Implementation toolkit for the Stratified Cancer Active Surveillance (STRATCANS) programme for early prostate cancer

This toolkit should be used in conjunction with the Implementation toolkit for the NICE Cambridge Prognostic groups and Predict Prostate

STRATCANS (https://stratcans.com)

NOTE- THIS VERSION AND RECOMMENDATIONS HAVE BEEN UPDATED WITH 5-YEAR FOLLOW UP DATA IN 2025

1. **STRATCANS** is a data driven, evidence-based risk stratified protocol for active surveillance follow-up. STRATCANS assumes all men have optimal upfront diagnostics with image guided biopsies (systematic +/- targeted biopsies).

2. Use of **STRATCANS** mandates adherence to the NICE Cambridge Prognostic Group (CPG) stratification system http://cambridgeprognosticgroup.com (Table 1). Men should also have been counselled with the https://prostate.predict.cam/ tool. We strongly recommended men have access to East of England developed **Know Your Options** website which explains the NICE guidance in lay language : https://www.canceralliance.co.uk/prostate. A flowchart of the diagnosis, informed decision-making process and the STRATCANS programme is shown in Figure 1.

3. **STRATCANS** is based on the following evidence base:

   • Survival rates in men with CPG1 and CPG2 are very similar over a 10-year lifespan with marginal gains from immediate radical therapy.

   • Men in CPG3 gain most from radical intervention with a 4-fold reduction in mortality compared to a policy of conservative management.

   • Using progression to CPG3 as an endpoint in a modern optimally characterised active surveillance (AS) cohort shows that only 11% men reach this endpoint over 5 years follow up (Gnanapragasam *et al* 2025)

   • Baseline factors predictive of CPG3 progression are PSA density (**PSAd**) and the **CPG** at the start. Presence of an MRI lesion can further help refine follow-up but have not yet been shown to predict progression in our research (please refer to these papers -

Gnanapragasam *et al* 2019, Thankapannair *et al* 2023, Gnanapragasam *et al* 2025 for reference material underpinning these statements

- The early outcomes of implementing STRATCANS have been published: Thankapannair *et al* 2023 and the 5-year outcomes in Gnanapragasam *et al* 2025.

- External validation in a large US multicentre cohort was presented in 2024 (Wang *et al* 2024 and manuscript in preparation.

4. This evidence base underpins the **STRATCANS** programme to rationalise follow-ups, MRI and biopsy need at the point of AS entry (Table 2).

5. **STRATCANS** outlines a 3-tier follow up strategy intensity which can then be allocated to nurse or consultant led care and different levels of follow up.

6. The strategy requires **patient engagement in PSA self-monitoring**. Patients must be aware of their personal PSA thresholds and triggers to reconnect with care providers. Use of a patient administered PSA tracker may help (e.g. trackmypsa.com, my records or my chart).

7. **STRATCANS** implementation requires careful auditing to ensure safety, pathway integrity and governance. Implementation at each trust should include maintaining a database to monitor outcomes and follow up and re-audit within a 5-year cycle

8. **STRATCANS** is proposed as a 5-year cycle with review at the end for each patient before either:

   - Repeating the 5-year cycle.

   - Moving an individual up to closer follow up (e.g. STRATCANS 1 to 2)

   - Re-evaluation of the suitability of AS and/or switching to treatment or watchful waiting as needed

NICE Cambridge Prognostic Group (CPG)	Criteria
1	Gleason score 6 (Grade Group 1) **AND** PSA < 10 ng/ml **AND** Stage T1–T2
2	Gleason score 3 + 4 = 7 (Grade Group 2) **OR** PSA 10–20 ng/ml **AND** Stage T1–T2
3	Gleason score 3 + 4 = 7 (Grade Group 2) **AND** PSA 10–20 ng/ml **AND** Stage T1–T2 **OR** Gleason 4 + 3 = 7 (Grade Group 3) **AND** Stage T1–T2
4	One of Gleason score 8 (Grade Group 4) **OR** PSA > 20 ng/ml **OR** Stage T3
5	Any combination of Gleason score 8 (Grade Group 4), PSA > 20 ng/ml or Stage T3 **OR** Gleason score 9–10 (Grade Group 5) **OR** Stage T4

Table 1 - Criteria of the NICE Cambridge Prognostic Groups (NG131)

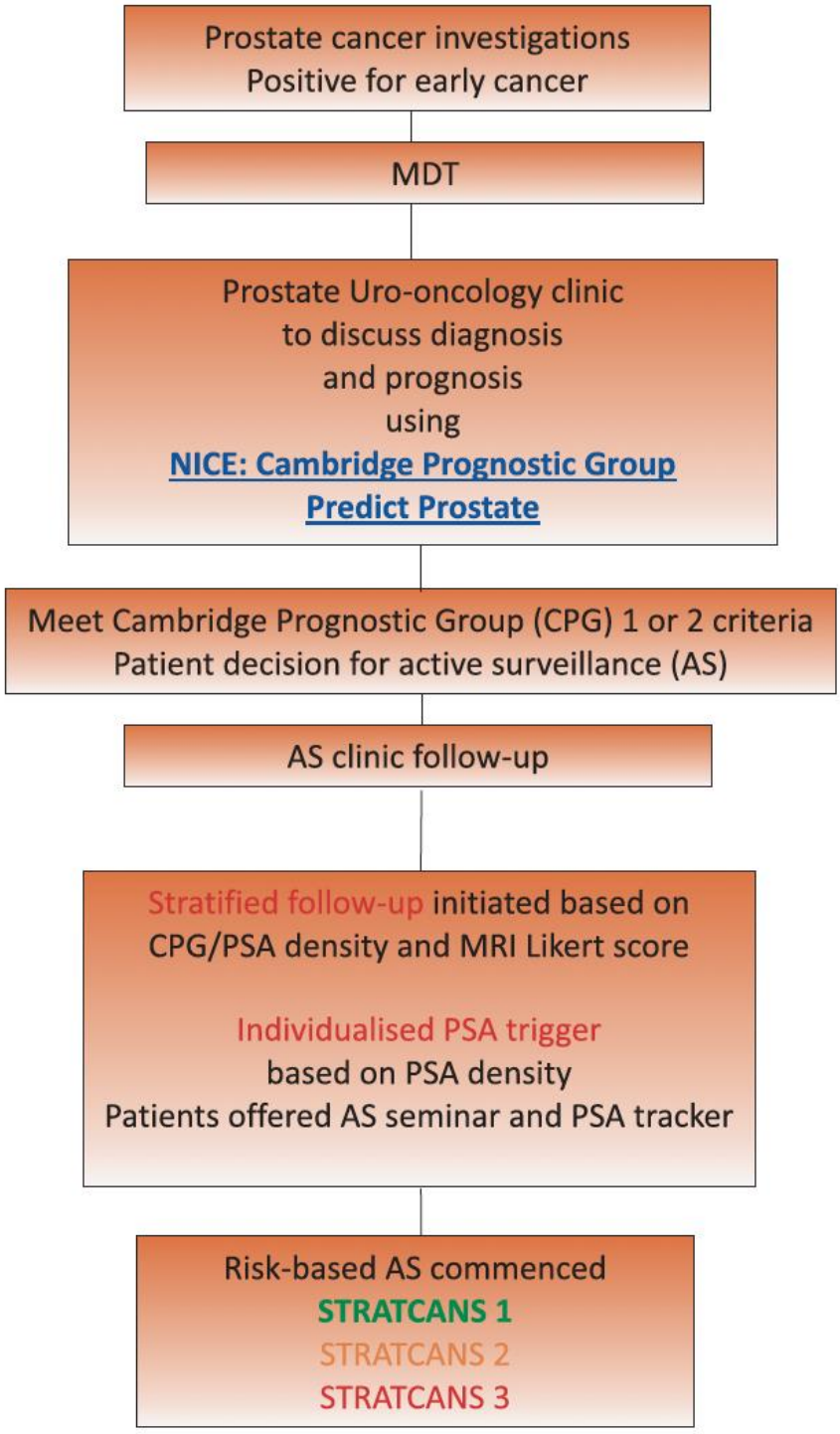

Figure 1 - Pathway for diagnosis, prognosis allocation and allocation of STRATCANS programme (from Thankapannair *et al* 2023)

Surveillance Group	Inclusion criteria at start of AS	Follow up
STRATCANS 1 Low Intensity	CPG1 PSAd<0.15	3-4 monthly PSA - patient self-monitor 18-24 monthly out-patients/telephone MRI no lesion – repeat at 5 years MRI (LIKERT/PIRADS 3-5) repeat 2 yearly No routine re-biopsy Triggered re-biopsy if any change
STRATCANS 2 Moderate Intensity	CPG2 **OR** PSAd ≥ 0.15	3-4 monthly PSA - patient self-monitor 12 monthly out-patients MRI no lesion – repeat at 5 years MRI (LIKERT/PIRADS 3-5) repeat 2 yearly No routine re-biopsy Triggered re-biopsy if any change
STRATCANS 3 High Intensity	CPG2 **AND** PSAd ≥ 0.15	3-4 monthly PSA - patient self-monitor 12 monthly out-patients MRI repeat yearly (regardless of PIRADS) Re-biopsy at 3 years * Triggered re-biopsy earlier if any change

Table 2 – The tiered risk stratified STRATCANS follow up programme. See also https://stratcans.com *Option to omit and discuss with patient

IMPORTANT NOTES

- STRATCANS is based on using progression to ≥ CPG3 as the endpoint.
- The model assumes all men have optimal upfront diagnostics with image guided biopsies
- Digital Rectal Examination (DRE) is not used as part of STRATCANS as long as MRI is possible, If not, replace MRI with DRE in the table above
- The PRECISE system should be used for MRI reporting while on AS (Englman *et al* 2024)
- Unless DRE is needed, clinic reviews can all be done remotely by telephone
- Patient not Present (PNP) follow-up is not safe or recommended.
- STRATCANS has not been formally tested in men with extensive intraductal or cribriform component and is therefore not advised to be used. Instead use clinical judgement.

Guidance for practical implementation of STRATCANS for active surveillance of early prostate cancer

1. STRATCANS- Active Surveillance (AS) entry criteria

• Use the CPG system and Predict Prostate webtool to counsel all men with prostate cancer in which immediate treatment or active surveillance are equal options (Figure 1). These classifications and decision support tools are recommended/endorsed by NICE NG131 and the EAU prostate cancer guidelines.

• Use NICE guidance to identify men suitable for AS and STRATCANS: namely CPG1 and 2.

• Use of percentage pattern 4, mm core length, core positivity, cribriform etc.… have not been definitively shown to predict AS progression and are not part of STRATCANS. Use of these to decide on AS inclusion and follow-up is up to the clinician discretion. 3 and 5-year outcome data has not shown a link between biopsy parameters (percentage core positive) and progression to ≥ CPG3 (Thankapannair *et al* 2023, Gnanapragasam *et al* 2025).

• Any MRI LIKERT/PIRADS can be included into STRATCANS as long as the clinical stage is T2 and no definite/clear extracapsular extension on MRI.

• An early second look/repeat biopsy is highly recommended to ensure no higher-grade disease is present if surveillance is to be risk-stratified. See evidence here: Gabb *et al* 2024

• Based on diagnostic CPG, PSAd and MRI LIKERT score; use Table 2 and/or https://stratcans.com to plan the individual patients AS follow up programme.

2. Patient education & support on active surveillance in STRATCANS

• *Patient self-monitoring and recording of their PSA and knowledge of their personal threshold* is critical to the STRATCANS programme (see section 3 below).

• Men starting AS should have a named CNS for support and a contact number or mechanism to contact that is robust.

• All men should be offered an education session on AS in person, on line or have access to educational material. One resource is from the NHS East of England Cancer Alliance: https://www.youtube.com/watch?v=qKEKwQ6xYus&t=42s

• Men must know the frequency of PSA testing required (3-4 monthly) and be aware of their own personal PSA threshold to look out for. They should be informed they are in a risk stratified AS follow-up and what their schedule of PSA, MRI and clinic reviews will be based on their STRATCANS tier (See exemplar letter below).

• Patient knowledge and empowerment is key -*Treat men as individuals*.

3. Investigations and monitoring during AS in STRATCANS

(i) PSA individualised thresholds on STRATCANS

- A personalised PSA threshold to trigger a review should be defined for each man based on their individual PSA density (PSAd) at the start of AS:
    - If starting PSAd is <0.15, then a PSA level that breaches PSAd 0.15 on two separate occasions (ideally 3-months apart) should be used as a trigger for an early review (e.g. If a man's PSA is 5 at start of AS and prostate volume is 70c i.e. starting PSAd is 0.07, the PSA threshold to look for is 10.5 i.e. PSAd has reached 0.15 - on 2 consecutive tests).
    - If the PSAd is ≥0.15, use a PSA based on PSAd 0.20
    - Higher PSA thresholds should be decided on a case-by-case basis.
    - The STRATCANS webtool can calculate the personalised PSA threshold.

- PSA repeated 3-4 months. Empower men to self-monitor their PSA and be aware of their personal threshold. One example is the trackmypsa.com patient self-management website.

- Digital rectal examination (DRE) are not required and follow-up can be done remotely. However, for patients who cannot have MRI, DRE and in person clinic visits are recommended.

(ii) MRI imaging frequency during STRATCANS

- Repeat MRI should be scheduled as follows:

- No lesion (PI-RADS / Likert 1–2) every 5 years

- Positive lesion (Likert 3–5) every 2 years (Table 2 and see https://stratcans.com)

- Men in STRATCANS 3 should have annual MRI regardless of lesion positivity.

- Use the PRECISEv1/v2 scoring system to compare MRI on AS (Englman *et al* 2024)

- MRI capsular contact or radiological suspicion of T3 are not absolute exclusions for AS but definite radiological or clinical T3a is.

(iii) Repeat biopsies during STRATCANS

- For STRATCANS 1 and 2, a triggered biopsy is recommended if triggered by a change in PSA and/or MRI.

• STRATCANS 3, Protocol re-biopsies at 3-years with the option to not proceed if all other parameters are stable. As in STRATCANS 1 and 2, a triggered biopsy is recommended if triggered by a change in PSA and/or MRI in between protocol re-biopsies.

(iv) Dealing with changes during STRATCANS

• If pre-set PSA is breached then first do earlier MR imaging before a change in surveillance. PSA changes/rises alone should not trigger a change in management. Perform a repeat MRI first. Based on the MRI consider options of repeat biopsy or continuing surveillance.

• If MR imaging shows a change (e.g. PRECISE score of 4) not amounting to progression to clear T3a offer a re-biopsy first. MRI that shows capsular contact but not clear ECE is still considered T2 and should have re-biopsy first before any decision to move to treatment.

• If imaging shows no change but a rising PSA, consider and offer re-biopsy as tumours can progress without image change -Thurtle *et al* 2019 , Gnanapragasam *et al* 2025

• MRI changes alone should not be a definite trigger for conversion to treatment as this may not be associated with a material change in the disease aggressiveness but rather a reflection of natural slow growth of a tumour.

• Tumours can progress even without image changes so it is imperative that protocol re-biopsy are considered (but not mandatory) as part of any AS programme - Thurtle et al 2019 , Gnanapragasam *et al* 2025, EAU Prostate Cancer Guidelines (2024).

• A change from CPG1 to CPG2 either through PSA or a biopsy change from Grade Group 1 to 2 should be discussed and the prognosis and STRATCANS tiers re- evaluated. AS remains a good option for ongoing management.

4. Ending STRATCANS active surveillance

• MRI changes to T3 (i.e. clear evidence of capsular breach) or biopsy progression to ≥ Grade Group 3 (CPG3) should be a trigger for treatment unless the patient is no longer suitable for active treatment and has moved to watchful waiting.

• Attaining CPG3 as PSA has breached ≥10 in men with Grade Group 2 disease does not necessarily mean AS has to end. These men can continue on AS but should be in STRATCANS tier 3 at least. However, this is an individual decision with the patient.

• Moving to watchful waiting is an individual discussion with the patients. As a guide, consider then when the life expectancy is below 10 years based on the UK ONS male life expectancy calculator. Or if increasing frailty (e.g. >6) on the Rockwood scales

• In any scenario above, the patient can choose to move to treatment if they wish and after having the appropriate counselling and information.

- Other scenarios e.g. change in core number and volume remain uncertain as to prognostic implications and is up to centre discretion. Recalculating prognostic estimates with Predict Prostate is recommended.

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Exemplar patient information text for men starting STRATCANS active surveillance

A risk based personalised approach to Active Surveillance monitoring for early prostate cancer- Stratified Cancer Active Surveillance (STRATCANS)

Active Surveillance is a process whereby regular monitoring is used to keep an eye on early cancer. We look for any signs of changes that might mean a need to reassess things or to consider perhaps switching to treatment.

Active Surveillance management

Active Surveillance has been shown through numerous studies over many years to be a very safe approach in managing early Prostate Cancer. You may have just started surveillance or have been under surveillance for many years and you will know that the key tools used for this are regular PSA blood tests, interval MRI scans, repeat biopsies, as well as clinic reviews. Over the years we have refined and improved our Active Surveillance program and have recognised that for many men, changes are often very slow and uncommon. As a result, we have developed an approach to reduce the number of unnecessary clinic visits and tests, and tailor the follow-up care for our men on surveillance. As a part of this, we will therefore use a personalised approach to your ongoing Active Surveillance and design your follow-up to suit your particular situation. Based on your personalised profile we will then arrange scheduled repeat clinic reviews, imaging and biopsies. Our aim is to deliver a surveillance program that is tailored to you and the type of prostate cancer you are diagnosed with. If your risk of disease progression is low your follow-up and review investigations (MRI/clinic review) may be at long intervals.

Importance of your own involvement in surveillance via arranging PSA Tests

Your involvement in your own surveillance is an especially crucial aspect of your care, hence getting regular three to four monthly PSA tests at your GP are important as well as your keeping a record of the results yourself so you know what it is. We will let you know the upper limit of your target PSA value (also called PSA threshold). It's important that you let us know if your PSA results exceed that value on 2 separate occasions so we can review you earlier if required. If you have not already got you own personal PSA threshold in your clinic letter, then please contact your clinical team. To assist you with keeping an eye on your PSA levels, you can use a booklet , your own spreadsheet, or you can use a website we've developed which you can manage yourself: https://trackmypsa.com. Please note that this is not monitored by us or anyone else and is purely to help you self-monitor.

Options for arranging PSA blood test

If your GP cannot arrange regular PSA test for you, please let your clinical team know and they can make alternative arrangements Please note - You will still need to check your own PSA result and keep a record as this will not be monitored by your clinical team. If you breach the PSA threshold we have given you as explained above please get in contact and not wait for your next usual surveillance appointment.