# Active Surveillance

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# Declarations of Interest

- Prostate Cancer UK
  - Advisory panel and honorarium
- Astellas
- Ferring

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# Discussion Objectives

- Current practice
- Evidence
- Prostate Cancer UK
- CNS role
- Challenges
- The future

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# My Current Role

- 20 years as Urology ANP
- Lead a team of 8 specialist nurses
- Nurse Led Clinics for Prostate Cancer
- TRUS Biopsies
- Service development and business planning
- BAUN Vice President

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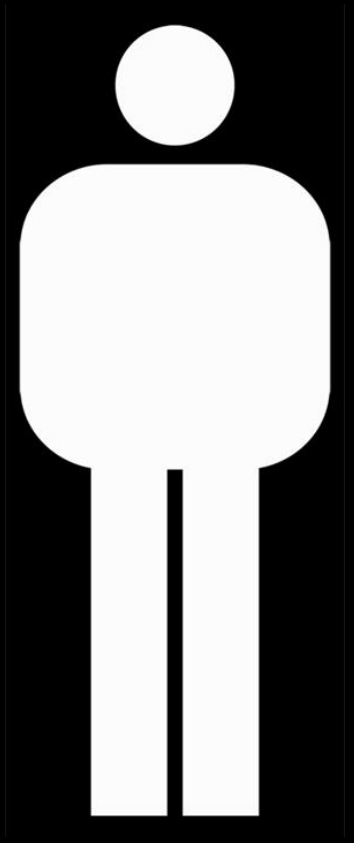
## Active Surveillance

## Current Practice



# Active Surveillance

- Active surveillance (AS) is a treatment offered to men with localised prostate cancer who would otherwise be suitable for radical prostatectomy (RP) or radical radiotherapy (RT)
- On AS men have regular tests to monitor their cancer
- Some men eventually require, or decide to have curative treatment, however many live healthy lives without need to take action and are able to avoid the side-effects of treatment

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# Clinical Decision for active surveillance

- MDT discussion
- Gleason, Grade Group
- PSA
- Tumour volume
- mpMRI
- Life expectancy and co-morbidities
- Patient choice

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# Active Surveillance Management

- Review at intervals with PSA
  - How often?
- DRE
  - Who does this?
- Repeat MRI, biopsies
  - How often?
- Protocol
  - When to cease AS?
- Who manages AS men
  - CNS, Consultant, Primary Care?

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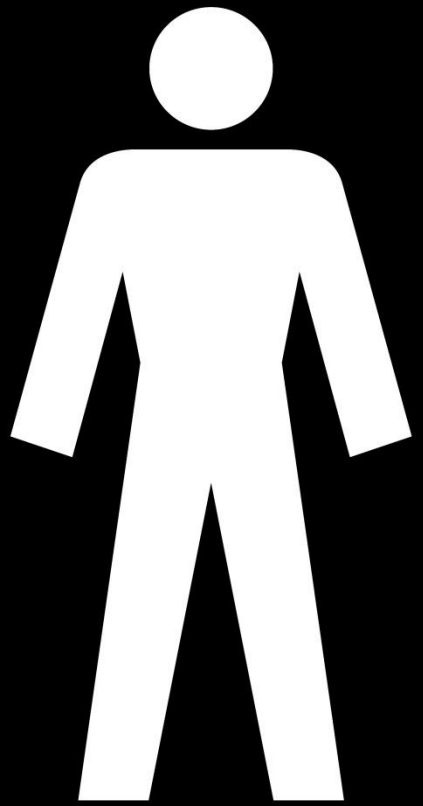
## Active Surveillance

## Evidence



# Table 2: Risk stratification for people with localised prostate cancer

| Level of risk | PSA | | Gleason score | | Clinical stage |
|---|---|---|---|---|---|
| Low risk | <10 ng/ml | and | ≤6 | and | T1 to T2a |
| Intermediate risk | 10–20 ng/ml | or | 7 | or | T2b |
| High risk[1] | >20 ng/ml | or | 8–10 | or | ≥T2c |

Abbreviation: PSA, prostate-specific antigen.

[1] High-risk localised prostate cancer is also included in the definition of locally advanced prostate cancer.

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# NICE Guidance (2019)

- **Active surveillance**
- 1.3.7 Offer a choice between active surveillance, radical prostatectomy or radical radiotherapy to people with low-risk localised prostate cancer for whom radical treatment is suitable. Use table 3 to discuss the benefits and harms with them. **[2019]**

- **Intermediate- and high-risk localised prostate cancer**
- consider active surveillance (in line with recommendation 1.3.9) for people who choose not to have immediate radical treatment1.3.12

- 1.3.13 Do not offer active surveillance to people with high-risk localised prostate cancer. **[2019]**

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# NICE Protocol for active surveillance (2019)

| Timing | Tests [a] |
|---|---|
| Year 1 of active surveillance | Every 3 to 4 months: measure prostate-specific antigen (PSA)[b]<br>Throughout active surveillance: monitor PSA kinetics[c]<br>At 12 months: digital rectal examination (DRE)[d]<br>At 12 to 18 months: multiparametric MRI |
| Year 2 and every year thereafter until active surveillance ends | Every 6 months: measure PSA[b]<br>Throughout active surveillance: monitor PSA kinetics[c]<br>Every 12 months: DRE[d] |
| [a] If there is concern about clinical or PSA changes at any time during active surveillance, reassess with multiparametric MRI and/or re-biopsy.<br>[b] Could be carried out in primary care if there are agreed shared-care protocols and recall systems.<br>[c] Could include PSA density and velocity.<br>[d] Should be performed by a healthcare professional with expertise and confidence in performing DRE. In a large UK trial that informed this protocol, DREs were carried out by a urologist or a nurse specialist. | |

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# Research

- The ProtecT trial (2016) evaluated the effectiveness of the three major treatment approaches to reducing prostate-cancer mortality and improving clinical outcomes in men with PSA-detected clinically localised disease.
- The results show that death from prostate cancer in such men remained low at a median of 10 years of follow-up, irrespective of the treatment assigned.
- In ProtecT active-monitoring group, almost half the men received no intervention during the 10-year follow-up period.

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# Research

- The PROMIS trial (2017) evaluated the role of multiparametric MRI in men with a clinical suspicion of prostate cancer
- The primary outcome was the detection of clinically significant disease (Gleason pattern 4)
- mpMRI shows double the sensitivity for significant prostate cancer of traditional TRUS biopsy alone
- Used as a triage test mpMRI allows some men to safely avoid biopsy.

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# Active Surveillance

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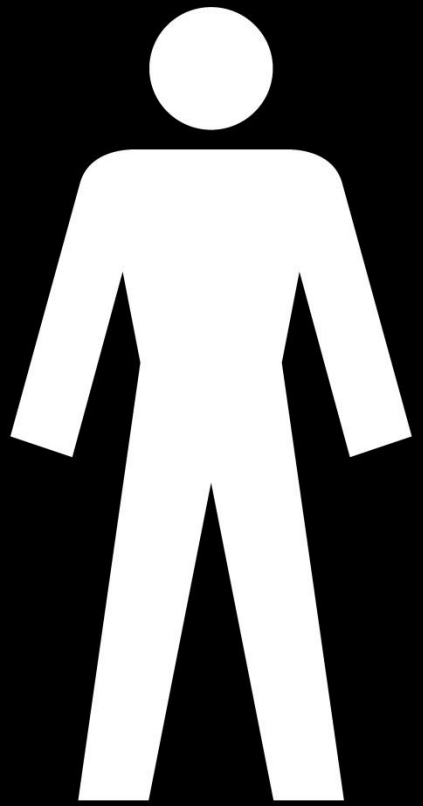

Prostate Cancer UK's mission is to stop men dying from prostate cancer through shifting the science over the next 10 years to focus on radical improvements in diagnosis, treatment, prevention and support.

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- In 2017 research was commissioned by Prostate Cancer UK to look in depth at active surveillance
- FOI request
- Survey of men with localised prostate cancer
- Qualitative data
- Literature search and review – global protocols, cohort studies and latest evidence on active surveillance
- Active surveillance ERG – panel meeting on 8th March 2018
- Achieved clinical consensus on best practice approach to AS using mpMRI (diagnosis and follow-up)

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**Inclusion criteria**

**Gleason grade: 3+3 – primary treatment recommended is active surveillance**

**Consider active surveillance for men with prostate cancer with the following characteristics:**

- **Gleason grade: 3+4 AND**
- **mpMRI T stage: ≤ T2* AND**
- **Biopsy and MRI should be concordant AND**
- **PSA Density of ≤0.2 ng/ml² AND**
- **Men enrolled onto active surveillance should be considered fit for radical treatment**
- **Note - Men who are suitable for active surveillance should have access to specialist information and support during the decision-making stage. Patient priorities should be considered, and all potential treatments, side-effects and risks should be discussed prior to active surveillance enrolment.**
- ***For men not suitable for MRI then clinical T staging should be used.**

**Exclusion criteria**

**Men not suitable for AS include:**

- **Gleason grade ≥4+3 with pattern 4 disease in more than 2 cores or >5mm of cancer in a single core** OR**
- **mpMRI T stage: ≥T3a*****
- ** Very low volume 4+3 – consider re-biopsy if patient wishes to have active surveillance. [Low volume defined as Gleason 4 pattern disease in 1 or 2 cores or <5mm of cancer in any core.]**
- ***For men not suitable for MRI then clinical T staging**

**Active surveillance follow-up protocol**

**Men on active surveillance should have access to a clinical specialist nurse**

**Men should be offered and have access to support / counselling during their time on active surveillance**

**Year 1 of AS**

- **Men should be provided with a personalised active surveillance plan, including details of, PSA interval, individualised PSA threshold for re-assessment and follow up. The personalised plan should be communicated to the patient's GP.**
- **A repeat PSA test should be conducted every 3-6 months**
- **A repeat MRI scan should be conducted at 12 months after baseline**
- **Consider deferring routine 12-month biopsy if patient is considered low risk of progression or re-classification. E.g. stable MRI and PSA**
- **DRE performed at 12 months where MRI contraindicated**
- **A repeat biopsy should be offered when MRI shows a suspicion of progression or if there is evidence of PSA changes (e.g. the individualised PSA threshold is breached)**

**Year 2+ of AS**

- **Men should be provided with an updated personalised active surveillance plan that should be communicated to their GP.**
- **A repeat PSA test should be conducted every 3-6 months**
- **A repeat MRI scan should be considered if a lesion was visible at baseline or the PSA rises and breaches the individualised PSA threshold.**
- **DRE considered on individual basis**
- **A repeat biopsy should be offered when MRI shows a suspicion of progression**
- **Clinical assessment of suitability for radical treatment should be reviewed periodically**

Table 3 – Prostate Cancer UK ERG on AS consensus statements on best practice of AS

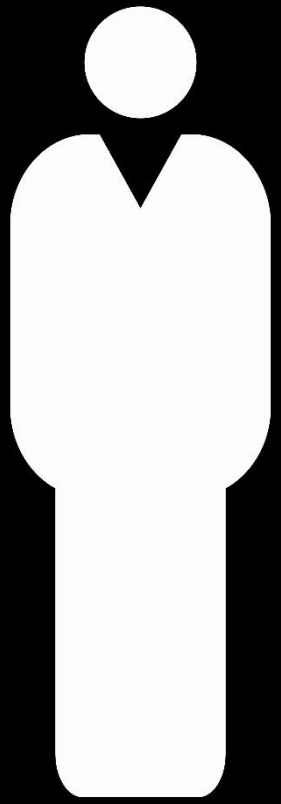
*Note - The active surveillance follow-up protocol acknowledges:*

- *there are limitations of using PSA kinetics as a predictor of biopsy reclassification. Hence, some men, especially the risk averse, may opt for an interval biopsy even if MRI images and PSA tests remain stable;*
- *It is not clear, from currently available evidence, what the ideal intervals for active surveillance follow up should be;*
- *the recommended surveillance protocol remains dynamic and will respond to evolving evidence.*

| When to stop active surveillance |
| --- |
| **The decision to change from active surveillance to radical treatment or watchful waiting should be made in light of the individual man's personal preferences, in addition to clinical features, comorbidities, functional impairment (i.e. e-Frailty index) and life expectancy.** |

## Active Surveillance

## CNS



# The CNS role in Prostate Cancer

- Every man with prostate cancer should have access to the expertise of nurse specialists throughout their treatment and care journey
- Positive impact on patient experience and outcomes
- Numbers of specialist nurse posts are not proportional to disease incidence
- Workload
- Reduction in nurses entering speciality
- Large numbers of nurses due to retire
- Multiple tumour types
- Ever evolving role

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I saw the prostate cancer booklet on his desk first, so before he told me I knew. They gave the me the Gleasons – at the time I didn't know what they were! Six I had, it was all foreign language! Nobody said this was this and this was that. I felt like the guy in the TV advert – he's walking, feels dizzy, couldn't hear anything

– Radical Prostatectomy Patient & Active Surveillance Rejecter

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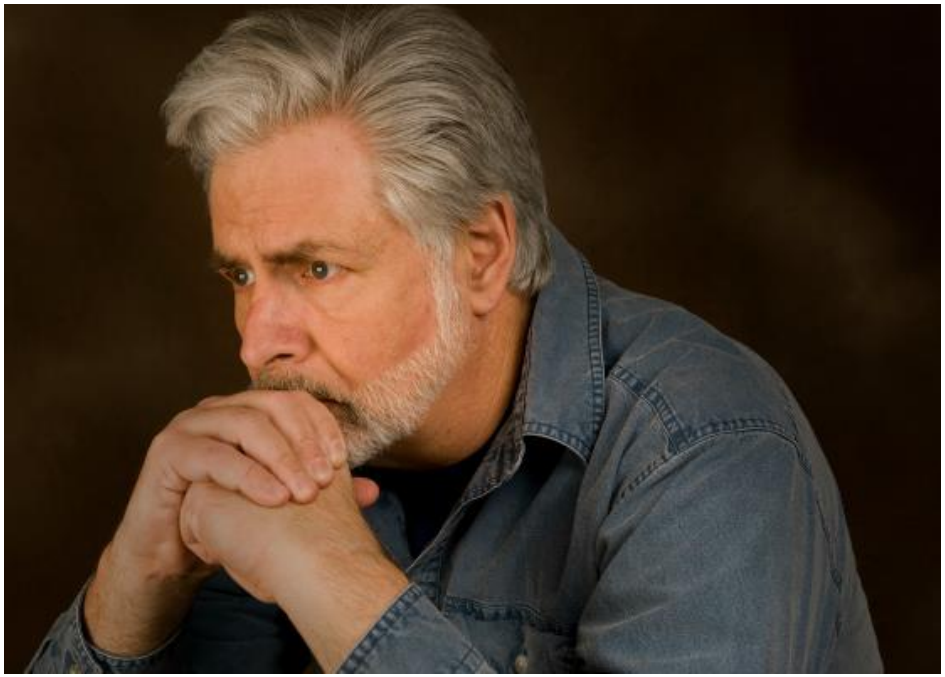
They said for prostate cancer under NO circumstances go online, you'll think you'll be pushing up the daises in a few months. When you're in that state of mind, it does play tricks

and you are trying to discern what's truth and what's not

Active Surveillance Patient



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# Key Areas for more Support

- **At certain times:**
- At diagnosis: feeling informed enough to choose AS and supported enough to make the decision
- The first 1-2 years: more worries at the beginning, when men will drop out
- **With certain people:**
- Single men,
- Men without a clear support network
- Men who have had a negative diagnosis experience
- Men who feel unconfident in their medical team

# BEST PRACTICE – DIAGNOSIS

**CLINICAL**

- Handled with empathy, care, respect, assurance
- Diagnosis and prognosis explained clearly
- Reassured their cancer is ***small***
- Information on prostate cancer generally
- An open dialogue during, and post-appointment
- Point of contact to ask questions
- Clear understanding of each treatment option
- Lay language, diagrams, literature
- Specialist, expert opinion on each
- Special assurances needed for AS: different

**EMOTIONAL**

- Ample time to consider each option
- Someone to talk through each option with
- In lieu of partner, nurses/buddy systems to step in
- Ability to draw on real experiences: be it from
- buddies, peers or video channels

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# BEST PRACTICE – ACTIVE SURVEILLANCE

THE PROCESS ITSELF

- Handled with empathy, care, respect, assurance
- More frequent testing at the beginning
- Only moving onto less frequent if stable
- Easy booking of follow-up appointments, reminders
- Consistency of care, who and where
- Expert place of care: urology as a good base
- Clarity on test results (esp. PSA)
  - Personal touch more important for results
  - If delivered by letter, changes contextualised

# The CNS role in AS

- At diagnosis
- Clinical knowledge and expertise
- Information and emotional support
- Point of contact
- Accessible
- MDT meeting
- Advocate
- Survivorship
- Ongoing……..

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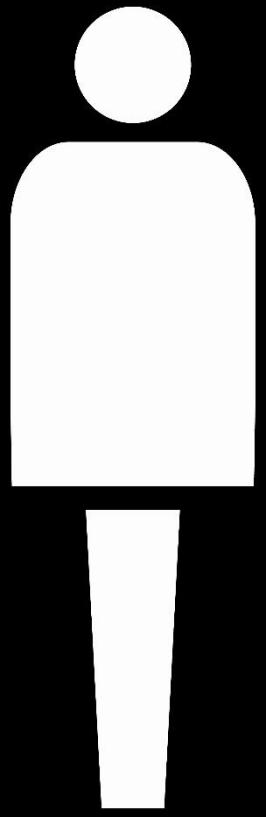
The aim of active surveillance is to catch changes in cancer– poor continuity of care and battling for appointments feels disconcerting and heightens anxieties

## Active Surveillance

## Challenges



# Managing Active Surveillance

- Consensus protocol
- Prostate cancer diagnostics
- Capacity and follow up
- Recall and referral back into system
- Compliance
- Funding
- When to transfer to watchful waiting
- Ongoing support – survivorship

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# Supported self-management and personalised follow-up

- Implementation by April 2020
- Funding supported by cancer alliances
- Different models
- TRUENTH
- Support worker
- Remote monitoring
- Cost effective

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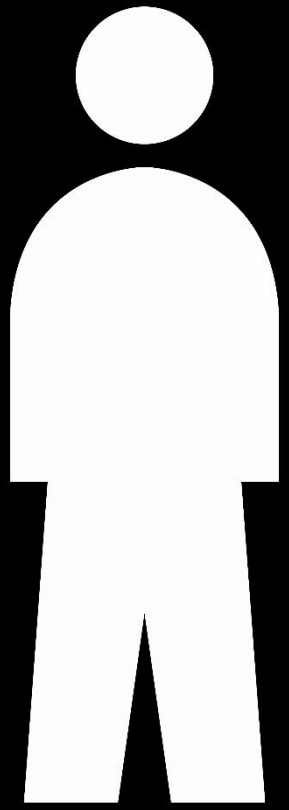
## Active Surveillance

## The Future



# The Future

- Evolving diagnostics
- Prostate cancer timed pathway
- Where and how do we manage follow up?
- Who manages follow up?
- How do we provide ongoing psychological support?

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