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)

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 mean 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 starting the STRATCANS programme is 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 6-8% of men reach this endpoint over 3 year.
   • 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 this criterion (Please refer here - Gnanapragasam *et al* 2019 for reference material underpinning these principles. The early outcomes and results of implementing STRATCANS have now been published: Thankapannair *et al* 2023. Early external in a US cohort has been presented at the AUA meeting in 2024 (Wang *et al* 2024)

4. This evidence base has been used to construct the **STRATCANS** programme to rationalise follow-ups, MRI and biopsy need at the point of AS entry (Table 2 and see https://stratcans.com). Appendix 1 also lays out the follow up in tabular flow form.

5. **STRATCANS** delivers a 3-tier follow up strategy intensity which can then be allocated to nurse or consultant led care and different levels of follow up. It allows triggers for earlier intervention personalised to the patient.

6. The strategy requires good patient education and engagement in self-monitoring. patients must be aware of their PSA and personal PSA thresholds and triggers to reconnect with care providers. Use of a patient administered PSA tracker may help (e.g. trackmypsa.com).

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 3-year cycle

8. **STRATCANS** is proposed as a 3-year cycle with review at the end for each patient before either :
   - Repeating the 3-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 as needed

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)

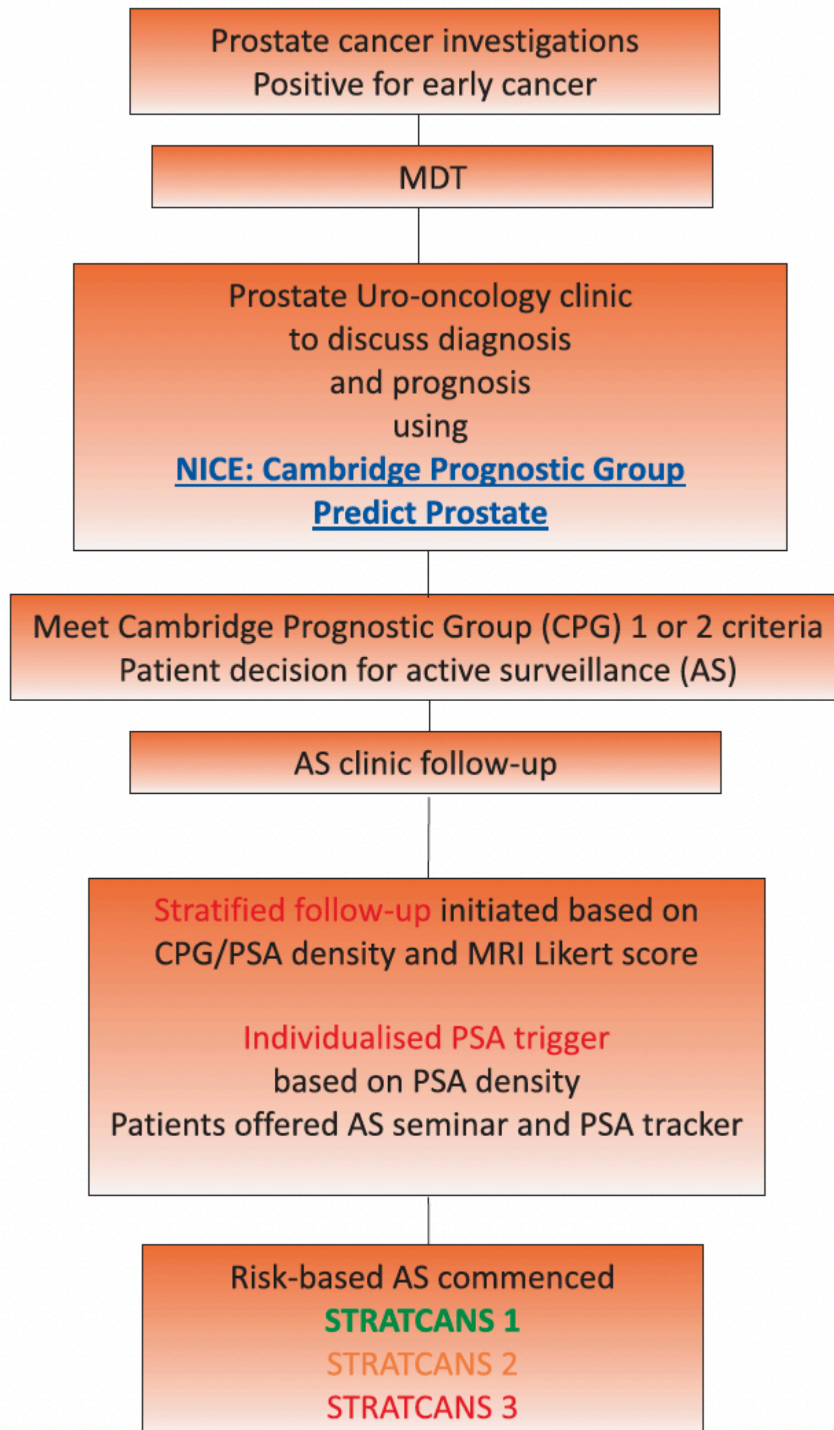

Figure 1 - Pathway for diagnosis, prognosis allocation and allocation of STRATCANS programme.

Surveillance Group	Inclusion criteria at start of AS	Follow up
1 **Low Intensity**	CPG1 PSAd<0.15	3-4 monthly PSA 18 monthly out-patients/telephone MRI at 3 years (no lesion) MRI at 18-months (PIRADS 3) MRI at 12 months (PIRADS 4-5) No routine re-biopsy Triggered re-biopsy if any change
2 **Moderate Intensity**	CPG2 **OR** PSAd $\geq$ 0.15	3-4 monthly PSA 12 monthly out-patients MRI at 3 years (no lesion) MRI at 18-months (PIRADS 3) MRI at 12 months (PIRADS 4-5) Re-biopsy at 3 years* Triggered re-biopsies earlier if any change
3 **High Intensity**	CPG2 **AND** PSAd $\geq$ 0.15	3-4 monthly PSA 6 monthly out-patients MRI 12 monthly (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

- Integrated use of the CPG groups, PSA density (PSAd) and MRI positivity in structuring stratified follow up in AS using progression to CPG3 as the endpoint.
- The model assumes all men have optimal upfront diagnostics with image guided biopsies in positive MRI cases.
- The follow up can be reviewed at 3 years and repeated with patients continuing in the same or a higher surveillance group if needed.
- Use of MRI lesion score can be used to adapt the strategy (Currently data on their impact on AS outcome and prognosis remains unclear).
- DRE is not used as part of STRATCANS as long as MRI is possible , If not replace MRI with DRE in the table above
- Unless DRE is needed a;; clinic reviews can be done remotely or on telephone

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

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).

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

• Use of percentage pattern 4, mm core length, core positivity, cribriform etc…. have not been definitely shown to predict progression on AS. Use of these metrics to decide on AS inclusion and follow up is up to the clinician discretion but is not an exclusion for STRATCANS at this time.

• Any MRI PIRADS can be included as long as the stage is T2 can be included into AS.

• 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 PIRADS score; use Table 2, Appendix 1 and/or https://stratcans.com to plan the individual patients AS follow up programme.

Patient education and support when starting on active surveillance and STRATCANS

• 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 here 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 PSA threshold to look out for. They should be informed they will be 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*.

Investigations and monitoring during AS in STRATCANS

(i) PSA individualised thresholds on STRATCANS

• A personalised PSA threshold for earlier review should be defined for each man based on their individual PSAd at the start of AS:

- If starting PSAd is <0.15, then a PSA level that breached PSAd 0.15 on two separate occasions 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 can 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. *Patient not Present (PNP) follow-up is not recommended.*

(ii) MRI imaging frequency during STRATCANS

• Repeat MRI should be scheduled as follows:

- No lesion (PI-RADS Likert 1–2) every 3 years
- Equivocal lesion (Likert 3) every 18 months
- Positive lesion (Likert 4–5) every 12 months (Table 2 and see https://stratcans.com)

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

• Use the PRECISE scoring system to compare MRI on AS (Caglic *et al* 2021)

(iii) Repeat biopsies during STRATCANS

• For *STRATCANS 1*, a triggered biopsy is only recommended if triggered by a change in PSA or MRI.

• *STRATCANS 2 and 3* - Protocol repeat biopsies at 3 years with the option to not proceed to biopsy if all other parameters are stable

(iv) Dealing with changes during STRATCANS

• If pre-set PSA is breached then consider earlier reimaging before re-biopsy. 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 imaging shows a change not amounting to progression to T3 (PRECISE 4, with or without a PSA breach) offer a re-biopsy out of protocol. 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

• Tumours can progress even without image changes so it is imperative that protocol re-biopsy are part of any AS programme - Thurtle et al 2019 , EAU Prostate Cancer Guidelines (2024), https://uroweb.org/guidelines/prostate

• MRI changes alone should not trigger recommendation for conversion to treatment.

• 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.

(vi) 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 . 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 ONS male life expectancy calculator.

• 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 and is up to centre discretion.

Exemplar patient information text for men starting STRATCANS active surveillance

A risk based personalised approach to Active Surveillance monitoring for early prostate cancer

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. In some circumstance if your risk of disease progression is low your follow-up and review investigations 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 in the attached letter or separately. It's important that you let us know if your 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 our Nurse Specialist. To assist you with keeping an eye on your PSA levels, you can use a booklet which we can send or you can use a website we've developed which you can manage yourself: https://trackmypsa.com. Please not that this is not monitored by us nor are My Chart results.

Alternative options for arranging PSA blood test.

If your GP cannot arrange regular PSA test for you, please let us know and we can arrange this for you at the hospital

Please note - You will still need to check your own PSA result and keep a record as this will not be monitored by us. If you breach the PSA threshold we have given you as explained above please get in contact with us and not wait for your next usual appointment.

References

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Appendix 1

Risk Stratified Active Surveillance Pathway (StratCans)

Diagnosis Clinic Biopsy Result

See in diagnosis clinic and use predict prostate https://prostate.predict.nhs.uk to guide personalised decision making (as recommended by EoE Cancer Alliance). This pathway assumes all men have had high quality image guided and/or transperineal template biopsies.

48hrs post

Decision phone call to CNS

Book to dedicated AS clinic

AS risk stratified follow up group and PSA threshold can be set. If patient has not yet had image guided or TP biopsies this needs to be booked now.

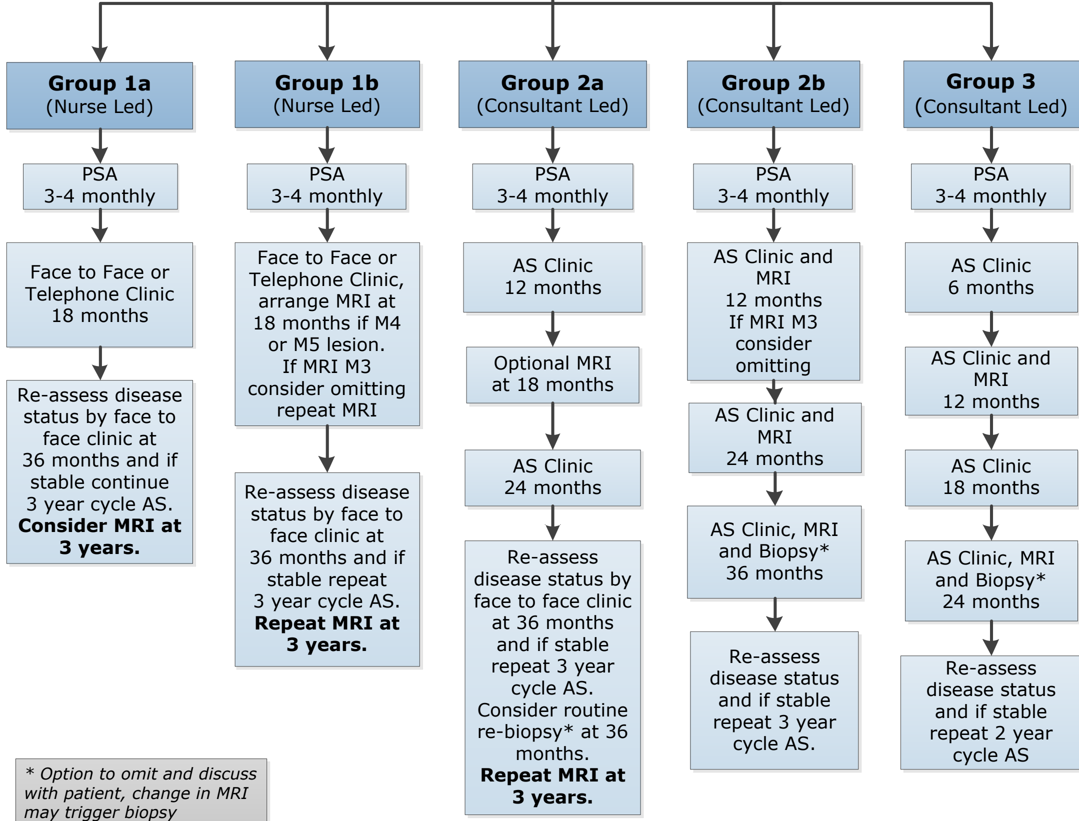
StratCans Active Surveillance Patient education and self management session.

To be held once a month as a group. Educate on active surveillance.

- Reason for risk based follow up
- Use of self management tools (trackmypsa.com)
- Holistic Needs Assessment

STRATCANS Active Surveillance

eHNA



** Option to omit and discuss with patient, change in MRI may trigger biopsy*

Information Box 1

CPG1 - Gleason score 6 (Grade Group 1) **AND** PSA < 10 ng/ml **AND** Stage T1–T2
CPG2 - Gleason score 3 + 4 = 7 (Grade Group 2) **OR** PSA 10–20 ng/ml **AND** Stage T1–T2

Group 1A - CPG1 AND PSAd < 0.15 and MRI M2 Likert/PIRAD
Group 1B - CPG1 AND PSAd < 0.15 and MRI M3-5 Likert/PIRAD
Group 2A - CPG2 OR PSAd ≥ 0.15 and MRI ≤ M2 Likert/PIRAD
Group 2B - CPG2 OR PSAd ≥ 0.15 and MRI M3-5 Likert/PIRAD
Group 3 - CPG2 AND PSAd ≥ 0.15 (MRI positive or negative)

PSA Thresholds

Use PSA density (PSAd) to guide thresholds. TypicalLy set PSA at PSAd of 0.15 or 0.20 using MRI defined volume.

Triggered re-biopsy - If PSA rising and breached pre-set levels or there is a change in MRI. Consider reassess PSA with new prostate volume estimate before deciding on biopsy. If Life Expectancy is less than 10 years - consider switching to Watchful Waiting instead.