
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The purpose of this National Clinical Guideline is to provide evidence based recommendations on the active surveillance of patients with prostate cancer through the integration of the best research evidence with clinical expertise, patient values and experiences.

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Disclaimer

This guideline ("the Guideline") was developed by a multidisciplinary Guideline Development Group ("the Group") and is based upon the best clinical evidence available together with the clinical expertise of the Group members. The Guideline supersedes all previous Health Service Executive (HSE), National Cancer Control Programme (NCCP), and National Clinical Effectiveness Committee (NCEC) guidelines on active surveillance for patients with prostate cancer. The NCCP is part of the HSE and any reference in this disclaimer to the NCCP is intended to include the HSE. Please note, the Guideline is for guidance purposes only. The appropriate application and correct use of the Guideline is the responsibility of each health professional. The Group's expectation is that health professionals will use clinical knowledge and judgment in applying the principles and recommendations contained in this guideline. These recommendations may not be appropriate in all circumstances and it may be necessary to deviate from this guideline. Clinical judgment in such a decision must be clearly documented. Care options should be discussed with the patient, his/her significant other(s), and the multidisciplinary team on a case-by-case basis as necessary. The NCCP accepts no liability nor shall it be liable, whether arising directly or indirectly, to the user or any other third party for any claims, loss or damage resulting from any use of the Guideline.

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1 Background

1.1 Purpose

The purpose of this National Clinical Guideline is to provide evidence based recommendations on the active surveillance of patients with prostate cancer through the integration of the best research evidence with clinical expertise, patient values and experiences. This guideline aims to address areas of care with new and emerging evidence, reduce variation in practice, and improve patient experience and service delivery.

This guideline supersedes the recommendations of the 'Active Surveillance' section within the Department of Health (2015) Diagnosis, staging and treatment of patients with prostate cancer (NCEC National Clinical Guideline No. 8).

1.2 Mandate

The National Cancer Strategy 2017-2026 (Department of Health, 2017) recommendation 37 states that: "The NCCP will develop further guidelines for cancer care in line with National Clinical Effectiveness Committee (NCEC) standards".

1.3 Scope

The scope of the guideline is to provide clinical recommendations on the active surveillance of patients with prostate cancer.

1.4 Target audience

This guideline is intended for all health professionals involved in the diagnosis, staging and treatment of patients with prostate cancer. While the CEO, General Manager and the Clinical Director of the hospital have corporate responsibility for the implementation of the recommendations in this Clinical Guideline, each member of the multidisciplinary team is responsible for the implementation of the individual guideline recommendations relevant to their discipline.

Whilst the guideline is focused on clinical care, it is expected to be of interest to patients with prostate cancer and their significant others. An accompanying Plain Language Summary of this guideline is available in Appendix V Plain Language Summary.

1.5 Target population

Patients that are covered by this guideline are:

- Adults (18 years or older) with newly diagnosed prostate cancer.
- Adults that have a diagnosis of prostate cancer currently enrolled on active surveillance.

2 Clinical Questions and Recommendations

2.1 Summary of Recommendations

Recommendation 2.2.1

For men with prostate cancer being considered for active surveillance a confirmatory biopsy is not routinely recommended*. All men must have undergone pre biopsy MRI followed by systematic and targeted biopsies prior to consideration for enrolment, this negates the need for a confirmatory biopsy.

*The National Clinical Guideline: Diagnosis and staging of patients with prostate cancer recommends that patients with suspected prostate cancer referred from a urologist have a multiparametric MRI pre prostate biopsy (Recommendation 3.1.1) (NCCP, 2022).

Quality of Evidence: Moderate **Grade of recommendation: Strong**

Recommendation 2.2.2

For patients who meet the following eligibility criteria and a life expectancy of >10 years, active surveillance is recommended:

- Any Gleason score 3+3 (Grade Group 1) or Gleason score 3+4 (Grade Group 2) with < 10% pattern 4 and absence of intraductal or cribriform pattern
- PSA < 20 µg/L
- ≤ cT2

Quality of Evidence: Moderate **Grade of recommendation: Strong**

Recommendation 2.2.3

In men with intermediate risk prostate cancer, active surveillance should be considered if clinically and pathologically favourable. This includes patients with < 10% pattern 4 and PSA < 20 µg/L and ≤ cT2a and absence of cribriform pattern or intraductal histology on biopsy.

Quality of Evidence: Low **Grade of recommendation: Weak**

Recommendation 2.3.1

All patients with prostate cancer being considered for active surveillance should be risk stratified and followed up using the most recent three-tier STRATified CANcer Surveillance (STRATCANS) strategy.

Quality of Evidence: Moderate **Grade of recommendation: Weak**

Recommendation 2.4.1

If a patient progresses beyond the eligibility criteria* for active surveillance, and has > 10 years life expectancy, then active treatment is recommended.

*Eligibility criteria:

- Low risk prostate cancer or intermediate risk prostate cancer with the following:
  - < 10% pattern 4 and absence of cribriform pattern or intraductal histology on biopsy
  - PSA < 20 µg/L
  - ≤cT2

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.4.2

A shared decision-making approach should be undertaken with the patient before moving to active treatment. Discussion should include:

- Patient preferences
- Life expectancy
- Comorbidities

Quality of Evidence: Low **Grade of recommendation: Strong**

Good practice points

- The following should be considered when recommending active surveillance to a patient:
  - Has the patient had a targeted biopsy
  - % positive cores
  - % pattern 4
  - Pattern 4 subtypes
  - PSA density
- In patients undergoing MRI targeted biopsy, there is an increased likelihood of increased positive cores and percentage cancer involvement within the core. Therefore these criteria should not be used alone to exclude patients from active surveillance.
- Repeat biopsy may be considered for patients where there is an increased risk of disease progression requiring intervention, for example, discordance between the MRI and biopsy findings, high PSA density.
- DRE is not recommended as a routine part of protocol during active surveillance for men with prostate cancer, especially if standard imaging procedures, such as transrectal ultrasound or multiparametric MRI (mpMRI), are being performed during active surveillance. DRE may be performed for purposes other than assessing the course of a disease (such as prostatitis).
- MRI imaging must be performed in accordance with the latest version of the PI-RADS technical guidelines. MRIs must be read by in-house radiologists

experienced in reading prostate MRIs who regularly attend the prostate multidisciplinary meeting.

- All prostate MRI reports must record prostate volume as defined by the latest version of PI-RADS.
- PSA density must be included in MRI reports if PSA is provided.
- MRI should be performed if PSA is rising (PSA-doubling time < 3 years).
- Patients with MRI PI-RADS 4 or 5 lesions should be reviewed at a multidisciplinary meeting.
- Progression on MRI should be evaluated by using the latest version of PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation).
- A change in MRI findings based on PRECISE criteria triggers a biopsy.
- Patients with discordant imaging and pathology findings should be discussed at a prostate tumour conference.
- Progression on MRI should be evaluated by using the latest version of PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation).
- When reviewing active surveillance MRIs, all previous MRIs should be available and they should be read by a radiologist who is experienced at prostate cancer MRI and attends the prostate tumour conference.
- In patients with a life expectancy of <10 years, consideration should be given to moving from active surveillance to a watch and wait approach.

Practical considerations for patient care

- All patients offered active surveillance should have access to a Clinical Nurse Specialist or Advanced Nurse Practitioner to discuss the benefits and harms and support shared-decision making. Some of the topics for discussion include:
  - Erectile dysfunction/sexual function
  - Urinary incontinence
  - Quality of life
- All patients offered active surveillance should receive written information detailing what is involved in the active surveillance protocol and details of their triggers of possible cancer progression.

2.2 Clinical question: In patients with a histological diagnosis of prostate cancer, what are the inclusion criteria for being offered active surveillance?

Evidence summary

Two controlled trials (Hamdy et al., 2023, Klotz et al., 2015), one meta-analysis (Baboudjian et al., 2022), a clinical guideline (EAU, 2024) and a consensus review statement (Lam et al., 2019) addressed this clinical question. The quality of the evidence to address the question is moderate. Studies include long-term follow up of 15 to 16 years, large patient numbers and endpoints of disease specific survival and overall survival. However, these studies were designed at a time before routine use of pre biopsy MRI which identifies lesions prior to biopsy.

Low risk disease

Evidence suggests that treating men with low risk prostate cancer does not offer any survival advantage. In a 15-year follow-up of the ProtecT trial, where 66% (n = 973) had low risk prostate cancer, disease specific survival was similar for patients in the active monitoring group, the prostatectomy group and the radiotherapy group at 10 and 15 years (Hamdy et al., 2023). Death from any cause occurred in 356 men (21.7%), with similar numbers in all three groups. Of the 104 men (6.3%) in whom metastases were diagnosed, 51 (9.4%) were in the active-monitoring group, 26 (4.7%) in the prostatectomy group, and 27 (5.0%) in the radiotherapy group. Although metastatic disease was higher in the active-monitoring group, it is important to note that these patients were not on a formal active surveillance programme, instead monitoring was based almost entirely on PSA. In the active-monitoring group, 133 men (24.4%) were alive without any prostate cancer treatment at the end of follow-up.

In a follow up of a large active surveillance cohort of patients with low risk and favourable intermediate risk prostate cancer the 10- and 15-year actuarial disease specific survival rates were 98%, and 94%, respectively while the 10- and 15-year overall survival rates were 80% and 62%, respectively (Klotz et al., 2015). Metastatic disease developed in 2.8% (n = 28) of the entire cohort. At 5, 10, and 15 years, 75.7%, 63.5%, and 55.0% of patients remained untreated and on surveillance.

Intermediate risk disease

In the ProtecT trial, where 34% (n = 505) of the randomised patients had intermediate or high-risk disease, there was no statistically significant difference in disease specific survival at 10 or 15 years between monitoring and treatment groups. Similarly, in the study by Klotz et al. 21% of patients were intermediate risk, disease specific survival and overall survival rates were high (Klotz et al., 2015).

In a meta-analysis evaluating the outcomes of active surveillance among patients with intermediate risk prostate cancer, the 10 year treatment-free, metastasis-free, cancer-specific, and overall survival ranged from 19.4% to 69%, 80.8% to 99%, 88.2% to 99%, and 59.4% to 83.9%, respectively (Baboudjian et al., 2022). Intermediate risk patients had similar treatment-free survival to low risk patients (risk ratio [RR] 1.16, 95% confidence interval (CI), 0.99–1.36, p = 0.07), but significantly higher risks of metastasis (RR 5.79, 95% CI, 4.61–7.29, p < 0.001), death from prostate cancer (RR 3.93, 95% CI, 2.93–5.27, p < 0.001), and all-cause death (RR 1.44, 95% CI, 1.11–1.86, p = 0.005). In a subgroup analysis of studies including patients with Gleason Grade ≤2 only (n = 4 studies), treatment-free survival and metastasis-free survival were similar between low risk and intermediate risk patients (Baboudjian et al., 2022).

When using an MRI targeted biopsy of focal lesions, the number of positive cores and the percentage of cancer core involvement identified is higher than compared to using a systematic biopsy alone. The type of biopsy should be taken into consideration when assessing the number of positive cores and percentage of cancer core involvement for active surveillance inclusion criteria.

The EAU prostate cancer guidelines state that in men eligible for active surveillance based upon systematic biopsy findings alone who did not have a pre-biopsy MRI, a re-biopsy within 6–12 months (usually referred to as ‘confirmatory biopsy’) seems mandatory to exclude sampling error (EAU, 2024). However, the DETECTIVE research indicates that men who are eligible for active surveillance after a combined systematic-and MRI-targeted biopsy do not require a confirmation biopsy (Lam et al., 2019). Furthermore, all members of the DETECTIVE consensus conference concurred that a change in PSA should require repeat-MRI and repeat-biopsy and that any abnormalities found on a subsequent MRI required a confirmed biopsy before starting active treatment (Lam et al., 2019).

Benefits and Harms

The benefits of long term active surveillance and deferring treatment include the avoidance of adverse effects caused by treatments such as radiation and surgery (erectile dysfunction, urinary incontinence etc.) without impacting overall suvival. At 5, 10, and 15 years, the Klotz et al. 2015 trial found 75.7%, 63.5%, and 55.0% of patients remained untreated and on surveillance.

The harms of long term active surveillance or deferring treatment include missing occult grade 4 prostate cancer or the low risk of developing metastatic disease (Klotz et al., 2015, Hamdy et al., 2023). It may also cause some anxiety for patients, their families and loved ones.

Preferences and values

The multidisciplinary Guideline Development Group including patient representatives recognise knowledge as an important patient and family value.

The Guideline Development Group believe that patients who understand the benefits and harms of deferred treatment and long term active surveillance will have the knowledge to make an informed decision about their care. It is important that the benefits and harms of active surveillance are communicated to the patient and the patient takes the time for reflection after conversation with the healthcare professional. This means that the values of disclosure and understanding are embedded into patient/clinical communication.

The Guideline Development Group also recognise the role of family preferences and values. It is important that family members are informed and understand the benefits and harms of active surveillance. This can help reduce some of the anxiety family members may experience.

Empowering patients in their treatment decisions leads to greater involvement and adherence to the active surveillance programme. Patients are required to have confidence to communicate with their health care professionals and take on the responsibility of the active surveillance programme.

Resources, capacity, equity and other considerations

No relevant cost-effectiveness literature was identified to address this clinical question.

The following resources, capacity and other considerations were discussed by the Guideline Development Group:

Availability of prostate cancer nurses

Services such as Patient Support Workers are in place however additional nursing capacity including Advanced Nurse Practitioners and Clinical Nurse Specialists, may also be required. All patients being offered active surveillance should have access to an Advanced Nurse Practitioner or Clinical Nurse Specialist to discuss the benefits and harms of long term active surveillance and deferred treatment. Prostate cancer nurses play an important role in providing support to the patient.

Multidisciplinary team capacity

Additional capacity will be required at prostate tumour conferences to review each active surveillance patient.

Other considerations

Equity and acceptability

Enrollment in active surveillance is dependent on diagnostic criteria, including MRI results. If an MRI is not available pre biopsy this can lead to an inequity in access to active surveillance for patients.

Recommendation 2.2.1

For men with prostate cancer being considered for active surveillance a confirmatory biopsy is not routinely recommended*. All men must have undergone pre biopsy MRI followed by systematic and targeted biopsies prior to consideration for enrolment, this negates the need for a confirmatory biopsy.

*The National Clinical Guideline: Diagnosis and staging of patients with prostate cancer recommends that patients with suspected prostate cancer referred from a urologist have a multiparametric MRI pre prostate biopsy (Recommendation 3.1.1) (NCCP, 2022).

Quality of Evidence: Moderate **Grade of recommendation: Strong**

Recommendation 2.2.2

For patients who meet the following eligibility criteria and a life expectancy of >10 years, active surveillance is recommended:

- Any Gleason score 3+3 (Grade Group 1) or Gleason score 3+4 (Grade Group 2) with < 10% pattern 4 and absence of intraductal or cribriform pattern
- PSA < 20 µg/L
- ≤ cT2

Quality of Evidence: Moderate **Grade of recommendation: Strong**

Recommendation 2.2.3

In men with intermediate risk prostate cancer, active surveillance should be considered if clinically and pathologically favourable. This includes patients with < 10% pattern 4 and PSA < 20 µg/L and ≤ cT2a and absence of cribriform pattern or intraductal histology on biopsy.

Quality of Evidence: Low **Grade of recommendation: Weak**

Good practice points

- The following should be considered when recommending active surveillance to a patient:
  - Has the patient had a targeted biopsy
  - % positive cores
  - % pattern 4
  - Pattern 4 subtypes
  - PSA density
- In patients undergoing MRI targeted biopsy, there is an increased likelihood of increased positive cores and percentage cancer involvement within the core. Therefore these criteria should not be used alone to exclude patients from active surveillance.
- Repeat biopsy may be considered for patients where there is an increased risk of disease progression requiring intervention, for example, discordance between the MRI and biopsy findings, high PSA density.

Practical considerations for patient care

- All patients offered active surveillance should have access to a Clinical Nurse Specialist or Advanced Nurse Practitioner to discuss the benefits and harms and support shared-decision making. Some of the topics for discussion include:
  - Erectile dysfunction/sexual function
  - Urinary incontinence
  - Quality of life
- All patients offered active surveillance should receive written information detailing what is involved in the active surveillance protocol and details of their triggers of possible cancer progression.

2.3 Clinical question: In patients with prostate cancer on active surveillance, what diagnostic tests and at what frequency should they be performed to detect disease progression?

Evidence summary

One meta-analysis (Rajwa et al., 2021), one prospective study (Thankapannair et al., 2023), one retrospective cohort study (Lonergan et al., 2020), two consensus review statements (Moore et al., 2023, Lam et al., 2019) and two clinical guidelines (National Institute for Health and Care Excellence (NICE), 2019, European Association of Urology (EAU), 2024) addressed this clinical question.

While there is only low level evidence to answer this question there is international adoption of this approach, good generalisability and further follow up is emerging, therefore the overall quality of the evidence was deemed moderate. Findings are consistent, particularly in recommending the main diagnostic tests for patients on active surveillance. There is some variation in the frequency of these tests and specific criteria for progression. The studies mostly focus on patients with low- to intermediate-risk prostate cancer and patients undergoing active surveillance in the era of MRI, which aligns well with the target population for this guideline.

Risk stratification

Currently international guidelines recommend identical active surveillance follow-up schedules for all patients with prostate cancer without considering different disease progression (NICE, 2019, EAU, 2024). Most recently a single centre prospective study has reported on the implementation of the three-tier STRATified CANcer Surveillance (STRATCANS) follow-up strategy (Thankapannair et al., 2023). This strategy has used NICE: Cambridge Prognostic Group (CPG) 1 or 2 (Table 1), prostate-specific antigen (PSA) density (PSAd), and MRI PI-RADS score at entry, to identify patients at three different risks of disease progression. This tiered system has tailored the intensity of follow-up (Table 1) (Thankapannair et al., 2023).

Thankapannair and colleagues found that men in the highest-intensity follow-up (STRATCANS 3) had the greatest risk of any pathological progression or progression to CPG ≥3 (6/27, 22.2% and 2/27, 7.4%, respectively). In contrast, men in the lowest follow-up tier (STRATCANS 1) had the least likelihood of progression, with over 95% remaining on active surveillance or converting to watchful waiting. It should be noted that this study is single centre, had a short follow-up period and a relatively small cohort that included patients already on active surveillance therefore representing a particularly good performing group who had not progressed before entering into STRATCANS (Thankapannair et al., 2023).

The Guideline Development Group agree that there is a paucity of high quality evidence on risk stratification for patients with prostate cancer being considered for active surveillance. Therefore the consensus of the Guideline Development Group is to recommend the most current three-tier STRATCANS stratification and follow up strategy.

Table 1 STRATCANS risk-stratified follow-up schedule and intervals of outpatient appointments, PSA testing, MRI scans, and recommendations for biopsy

STRATCANS Tier	Inclusion Criteria (STRATCANS)	Cambridge Prognostic Group risk stratification	Follow-up schedule
1	Cambridge Prognostic Group 1 and PSAd <0.15	Cambridge Prognostic Group 1: Gleason score 6 (grade group 1) **and** PSA less than 10 µg/L **and** Stages T1–T2	3-6 monthly PSA 18 monthly virtual outpatients MRI PI-RADS 1–2—repeat at 3 yr MRI PI-RADS 3—repeat at 18 mo MRI PI-RADS 4–5—repeat at 12 mo No routine rebiopsy Triggered rebiopsy if any change
2	Cambridge Prognostic Group 2 or PSAd >0.15	Cambridge Prognostic Group 2: Gleason score 3 + 4 = 7 (grade group 2) or PSA 10 µg/L to 20 µg/L **and** Stages T1–T2	3-6 monthly PSA 12 monthly virtual outpatients MRI PI-RADS 1–2—repeat at 3 yr MRI PI-RADS 3—repeat at 18 mo MRI PI-RADS 4–5—repeat at 12 mo Rebiopsy at 3 yr[a]

			Triggered rebiopsies if any change
3	Cambridge Prognostic Group 2 and PSAd >0.15	Cambridge Prognostic Group 2: Gleason score 3 + 4 = 7 (grade group 2) or PSA 10 µg/L to 20 µg/L **and** Stages T1–T2	3-6 monthly PSA 6 monthly virtual outpatients MRI (any PI-RADS)—repeat at 12 mo Rebiopsy at 3 yr[a] Triggered rebiopsies if any change

MRI = magnetic resonance imaging; PSA = prostate-specific antigen; PSAd = PSA density; STRATCANS = STRATified CANcer Surveillance.

[a] Option to omit and discuss with patient.

PSA Testing

All sources support PSA testing as a critical component of active surveillance. The recommended frequency of testing ranges from every 3 to 6 months, and PSAd and kinetics should also be monitored (Moore et al., 2023, NICE, 2019, EAU, 2024). In the STRATCANS follow up strategy PSA was repeated every 3 months regardless of the follow-up tier (Thankapannair et al., 2023). Within this protocol a personalised PSA threshold for earlier review was defined for each man based on their individual PSAd at the start of active surveillance: if the starting PSAd was <0.15, then a PSA level that breached 0.15 on two separate occasions 3 months apart was used as a trigger for an early review. If the PSAd was >0.15, then a PSAd threshold of 0.20 was used. Higher PSA thresholds were decided on a case-by-case basis (Thankapannair et al., 2023). Furthermore, in a retrospective study by Lonergan and colleagues, it was found that PSAd ≥ 0.15 was associated with biopsy reclassification within 3 years of commencing active surveillance (Lonergan et al., 2020).

MRI

MRI should be used routinely but not as a stand-alone test. MRI is useful for monitoring changes and guiding biopsies, particularly when PSA changes occur (Rajwa et al., 2021, NICE, 2019, EAU, 2024). In the STRATCANS follow up strategy a repeat MRI is risk scheduled based on the presence of a lesion on diagnostic biopsy. A repeat MRI is recommended every 3 years if there is no lesion present (PI-RADS 1–2), every 18 months for an equivocal lesion (PI-RADS 3) and every 12 months for a positive lesion (PI-RADS 4–5). Patients in the highest-risk STRATCANS group have an annual MRI regardless of lesion positivity (Thankapannair et al., 2023). Thankapannair and colleagues found that men with MRI-visible lesions (especially PI-RADS 4–5) experienced an additional higher risk

of progression within the subgroups. Conversely, MRI invisibility demonstrated a favourable marker for non-progression.

DRE

There is decreasing emphasis on DRE. However, some guidelines still recommend DRE during active surveillance (NICE (2019) - DRE to be done during the first year of AS), (EAU-Guidelines (2024) - DRE at least once yearly), while others suggest it is redundant if MRI is available (Moore et al., 2023). In the STRATCANS follow up strategy DRE was not required (Thankapannair et al., 2023).

Repeat Biopsy

Repeat biopsies are recommended, but their frequency may be reduced if PSA and MRI remain stable. Routine biopsies every 3 years are suggested, but they can be omitted under stable conditions, with changes in PSA or MRI triggering a biopsy (Moore et al., 2023, EAU, 2024). According to the NICE guidelines, those who have a lower risk of prostate cancer progression (mpMRI PI-RADS score 1 or 2) can choose not to get a prostate biopsy (National Institute for Health and Care Excellence, 2019). However, to avoid a small risk that in some cases significant cancers may be missed, they recommend clinicians to discuss the risk and benefits with the patient. Protocol repeat biopsies are recommended every 3 years for STRATCANS 2 and 3, with the option not to proceed if other features are favourable (Thankapannair et al., 2023). For STRATCANS 1, a biopsy is only recommended if triggered by a change in PSA or MRI (Thankapannair et al., 2023). Disease progression from CPG1 to CPG2 and progression to >CPG3 using biopsy found that n=6 and n=2 patients respectively, were upgraded. All outcomes from protocol (non-triggered) biopsies were not assessed in STRATCANS as follow-up was too short (Thankapannair et al., 2023).

Benefits and Harms

The benefits of determining necessary diagnostic tests and their frequency during prostate cancer during active surveillance include avoidance of unnecessary tests (biopsy, DRE) and less burden on the healthcare system. Furthermore it is patient friendly in terms of pain, anxiety, time and travel costs.

The harms of determining necessary diagnostic tests and their frequency during prostate cancer during active surveillance include potential over investigation and morbidity (e.g. from repeat biopsies) and less frequent tests (biopsy) might make some patients feel anxious. More frequent tests (MRI) could put a strain on the resources that are available in the healthcare system.

Preferences and values

The multidisciplinary Guideline Development Group including patient representatives recognise knowledge as an important patient and family value.

The Guideline Development Group believe that patients who understand the benefits and harms of their treatments and their frequency will have the knowledge to make an informed decision about their care. It is important that the benefits and harms of active surveillance are communicated to the patient and the patient takes the time for reflection after conversation with the healthcare professional. This means that the values of disclosure and understanding are embedded into patient/clinical communication.
The Guideline Development Group also recognise the role of family preferences and values. It is important that family members are informed and understand the benefits and harms of active surveillance. This can help reduce some of the anxiety family members may experience.
Enabling patients to become more empowered in their treatment decisions leads to greater involvement and adherence to the active surveillance programme. Patients are required to have confidence to communicate with their health care professionals and take on the responsibility of the active surveillance programme.

Resources, capacity, equity and other considerations

No relevant cost-effectiveness literature was identified to address this clinical question.

The following resources, capacity and other considerations were discussed by the Guideline Development Group:

Availability of prostate cancer nurses

Services such as Patient Support Workers are in place however additional nursing capacity including Advanced Nurse Practitioners and Clinical Nurse Specialists, may also be required. All patients being offered active surveillance should have access to an Advanced Nurse Practitioner or Clinical Nurse Specialist to discuss the benefits and harms of long term active surveillance and deferred treatment and to explain what is involved in the active surveillance protocol. Prostate cancer nurses play an important role in providing support to the patient.

Education of patients

All patients being offered active surveillance will require access to educational material on the active surveillance protocol.
Patients may be offered an education session in person through an Advanced Nurse Practitioner or Clinical Nurse Specialist, on line or through written material. Patients may be directed to the patient education resources on the STRATCANS website.

Multidisciplinary team meeting capacity

Additional capacity will be required for providing multiple tests for each active surveillance patient.

MRI access and interpretation

Patients enrolled on active surveillance will require access to MRI. The Guideline Development Group highlighted that this may require updating MRI scanners and increasing MRI capacity. MRIs must be read by in-house radiologists experienced in reading prostate MRIs who regularly attend the prostate multidisciplinary meeting. Therefore trained personnel to acquire and interpret MRIs will also be required. Both capital and revenue costs will be necessary.

PSA testing

Patients enrolled on active surveillance will require access to PSA testing. To meet the need of additional PSA testing capital and revenue costs may be required.

Other considerations

Equity and acceptability

Enrollment in active surveillance is dependent on diagnostic criteria, including MRI results. If an MRI is not available pre biopsy this can lead to an inequity in access to active surveillance for patients.

Recommendation 2.3.1

All patients with prostate cancer being considered for active surveillance should be risk stratified and followed up using the most recent three-tier STRATified CANcer Surveillance (STRATCANS) strategy.

Quality of Evidence: Moderate **Grade of recommendation: Weak**

Good practice points

- DRE is not recommended as a routine part of protocol during active surveillance for men with prostate cancer, especially if standard imaging procedures, such as transrectal ultrasound or mpMRI, are being performed during active surveillance. DRE may be performed for purposes other than assessing the course of a disease (such as prostatitis).
- MRI imaging must be performed in accordance with the latest version of the PI-RADS technical guidelines. MRIs must be read by in-house radiologists experienced in reading prostate MRIs who regularly attend the prostate multidisciplinary meeting.
- All prostate MRI reports must record prostate volume as defined by the latest version of PI-RADS.
- PSA density must be included in MRI reports if PSA is provided.
- MRI should be performed if PSA is rising (PSA-doubling time < 3 years).
- Patients with MRI PI-RADS 4 or 5 lesions should be reviewed at a multidisciplinary meeting.

- Progression on MRI should be evaluated by using the latest version of PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation).
- A change in MRI findings based on PRECISE criteria triggers a biopsy.

Practical considerations for patient care
• All patients offered active surveillance should receive written information detailing what is involved in the active surveillance protocol and details of their triggers of possible cancer progression.

2.4 Clinical question: For men with prostate cancer being treated with active surveillance what are the triggers of cancer progression that require conversion to radical treatment?

Evidence summary

A meta-analysis (Rajwa et al., 2021), a case control study (Ahlberg et al., 2024), two consensus statements (Englman et al., 2024, Moore et al., 2023) and three international guidelines (NCCN, 2024, , EAU, 2024, NICE, 2019) addressed this clinical question.

The overall quality of the evidence was low. However, the evidence to address the question was consistent in its findings and directly relates to the patients being addressed - patients undergoing active surveillance in the era of MRI.

PSA and MRI progression

There is international consensus that PSA progression is not an automatic trigger to convert to radical treatment (Moore et al., 2023). An international guideline (EAU, 2024) and an international consensus statement (Moore et al., 2023) agree that a change in PSA should be followed up with an MRI with the option of a biopsy after, rather than immediate biopsy or discussion of radical treatment.

Histopathology

There is agreement in international guidelines that progression on histopathology is a trigger for discussion on conversion to radical treatment (NCCN, 2024, EAU, 2024). The histopathology criteria to trigger conversion to radical treatment is debated in the era of MRI and targeted biopsy. The case-control conducted by Ahlberg et al. (2024) compared triggers for conversion to radical treatment over two different time periods (2008-2014 vs 2015-2020) in Sweden and demonstrated that histopathology remained the most common trigger for conversion to radical treatment.

Patient preference, comorbidities and life expectancy

The NICE guideline also outlines that an important trigger for conversion to radical treatment may be patient preference (NICE, 2019). NICE recommends that if a person wishes to move from active surveillance to radical treatment at any stage in their care, a shared decision making approach should be used taking into account person's preferences, comorbidities and life expectancy.

Definition of MRI progression

Rajwa et al. (2021) conducted a meta-analysis to assess the diagnostic utility of serial MRI on active surveillance for patients with prostate cancer. The meta-analysis compared the diagnostic utility of PRECISE vs. institution-specific criteria definition

of MRI progression and found that there were no significant differences in the pooled sensitivity and specificity of PRECISE and institution-specific criteria. However, the results of this meta-analysis should be interpreted with caution as the studies were found to have significant heterogeneity in relation to study design, the inclusion criteria for enrolment in AS, MRI intervals, definition of prostate cancer progression and length of follow-up.

The guideline development group considered the advantages and disadvantages of using the PRECISE criteria versus institution specific criteria to define MRI progression and agreed that the use of PRECISE may increase consistency in the language used to report MRI progression. The group agreed that the use of the latest PRECISE criteria (Englman et al., 2024) to evaluate MRI progression is considered good practice.

Benefits and Harms

Identifying the triggers of cancer progression that require conversion to radical treatment will reassure some patients that there will be an opportunity to treat if required. This conversion from active surveillance to radical treatment is provided by an evidence-based algorithm providing further reassurance to the patient and therefore may help to reduce any anxiety or uncertainty of being on active surveillance. In addition this provides reassurance to the healthcare professional there is treatment consensus across active surveillance protocols and consistency of evaluation (e.g. via PRECISE). Serial collection of data minimises the risk of overtreatment (benefit of active surveillance) and results in greater patient sub-selection.

The harms of identifying the triggers of cancer progression that require conversion to radical treatment include unnecessary treatment (under treatment and overtreatment). Diagnostic tests are not perfect and may result in false positive and false negative results. The patient may be exposed to the side effects of biopsy including sepsis and scar tissue, toxicity of treatments, incontinence and erectile dysfunction.

Preferences and values

When monitoring prostate cancer and potentially switching to active treatment, prostate cancer patients on an active surveillance treatment plan prioritise knowledge and understanding of the evidence base underlying the treatment guidelines, particularly the regular monitoring of cancer status and the trigger points for switching to active treatment.

Recognising that each patient's experience with cancer and treatment is unique, preferences can vary widely based on factors such as personal health goals, lifestyle considerations, family’s view and tolerance for side effects. Patients need

reassurance that multidisciplinary meetings are in a position to consider the best possible evidence-based treatment for the individual patient.

Ongoing patient education and open communication play crucial roles in ensuring that patients are well-informed participants in shared decision-making processes. Empowering patients with knowledge about treatment options, potential risks, and benefits allows them to make choices aligned with their values and preferences, ultimately fostering a sense of agency and autonomy in their cancer journey. This communication and education should be ongoing, i.e. not limited to the initial consultation/s but available at a variety of times.

Education and communication with the patient and their family is key to ensuring that the patients and their loved ones know that they are being treated following an evidence based protocol. Patients are often exposed to numerous options and an excess of information (e.g. through conversations or health information seeking outside of consultations with their medical team). Building trust in the medical team as the primary and most reliable source of information on the treatment will reassure patients that all options are being considered. Adequate time for communication with patients to ensure their understanding of their options is also essential. It could therefore be beneficial to have different team members available to answer patient questions over multiple sessions, as it is very difficult for patients to absorb all relevant information and consider all of their questions in a single consultation. Patients should be given the opportunity to bring a trusted family member or friend to these consultations to provide assistance. Issues around quality of life should also be addressed with the patient.

While oncological control is of utmost importance, patients should be reassured that other issues arising from their disease and treatment (e.g., urinary incontinence, sexual function, fatigue, and bowel function) are also a priority and receive support and potential toxicities should be part of the communication. Likewise, specific factors with prostate cancer treatment relating to patient characteristics (e.g. sex, age, etc.) should be communicated.

The importance of having a linked Clinical Nurse Specialist or Advanced Nurse Practitioner and the provision of personalised care plan for each patient may reassure them and allow them to self-manage their care.

Resources, capacity, equity and other considerations

MRI access and interpretation

Patients enrolled on active surveillance will require access to MRI. The Guideline Development Group highlighted that this may require updating MRI scanners and increasing MRI capacity. MRIs must be read by in-house radiologists experienced in reading prostate MRIs who regularly attend the prostate multidisciplinary meeting.

Therefore trained personnel to acquire and interpret MRIs will also be required. Both capital and revenue costs will be necessary.

Recommendation 2.4.1

If a patient progresses beyond the eligibility criteria* for active surveillance, and has > 10 years life expectancy, then active treatment is recommended.

*Eligibility criteria:

- Low risk prostate cancer or intermediate risk prostate cancer with the following:
  - < 10% pattern 4 and absence of cribriform pattern or intraductal histology on biopsy
  - PSA < 20 µg/L
  - ≤cT2

Quality of Evidence: Low **Grade of recommendation: Strong**

Recommendation 2.4.2

A shared decision-making approach should be undertaken with the patient before moving to active treatment. Discussion should include:

- Patient preferences
- Life expectancy
- Comorbidities

Quality of Evidence: Low **Grade of recommendation: Strong**

Good practice points

- Patients with discordant imaging and pathology findings should be discussed at a prostate tumour conference.
- Progression on MRI should be evaluated by using the latest version of PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation).
- When reviewing active surveillance MRIs, all previous MRIs should be available and they should be read by a radiologist who is experienced at prostate cancer MRI and attends the prostate tumour conference.
- In patients with a life expectancy of <10 years, consideration should be given to moving from active surveillance to a watch and wait approach.

Practical considerations for patient care

- All patients enrolled on active surveillance should receive written information detailing what is involved in the active surveillance protocol and details of their triggers of possible cancer progression.

3 Methodology

3.1 Establishment of a Guideline Development Group (GDG)

A Guideline Development Group was responsible for the development and delivery of this National Clinical Guideline and included representatives from relevant medical professionals and stakeholders (see Appendix I Members of the Guideline Development Group).

3.2 List of clinical questions

Clinical question 2.2 (code: PCa_AS1)

In men with a histological diagnosis of prostate cancer, what are the inclusion criteria for being offered active surveillance?

Population	Men with a histological diagnosis of prostate cancer
Intervention	Inclusion criteria- risk criteria (NCCN prostate cancer risk stratification), Gleason score/Grade group, MRI findings, PSA level, PSA density, number/percentage positive biopsy cores, comorbidities, patient preferences, family history, age , BRCA status
Control	-
Outcome	Disease-specific survival, metastasis-free survival, biochemical progression, quality of life

Clinical question 2.3 (code: PCa_AS4)

In men with prostate cancer on active surveillance, what diagnostic tests and at what frequency, should diagnostic testing be performed to detect disease progression?

Population	Men with a histological diagnosis of prostate cancer
Intervention	Diagnostic tests- PSA tests, MRI scans, DRE, biopsy and frequency
Control	-
Outcome	Detection of disease progression (Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value)

Clinical question 2.4 (code: PCa_AS5)

For men with prostate cancer being treated with active surveillance what are the triggers/indicators of cancer progression that require conversion to radical treatment?

Population	Men with prostate cancer being treated with active surveillance
Intervention	Indicators of cancer progression- MRI findings, PSA level, PSA density

Control	-
Outcome	Change in risk of cancer progression Change in Gleason score

3.3 Describe and document the evidence search

The clinical questions outlined above were used to conduct a literature search of primary literature. A systematic literature review protocol was developed for the guideline development process by the HSE librarians in conjunction with the NCCP and is available upon request. The literature search strategies for each key question are available upon request.

3.4 Describe the method of screening and evidence appraisal

An evidence methodologist and two research officers screened the literature searches independently to identify relevant primary papers. Any disagreements on primary paper inclusion were agreed through discussion.

All included primary papers were appraised using validated checklists developed by the Scottish Intercollegiate Guideline Network (SIGN).

There were three main points considered when appraising the research evidence:

- Are the results valid? (internal validity)
- What are the results? (statistical and clinical significance)
- Are the results applicable/generalisable to the patient/population of the guideline? (external validity)

3.5 Formulation and grading of recommendations

The evidence to address the clinical questions, both from primary literature and international guidelines, was extracted into evidence tables.

Recommendations were formulated through a formal structured process. An 'Evidence to Decision Framework' was completed for the clinical questions. The following domains were discussed by the Guideline Development Group:

Evidence summary

The body of evidence was reviewed and discussed taking into account the types of studies available, the quality of those studies and their degree of bias, the precision of the results, and whether all studies were consistent in their findings. The directness of the evidence and generalisability to the target population were also considered.

Benefit and harm

The balance of potential benefits versus potential harms of the proposed recommendations were considered.

Preferences and Values

The preferences and values of the patient were discussed and considered, noting particularly the acceptability of the proposed recommendations to patients and their carers' in the context of the balance of benefits and harms.

Resource, capacity, equity and practical considerations

Any factors which may affect the implementation of the proposed recommendations were discussed and documented. Potential issues around equity was explicitly considered.

Following discussion on the four domains above the recommendations were agreed by the Guideline Development Group. The following terms were considered for use in recommendations:

- is recommended
- should be considered
- may be considered
- is not recommended

The use of these terms are dependent on all four domains outlined above. Each recommendation was assigned a quality of evidence and a grade of recommendation by the Guideline Development Group. Good practice points and practical considerations for patient care were also agreed by the Guideline Development Group. Further information on the grading systems used are documented in Appendix VI Grading the recommendations in this guideline.

3.6 Consultation

National review

The draft guideline was signed-off by the Guideline Development Group before going to national stakeholder review.

It was placed on the NCCP website and circulated to relevant organisations and individuals for comment between XXXX and XXXX.

Stakeholders were asked to comment on the comprehensiveness of evidence used to form the recommendations. Stakeholders were required to submit feedback with supporting evidence on a form provided along with a completed conflict of interest form.

International review

The draft guideline was also submitted for international expert review. The Guideline Development Group nominated the following experts to provide feedback on the draft guideline:

- Xxxx
- Xxxxx
- Xxxxx

The reviewers were chosen by the Guideline Development Group based on their in-depth knowledge of the subject area and guideline development processes. The review followed the same procedure as the National Review.

All feedback received was reviewed by the Guideline Development Group. Suggested amendments and supporting evidence were reviewed and consensus reached to accept or reject the amendments. All modifications were documented and the report is available upon request.

3.7 National implementation plan

An implementation plan was developed based on the NCEC Implementation guide (Department of Health, 2018). It outlines the actions required to implement each recommendation, who has lead responsibility for delivering the action, the timeframe for completion and the expected outcomes of implementation (see Appendix III National Implementation Plan).

This National Clinical Guideline including the implementation plan should be reviewed by the multidisciplinary team and senior management in the cancer centre/hospital as it outlines the actions required to implement the recommendations.

The CEO, General Manager and Clinical Director of each cancer centre/hospital have corporate responsibility for the implementation of the National Clinical Guideline and to ensure that all relevant staff are appropriately supported to implement the guideline.

The National Clinical Guideline will be circulated and disseminated through the professional networks who participated in developing and reviewing this document.

3.8 Governance and approval

The final draft of the guideline was Quality Assured internally by a member of the NCCP Evidence and Quality Team to confirm adherence to the National Standards for Policies, Procedures, Protocols and Guidelines (Department of Health, 2015).

The guideline, along with confirmation of the outcome of the Quality Assurance process, was then submitted to the NCCP Executive on XXXX for approval.

A full list of the members can be found in Appendix II Membership of NCCP Executive.

3.9 Communication and dissemination plan

This National Clinical Guideline is available on the HSE National Central Repository.

A Communication and Dissemination Plan was developed by the Guideline Development Group to raise awareness of the development of this guideline, to ensure effective communication and collaboration with all key stakeholders throughout the various stages of guideline development process and to maintain momentum for the widespread adoption of the guideline.

In conjunction with the HSE Communications Division, key stakeholders were identified and a list of strategies was developed to inform them of the new guideline (see Appendix IV Communication and Dissemination Plan). The implementation of the guideline will also be supported by communication, training and education.

3.10 Monitoring, evaluation and audit

Monitoring and evaluation

Each cancer centre/hospital should implement a systematic process of gathering information and tracking over time to achieve the objectives of this guideline.

The Prostate Tumour Conference in each cancer centre/hospital should monitor the implementation of recommendations specific to their practice.

Audit

It is important that implementation of this National Clinical Guideline is audited to ensure that this guideline positively impacts patient care. Each cancer centre/hospital should audit implementation of this guideline at least annually.

3.11 Review/update

This guideline was issued on dd/mm/yyyy and will be considered for review by the NCCP in three years.

Surveillance of the literature base will be carried out periodically by the NCCP. Any updates to the guideline in the interim period or as a result of three year review will be noted in the guidelines section of the NCCP websites.

4 Abbreviations

CEO	Chief Executive Officer
CPG	Cambridge Prognostic Group
DoH	Department of Health
DRE	Digital rectal examination
EAU	European Association of Urology
GRADE	Grading of Recommendations Assessment Development and Evaluation
HSE	Health Service Executive
mpMRI	Multiparametric Magnetic Resonance Imaging
MRI	Magnetic Resonance Imaging
NCCN	National Comprehensive Cancer Network
NCCP	National Cancer Control Programme
NCEC	National Clinical Effectiveness Committee
NICE	National Institute for Health and Care Excellence
PI-RADS	Prostate Imaging Reporting and Data System
PRECISE	Prostate Cancer Radiological Estimation of Change in Sequential Evaluation
PSA	Prostate specific antigen
PSAd	Prostate specific antigen density
QoL	Quality of Life
SIGN	Scottish Intercollegiate Guideline Network
STRATCANS	STRATified CANcer Surveillance

5 Glossary of Terms

Active Surveillance

Closely watching a patient's condition but not giving any treatment unless there are changes in test results that show the condition is getting worse. Active surveillance may be used to avoid or delay the need for treatments such as radiation therapy or surgery, which can cause side effects or other problems. During active surveillance, certain exams and tests, such as blood tests, imaging tests, and biopsies, are done on a regular schedule to monitor the condition. Active surveillance may be used in certain types of prostate cancer and in some other types of cancer. It is a type of expectant management.

Benefits and Harms

Benefits refer to improved quality of life and reductions in mortality and morbidity. There are physical risks of harm such as exposure to radiation and there are also emotional and psychological risks of harm such as anxiety and depression.

Case control study

The observational epidemiologic study of persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing the diseased and non-diseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups.

Confirmation biopsy

This is defined as the first biopsy following the diagnostic biopsy. According to the European Association of Urology, a re-biopsy within 6–12 months—often referred to as a "confirmatory biopsy"—seems necessary to rule out sampling error in men who qualified for active surveillance based only on the results of a systematic biopsy and who did not have a pre-biopsy MRI.

Disease-Free Survival (DFS)

Disease-free survival (DFS) refers to the length of time after primary treatment for cancer ends that a patient survives without any signs or symptoms of that cancer. Measuring DFS in clinical trials helps evaluate how well a new treatment works by determining the period during which patients remain free from the disease after treatment.

Disease progression

Cancer that continues to grow or spread.

Disease free survival

In cancer, the length of time after primary treatment for a cancer ends that the patient survives without any signs or symptoms of that cancer.

DRE
An examination in which a doctor inserts a lubricated, gloved finger into the rectum to feel for abnormalities. Also called digital rectal examination.

Gleason score
A way of describing prostate cancer based on how abnormal the cancer cells in a biopsy sample look under a microscope and how quickly they are likely to grow and spread. Most prostate cancers contain cells that are different grades. The Gleason score is calculated by adding together the two grades of cancer cells that make up the largest areas of the biopsied tissue sample. The Gleason score usually ranges from 6 to 10. The lower the Gleason score, the more the cancer cells look like normal cells and are likely to grow and spread slowly. The Gleason score is used to help plan treatment and determine prognosis (outcome).

Good practice points
Good practice points are based on the clinical expertise of the Guideline Development Group.

Grade Group
A way of describing prostate cancer based on how abnormal the cancer cells in a biopsy sample look under a microscope and how quickly they are likely to grow and spread. It is based on the Gleason score, which is another type of prostate cancer grading system. Grade Group scores range from 1 to 5. The lower the Grade Group score, the more the cancer cells look like normal cells and are likely to grow and spread slowly. The Grade Group system is used to help plan treatment and determine prognosis (outcome).

Magnetic Resonance Imaging
A procedure that uses radio waves, a powerful magnet, and a computer to make a series of detailed pictures of areas inside the body. A contrast agent, such as gadolinium, may be injected into a vein to help the tissues and organs show up more clearly in the picture. Magnetic resonance imaging may be used to help diagnose disease, plan treatment, or find out how well treatment is working. It is especially useful for imaging the brain and spinal cord, the heart and blood vessels, the bones, joints, and other soft tissues, the organs in the pelvis and abdomen, and the breast. Also called MRI, NMRI, and nuclear magnetic resonance imaging.

Meta-analysis
A process that analyses data from different studies done about the same subject. The results of a meta-analysis are usually stronger than the results of any study by itself.

Metastatic disease
Cancer that has spread to another part of the body.

Overall Survival (OS)
Overall survival (OS) is defined as the length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive. It is a crucial measure used in clinical trials to assess the efficacy of a new treatment. The calculation of overall survival does not take into account the cause of death; it simply measures the time a patient lives after diagnosis or initiation of treatment regardless of whether the death was due to cancer or another cause.

Practical considerations regarding patient care
These are statements developed with the patient Guideline Development Group members on issues that were important to them with regards to their own experience.

Preferences and values
The patient preferences and values statements were developed by the multidisciplinary Guideline Development Group including patient representatives. Patient members were given priority during guideline meetings to discuss preferences and values.
The Guideline Development Group tried to identify what an informed patient and their families would prefer. The value statements refer to what the Guideline Development Group believe are the values that are driving patient and family preferences.

Prospective cohort study
A research study that follows over time groups of individuals who are alike in many ways but differ by a certain characteristic (for example, female nurses who smoke and those who do not smoke) and compares them for a particular outcome (such as lung cancer).

PSA test
A laboratory test that measures the amount of prostate-specific antigen (PSA) found in the blood. PSA is a protein made by the prostate gland. The amount of PSA may be higher in men who have prostate cancer, benign prostatic hyperplasia (BPH), or infection or inflammation of the prostate. Also called prostate-specific antigen test.

PSA density
PSA density compares levels of PSA to the size of the prostate. It is calculated using the serum PSA level divided by the prostate gland's volume.

p-value
The p-value is related to the significance level. If the critical alpha value is 0.05, then the p-value must be smaller than 0.05 for the test to have a statistically significant result. If the p-value is greater than the critical alpha value, then the test does not have a statistically significant result.

Radiological Imaging
Radiological imaging involves various imaging techniques to create detailed pictures of the inside of the body. These methods use different forms of energy, such as x-rays, ultrasound, radio waves, and radioactive substances. Radiological imaging is essential for diagnosing diseases, planning treatments, and monitoring the effectiveness of therapies.

Repeat biopsy
A repeat biopsy is usually performed in case of a negative initial biopsy

Retrospective study
A study that compares two groups of people: those with the disease or condition under study (cases) and a very similar group of people who do not have the disease or condition (controls). Researchers study the medical and lifestyle histories of the people in each group to learn what factors may be associated with the disease or condition. For example, one group may have been exposed to a particular substance that the other was not. Also called case-control study.

Shared decision-making approach
A shared decision-making approach is between the healthcare professional and the patient. It provides patients with a measure of understanding and control over their treatment. Clinicians should disclose the potential benefits and harms of a treatment to the patient. Clinicians should also help elicit patients' values regarding treatment. Patients should be allowed to have family members present during shared decision-making if they would like to. Written information on the items relevant to shared decision-making, including the benefits and harms of the treatment options, should be provided to all patients.

Systematic biopsy
A systemtaic prostate biopsy is based on systematic prostate sampling and a minimum number of 12 cores should be taken.

Tumour conference
Previous known as multidisciplinary team (MDT) meetings. A tumour conference involves a group of people from different healthcare disciplines, who meet together at a given time (whether physically in one place, or by video or tele-conferencing) to discuss a given patient and who are each able to contribute independently to the

discussion on diagnosis and to make recommendations on patient management. It provides a forum for multidisciplinary teams to regularly convene and discuss the diagnosis and management of cancer patients.

6 Appendix

Appendix I Members of the Guideline Development Group

A conflict of interest form was signed by all members of the Guideline Development Group. No conflicts of interest were declared.

Name	Title/position	Role on guideline group*
Chairs of the Guideline Development Group		
Mr David Galvin	Consultant Urologist, The Mater Misericordiae University Hospital, St. Vincent's University Hospital	Co-chair, writing member
Dr Eve O'Toole	Head of Evidence & Quality Hub, NCCP	Co-chair, writing member
Patient representatives		
Mr Tom Hope	Patient/Service User Partner	Writing member
Mr Paul Power	Patient/Service User Partner	Writing member
Urology		
Mr Peter Lonergan	Consultant Urologist, St.James's Hospital	Writing member
Ms Lorraine Scanlon	Urology SpR, St.James's Hospital	Contributor
Mr Garett Durkan	Consultant Urologist, University Hospital Galway	Contributor
Radiology		
Prof Conor Collins	Consultant Radiologist, St. Vincent's University Hospital	Writing member
Dr Ruth Dunne	Consultant Radiologist, Beaumont Hospital	Writing member
Radiation Oncology		
Mr Brian O'Neill	Consultant Radiation Oncologist, St. Lukes Radiation Oncology Centre	Writing member (Until September 2024)
Pathology		
Dr Tom Crotty	Consultant Pathologist St. Vincent's University Hospital	Contributor
Nursing		

Ms Catherine McGarvey	Advanced Nurse Practitioner, The Mater Misericordiae University Hospital	Writing member
Ms Rachel Dalton	Advanced Nurse Practitioner, St.James's Hospital	Contributor
Ms Anna Loughlin	Advanced Nurse Practitioner, St.James's Hospital	Writing member
Medical Ethics		
Professor Leah McClimans	Associate Professor, Philosophy, University College Cork	Contributor (Until September 2023)
Evidence		
Dr Helena Gibbons	Senior Research Officer, NCCP	Project manager, researcher, writing member
Dr Ozlem McDonnell	Senior Research Officer, NCCP	Project manager, researcher, writing member (From September 2023)
Ms Louise Murphy	Senior Research Officer, NCCP	Writing member
Mr Paul Flood	Research Officer, NCCP	Writing member
Mr Gethin White	Librarian, HSE	Information services
NCCP		
Ms Eileen Nolan	National Programme Manager for Urological Cancers, NCCP	Writing member

*Writing members of the Guideline Development Group have attended at least 75% of Guideline Development Group meetings

Appendix II Membership of NCCP Executive

Name	Role and position

Sign-off by Chair of Approval Governance Group

National Clinical Guideline: was formally ratified and recorded in the minutes of the Approval Governance Group on ….

Name: (print)	
Title:	
Signature: **(e-signatures accepted)**	

Appendix III National Implementation Plan

National Clinical Guideline:
Date National Clinical Guideline approved:
Expected date of full implementation:
Lead responsibility for national implementation: Hospital/Cancer Centre/Prostate Tumour Conference

Implementation action	Implementation barriers / enablers	List of tasks to implement the action	Lead responsibility for delivery of the action	Expected completion date	Expected outcomes
Develop a communication and dissemination plan to ensure that cancer centres are aware of guideline recommendations.	Enablers: Assistance of HSE Communications and HSE Digital Potential Barriers: Professional-patient interaction given complex nature of treatment. Patient perceptions and treatment preferences.	Please see Appendix IV Communication and Dissemination Plan	NCCP	Following guideline publication	Increased awareness of National Clinical Guideline recommendations.
Access to additional resources - access to imaging equipment - increase imaging capacity - access to ANPs and CNSs	Enablers: National Cancer Strategy recommendation 14: *The NCCP, working with the other Directorates in the HSE and with the Department of Health, will develop a rolling capital investment plan, to be reviewed annually, with the aim of ensuring that cancer facilities*	Secure funding through the HSE service planning process for equipment and access to imaging capacity.	Health Regions NCCP as per National Cancer Strategy recommendations 14, 16, 50.	XXXX	All patients with prostate cancer will have equal access to the appropriate diagnostic equipment and staff.

Implementation action	Implementation barriers / enablers	List of tasks to implement the action	Lead responsibility for delivery of the action	Expected completion date	Expected outcomes
	meet requirements. National Cancer Strategy recommendation 16: *The NCCP will ensure that consultant appointments for radiology, endoscopy and histopathology, where necessary, are made in conjunction with appointments in other disciplines such as surgery and medical oncology.* National Cancer Strategy recommendation 50: *The NCCP, aided by a cross sector group, will draw up a comprehensive workforce plan for cancer services. This will include an interim assessment of staffing needs at medical, nursing and health & social care professional levels by mid-2018.* Potential Barriers: Lack of radiology resources - access to imaging equipment and staff.	Secure funding through the HSE service planning process for further staffing.			Accurate diagnosis and accurate surveillance.

Appendix IV Communication and Dissemination Plan

Key stakeholders were identified by the GDG and in conjunction with the HSE Communications Division, a list of strategies was developed to inform these stakeholders of the new guideline. Some strategies will include:

- Official publication and launch of the guideline.
- Direct communication from NCCP Director to hospital and cancer network managers raising awareness and setting out expectations/actions.
- Circulation to the networks who participated in developing and reviewing the guideline.
- Circulation to NCCP staff.
- Liaison with HSE Clinical Programmes, academic faculties and professional bodies for dissemination to their members.
- Inform relevant voluntary organisations and patient advocacy groups that the guideline has been updated and is available for representation in their patient and public information.
- Promotion through the HSE/NCCP website, internal HSE media, social and print media.
- NCCP to include details of the guideline in presentations by clinical leads, sub-group chairs, NCCP Director.
- NCCP to promote the guideline at conferences, workshops, and CPD sessions.

A plain language summary of the guideline is included as a key element of the Communication and Dissemination Plan - for patients, their families and other non-specialists who may be interested in the potential implications of the recommendations within the guideline and what it may mean for them.

Description of stakeholder communications	Communication method	Owner	Timeline
Patients			
Plain language summary	Guideline	Project team	Pre 'go live'
Guideline Development Group			
New guideline alert	Email	Project team	Pre 'go live'
National stakeholders			
New guideline to Hospital Managers/Cancer Network Managers	Email	National Director, NCCP	Pre 'go live'
New guideline to relevant stakeholders (incl. National groups, organisations,	Email	Project team	Pre 'go live'

faculties, patient support & advocacy groups, international reviewers)			
New guideline to NCCP staff	Email	Project team	Pre ‘go live’
Press Release (HSE website)	Article	Project team/HSE Comms	Official launch
Social media coverage (Irish and English)	“X” posts	Project team	‘go live’ & official launch
News articles	Article	Project team/ HSE Comms	Within 2 months of 'go live'

Appendix V Plain Language Summary

Summary of National Clinical Guideline

This National Clinical Guideline contains evidence-based recommendations.

This guideline is for patients diagnosed with prostate cancer whose cancer may be suitable for "active surveillance". Active surveillance is where you watch patient's cancer closely and only start treatment if test results show it is getting worse**.** The document explains which patients' prostate cancer can be managed with active surveillance. It also outlines the tests used to monitor the cancer during active surveillance and how often to get the tests.

It covers:

- which patients are suitable for active surveillance enrolment
- what type of tests should be included on an active surveillance protocol
- how often should patients receive each test on an active surveillance protocol
- when should a patient switch from active surveillance to a different treatment

The document also describes the changes in test results that may lead to switching to a different treatment. Ask your doctor or any member of your treating team if you want to know about your test results or treatment options.

What does this guideline mean for you?
Questions you may want to ask your healthcare professionals?

- What are my options?
- Where will my appointments be?
- How often will I see my doctor or nurse?
- Who will be in charge of booking my tests?
- When will I get test results and who will give them to me?
- What symptoms should I look out for and report?
- Who do I contact if something doesn't feel right or I am feeling unwell?
- What treatment could I have if my cancer grows?

Understanding the language

Medical Term	Plain language explanation
Active surveillance	Closely watching a patient's condition but not giving any treatment unless there are changes in test results that show the condition is getting worse. Active surveillance may be used to avoid or delay the need for treatments such as radiation therapy or surgery, which can cause

	side effects or other problems. During active surveillance, certain exams and tests, such as blood tests, imaging tests, and biopsies, are done on a regular schedule to monitor the condition. Active surveillance may be used in certain types of prostate cancer and in some other types of cancer. It is a type of expectant management.
Disease progression	Cancer that continues to grow or spread.
Prostate biopsy	The removal of cells or tissues in the prostate for examination by a pathologist
PSA test	A laboratory test that measures the amount of prostate-specific antigen (PSA) found in the blood. PSA is a protein made by the prostate gland. The amount of PSA may be higher in men who have prostate cancer, benign prostatic hyperplasia (BPH), or infection or inflammation of the prostate. Also called prostate-specific antigen test.
MRI	An imaging scan that uses magnets and radio waves to take detailed pictures (2D/3D) of the body's organs, muscles, soft tissues, and structures. It does not use radiation. It is sometimes used to clarify queries on other scan.

Appendix VI Grading the recommendations in this guideline

The Guideline Development Group assigned each recommendation a quality of evidence and grade of recommendation. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach provides an explicit system for rating the quality of evidence and whether the recommendation is strong or weak (Guyatt et al., 2008).

Quality of evidence

It is recognised that in guideline development that just assessing the level of evidence does not take into account the methodological quality of each individual study or the quality of the body of evidence as a whole (Harbour and Miller, 2001). The Guideline Development Group used an amended GRADE system which considers the following factors when classifying the quality of evidence; high, moderate or low (Guyatt et al., 2008):

- Study design
- Study design limitations
- Consistency of results
- Directness of the evidence
- Imprecision of results
- Reporting bias

Table 2 Quality of evidence adapted from GRADE working group 2013

High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Grade of recommendation

There are two grades of recommendation: strong or weak. These reflects the balance of the following items:

- The quality of the body of evidence
- The balance between benefit and harm to patient

- Patient preferences and values
- Resources/cost

Table 3 Grade of recommendation adapted from GRADE working group 2013

Strong	A strong recommendation is one for which the Guideline Development Group is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention). Strong recommendations are not necessarily high priority recommendations. A strong recommendation implies that most or all individuals will be best served by the recommended course of action.
Weak	A weak recommendation is one for which the desirable effects probably outweighs the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists. A weak recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences, and values. When there are weak recommendations caregivers need to allocate more time to shared decision-making, making sure that they clearly and comprehensively explain the potential benefits and harms to a patient.

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