Nurse-led model for suspected prostate cancer: Final Report

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Definitions and Abbreviations

ACNS: advanced clinical nurse specialist, an experienced and highly educated registered nurse working (usually at level 7 or above) within a specific field of practice. Educated to MSc or above, and with successful completion of the Advanced Clinical Examination and Decision-Making Course and the Non-Medical Prescribing course.

Cancer tracker: a member of the cancer services team that is specifically dedicated to supporting the pathway of cancer patients in the Board

CCA: cost consequence analysis, an economic evaluation method that compares the costs and consequences of different options.

CNS: clinical nurse specialist, a registered nurse (usually working at level 6 or above) with relevant experience and post-registration education for working within a specific area of practice.

DNA: did not attend – when a patient misses their appointment, it is referred to as DNA.

DRE: digital rectal examination, a procedure where a doctor or nurse checks inside the anus and rectum to feel for abnormalities.

GP: general practitioner

IQR: inter-quartile range, a measure of the spread of the data.

ISAT: intervention scalability assessment tool, a tool to assess the suitability of health interventions for scale-up.

MDT: multi-disciplinary team, a group of professionals from different clinical backgrounds who work together to plan and provide care for patients/service users.

MRI: magnetic resonance imaging, a non-invasive medical imaging technique.

NHS: national health service

NICE: national institute for health and care excellence, a non-departmental public body that produces clinical guidelines for the NHS and wider health and care system.

P: patient participant

PN: pathway navigator, a Band 4 member of the hospital team who helps patients with a suspected cancer diagnosis navigate their care pathway. The role can vary within and between organisations.

PSA: prostate-specific antigen, which can be measured in the blood to help detect prostate cancer and other conditions.

Public contributor: a person unconnected to the organisations or staff involved, with recent lived experience of cancer

S: staff participant

SIMD: Scottish index of multiple deprivation, the Scottish Government's official tool for identifying areas in Scotland of concentrations of deprivation.

SPOCH: single point of contact hub; a centralised service to support patients and keep them updated throughout their cancer journey

TOC: theory of change, a way of explaining how an intervention or set of interventions is expected to lead to specific outcomes.

TP or TRUS biopsy: transperineal or transrectal ultrasound-guided biopsy, the two most commonly used methods to detect prostate cancer, which involve taking small samples of prostate tissue using thin needles.

TrakCare: the healthcare information system used for electronic shared patient records.

Research Team

NHS Fife	University of Stirling
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Lay summary

Prostate cancer is one of the most common cancers in the UK. Early diagnosis and treatment often make prostate cancer curable. In Scotland, patients should wait no longer than 2 months to start treatment, from when cancer is first suspected. Meeting this target can be challenging, particularly with an ageing population and rising cancer cases. It needs enough specialists to ensure patients are not left waiting too long.

Hospital clinics are usually run by specialist doctors. Involving advanced specialist nurses can enhance cancer services by improving efficiency. For example, they can take on some of the tasks previously undertaken by doctors. Specialist nurses are highly trained and provide comprehensive, high-quality and effective care.

A research team tested nurse-led clinics for patients with suspected prostate cancer in Fife, Scotland. Specialist nurses assessed and diagnosed patients in these clinics. They supported them until a decision was made about treatment. The research team worked with patients and others to develop, implement and evaluate this new approach.

The findings suggest that the nurse-led pathway reduced the number of people involved in patient care and cost less than the traditional consultant-led approach. However, it did not appear to reduce the time to diagnosis. Specialist nurses experienced higher job satisfaction during the project when recognised by clinical colleagues in their new role. Patients were satisfied with the quality of the service and felt well-informed and cared for. Staff involved in the new clinics noted challenges however, such as increased admin work and inconsistency in how referrals were allocated to clinics by senior clinical staff. This project highlights that nurses must be well-trained and supported, and there needs to be investment in the nursing workforce to handle growing demand for diagnosis.

Scientific abstract

Background

Clinical and managerial staff in NHS Fife, in discussion with patients, wished to explore new ways of working to help reduce the waits for diagnosis and treatment for prostate cancer. An advanced clinical nurse specialist, working with her team, designed a nurse-led model for the diagnostic pathway. In this model, advanced clinical nurse specialists would run 'rapid access' diagnostic clinics for urgent suspected prostate cancer referrals meeting certain criteria. This was anticipated to reduce the waits for a diagnostic appointment and to free up urology consultant time for treatment. The new pathway was implemented in August 2023.

Objective

To develop and implement a nurse-led diagnostic model in NHS Fife for the assessment and management of suspected prostate cancer referrals, and to evaluate both the implementation and the effectiveness of the new model, to provide recommendations for the transition of evidence into mainstream practice.

Methods

A mixed methods hybrid effectiveness-implementation design, assessing a range of implementation, service and clinical outcomes as determined by the theory of change. To enable sufficient exploration of context and process, a naturalistic case study approach was used. Data were collected and synthesized from patient records and routine health services data, bespoke surveys of patients, semi-structured interviews with staff and patients, and observations and field notes. A modified cost consequence methodology was used to examine resources and costs of the new pathway in comparison to the pre-implementation pathway. Descriptive and inferential analysis was conducted of the routine datasets. Qualitative data were analysed using reflexive thematic analysis.

Results

The routine data accessed for this evaluation was problematic. First, implementation cohort patients (after December 2023) met a certain criteria for age and PSA to be eligible for the nurse-led clinic. When patients in the pre-implementation cohort were matched against these criteria, the sample size was small (N=16, from N=149). Second, contemporaneous data was not made available for the consultant-led pathway. This meant external influences specific to the implementation period (such as increased waits for biopsies) could not be excluded. When patients were matched for age and PSA criteria set for the nurse-led pathway, patients in the implementation cohort waited slightly longer on average (10 days vs 6.5 days), between referral and attending clinic, than the pre-implementation cohorts; time to diagnosis was also longer on average (49 days vs 39 days). However, these findings should be treated with caution given the data limitations. There was no evidence that the time to make a treatment decision was significantly different for the nurse-led pathway. The economic analysis indicated a lower cost for the nurse-led pathway compared to the consultant-led pathway in each of the pre-implementation comparator groups.

The patient survey and interview data indicated that most patients felt informed and satisfied with their nurse-led pathway experience. Urology team members described the potential of the new pathway to reduce delays and improve efficiency, but also revealed challenges like increased administrative demands and inconsistent application of the new clinic criteria, which could impact workloads. They emphasised the importance of gaining support and confidence through trying the pathway, mentorship, and adapting to lessons learned during implementation. They also highlighted positive patient experiences, with better communication, rapport and person-centred care when nurses were involved early and consistently in the diagnostic process.

Conclusions

The NHS Fife improvement project demonstrated that nurse-led diagnostic clinics for prostate cancer can be implemented alongside consultant-led clinics, with good outcomes for quality of care and patient experience. Whilst qualitative data suggested there were improvements in efficiency, with patients being seen quickly following a referral, analysis of the routine data did

not suggest that they reduced delays or improved efficiency across the whole pathway. Since the nurse-led clinics were run in addition to consultant-led clinics, and there was no significant increase in capacity to provide subsequent diagnostic assessments (such as imaging and biopsies), it is perhaps inevitable that overall waiting times were not reduced. In addition, the monthly numbers of patients seen by the service increased by 28%, between the pre-implementation and implementation phases. Advanced specialist nurses played a key role in enhancing communication, patient experience and timely decision-making. While patients found the model acceptable, scaling it up would require learning from this case and successful models elsewhere. Key considerations include deciding whether the pathway should replace or complement consultant-led clinics, ensuring robust referral vetting, and addressing staffing, training and administrative needs. Sustainable implementation depends on a well-supported cohort of advanced nurse specialists and adequate investment in their recruitment and retention, focusing on increasing workforce capacity to meet rising demand.

1 Introduction/background

Prostate cancer is the most common cancer in men in the UK, accounting for more than a quarter (28%) of male cases (2017-19), and affecting one in eight men (Cancer Research UK, n.d.). Incidence has increased over recent decades, but advancements in diagnosis, treatment and awareness have contributed to improved outcomes for men in the UK (Tan et al., 2024). Survival rates are high compared to other cancers, particularly where detection and treatment occur at early stage (Nuffield Trust, 2024). The UK currently does not have a national screening programme for prostate cancer, due to concerns about overdiagnosis and overtreatment from PSA (prostate-specific antigen) testing. However, the current policy that makes PSA testing available to men who request it has led to high rates of unsystematic testing that risks reflecting and reproducing health inequities (Vickers et al., 2023).

The standard of care for diagnosing prostate cancer in the UK focuses on early detection while minimising unnecessary interventions and overdiagnosis. The process typically involves an initial risk assessment conducted in general practice, involving a PSA test and a digital rectal examination (DRE). Family history and age are also taken into consideration in this initial assessment. Men with elevated PSA levels, abnormal DRE findings, or symptoms of concern (such as frequent urination, blood in urine or lower back pain) are referred to urology specialists as suspected cancer (NHS Scotland, 2022). Further assessment conducted by specialist urology teams involves advanced diagnostic imaging (mpMRI), followed by either transrectal ultrasound-guided (TRUS) or transperineal (TP) biopsy.

The NHS Scotland cancer pathway has a 62-day standard, whereby 95% of eligible patients should wait no longer than 62 days from urgent suspicion of cancer referral to first cancer treatment (with 5% tolerance level due to clinical appropriateness). To date, this standard is not met by any Health Board. Performance is particularly poor for prostate referrals, with 42% meeting 62-day standard from April to July 2024 (Public Health Scotland data). Boards highlight that staffing issues combined with high numbers of referrals continue to limit capacity and impact on performance. NHS Fife's prostate cancer waiting times performance are well below the national target of 95% with pre-implementation performance at 21.7% (March 2023).

Clinical and managerial staff in NHS Fife, in discussion with patients, wished to explore new ways of working to help bring the prostate cancer waiting times down. An improvement project was conceived to involve urology advanced clinical nurse specialists (ACNS) to a greater extent in the diagnostic process.

Improvement projects like this are often not evaluated well because they are complex: they involve intervening within a complex adaptive system and often contain multiple interacting elements; there may not be a clear consensus on what constitutes a successful outcome; and there may be limited resources or time available (Greenhalgh & Papoutsi, 2019). However, evaluations are important for determining what worked well, what did not work well, and what changes can be made to improve the success of future projects.

Funding to refine, implement and evaluate the improvement project was sought and obtained from Cancer Research UK. Cancer Research UK's 'Test Evidence Transition' (TET) programme aims to accelerate the adoption of impactful innovations and reduce inequality in access to proven interventions. Through funding and fostering collaboration, TET provides spaces to explore and evaluate pathway innovations. The nurse-led prostate cancer diagnosis project received funding through the first phase of the TET programme. It was a collaboration between NHS Fife and a multidisciplinary academic team at the University of Stirling. The project began on 1st May 2023.

2 The improvement project

2.1 Project management and governance

Cancer Research UK (CRUK) took an 'Active Commissioner' role (Hamilton-West et al., 2024); a key contact for CRUK (Dr Claire Sloan, Senior Researcher) worked closely with the project team throughout, supported by others in the Evidence and Implementation department, and members of an independent Steering Group and external peer reviewers.

The principal investigator, taking overall responsibility for the project at NHS Fife, was Jane Thomson, Advanced Clinical Nurse Specialist at NHS Fife. The chief investigator, taking overall responsibility for the research evaluation, and for overall conduct of the study, was Dr Erica Gadsby, an Associate Professor at University of Stirling. The team incorporated clinical and project management staff based at NHS Fife, and multi-disciplinary research staff based at University of Stirling. The project was co-sponsored (via a collaboration agreement) by the University of Stirling and NHS Fife, who together ensured proportionate, effective arrangements were in place to set up, run, finance, manage and report the research project.

The project was overseen and managed by a project management group, which included a wider team of academics at University of Stirling, and clinical staff and strategic managers from NHS Fife. Also on this group were four public contributors recruited specifically for the two CRUK TET projects in Scotland. This group met five times during the project. Smaller working groups met more frequently in between these meetings, led by Jane and/or Erica.

A project steering group was formed to provide guidance and strategic direction. This group included representatives of both study sponsors and the funder, as well as representatives of patient advocacy groups (Maggie's and Prostate Scotland). This group met online four times during the project and received regular progress reports.

The early conception of the improvement project was informed by patients who were involved in preliminary discussions about the proposal. These were recruited via and hosted by the Maggie's Centre in Fife. Maggie's are a nationwide charity that provides support and evidence to cancer patients and their families. Five men with lived experience of prostate cancer took part in the small group discussion. The focus was on their experiences of the diagnostic pathway. The discussion utilised a photo elicitation method, which provided insights around three themes: the

importance of communication with healthcare professionals; having access to the point of contact; and understanding what support is available. These discussions shaped the focus of our patient interview guide.

2.2 Rationale for improvement project

Faster diagnosis for suspected cancer is a policy target across the UK (Healthcare Quality and Improvement Directorate, Scottish Government, 2023). Scottish Government prioritises earlier and faster diagnosis recognising that Scotland remains behind internationally. In Fife, data illustrated significant waits between steps from referral for urgent suspected prostate cancer to diagnosis, exacerbated by the increase in referrals since the pandemic. This impacted the capacity to see patients in a timely manner, both pre- and post-diagnosis. Focus group discussions with prostate cancer patients in Fife held June 2022 highlighted delays in the current process and the need for an improved patient pathway that is more person-centred. Key themes identified were long waits for appointments, no clear timescale for the process, communication deficits with limited understanding of who they were seeing for what, and lack of clarity regarding process. A review of the pathway of a random selection of eighteen patients in March 2023 identified delays and significant variations across the pathway.

The improvement described in this project had the potential to streamline referral pathways, reduce the time to diagnosis, and provide a more person-centred diagnostic service. The rationale for this study was to capitalise on key opportunities to support the effective and efficient use of resources across the health care system, at the same time as delivering excellent patient experience.

2.3 Aims and objectives of the improvement project

The improvement project was designed to shift key tasks and responsibilities in the prostate cancer diagnostic pathway from Urology Consultants to Advanced Clinical Nurse Specialists (ACNS), supported by patient Pathway Navigators (PNs). PNs are generally from healthcare backgrounds but prior to this project, their role was administrative and primarily focussed on patient communication (e.g. signposting).

The project team worked together to conduct a mapping of the diagnostic pathway, resulting in ‘swimlane’ diagrams for the current state (before the improvement project) and the desired future state (after the improvement project), showing who is responsible for each step in the diagnostic process. The diagnostic pathway prior to the improvement project is illustrated in Figure 1.

As the diagram shows, the urology consultant was responsible for vetting GP referrals, seeing the patient in the one-stop diagnostic clinic, requesting and reviewing imaging scans, and performing the TP biopsy. In this pathway, the first contact the ACNS had with the patient was when they discussed biopsy results and potential treatment options in the histology/news clinic, prior to their case being discussed in the multidisciplinary team meeting. It was at this point also, that the patient pathway navigator first met those patients with confirmed cancer. In patient feedback

prior to developing the improvement project, it was noted that nurse specialists could be involved much earlier, to improve the communication with and support of the patients from the start.

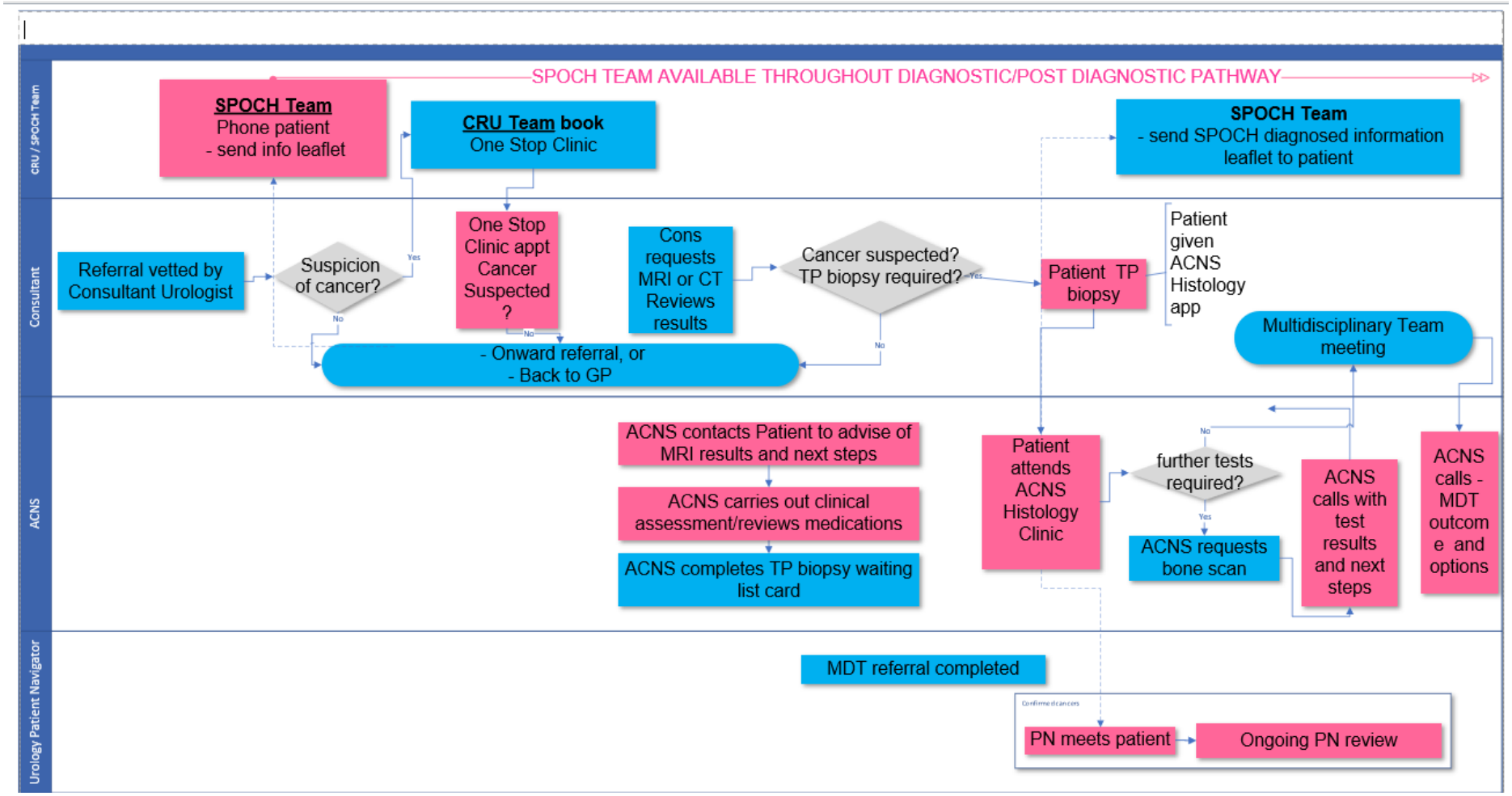
On the basis of this mapping, the objectives of the improvement project were clarified as below.

The improvement objectives were to:

1. Develop new vetting guidance for prostate cancer referrals, to identify patients suitable for the nurse-led pathway, and to identify those who should be seen within the consultant-led clinic.
2. Establish nurse-led prostate diagnostic clinics, to run alongside usual consultant-led clinics at least initially, with the potential to decrease the latter as time went on. Some tasks performed during the diagnostic clinics would be transferred from consultants to ACNS, supported by PNs, following suitable training.
3. Improve communications with the patient; the ACNS, supported by PNs, to communicate with and see the patients throughout the diagnostic journey, tracking and following up test-results from the start to the end.

The change proposed in this project had the potential to improve patient experience and make more efficient use of consultants' time.

Figure 1: 'Current state' flow diagram, prior to improvement project (May 2023)



2.4 Explanation of the improvement project

The improvement project is described using a completed Template for Intervention Description and Replication (Appendix 1: Improvement project description, using TIDieR framework) (Hoffmann et al., 2014).

The improvement project consists of a revised patient pathway and was run by an ACNS or ACNS trainee. They were mentored by a specific consultant urologist and supported by the consultant urologist team and two PNs. Key stages of the project included:

1) Development of a process and new clinic criteria for vetting/sorting the GP referrals (Appendix 2: Standard operating procedure: rapid access diagnostic clinic).
2) Planning and implementation of 3 new outpatient clinics (Rapid Access Diagnostic Clinics) across two hospital sites in NHS Fife, to be run by ACNS, supported by PNs.
3) Identifying relevant training needs for ACNS/ACNS trainee and PNs and delivering training and mentoring as required.

The mapping of the future-state (post improvement project) pathway is illustrated in Figure 2, below. This diagram shows the significantly reduced workload related to those patients allocated to the nurse-led pathway, with a consequent increase in tasks and activities conducted by the ACNS and PNs. In addition, the ACNS and PNs are involved from the very beginning of the secondary care diagnostic pathway in the future-state model.

According to the Standard Operating Procedure, in the new face-to-face diagnostic clinic appointment, the patient initially meets with the PN who conducts a flow and scan, urine test, measures height and weight and, if necessary, takes blood for testing. Thereafter, the ACNS discusses history of presenting condition, past medical history, medication history and undertakes assessments such as a DRE. If the patient requires further investigation, the ACNS request MRI and/or biopsy appointments. Later, the ACNS or ACNS trainee phones the patient to communicate the results of the MRI and advise if a biopsy is needed. The patient is subsequently called to a face-to-face histology clinic appointment, during which the ACNS or ACNS trainee will discuss the results of the investigations and the diagnosis.

The improvement project evolved throughout implementation, in response to learning and in response to changes in the environment (particularly staffing). The TIDieR template was used to keep a track of key changes. The main aspects of change were:

1) number of clinics held each week, which fluctuated between one and three.
2) the vetting process: initially it was intended that the consultants would vet referrals. However, as the nurse-led clinics were not being used to their full capacity, the ACNS volunteered to support vetting. When the ACNS was replaced by the ACNS trainee (from May 2024), nurse-led clinics were reduced to one per week. At this point, consultant vetting was satisfactory to ensure that the clinic was full. However, the ACNS trainee

double checked the consultant referrals and removed any referrals she felt to be inappropriate.

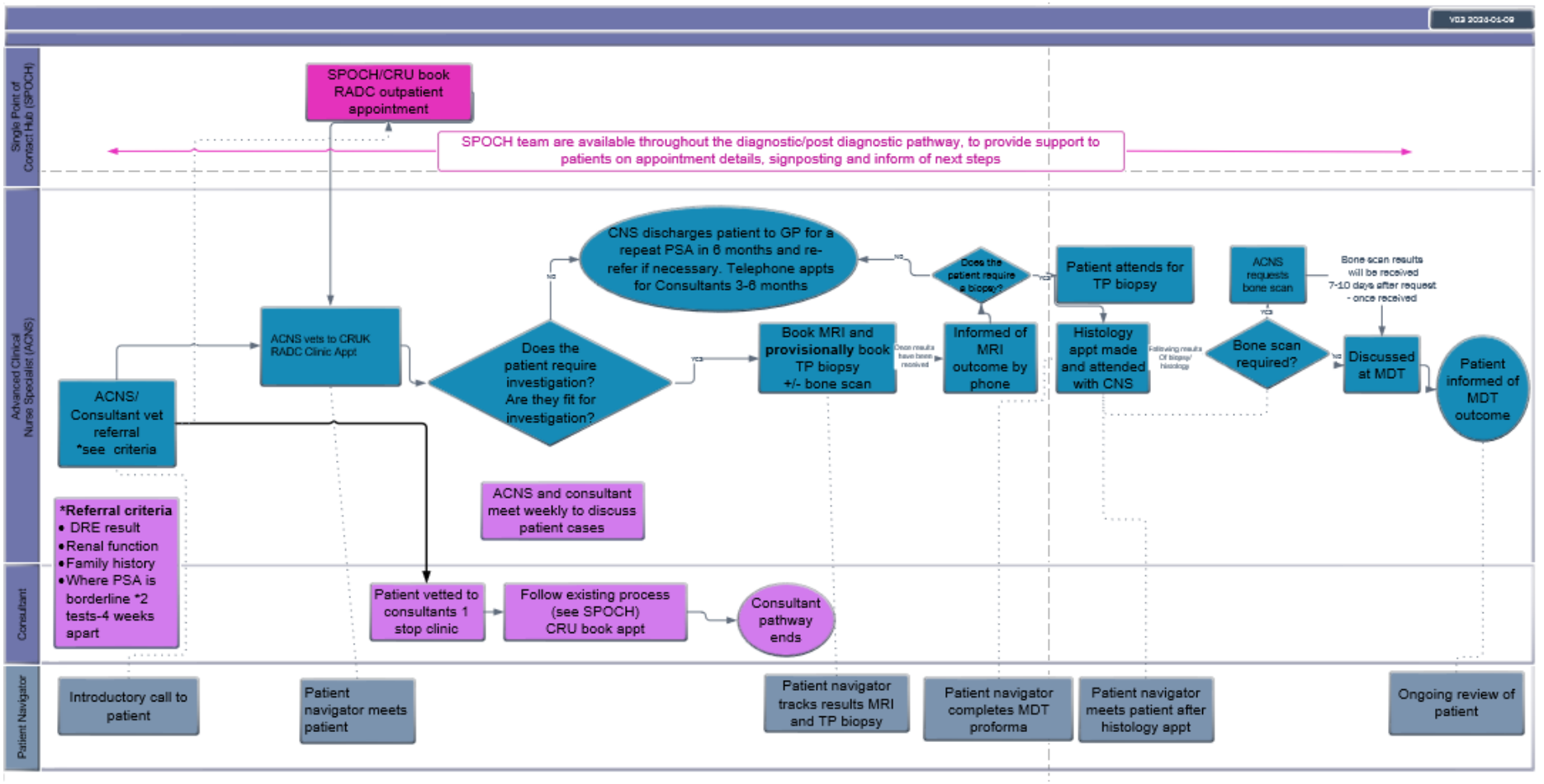
3) staff changes: a CNS temporarily joined the team and from October 2023 to May 2024 ran some of the histology clinics; an ACNS trainee took over from the ACNS when she left in April 2024, with an overlap period of 2 months for handover; a PN joined the 'retire and return' scheme, which reduced her working hours (which were not replaced).
4) inclusion criteria for the clinic: initially the criteria for the nurse-led clinic were "PSA<10, no haematuria, no bone pain". However, it was agreed from the start that patients would be assessed on a case-by-case basis with a consultant, and if deemed appropriate, patients with a higher PSA, with or without bone pain, might be seen in the nurse-led clinic if deemed appropriate by those doing the vetting. Additional criteria were subsequently added. The first change was introduced in December 2023 when it was agreed that patients over 75 years old should be seen by consultants rather than ACNS, due to potential multi-morbidities. Further changes took place in April 2024, when the ACNS trainee took over from the ACNS. It was clarified that no patients with multimorbidity would be seen in the new pathway. The main addition was that patients had to be suitable for MRI (previously ACNS could request CT) and "no bone pain" criteria was removed. This ensured that patients were eligible for treatment and those who were more complex (with limited treatment options) would be seen by consultants.

The following tools were developed as part of the improvement project (see Appendices 3-6):

- Bladder Diary Instructions
- IPSS questionnaire
- Flow and scan patient questionnaire
- Patient leaflet about the new pathway

All tools were shared with patients before their first appointment in the clinic. Asking patients to complete a bladder diary and IPSS questionnaire (validated symptom score) gives a better understanding of the severity of urinary symptoms and gives a baseline prior to commencing any treatment e.g., oral medications; it can be repeated again while assessing the effectiveness of any medications or advice given. During the consultation ACNS also assesses any underlying causes and lifestyle habits e.g., type of foods and drinks that can cause irritation to the bladder, and advises accordingly. NICE guidelines recommend these tools and assessments.

Figure 2: 'Future state' flow diagram, following implementation of improvement project (mapped in May 2023)



3 The evaluation of the innovation project

3.1 Design

The research evaluation aimed to assess whether the proposed intervention, to deliver an advanced clinical nurse specialist-led diagnostic pathway for patients in NHS Fife referred with suspected prostate cancer, is appropriate, feasible, effective and potentially scalable. Since we sought to understand a potential improvement within a complex system, we used a hybrid effectiveness-implementation design that assessed both the efficiency of the new pathway and its implementation strategy, in support of rapid translation (Curran et al., 2012).

The evaluation was theory-informed, using an explicit theory of change (TOC) developed at the outset by the project team, with input from public contributors, clinicians and other stakeholders. The TOC is shown in Figure 3. It explains how the improvement project is expected to produce its results, outlining the mechanisms of change as well as the key assumptions that underpin the project's success. The TOC was used to identify indicators that were meaningful, feasible and appropriate for the project's evaluation. These are summarised in Table 1.

To enable sufficient exploration of context and process, a naturalistic case study design was used. This design is ideally suited to real-world, sustainable intervention development and evaluation where exposure to the intervention occurs in natural circumstances (Swanborn, 2010). Where appropriate, outcomes were assessed prior to and following the intervention. This design allowed for in-depth exploration of the intervention, its implementation, and the context in which it was implemented, drawing on data from multiple sources. This provided a rich understanding of the complexities of the intervention and helped to identify factors that influenced its effectiveness and implementation. It also helped to identify changes and developments over the implementation period.

Ethics approval for this study was granted by South Central – Oxford A Research Ethics Committee (23/SC/0252). Management approval was granted by NHS Fife, on the basis of the favourable opinion from the Research Ethics Committee, and the Organisation Information Document site agreement (IRAS project ID: 326327).

3.1.1 Patient and public involvement

Four public contributors (three female, one male) with lived experience of a cancer diagnosis were recruited to support this study. In addition to taking part in the project management group, the public contributors have met regularly with the research team to provide lay perspectives at all stages. Their input helped to shape the theory of change and data collection tools, thus ensuring lay perspectives in the former, and appropriate language in the latter. To inform data analysis, they were involved in analysing qualitative data during the initial coding stage.

Some specific examples of the input from the public contributors are:

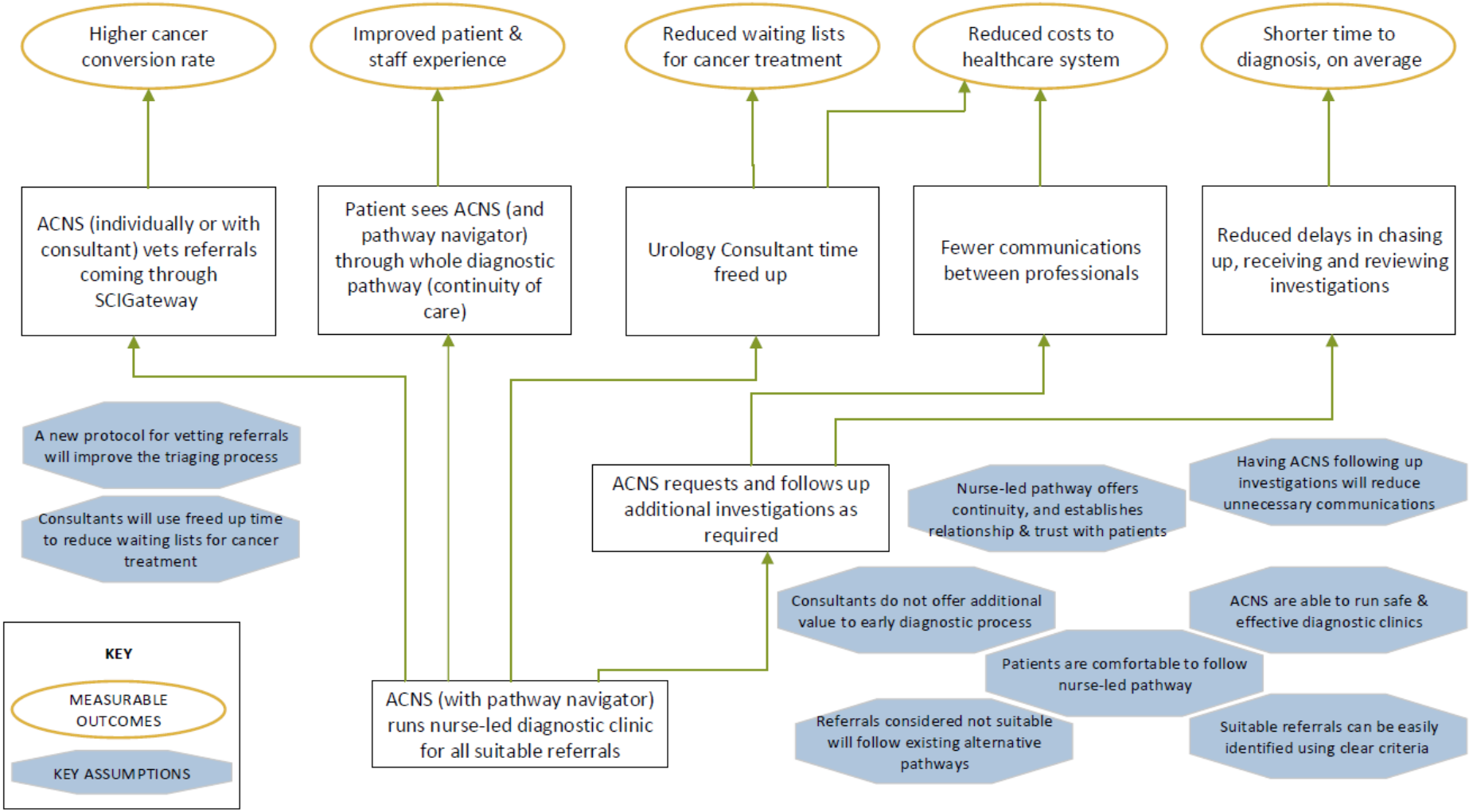
- Their feedback ensured that all questions in the interview guide and patient questionnaire were written in lay language and easily understandable by members of the public.
- Patient questionnaire was revised with additional question included to capture patient satisfaction with the pathway and reorganising the order of questions for clarity.
- Draft TOC was adjusted to ensure language around patient experience was inclusive.
- Public contributors were co-authors of the protocol paper by providing lay perspectives into the draft.

The full protocol for the research evaluation is presented in Appendix 7.

Table 1: A summary of indicators for the project's evaluation

Outcomes, mechanisms and context	**Indicators**
Reduced cost to healthcare system	• Clinical effectiveness • Resource allocation • Efficiency and flow
Higher cancer diagnostic rate	• % of referrals diagnosed as prostate cancer before and after implementation
Shorter time to diagnosis	• Time from referral to diagnosis, before and after implementation
Shorter time to decision to treat	• Time from referral to decision to treat, before and after implementation
Improved patient experience	• Acceptability/appropriateness • Patient safety • Anxiety
Urology clinic setting	• Acceptability/appropriateness of nurse-led clinics • Feasibility • Fidelity • Sustainability

Figure 3: Theory of change (TOC) for the Fife prostate diagnosis improvement project



3.2 Data collection

3.2.1 Routine quantitative data

Routine quantitative data was collated by the project manager at NHS Fife from SCI/Trakcare, the Cancer Waiting Times tracking database, eCASE (the local audit system) and (for the implementation cohort) the local patient management Excel. This was done with the support of an information analyst. All personal identifying information was removed, and the data was transferred to the research team for analysis in accordance with our data sharing agreement and data management plan.

Data was extracted/collated for 3 time periods:

i. Pre-Covid: for a period of 3 months in a pre-pandemic period (May to July 2019), to analyse key measures in what might be considered a 'business as usual' environment.

ii. Pre-implementation: for a period of 3 months immediately prior to implementation (May to July 2023), to analyse key measures immediately prior to the change in pathway (post-pandemic).

iii. Implementation: for 9 months in phase 2 (August 2023 to April 2024), in order to analyse key measures following the change in pathway.

Data included all NHS Fife patients referred to the Urgent Suspected Cancer pathway for the urology diagnostic clinic within the given time periods. Data for both pre-pandemic and pre-implementation cohorts were planned to be used to adjust for the effects of the Covid-19 pandemic, but small numbers meant that this was not possible. Additionally, the pre-pandemic dataset was excluded from the main analyses as it does not reflect the current operational environment and does not provide a suitable comparator group for evaluating the intervention. Further details are provided in the appendix (Appendix 8: Technical Report: routine data analysis). Pre-Covid data are presented for completeness. Comparisons were made between pre-implementation and implementation cohorts. The measures included in the dataset are summarised in Table 2.

3.2.2 Patient Survey Data

All consenting patients referred to the nurse-led urology diagnostic clinic during a 12-month period within the implementation phase were asked to complete a short online (anonymous) questionnaire, asking about their experience of the diagnostic pathway *up to* the point of diagnosis. Participants were recruited within two and four weeks of completing the pathway (by clinic staff/patient navigators) and encouraged to complete it at home. One reminder was sent (via phone, email or text message depending on the patient preference) to complete the survey.

Table 2: Measures included in the routine datasets

Measure		Cohorts 1 & 2	Cohort 3
Patient age		✓	✓
SIMD Quintile	Deprivation	✓	✓
Referral details	Various*		✓
Vetting date			✓
Diagnostic clinic attendance date		✓	✓
PSA		✓	✓
MRI date		✓	✓
Bone scan date		✓	✓
Biopsy date		✓	✓
Diagnosis		✓	✓
Pathway defined outcome		✓	✓
Diagnosis news date		✓	✓
First MDT date		✓	✓
Treatment data	Various*	✓	✓

*Note, various may include: referral source, referral quality, referral date, type of initial treatment, date of first treatment.

3.2.3 Patient Interview Data

A small subset of patients was invited to take part in a semi-structured telephone interview with an experienced member of the research team, lasting between 17 and 35 minutes (average = 28 minutes). These took place from March to June 2024. Interview guides were developed with input from stakeholders and public contributors and were informed by the analysis of the patient surveys.

Interview participants were recruited by PT (researcher). The study team randomly selected participants from those who expressed interest in participating in a telephone interview. Potential participants could express their interest after the completion of the survey. We included new patients who had attended the nurse-led diagnostic clinic in the previous 3 months. Exclusion criteria were those who were currently undergoing radical treatment, those who were unable to

give informed consent, or those who had contraindications (e.g., symptoms or medical conditions) that might prompt difficulty or distress.

3.2.4 Staff Interview Data

A purposive sample of staff either involved in implementing the intervention, or directly affected by the new pathway (urology consultants, nurses, administrative staff, patient pathway navigators) were interviewed between January and July 2024. Interview guides were developed with input from stakeholders and public contributors and were informed by the analysis of other data. All interviews were audio-recorded with permission, anonymised and transcribed by a professional transcriber.

3.2.5 Project documentation and field notes

A range of other data such as meeting notes, action plans, team discussions, self-reports/audits by the implementation team, and observations were collected throughout the study period to examine the implementation of the intervention. The collection of this data was facilitated by the participatory implementation process and close working of all relevant stakeholders. Data focused on assessing fidelity (in relation to the implementation plan) and adaptation, adoption and acceptability (particularly amongst different groups of staff), delivery settings and workforce, implementation infrastructure, and sustainability. Data collection and information sources were geared towards enabling us to answer the relevant questions posed in the Intervention Scalability Assessment Tool (ISAT) (Milat et al., 2020).

3.3 Data analysis

All data sources were analysed separately as one piece of a jigsaw, with each piece contributing to understanding of the whole phenomenon (Hancock et al., 2021).

3.3.1 Qualitative data analysis

Qualitative data were analysed within NVivo (Lumivero, 2022), following Braun and Clarke's (2021) approach to reflexive thematic analysis. Initial coding combined deductive coding, based on the TOC, and inductive coding, driven by the data. Coding was completed by two members of the research team (PT and MM) who met regularly to discuss the coding process. Regular meetings with other members of the research team offered additional space for reflection on analysis. Where appropriate, our public contributors were asked to inform aspects of analysis and interpretation through feedback and discussion. The research team shared with them initial coding of first patient and staff interviews for discussion. Their feedback informed interpretation of data and identified new areas to explore during the following interviews.

3.3.2 Quantitative data analysis

Quantitative data was analysed within IBM SPSS v28 (IBM Corp, 2021). Data from the first two cohorts and the third were created independently and used for different purposes. Integration into a single dataset required some recoding, with advice from the NHS team. The pre-Covid cohort was excluded from inferential analysis because it does not reflect the current operational environment and exhibited greater historical variability in referral practices, however the

descriptive data is included for completeness. The pre-implementation cohort, representing the system immediately prior to the intervention, was chosen as a more stable and temporally relevant comparator for assessing intervention effects. The vetting criteria for the implementation cohort changed over the course of the project and allowed for non-protocolised, clinical judgements. The simplified criteria of patient's aged under 76 and PSA count of less than 10ng/ml was used to identify patients intended for the nurse-led pathway; this accounted for the majority of vetting decisions. This enabled matching of patients in the previous cohorts to allow for testing of differences in time between referral and first appointment, referral and diagnosis. Group differences between the pre-implementation and implementation cohorts were tested using the non-parametric Mann-Whitney test. Differences tested included: days to patient being first seen; days to diagnosis; and days to decision-to-treat.

3.3.3 Over-arching analysis

When the first stage of analysis was complete, data was then reduced to a series of thematic statements or summaries for each data source (Billings, 2004). The second stage of analysis involved pattern-matching across the data, seeking rival explanations, linking data to propositions (generated by our ToC), and building explanations. The propositions at the heart of the improvement project were:

1. The nurse-led diagnostic pathway will create efficiencies (such as time and resource use) in the diagnostic process.
2. The nurse-led diagnostic pathway will lead to fewer unwarranted delays in the pathway.
3. The nurse-led pathway will have positive implications for patients' experience of the diagnostic process.

Organisational, behavioural and implementation theories were employed, alongside public contributor input, to inform interpretation of data. For example, the consolidated framework for implementation research informed our analysis of factors that influence implementation, including staff readiness, intervention characteristics and external pressures. Since the improvement project was unfolding in a complex environment with dynamic and unpredictable actions and interactions, we viewed the evaluation situation through the lens of systems thinking, looking beyond unanticipated consequences to being genuinely open to emergent outcomes.

3.4 Health economic analysis

The objectives of the economic analysis are linked to the measurable outcome "Reduced costs to healthcare system" outlined in the TOC (Figure 3 Theory of Change) and are as follows:

- To identify and map key events on the patient pathway in line with the scope of the interventional change;
- To identify and describe key resources and costs for each patient pathway;
- To evaluate the cost consequence of the Intervention pathway in comparison to Pre Intervention and explore the robustness of these estimates.

The outcomes were met using a modified cost consequence methodology using a decision analytical model built with TreeAge Pro Healthcare software. A full explanation of the modelling is provided within the Technical Report (Appendix 9: Technical report: health economic analysis).

The study population comprised people who were referred to the urology team in NHS Fife for suspected prostate cancer during the observation period pre- and post-implementation. Vetting guidance for suitability for the nurse-led pathway was applied to routine patient data to meet the following inclusion criteria, to ensure validity of the comparison:

- Age 75 years or under AND
- A PSA of less than 10.00

The base case group comprised patients receiving consultant-led care, as per Figure 1: 'Current state' flow diagram, prior to improvement project (May 2023), who met the inclusion criteria above. The comparator group comprised patients eligible for the new nurse-led pathway, as per Figure 2: 'Future state' flow diagram, following implementation of improvement project (mapped in May 2023), who met the inclusion criteria.

The time horizon of the model was linked to the longest time period between referral and diagnosis noted in the routine data (149 days). Given this timeline is less than one year, no discounting was applied.

For the model, the outcomes that were relevant to achieve the objectives of the CCA were:

- Age: 75 years or less to meet nurse-led pathway vetting guidance;
- PSA: Less than 10ng/ml to meet nurse-led pathway vetting guidance;
- Gleason score: Indicative of severity of cancer;
- Resource use: Which resources were required by each group on the pathways to enable costs calculation.

All outcomes were calculated using routine patient data supplied by NHS Fife.

Resources relevant for consideration in this analysis were:

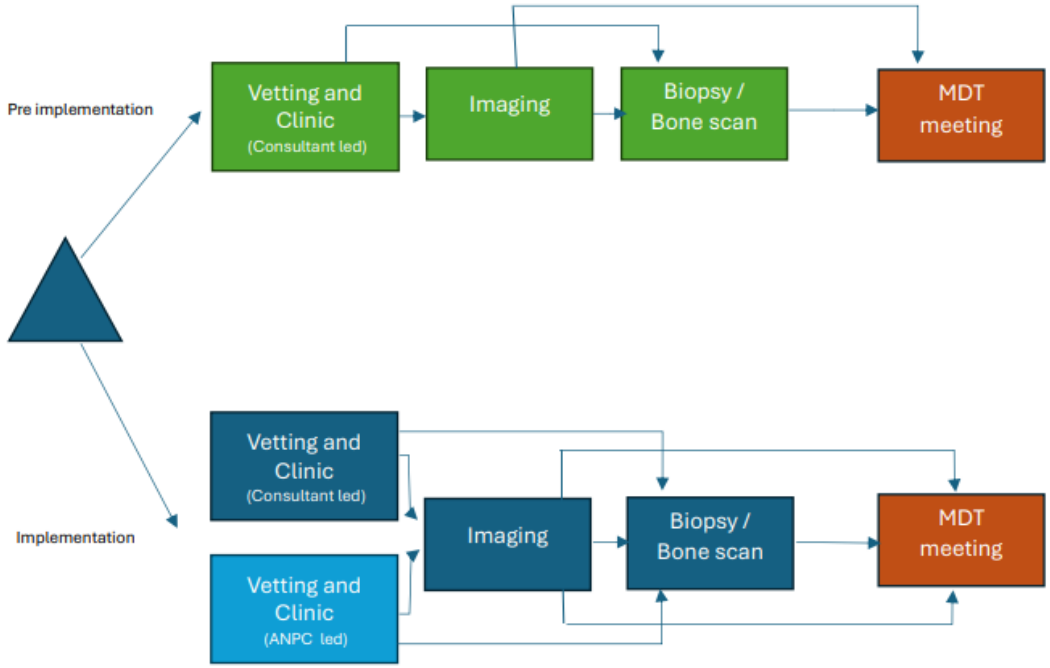
- Vetting of GP referrals;
- Attendance at outpatient clinic;
- Clinical imaging: This includes mpMRI (magnetic resonance imaging), CT (computed tomography) and Bone (Dexa) scans. The requirement for imaging is based on clinical presentation and is therefore variable amongst patients;
- Biopsy;
- Multidisciplinary team (MDT) meeting: As the end point for the diagnostic pathway for both consultant and nurse-led pathways.

Where possible, costs for the Scottish NHS were used and national costs for NHS England when these were not available. Where national costs were used, consultant-led estimates were used for valuation of resources on the consultant-led pathway and non-consultant-led estimates for the nurse-led pathway. National costs take into consideration both activity (such as duration of contacts in minutes for GRP001 Outpatient care and contacts) and resource costs (such as pay costs, supplies and service costs and overheads) (NHS England, 2024). National cost estimates

for activities identified along the pathways of the model will therefore include running and support costs. As such, additional costing (such as staff nurses to support Consultant-led care and Patient Navigators to support the ACNS pathway) was not required. All costs are reported in GBP (£) and adjusted using Bank of England CPI data for December 2024 where required.

In the current model, the initial decision is between the pre-implementation and implementation pathways. Patients enter the pathway and have the chance to either follow the consultant-led or a combination of consultant and nurse-led pathway. The patient will be vetted, attend the consultant-led (one stop) clinic or the nurse-led (rapid access diagnostic) clinic and may require imaging including mpMRI, CT, bone scan and biopsy or no imaging. The end point of the patient pathways in the model is the first MDT meeting. A simplified model is presented in Figure 4, with a full model overview in Appendix 9: Technical report: health economic analysis.

Figure 4: Simple model diagram



4 Findings of the improvement project

4.1 Participants

Within the 12-months implementation period, 315 patients had their first outpatient appointment in the clinic (before the end of July 2024). Table 3 presents a summary of number of participants per data source.

Table 3: Summary table of participants

Source	Number of participants
Routine data	523
Patient survey	162
Patient interviews	10
Staff interviews	12

4.1.1 Routine datasets

The routine datasets provided data for pre-Covid (n=80), pre-implementation (n=150) and implementation (n=293) cohorts. This was approximately 27, 50 and 33 patients per month respectively - the implementation cohort being a subset of all urgent suspected prostate cancers referred to the service. Group values for patient characteristics, diagnostic rates and service provision characteristics are presented below. Where values were not available, numbers differ from the overall count. The normality of distributions varied across cohorts and so medians are used to describe the data. Means are presented for completeness. Patient age and deprivation indices were broadly similar across the cohorts (Table 4), indicating that a wide range of patients were seen by the service. The PSA count reduced with progressive cohorts.

Table 4: All patient characteristics across the three cohorts.

Measure	Cohort	N	Mean (st.dev.)	Median (IQR)	Min	Max
Age (yrs)	Pre-Covid	80	69.7 (11.3)	69.0 (17)	39	97
	Pre-implementation	150	69.2 (9.17)	68.5 (14)	44	91
	Implementation	293	66.6 (7.59)	67.0 (11)	46	85
SIMD deprivation (quintiles)*	Pre-Covid	80	3.1 (1.55)	3.0 (4)	1	5
	Pre-implementation	150	3.0 (1.40)	3.0 (2)	1	5
	Implementation	292**	3.1 (1.42)	3.0 (2)	1	5
PSA (ng/ml)	Pre-Covid	32	106 (318.0)	22 (45.3)	5	1719
	Pre-implementation	50	64 (130.5)	14 (40.1)	0	630
	Implementation	292**	11 (18.8)	6.8 (5.1)	0	221

*1(high)-5(low), ** missing data n=1.

Since no data were provided for the consultant-led pathway which ran in parallel with the nurse-led implementation pathway, we matched patients from the first two cohorts with the main vetting criteria for the nurse-led pathway (age under 76 years and PSA under 10ng/ml). Group values for patient level characteristics and service provision characteristics are presented below. Only 7/80 (8.8%) and 16/150 (10.6%) of patients in the pre-Covid and pre-implementation cohorts met these criteria (Table 5). 199/293 (67.9%) of patients in the implementation cohort met these criteria; the remainder are explained by changing criteria, additional criteria not shown

in the dataset, and clinical judgement. The numbers in the pre-Covid cohort were too low to provide reliable estimates and the pre-implementation estimates should be treated with caution. Age and deprivation indices medians were similar across the cohorts. In a pattern reflective of the inclusion of all patients, the median PSA count reduced across the cohorts, with only a 0.5ng/ml difference in medians between the pre-implementation and implementation cohorts.

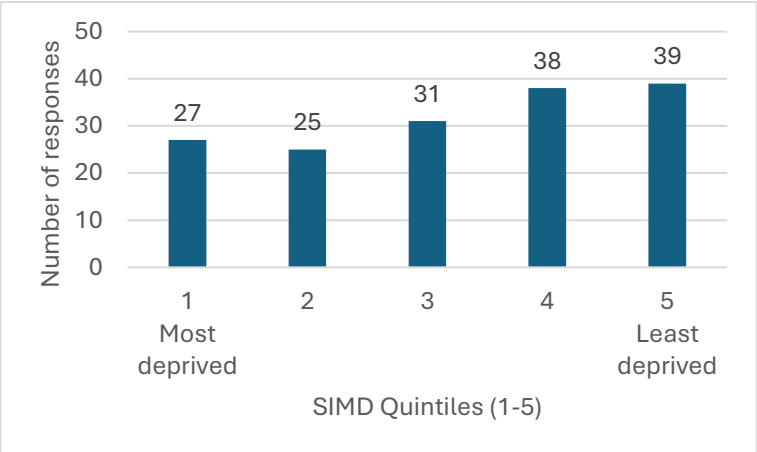
Table 5: Vetting criteria matched patient characteristics across the three cohorts.

Measure	Cohort	N	Mean (st.dev.)	Median (IQR)	Min	Max
Age (yrs)	Pre-Covid	7	65.4 (8.14)	68.0 (13)	52	75
	Pre-implementation	16	64.1(6.61)	65.5 (8)	52	73
	Implementation	199	63.9(6.29)	64.0 (10.00)	46	75
SIMD deprivation (quintiles)*	Pre-Covid	7	2.9 (1.86)	3.0 (4)	1	5
	Pre-implementation	16	2.5 (1.32)	2.5 (3)	1	5
	Implementation	199	3.2 (1.42)	3.0 (2)	1	5
PSA (ng/ml)	Pre-Covid	7	7.8 (1.44)	8.0 (1.4)	5.1	9.8
	Pre-implementation	16	5.8 (2.29)	6.2 (2.7)	0	8.2
	Implementation	199	5.7 (2.14)	5.7 (2.8)	0.3	9.9

4.1.2 Patient survey

A total of 162 patients who were referred to the nurse-led clinic completed the patient survey from 15th January 2024 to 27th July 2024. The mean age of participants was 67.4 years (*SD* = 6.7; Missing = 2). The majority were white (*N* = 159; Scottish/Irish/British/Welsh/English/British, *N* = 158; Missing = 3), and the majority reported their sexual orientation as heterosexual (*N* = 160; Gay, *N* = 2; missing = 2). Participants were spread across the five SIMD (Scottish Index of Multiple Deprivation) quintiles, as shown in Figure 5.

Figure 5: Number of survey participants in each SIMD quintile (N=162)



Note: two participants did not provide a postcode and therefore no SIMD is reported.

4.1.3 Patient interviews

Semi-structured interviews were conducted with ten patients. Three of these had been diagnosed with cancer at the time of the interview. The ages of participants ranged from 56 to 69 years (mean age = 66, mode = 69).

4.1.4 Staff interviews

Semi-structured interviews were conducted with eleven members of staff working in the urology team. These included eight clinical staff (ACNS, CNS, consultants, PNs) and three administrative staff. Eight participants were directly involved in the design or delivery of the new pathway. Length of service with NHS varied from six months to eight years.

4.2 Results

One of the primary reasons for using a mixed-method case study approach in this research was to gain a holistic understanding of a complex and dynamic situation. Sections 4.3 to 4.5 integrate the results, focusing the narrative on central themes and relationships and presenting insights that emerged when the data was viewed as a cohesive whole. This section (4.2) summarises the results of each dataset separately as a prelude to the integrated analysis.

4.2.1 Quantitative findings

Routine data

Results from the routine dataset analysis are presented first to represent all the patients in the cohorts, and then we present data for a sub-set which are matched for the age and PSA criteria set for the nurse-led pathway.

Analysis of the routine datasets found that there were differences in cancer diagnostic rate (the percentage of referrals diagnosed with cancer) across the three cohorts. A descriptive overview of the percentages (Table 6) show this was highest in the pre-Covid cohort; the diagnostic rate within the implementation cohort was only 2.5% above the pre-implementation cohort, at 36.5%. Whilst we do not know why diagnostic rates are lower post-Covid, we might speculate that this is due at least in part to raised public awareness due to several high-profile individuals in the UK publicly sharing their experiences with prostate cancer, and public awareness campaigns and celebrity endorsements. Looking at post-Covid data, broadly similar proportions of patients were found to have cancer before and during implementation of the nurse-led pathway.

Table 6: All patient diagnostic rates across the three cohorts.

Cohort	N	Diagnosed with reportable cancer (%)
Pre-Covid	80	33 (41.3%)
Pre-implementation	150	51 (34.0%)
Implementation	292	107 (36.5%)

It is possible that delays in diagnosis may allow tumours to progress, or that changes in the diagnostic process may mean that cancers are missed or graded differently. For reference, grading from one to four shows a progressive increase in the size and spread of tumour (Rosen &

Sapra, 2023). A stage 4 tumour would be metastatic/advanced. A descriptive overview of tumour size for the implementation cohort shows an increase in tumours found at grade two rather than three, compared with pre-implementation (Table 7). These results could indicate that tumours were found at an earlier stage, or that patients with larger tumours were vetted to the consultant pathway during the implementation phase (this could not be verified with the data available). The numbers included in the data with recorded metastases or affected lymph nodes were too small to analyse and so are not shown. Gleason score was only available for the implementation cohort, for most patients with a cancer diagnosis. These ranged from 6 to 9, with 71% (n=66) of those with a score, having a score of 7.

Table 7: Tumour grading at the time of diagnosis across the three cohorts.

Cohort	1	2	3	4	x	Total
Pre-Covid N (%)	0 (0%)	14 (48.3%)	14 (48.3%)	1 (3.4%)	0 (0%)	29 (100%)
Pre-implementation N (%)	2 (5.1%)	10 (25.6%)	24 (61.5%)	1 (2.6%)	2 (5.1%)	39 (100%)
Implementation N (%)	5 (5.7%)	43 (48.9%)	39 (44.3%)	0 (0%)	1 (1.1%)	88 (100%)

*x – not gradable.

Data on the length of time between referral and vetting were not relevant for the first two cohorts but took a median of 1 day in the implementation cohort (Table 8). Across the three cohorts, it took a median of ten days for patients to attend their first appointment. There are a few extreme exceptions which are explained (e.g., patient declined first appointments) but are retained in the analysis. It is notable that this variation reduces across the cohorts. The median number of days between referral and diagnosis (for patients with cancer) increases across the cohorts, with an increase median of 12 days between the pre-implementation and implementation cohorts. The median number of days to the decision to treat (for patients with cancer) reduced after Covid but increased again by 13.5 days for the implementation cohort. However, it is important to remember the limitations in the data already highlighted.

This means overall, that vetting was performed quickly; the median time to see a patient did not change in the implementation phase but mean time from referral to diagnosis increased during implementation compared with pre-implementation.

Table 8: All patient service characteristics across the three cohorts.

Measure	Cohort	N	Mean (st.dev.)	Median (IQR)	Min	Max
Days between referral and vetting	Implementation	293	1.4 (4.51)	1 (1)	0	71
Days between referral and first appointment*	Pre-Covid	78	35.8 (194.00)	10 (5)	4	1718
	Pre-implementation	149	13.7 (27.60)	10 (8)	2	295
	Implementation	293	11.4 (7.73)	10 (6)	1	86
Days between referral and diagnosis**	Pre-Covid	33	34.45 (26.83)	31 (31)	1	149
	Pre-implementation	51	43.2 (28.25)	35 (19)	10	141
	Implementation	107	48.9 (17.82)	47 (15)	2	148
Days between referral and decision to treat**	Pre-Covid	29	61.1 (23.05)	64 (35)	19	106
	Pre-implementation	48	58.1 (23.53)	54.5 (20)	21	133
	Implementation	97	67.2 (17.36)	68.0 (18)	15	133

* This does not account patients who did not attend the first offer of an appointment.

** Data for those with a cancer diagnosis only.

When using vetting-matched cases (patients 75 years or under, with a PSA of less than 10ng/ml) (Table 9), the diagnostic rate for the first two cohorts was much higher than when using all data (Table 7). The diagnostic rate for the implementation cohort was 29%. This means that the proportion of patients diagnosed with cancer appeared to reduce to a third during implementation. The very high rates, and very low numbers in the first two cohorts, means that attributing any differences to difference in pathway should not be assumed. However, the reduced cancer rate likely stems from the vetting criteria used for the nurse-led clinic. Patients with more complex conditions, such as multi-morbidity and higher PSA scores, are managed by the consultant-led clinic. Consequently, the consultant-led clinic is more likely to see a higher number of cancer cases than the nurse-led clinic. As we do not have data from the consultant-led clinics during the implementation phase, we cannot explore this further.

Table 9: Vetting criteria matched diagnostic rates across the three cohorts.

Cohort	N	Diagnosed with reportable cancer (%)
Pre-Covid	7	7 (100%)
Pre-implementation	16	15 (94%)
Implementation	222	58 (29%)

A descriptive overview of tumour size for patients with a cancer diagnosis (Table 10) showed an increase in implementation cohort patients diagnosed at grade one (2.8% increase) and grade two (14.5% increase) rather than three (17.4% decrease), when compared with pre-

implementation. As indicated for Table 7, this could mean that tumours were found at an earlier stage (smaller size) in the nurse-led pathway, but patients with larger tumours may have been vetted to the consultant-led pathway for other clinical reasons.

Table 10: Vetting criteria matched tumour grading at the time of diagnosis across the three cohorts.

Cohort	1	2	3	4	x	Total
Pre-Covid N (%)	0 (0%)	7 (100%)	0 (0%)	0 (0%)	0 (0%)	7 (100%)
Pre-implementation N (%)	1 (9.1%)	6 (54.5%)	4 (36.4%)	0 (0%)	0 (0%)	11* (100%)
Implementation N (%)	5 (11.9%)	29 (69.0%)	8 (19.0%)	0 (0%)	0 (0%)	42* (100%)

*Missing data, *n* = 4. ** Missing data, *n* =16.

The time between referral and vetting was the same for this subgroup compared to including all patients, approximately one day (Table 11). The median time between referral and first appointment was 3.5 days more in the implementation cohort than the pre-implementation. In addition, for patients diagnosed with a cancer, the median time to diagnosis was ten days more in the implementation cohort compared with the pre-implementation cohort. The median time to make a decision to treat was only 6.5 days longer in the implementation period.

Contemporaneous data are not made available for the consultant-led pathway, which shares most of the investigations between the first appointment and diagnosis and the decision to treat, and so secular influences specific to the implementation period (such as higher demand and/or reduced capacity in diagnostic assessments such as imaging and biopsies) cannot be excluded. This analysis cannot account for any influence of weekends which may influence such short timespans. The results suggest that for patients aged 75 or under, and with a PSA of less than 10ng/ml, the median time to be seen in clinic, receive a diagnosis and a treatment decision increased in the nurse-led pathway compared to the pre-implementation consultant-led pathway. However, the numbers of this type of patient are small in the pre-implementation cohort and so comparisons should not be drawn confidently where only descriptive statistics have been used. Below we present findings for inferential statistics, where assumptions were met; we can be more confident of the estimation of differences between cohorts.

Analysis of any differences between time to first appointment, time to diagnosis and time to decision to treat, between the pre-implementation and implementation cohorts, was conducted using Mann-Whitney test (difference between medians) and the Kolmogorov-Smirnov test (difference between distributions), both 2-tailed, $p<0.05$. The time to first appointment Mann-Whitney test confirmed a significant increase in the time to the first appointment in the implementation cohort ($U=2081$, $df=214$, $p=0.041$, $r = .14$ - a small effect), but the Kolmogorov-Smirnov test did not show a difference in distributions. The Mann-Whitney test confirmed a significant increase in the time to diagnosis in the implementation cohort ($U=617.0$, df 72, $p=0.013$, $r = .29$ - a small to medium effect). The Kolmogorov-Smirnov test indicated a difference

in distribution (D=1.536, df 72, p=0.018). There was no evidence of a significant difference in time to the treatment decision.

Table 11: Vetting criteria matched patient service characteristics across the three cohorts.

Measure	Cohort	N	Mean (st.dev.)	Median (IQR)	Min	Max
Days between referral and vetting	Implementation	199	1.1 (1.91)	1.0 (1)	0	14
Days between referral and first appointment*	Pre-Covid	7	9.7 (2.98)	11.0 (6)	6	13
	Pre-implementation	16	8.3 (5.25)	6.5 (9)	2	20
	Implementation	199	11.3 (6.00)	10.0 (7)	2	46
Days between referral and diagnosis**	Pre-Covid	7	58.4 (40.32)	43.0 (14)	38	149
	Pre-implementation	16	50.4 (34.8)	39.0 (13)	18	141
	Implementation	58	51.9 (13.37)	49.0 (14)	33	91
Days between referral and decision to treat**	Pre-Covid	7	83.4 (13.54)	76.00 (21)	68	106
	Pre-implementation	15	69.7 (24.45)	62.5 (31)	30	133
	Implementation	50	76.6 (15.70)	69.0 (16)	37	133

* This does not account for patients who did not attend the first offer of an appointment.

** Includes patients with a cancer diagnosis only.

The percentage of patients seen within 14 days was lower by nearly 7.6%, but 4.1 times the number of patients (aged 75 or under, with a PSA less than 10ng/ml) were seen each month (on average) (Table 12).

Table 12: Vetting criteria matched % patients seen within 14 days, across the three cohorts.

Cohort	N	Within 14 days N (%)
Pre-Covid	7	7 (100%)
Pre-implementation	16	14 (87.5%)
Implementation	199	159 (79.9%)

The patient survey

The patient survey indicated that most respondents (91%) felt they had enough information about their referral and what to expect at their diagnostic clinic appointment. The majority (85%) felt very satisfied with their care from point of referral to diagnosis at the clinic. Most respondents identified their main contact person as the specialist nurse (74%), found it very easy to contact that person if they needed to (67%), and perceived that person to be very helpful (82%).

Respondents reported having had a range of clinical assessments performed during the diagnostic clinic appointment, including: a digital rectal examination (88% of respondents), blood tests (44%), flow and scan (94%) and urine sample (75%). 14% of respondents reported having been prescribed medication during their diagnostic appointment, and 91% reported being referred for further testing (e.g., MRI, CT, bone scan). 5% were referred back to their GP, and 4% were referred to other teams or discharged. Only 14% of participants reported moderate to high levels of anxiety (score of 3+) in the weeks after their diagnostic clinic appointment (Median = 0, IQR = 0, 1; Min = 0, Max = 6; Missing = 12).

4.2.2 Qualitative findings

The patient interviews

The patient interviews highlighted three themes, all related to the acceptability of the nurse-led pathway. The first theme was the value of **being informed**. Interviewees reported being satisfied with the amount of information they received and had procedures and next steps explained to them throughout the pathway. They valued straightforward, clear, in-depth and honest information.

> "It was all explained to me in detail what'd be going on and how it'd be happening, and what they're looking for." (P1)

Some patients would have liked more written information, for example about the type of tests that were going to be performed, and the questions (e.g. about urinary habits) that they were going to be asked. One patient would have liked the final diagnostic conclusions clearly expressed in writing (due to complexity of technical terms). Interviews highlighted how important it was to patients that staff speaking to them had all the information they needed to know about them and their situation. A disruption in communication could occur when a key person (i.e. the ACNS) was on leave.

> "T*he nurse asked me to call back within five days of the appointment and actually, … I had to phone two or three times before I got through to her because she was on holiday, and they did pass on to the department to say that I'd called but nobody ever called me back until I eventually got through to [ACNS]*". (P10)

However, participants felt that being able to speak to a nurse specialist might mean having a quicker response to patient concerns, than if they were to wait to speak to a consultant. Participants linked the longer waiting times to see consultants to current pressures experienced in NHS. They could be aware of them from the media or hearing of experiences from friends and family who recently accessed health services.

> "There's enough pressure on consultants at the moment, so therefore anything that alleviates the pressure from the NHS to allow patients to be assessed appropriately is a good idea. So, I think there'll be many more people who will go through a clinic like that, if we had to wait for a consultant, doctor consultant, then many less people would be seen and that would not be as efficient, as effective." (P8)

The second theme was **person-centred experience**. Participants described the diagnostic process as one in which they felt part of and involved in; the consultation being relaxed and unhurried meant they felt at ease and had time for questions and explanations, and to be understood. The nurses were described as friendly, comforting, not impersonal, professional and not intimidating.

> "They were treating me like a person, not an object." (P1)

> "Whereas the approach and the speed that the clinics going, does a lot to put your mind at rest. Although you've still got the cancer etc, it does alleviate some of the, a lot of the worry." (P7)

The third theme was **perceived efficiency and coordination** (including information flow). Interview data indicated that patients are now quite used to skill mixing in healthcare and seeing nurse specialists, and appreciate the training and experience involved in becoming a specialist.

> "I suppose for someone of my age there is a hierarchical order … I am aware of the changes that's going on in the NHS. I am aware that it does make sense to leave the consultants and doctors doing the operation … I was satisfied in the knowledge of the people that were delivering the messages were sufficiently knowledgeable to answer any questions. I didn't necessarily feel I was getting fobbed off with the junior member of staff" (P3).

Participants reflected on NHS pressures, and in that context perceived the pathway to be a good use of resources, in terms of reducing the burden on the consultants and protecting consultants' time for things that only they can do. Qualitative data revealed a general understanding amongst patients of NHS pressures, which means that many patients see skill mixing as 'common sense', and as something they are used to in other NHS services.

In interviews and the survey, patients perceived the pathway to be a good use of resources, in terms of having specialist nurses running the diagnostic clinics, reducing the burden on consultants. Several interviewees described being very aware of the high level of training, qualifications and experience held by nurse specialists.

> "I have no problem with it. Nurses I know can specialise to a high degree in a variety of disciplines" (P6).

These three themes were further supported by data from free-text comments in the patient survey.

The staff interviews

The staff interviews highlighted three additional themes. The first theme, **'thinking in systems'**, drew attention to the inter-related elements in the system and the importance of considering the whole patient journey. For example, it was recognised that seeing patients in the new pathway could mean reduced waits for a diagnostic clinic appointment and could prioritise consultant clinics for more complex patients. But it has implications for admin time and the support required

by a range of staff. It could release consultant capacity elsewhere (e.g., for other patients, including bladder or kidney cancer), but does not necessarily reduce waiting lists for prostate cancer treatment due to the increased demand on cancer waiting lists.

> "It is freeing up time for complex, sick patients to be seen by others. So, although we're not saying, oh well we've saved three sessions of consultant time, we kind of have because it's allowing them to see other patients and see them." (S3 Service manager)

> "If they're not obviously being seen by us [consultants] then it means that it frees up that time to see another patient who's also waiting, so it might be somebody that's got a testicular mass or got blood in their urine. So, another urgent patient that otherwise would have had to wait and for every patient [ACNS] sees in clinic, it's one less patient that we have to see in our clinic. So, there's a direct parallel and benefit from our time that [ACNS]'s providing." (S7 Consultant)

Interview data showed that the implications of the new pathway (for example on consultant workload), depended in part on the complexity of cases in the new pathway, which in turn depended on clinic criteria and adherence to that at vetting, and the confidence of the ACNS. Inconsistent application of the clinic inclusion criteria was felt to be due in part to concerns about the perceived value of the new pathway. For example, where vetting was done by a consultant who didn't see the potential value of the new pathway, this could lead to too few patients being referred (thus wasting nurse clinic time). Where vetting was done by a consultant who treated the consultant-led and nurse-led clinics the same, this could lead to inappropriate referrals (which might require more support for the ACNS from consultant colleagues).

The effectiveness of the new pathway (in terms of creating efficiencies) was also seen to depend on the background systems for tracking patients, which were felt to be inefficient as they rely on staff members manually checking whether results are available on Cancer Tracker, rather than receiving a notification. For example, the consultant radiologist updates results on the Cancer Tracker, but the MDT coordinator checks manually to see if results are available and then sends an email to the consultant/ACNS to say that results are ready to review. Therefore, shortening the time to diagnosis relied on rapid communication and/or proactive tracking of test results and responsive subsequent action, which took more time than staff previously anticipated. As illustrated in the following quote, this was challenging when one ACNS reported a high case workload:

> "Yes, so [MDT coordinator]'s part of the cancer waiting times team, he works for [data manager] who works out their data, and his role is the MDT coordinator. So [MDT coordinator] watches our patients along the cancer pathway and looks for waiting times and for slippages and where if people are perhaps seen, they might just fall into the waiting times. So, as I said both the clinicians had a fear that they would miss people, especially [ACNS] with the volume that were going through, for one person it was lot. I mean she had a caseload of over 200 patients at one point and it's a lot for one person. But [MDT coordinator] also looks at the MRI scan and the TP biopsies and that, and I know

> the patient navigators do monitor, he is a bit of a safety net for us. He's looking at them anyway as part of his job for the cancer waiting times, so he has a call once a week with the clinician that's running the clinic and they just go through the patients and [MDT coordinator] will give a week update with where they are with things, so it's a good safety net". (S8 Project manager)

In turn, more time spent by ACNS and PNs on supporting the new pathway meant less time available for other activities (e.g., working on other pathways). It was also recognised that shortening the time to diagnosis relied on rapid access to other diagnostic services (e.g. biopsy slots) and may lead to bottlenecks later. The volume of patients requiring a TP biopsy procedure in NHS Fife has increased; in 2024 there were 318 biopsies, compared to 259 in 2023, representing an increase of 22.8%. Whilst the capacity has increased, this is still not in line with demand. This is experienced in other cancer pathways.

The second theme, **'implementation as a learning process'**, drew attention to the attitudes and support required to facilitate learning and change. At the start of the implementation process, data revealed that the new pathway was not supported to the same extent by all urology consultants. Concerns were in part around the potential implications for patient outcomes, for example if the nurse's decision making led to over investigation. There was some evidence in qualitative interviews that ACNS and consultants provided conflicting advice to a patient due to difference in opinion on the need for investigation. However, there were also concerns related to consultants' own work and workload, with a desire to protect their existing roles in the diagnostic process, and also with a concern about their own clinics changing, for example as a result of being left with only the most complicated patients.

> "I have had consultants say to me it actually makes their job quite hard because all the patients they see are sick. So they don't get that easier patient who comes in who actually they can say, oh, this is really nice Mr so and so, we can take you down this pathway and everything's fine. So it doesn't quite as much effort and quite as much emotional effort as the sort of sicker patients, more complex patient does. So conversely it might actually make our consultant workforce a little bit more stressed because their patient clientele are a bit harder to work with." (S3 Service manager)

Implementation was seen as a learning process; support for the new pathway grew in response to trying it out. Support and mentorship from senior colleagues also gave confidence and reassurance regarding clinical decisions made by the ACNS. Throughout implementation, staff discussed how they adjusted the improvement project and its implementation in response to learning. The consultant mentor was important not only to provide advice and space for discussion for ACNS but also being the bridge between ACNS and other consultants that might have had concerns about the new pathway.

> "[The] consultant had said, [pause] 'I think you're seeing patients outside your criteria.' And I kindly responded and said, 'But it's a test of change, so things change over time, as competency changes over time.' And then referred the person to my mentor, just in case

> there was any concerns and assured the person that, you know, I always - I did discuss things with my mentor." (S1, ACNS)

Rarely, the ACNS and consultant mentor had different opinions, but the mentorship allowed space to develop the ACNS's clinical decision making.

> "We [consultant mentor] hear from [ACNS] first what she wants to do, and then we will decide. It's always a short decision but always I, we wait for [ACNS], what she thinks, to see- It's very rare that we think of something else" (S6 Consultant)

The third theme, **'quality of care'**, highlighted elements of the new pathway that related to quality of care and patient experience. Interviewees who directly engaged with patients felt that when the ACNS and PN saw patients from the start of the diagnostic journey, they were able to get to know the patient's story (and level of understanding) better, and to build rapport and trust before a diagnosis was delivered.

> "I think our specialist nurses focusing just on this part of their practice, they have more time, and they have more connection to patients. They are able to establish this rapport more easily than us [consultants]." (S9 Consultant)

Interviewees felt that patients were therefore more comfortable asking questions and could become more informed about their situation. The communication and conversation at the outset of the diagnostic journey, and having enough time for that to be person-centred, was perceived to be important in terms of improving patient experience throughout the journey – particularly where patients saw the same team members throughout.

4.2.3 Health economic analysis findings

Study parameters

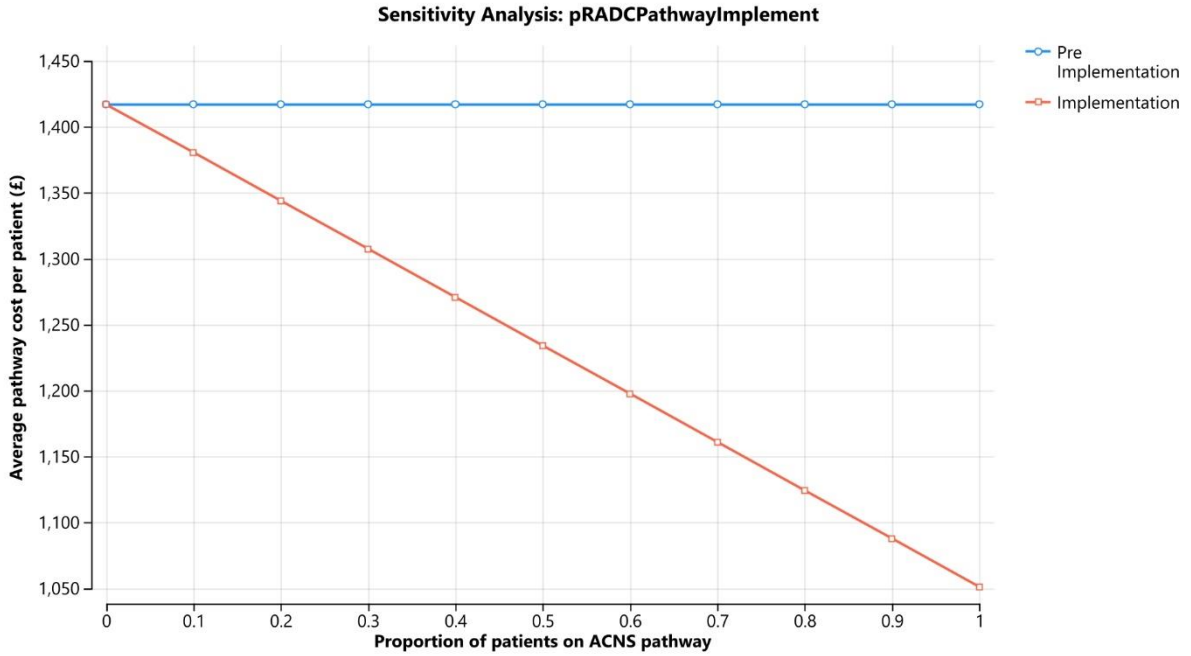
Clinical event probabilities were calculated from a sample of 16 patients for the pre-implementation (consultant-led) pathway. The implementation (nurse-led) sample comprised data from 200 patients. A summary table of all model probabilities and costs is included in Appendix 9: Technical report: health economic analysis.

Base case results

Base case results indicate a lower cost of the nurse-led pathway (£1049.00 per patient [95% CI £1043.00 - £1056.00]) when compared to consultant-led (£1417.00 per patient [95% CI £1416.00 – £1428.00]). Using the current vetting guidance for suitability of the nurse-led pathway, the implementation dominates consultant-led care with average cost of the prostate diagnosis pathways up to first MDT meeting of £1377.00 (95% CI £1370.00 – £1383.00) per patient.

Increasing the number of patients on the nurse-led pathway will logically result in reducing overall prostate diagnosis pathway costs as outlined in Figure 6.

Figure 6: Impact of increasing the probability of ANPC pathway on overall service cost



Sensitivity analysis

Results of the one-way sensitivity analysis indicate that the probability of attending the nurse-led pathway was the most influential variable driving the base case result.

Given that the need for imaging is clinically driven, further sensitivity analysis was undertaken whereby the probability of imaging tests (specifically MRI) was set equally between the consultant-led and nurse-led pathways. This allows for a comparison of resource costs that is not driven by patient acuity or need. Base case strategy dominance favouring the intervention was unchanged regardless of MRI need (Consultant probability used; Implementation £1376.00 [95% CI £1369.00 – £1382.00] vs £1419.00 (95% CI £1413.00 – 1425.00, ACNS probability used; Implementation £1378.00 [95% CI £1372.00 - £1385.00] vs £1421.00 [95% CI £1415.00 – 1427.00]). This finding suggests that the lower costs associated with the nurse-led pathway from the base case are not driven by a lower need for MRI imaging within the cohort of patients eligible for nurse-led care.

Results of the probabilistic sensitivity analysis favoured the implementation (mix of nurse-led and consultant-led) pathway in 100% of the 10,000 samples, with average pathway costs of £1368.00 (95% CI £1366.00 - £1371.00) compared to pre-implementation (all Consultant-led) £1414.00 (95% CI £1411.00 - £1417.00). This indicates that the base case findings are not sensitive to resource cost estimates.

4.3 What seems to work for whom?

The propositions at the heart of the improvement project (articulated in our TOC) were:

1. The nurse-led diagnostic pathway will create efficiencies in the diagnostic process.
2. The nurse-led diagnostic pathway will lead to fewer unwarranted delays in the pathway.
3. The nurse-led pathway will have positive implications for patients' experience of the diagnostic process.

NHS Fife experienced some challenges in implementation described further in section 4.5. Despite these challenges, improvements in the diagnostic pathway in relation to some of our three propositions were supported. Where they were not supported, useful information has been gathered regarding explanations.

4.3.1 Efficiencies

The nurse-led pathway does appear to create some efficiencies in the diagnostic process. The nurse-led pathway accrues lower costs than the consultant-led pathway up to the first MDT meeting (£1049.00 vs £1417.00 per patient). However, not all patients will be eligible for the nurse-led pathway under the vetting guidance for the implementation. Over the course of the project, 12.5% of patients were eligible for the nurse-led pathway. Using this figure, the implementation dominates consultant-led care with average cost of the prostate diagnosis pathways up to first MDT meeting of £1421.00 (95% CI £1415.00 – £1427.00) per patient.

The new clinic referral criteria introduced as part of the nurse-led pathway generally ensured that the ACNS felt confident assessing those patients in her clinic. However, the criteria did change as part of the learning process, as this interviewee explains:

> "Initially the protocol had, you know, it was PSA less than 10, positive digital rectal examination, if there was a family history. So, there were, you know, it was based on NICE guidelines and discussion with the consultants. But it's a test of change, so some things do change, and I think it's like everything else, when you gain confidence in your competency- [pause] your competency improves" (S1, ACNS).

Having the ACNS involved in vetting the referrals helped to ensure the nurse-led clinics were appropriately filled. There were also suggestions of positive implications for non-consultant staff, with their involvement in the whole diagnostic process helping them to feel more visible and valued, and potentially leading to changes in their roles/responsibilities (and ultimately possibly a grade/pay review). However, the process of vetting was not always clear, with varied descriptions of how it worked in practice. Perhaps as a result, application of the new clinic criteria was not always consistent. This inconsistent application could reduce potential efficiencies either resulting in too few patients being referred to the nurse-led clinics, thus leaving empty slots, or resulting in inappropriate referrals. For inappropriate referrals, the risk was perceived to be potential over-investigation, or unanticipated involvement of the consultant in the diagnostic process. Qualitative data suggested that 'double-vetting' was occurring, whereby a consultant on call was allocating patients to the ACNS clinic, then when the ACNS was in, she would look at

those vetted to check for appropriateness and/or go into the referrals list to identify more who would be suitable. The following quotes describe some of the different ways in which the vetting process played out:

> "So, the expectation would have been that consultants would have referred patients to me, you know? But to be quite honest I wouldn't have seen the amount of patients that I've seen if I'd had to wait for some of the consultants referring patients to me, then I might have been twiddling my thumbs and my clinic might not have been as busy and that" (S1, ACNS).

> "My understanding is that [ACNP] goes into the lists and identifies people that she thinks are suitable. She then has a conversation with the consultant to ensure that these patients are suitable and then she sees them. So, I think it's a team decision" (S3, service manager).

> "I'll look at what we've been referred with, make sure it's an urgent suspected cancer referral, make sure it's prostate. Make sure that there's no reasons why I can't see the patient. So, if there's any investigations that would need done that I wouldn't be capable of doing, and then I will look at their past medical history and their medications to make sure I've got enough information and then I'll accept them on to the clinic" (S11, ACNS).

> "They send a referral for all their urology cases and we have a criteria that [ACNS] will be eligible to see, we onward the referral to [ACNS], that they fit the criteria, and she will review them almost then the same day and the proper action needed next is for her to see the patient. I usually review her decisions on those patients prior to seeing them, I will sit with her, see what she thinks" (S6, Consultant),

The appropriateness of the vetting relied on clinicians understanding the process and the purpose and potential of the nurse-led clinic, which was seen to change over time.

> "I still don't think that every one of the clinicians understands the, erm, the place for rapid access. I think that's improving still slowly because I'm getting less inappropriate referrals. I still get a lot of, now referrals for patients that aren't referrals for rapid access, they're referrals for telephone clinics and patients who are known prostate cancers and, just I think because the consultants know that I'm on the vetting system, they feel that that's the quickest way to- If it's a patient who's under our service, in the nursing team, sometimes they'll just vet a patient to me who is maybe on hormone therapy or something like that, rather than an email, because I'm there" (S11, ACNS).

> "At the beginning we have a few problems with the, because the patients that were referred to [ACNS] was outside her criteria, but once you have patients in your clinic you cannot tell them you go back. So, she has to deal with them … and now [ACNS] sees only the patient within the criteria" (S6, consultant).

The nurse-led pathway has streamlined the number of people communicating with the patient throughout the diagnostic journey, essentially led by one ACNS.

> "First, she will call the patient up, look you are referred to me, you will be seen in the clinic. Then she will see them, and then once he will see her, she will phone them with the result of the scan, then and she will follow the dates to be sure that they get the date for the biopsy. So that's all the same person regardless of who is doing the job to the patient. Then she will follow the MDT" (S6, consultant).

This compares with the consultant-led clinic where up to five different people might be communicating with or following up on a patient: first, the consultant on call who phones the patient to explain the referral to the urology clinic; then the clinician who is running the clinic, then the clinician doing the biopsy and following up the result, then the clinician "who will sign off the pathology on the MDT [multidisciplinary team meeting]" (S6, consultant), then the clinician (one of the consultants) who will deliver the information at the MDT.

However, the staff interviews highlighted that several people were involved in following up investigations. The ACNS was very proactive, alongside the PN, in manually checking for and chasing up results of investigations, to try to iron out any potential delays. At the same time, the cancer tracker would be tracking results and advising when results were available.

Diverting some patients to the nurse-led pathway could prioritise the consultant clinics for more complex patients and give them a greater focus on treatment decisions. It could also release consultant capacity elsewhere, for example for bladder or kidney cancer patients. However, whilst one of the desired outcomes was reduced waiting lists for cancer treatment, this interviewee explained the complexity of achieving this in a situation with a high backlog and a constant flow of new referrals:

> "Patients who are in a more straightforward pathway to diagnosis have been pulled from the consultant clinics into [ACNS]'s clinic. She's doing that physically. … it leaves capacity for the consultants to then see the more complex patients, so that their time, the patients who are more complex are getting, or the patients are getting more timely appointments with the relevant individual. So, although, it's difficult to see on a waiting list reduction as such, because the waiting lists are so big. So, we don't see that. There's always going to be patients in the background who will fill these slots, so it's not a money-saving idea, it's not about, it just gets the patients seen in more timely fashion by an appropriate healthcare professional" (S3, service manager).

This interviewee went on to explain that as it is, the improvement project wouldn't 'free up' consultants' time (which they might spend on doing more treatments, for example), because "their clinic slots will still be filled because we have a fairly large population in Fife who are referred into us on a weekly basis". However, it "means that hopefully the people will not wait; the patients will not wait so long to be seen" (S3, service manager). Since the consultant clinics see a wider range of patients including e.g., bladder cancers and kidney cancers, then these patients

could be amongst those being seen more quickly because of the nurse-led prostate cancer clinic. This interviewee explained the challenges of communicating this kind of change as a success even though it hasn't necessarily freed up consultant time or saved money:

> "So, although we're not saying, 'oh well we've saved three PAs, three sessions of consultant time', we kind of have because it's allowing them to see other patients" (S3, service manager).

This situation was partly a result of a change in intention over time. At the project outset, the intention was to replace some of the consultant-led clinics with nurse-led clinics. This would have meant that consultants would have carried out quantifiably less time in diagnostic clinics; time which they might then allocate to other functions. However, when it came to implementation it became clear that the nurse-led clinics would be *in addition to* the consultant-led clinics. This was because consultant clinics also see patients on other urological cancer diagnostic pathways and would still be seeing suspected prostate cancer patients who did not meet the criteria for the nurse-led pathway. This also meant that clinical staff that supported consultant-led clinics were not available to assist with the nurse-led clinics and PNs were required to step into that role instead (following some additional training).

In considering whether the nurse-led pathway created efficiencies, we also considered whether anything was sacrificed in the pursuit of those efficiencies. We were interested in clinical outcomes, implications for staff involved either directly or indirectly, and implications for other parts of the system.

Since prostate cancer is a difficult cancer to manage, the decision making along the diagnostic journey needs to be what one consultant interviewee described as "nuanced" and "difficult to protocolise". This interviewee felt that in a nurse-led pathway there may be a greater chance of over-investigation:

> "I think the tendency with any nurse-led type situation is for the threshold for investigation to be lower and in doing so, so that nothing, so that's less risk of missing things but the downside to that is that more patients will be, will have an investigation which they otherwise probably wouldn't have done. … there's the general feeling that we don't want to or need to be diagnosing very, very low risk prostate cancer … because it's not a life-threatening condition but it often leads to significant, you know, potentially surgical intervention or radiotherapy or things like this which have got detrimental side effects. So, it's much easier to stop that process at the beginning than it is when you've already diagnosed someone with prostate cancer, and then trying to say, well actually it's not that big a deal, you don't need to worry about it. They're more like to worry about it when you've made the diagnosis than at the beginning to say, you know, we can just monitor your PSA and things like that" (S7, consultant)

In light of this, and as part of the learning process, the nurse-led clinic criteria changed to be more restrictive. As this interviewee explained, this nuanced decision making is related to staff confidence, and is an area of continued discussion and reflection:

> "Once they're in [ACNS]'s clinic then I think it's more difficult for [ACNS] to take them out of that pathway and to stop investigating them, and I think that's probably more where the consultant role is, is to decide which patients shouldn't be investigated. I think that is still something that's, we're still talking about it in terms of how we ensure that we don't end up over investigating a population" … "The feeling was that [ACNS] would inevitably put these patients forward for an MRI and the pick-up rate for anything significant for that cohort of patients was very low, so it felt it was better to come and see a consultant, probably repeat the examination, have a bit more confidence to say, actually that's fine, we don't need to do any more investigation" (S7, consultant).

Implementation of the new pathway relied on support from the consultants in the urology team. This support had time implications for them. It ranged from delivering additional training (e.g., in DRE) not available as part of advanced nursing practice training, to less formal mentorship and guidance of the ACNS and the provision of ad hoc learning opportunities (e.g., through shadowing). Implementation also had implications for ACNS and PN workload, and administrative time and support required, which was felt to be under-estimated at the outset.

> "I think I've seen nearly 280 plus patients, it's quite a big workload for one person … you know, being able to contact the patients, give them the results …" (S1, ACNS).

> "we didn't really think about the jobs that it was going to, additional tasks, should I say, it was going to create" … "So, referring for MRIs, reading MRI reports, interpreting them, deciding if the patients need a biopsy, speaking to consultants about them, referring them on if they need referring on, referring for biopsies, if they need biopsies. It's a lot of extra things that they weren't having to do before" (S11, ACNS).

One interviewee reflected that the administrative workload in such projects is often unanticipated, noting that the consultant clinics have secretarial support, which is not available to the nurse clinics:

> "We often put clinical processes in place in the NHS and we don't really take account of the admin work that goes along with that, and what we end up with is very highly experienced clinical staff doing admin stuff, admin work, and that's okay to a certain extent but if we're going to increase them we need to look at whether that secretarial support, so, the consultants who have been seeing these patients have secretarial support, who would write the letters and write the follow up and write the, so, we have to make sure that if we put in nurse-led clinics that there's admin support with that so that they're not doing all of it at once, which is a mistake that we have made in the past with these kind of developments" (S3, service manager).

The additional workload for the ACNS and PNs meant they had less time for other activities, such as working on other pathways.

> "So, since this rapid access clinic started, I'll speak for myself here, but I know it's not just me. But for me, it's because there's a lot of extra work, I sometimes find I don't have time for the jobs that I did previously. So, phoning patients that have just been discharged from hospital after their prostatectomy, I don't always have time to do that now, and it's usually because I'm doing the survey calls or I'm working on the clinic" (S10, PN).

One assumption underpinning the TOC was that patients would be comfortable to follow the nurse-led pathway, and that aspects of patient experience would not be sacrificed for increased efficiencies. This appears to be supported by our data, as further explored under the patient experience heading below.

If there are potential disagreements between the ACNS and the consultant regarding the suitability of a patient for further investigation, this can be a difficult experience for the patient. Such disagreements might come to light when a patient meets the consultant for the first time, when they attend for biopsy. These quotes are examples of where patient experience might have been less than ideal:

> "One of my patients had said that they'd gone to get a biopsy, TP biopsy and a consultant had said, "I don't know what you're here for." ... so I can only put myself in the position of the patient, so you're going to have quite an invasive procedure and a comment or that's what the patient told me the comment was, so that would have upset me. But that patient's result came back and that patient has cancer, so then ... that referral was right. ... in fact the patient had the procedure and that patient's results came back and they had cancer" (S1, ACNS).

> "Yes, so there's been a few people that have gone through the clinic that have had a high PSA and met the criteria at MRI for a biopsy but then when they've gone for the biopsy the consultant doing the biopsy has asked them if they want to go ahead with it, and the patients obviously at that point are confused why they're being invited for a biopsy" (S5, CNS).

Reflecting on the consultant's comment earlier about the nuanced nature of prostate cancer diagnosis, and whether or not a diagnosis is always 'a good thing', this might represent a mis-match between the decision making of consultants and the ACNS. When faced with opposing advice between the consultant and ACNS, patients were required to choose which advice they would like to follow. If the patient decided not to proceed with the biopsy during their biopsy appointment (following the consultant's advice), it resulted in an unused biopsy appointment, which represented an in-efficient use of resources.

> "The consultant at [biopsy appointment] who had an open discussion with me on the MRI findings and he basically gave me some information that he thought that the MRI finding was, graded it slightly higher of risk than what, I'm sure was his opinion on that. So, he

> didn't recommend I don't go through with the biopsy, he left that decision with me, and he said, on balance with, again with my blood, PSA levels being low and that he would perhaps have seen the risk being grade that scored slightly lower as a two on the scale, I think the scale went to five. And as it was, I think I'd been graded as a three. So, and it'd be marginal. So as a result, I decided, after considering what I was being told, not to go ahead with the biopsy. (P4)

4.3.2 Delays

The routine data analysis found that for patients on the nurse-led pathway there was no change in the time to be seen (compared with all referrals in the pre-implementation phase), but slight delay in time to be diagnosed. Because of low pre-implementation numbers and a lack of parallel consultant-led pathway data, we cannot conclude from this that the new pathway causes delays. Patients (including those diagnosed with cancer) who participated in the evaluation found the nurse-led diagnostic pathway to be surprisingly rapid, with shorter waits than anticipated.

A patient navigator suggested that more proactive tracking of patients' journeys in the nurse-led pathway can potentially reduce unnecessary delays, for example:

> "So, rather than the traditional pathway where a GP would refer in, a consultant would vet the referral and then book them onto a one stop [clinic], and then see them, decide whether or not they need an MRI, the MRI gets reported, and then it might sit in a consultant's in tray for a couple of weeks, and then they might decide they need a biopsy … Nurses are doing it, so [ACNS trainee] will see the patient, usually perform a DRE, decide if it's appropriate to go for an MRI, book the MRI there and then. The MRI will get done within two weeks, and both the cancer trackers and me and [other patient navigator] keep an eye out for these MRI results coming in" (S10, PN).

The ACNS, in attempting to speed up the diagnostic process, sometimes encouraged patients to call into SPOCH (single point of contact hub), who were then obliged to chase up and respond.

> "I think the patients also, you know, I have added additional pressure to myself, on myself and others, by saying, okay, after five working days just phone up and get the results. Whereas we would normally be leaving it for the cancer tracker to let us know about the patients that are coming through" (S1, ACNS).

Informal discussion with the SPOCH team suggested that they had noticed additional phone calls and that these were challenging to manage due to staff availability. This learning was fed back to the clinical team, and this encouragement to call SPOCH for MRI results was stopped during the implementation period.

4.3.3 Patient experience

Patients reported positive experiences of the nurse-led diagnostic clinic and frequently described the staff involved in their care as being professional, knowledgeable, experienced and capable of answering any questions. Patient interviewees highlighted the importance of feeling confident in and reassured by diagnostic conclusions and subsequent decisions made by clinicians.

> "[ACNS] went through that with me at the time, and [ACNS] was very reassuring about what [ACNS] thought was going on, and [ACNS] said that, you know, that I'm going to refer you on for an MRI scan. [ACNS] said, I can't find anything, just to rule it out. So, it was quite reassuring …. So, from the start I felt reassured at every stage" (P10).

> "All my individual concerns and questions were being answered. Everything was explained, what was going to happen, timescales although I was obviously very concerned about the possible outcome, it was very reassuring being in a process where there was a roadmap, a plan, where possible outcomes were explained to me. It was very, very reassuring" (P6).

Patient comments in the questionnaire and in interviews highlighted numerous examples of person-centred care, and patients reported feeling like they were 'in good hands'. When the ACNS and PN saw patients from the start of the diagnostic journey, they could build rapport and trust before a diagnosis was delivered, and they got to know the patient's story (and level of understanding) better. Staff interviewees also suggested it can be easier for patients to discuss their diagnosis with the same healthcare professional that has been involved from the start; when patients are more informed, discussions about the next steps can be easier.

Data suggested it can be useful to streamline the number of professionals communicating with a patient throughout the diagnostic journey. Having fewer clinicians involved in the pathway can lead to enhanced communication with the patients.

> "the original [consultant-led] pathway had so many different people involved, … in fact I don't really think that they knew the patient that well. It was just a superficial contact, on to the next one, on to the next one. And I think the [new pathway] has allowed the patient to actually, you know, they would, I need to speak to [ACNS], or I need to speak to [patient navigator] or the other [patient navigator], you know? They have a named person, or people that they can contact… I think it's made a difference that way, so it's very much enhanced communication, using less people but more of a continuous information given, patients feel very comfortable to be able to phone up and just ask, can I just check this, clarify this" (S1, ACNS).

Patients commented in interviews and the survey that they felt they had sufficient information and that everything was explained to them along the journey. Some patients would have liked more written information, for example about the type of tests that were going to be performed, and the questions (e.g. about urinary habits) that they were going to be asked. One patient would have liked the final diagnostic conclusions clearly expressing in writing, due to the complexity of technical terms.

The PNs were felt by some staff interviewees to offer an additional level of continuity of care, alongside the ACNS, which can enhance the patient's experience.

> "It [tests with PN during diagnostic clinic] was very good. [PN] was very young, clearly doing a lot of these so [PN] knew exactly what [PN] was doing. It was private. I wasn't put

> under any pressure or anything, it was done very professionally and quick, which was good." (P8)

The majority of survey participants felt very satisfied with their care from point of referral to diagnosis at the clinic (85.4%, Median = 5, IQR = 5,5; Min =3, Max = 5; Missing = 4), and numerous respondents used free-text comments to highly praise the nurse-led clinic and the service they received.

4.4 What are the explanations for succeeding in improving the cancer diagnostic pathway?

The context for introducing nurse-led diagnostic clinics was receptive; our data confirmed that in general, both clinical staff and patients had experience of and felt comfortable with 'skill-mixing' in healthcare. In NHS Fife, like many boards, there was also a strategic need to do something about persistent and lengthy waiting lists. There was therefore support across some (though not all – see 4.5) senior managerial and clinical staff for this improvement project. This was important since, as already noted, implementation of the new pathway relied on support from the consultants in the urology team.

This improvement project was led by the ACNS who herself would be delivering the nurse-led clinics. The fact that she was very committed to taking on diagnostic clinics, had lots of experience (with an MSc in advanced practice cancer nursing, 28 years working in oncology nursing, and prior experience of setting up and running nurse-led clinics), and was confident in her ability to take patients through the diagnostic process, meant that she was instrumental in driving the project forward. In some instances, the success of the project, for example in terms of reaching the point of diagnosis more quickly, relied on the ACNS going 'above and beyond', to be involved in vetting patients and in tracking and chasing diagnostic results.

The professionalism and expertise of the ACNS was a vital aspect of this project. One service manager reflected that the *way* a nurse engages with a patient is different to a consultant, which can have advantages when it comes to patient experience:

> "I think nurses have a slightly different approach to reviewing their patients, monitoring their patients, and you can actually I suppose mold the clinical nurse specialist role, or the sort of nursing side of it, along with the medical diagnostic side so you can get both things at one time" … "you get that kind of psychological, social care as well as the clinical care, at the same time". (S3, service manager).

Given the concerns about potential over-investigation (see 4.3.1), it was felt appropriate in this project that the consultant-led clinic continued to take more complicated cases (focusing on patients with multimorbidity). A consultant surgeon (prostate) in another NHS Board explained that there is little point in looking for localised prostate cancer in a man in his late 70's who has multi-morbidities and who therefore has a low chance of living ten years or more. However, it can be difficult, particularly for less experienced nurse specialists, to make the decision not to investigate. Consequently, he explained, there is a risk of "massively over-diagnosing a lot of men

with low-risk cancer". In the experience of this consultant (who works in a Board where all diagnostic clinics are run by nurse specialists), as nurse specialists become more experienced, they become more comfortable taking those decisions. As the Fife implementation progressed, and when the experienced ACNS left her post, it was found that the criteria for the nurse-led clinic could be changed to accommodate a new, less experienced ACNS.

Inter-personal relationships and communication between clinicians was found to be important in achieving this project's objectives. It was felt that this improved during implementation.

> "I think the real improvement has come with the consultant team, that people are more aware of what my role is and then that means that they're able to identify when they feel that I would be helpful to see a patient as well. ... So, I do feel that there's more of an ease. I would feel more comfortable to ask for something from them as well and I feel although everything's kind of virtual and emails and things like that, I suppose visible is not the right word, but I do feel more visible and more a part of the team." (S11, ACNS)

Patient navigators took on many new roles within this new pathway. It has been important that they were willing and able to learn and further develop new skills, including urine flow and bladder scans, taking bloods, filling in databases and maintaining them.

4.5 What are the explanations for not succeeding in improving the cancer diagnostic pathway?

Whilst the context for the nurse-led pathway was broadly receptive, not all senior colleagues were advocates. Initial mixed opinions about the new pathway among consultants made it challenging for the ACNS and the project manager to clarify the new clinic's inclusion criteria. This was overcome when one of the consultants volunteered for the mentorship role and thus provided that expertise.

> "It was quite difficult to pin somebody down to help us develop that criteria, you know, for the clinic and who goes to [ACNS]'s clinic, who goes to a consultant clinic. You know, that's something that needs set by a consultant, it's not down to management or down to [ACNS] or the cancer team. It does need that guidance from the consultants, and obviously that's really important because we need to know who can go to [ACNS]'s clinic" (S4 Project manager)

The nurse-led pathway was not a like-for-like replication of the consultant-led pathway in terms of how it was run. For example, they were not allocated the same staffing or space, which was felt to make nurse-led clinics less efficient than they could be.

> "In an ideal world we would have the same clinic space as the consultants. So, we often get a smaller room. We would have the same staffing as the consultants" ... "The one-stop clinics and the consultant equivalents, they have I think on average three staff responsible for all of the investigations that need to be done prior to seeing the consultant, and there doesn't seem to be quite as much waiting about when the patients

> are seeing the consultants. But we obviously have the one member of staff who is taking blood tests, doing all, everything that needs to be done, heights and weights and all of that sort of thing. So that can sometimes be a challenge" (S1, ACNS).

Whilst patient navigators were intended to be a key part of the nurse-led pathway, their role in it seemed to be less well understood by others; in implementing the new pathway, they seemed to be adding to their workload, without clear indication of what they would stop doing as a result. Whilst it was noted that interpersonal relationships and communications amongst clinicians had improved, field observations noted that this was not the case for PNs. Their role grew to include many of the administrative and information gathering aspects of the ACNS role, and included some clinical tasks (such as taking bloods, testing urine and conducting a bladder scan). The planning of clinics didn't account for the PNs' roles across different clinics, held in different hospitals at the same time.

> "It's unfortunate that our histology appointments run on the same day as the new clinic, one of them, that's a Monday. Unfortunate because if one of the patient navigators is off, either on annual leave or away doing something else, these histology patients don't always get seen which means we've sort of missed that little gap where we like to get in" … "So I feel sad that we're missing that because what we're then having to do is phone the patient at a later date to say you were in at histology, you spoke with so-and-so and we really should have met with you after that, but unfortunately we weren't in the building" (S2, PN).

The implementation and evaluation of this improvement project highlighted the difficulty of reducing the time of an overall pathway by acting on one part within it. One ACNS participant felt that the quality of referrals from GPs made it challenging to identify patients for the new clinic, which sometimes required further time to be spent on the vetting process. Occasionally, inappropriate referrals were seen in the nurse-led clinic, which was a waste of time for both the staff and the patient, as this example shows:

> "[W]e got a gentleman in our new clinic, so when I went to speak to him, he said, "I don't know why I'm here." And I said your PSA was high. He said, "Yes, I'm on antibiotics, I'm on them just now, they don't finish until Thursday (…) and the GP's given me another appointment on the [later date] to go back for PSA check because he wants to check it again." (…) I had a wee look and right enough, the GP had referred him in, the GP had taken a PSA test, had taken a urine test. The GP had sent the referral to us, the patient had a urine infection. So that was picked up, he'd already started his antibiotics but because we're on the ball with seeing the patients now, the patient's referral was actually to us. We'd given him an appointment and that had all happened while that, the antibiotics were being issued. So, we were so quick for that man, that he actually had a wasted journey coming in." (S2, PN)

Our evaluation suggested that a reduced wait for the diagnostic clinic can lead to bottlenecks later in the pathway. These quotes, for example, described the pressures in diagnostic assessments and treatment:

> "Although the study is very much about the diagnostics, so it's important that we're trying to get the beginning sorted but obviously the end needs to be looked at as well, and that's about starting treatment. The TP biopsies, that's added a bit of pressure on the TP biopsies. Patients need to, for their biopsy, so I think they've had to add more additional TP biopsy clinics because there's only a few consultants that do them" (S1, ACNS).

> "[He is the] only robotic surgeon that deals with prostate cancer. There is only one robot in NHS Fife and there's other cancers that use it. So, there are many patients with prostate cancer that are coming through the system, coming through my system as well as others. So, there is pressure within the NHS [pause] in order to see the patients within the 31, 62 day timelines, but there is many patients that have been diagnosed with prostate cancer, so that's a pressure. … So that's your robotic surgery, also getting the patients started on their radiotherapy. So, we're not a cancer centre, patients have to go through to Edinburgh and we have, there's an oncologist who does outreach from Edinburgh to here, and their clinics are very, very busy" (S1, ACNS).

> "The benefits of being seen quickly and then having a diagnosis and then the whole thing slowing down a wee bit because they're waiting to see maybe oncology or the consultant- I'm not sure if- Because we had that pressure prior to starting the clinic, could we be adding to that pressure by seeing people quicker? I don't know. That's, because I do know before the clinic started, especially oncology seemed to be quite a wait. So if we're seeing patients faster, it's wonderful but if they're getting past the histology part and then there's a hold up with the next stage, then that maybe the next thing that needs to be looked at" (S2, PN)

The promise of quick communication from a particular individual (e.g. ACNS) falls when that individual is off work. This can lead to a breakdown in communication or frustration (especially if they were told one thing and experienced another). Qualitative comments in the patient survey highlighted the negative impact a lack of information or poor communication can have on patients. Examples of poor communication occurred across the pathway, from primary care to communication of results.

5 Main lessons learned and implications for transition

5.1 Working towards diagnostic pathway improvements that could have impact

This improvement project focused on the problem of growing demand and long waiting lists for prostate cancer diagnosis. This is a significant concern across Scotland/the UK. Addressing this problem via skill-mixing is consistent with policy/strategic directions and priorities and could

enable clinical teams to be more adaptable and responsive to changes in workforce, demand and practice. The outcomes of this improvement project addressed the problem to a limited extent, in terms of taking a sub-set of prostate cancer referrals through the nurse-led diagnostic journey. The evaluation suggested that scale up of this intervention could be strategically useful, if done in the right way; indeed, nurse-led pathways for prostate cancer diagnosis are already implemented in some Boards in Scotland. The economic analysis suggested that the introduction of the nurse-led pathway would reduce pathway costs (compared with consultant-led care) from GP referral to the point of diagnosis.

The evidence from this project supports other published literature suggesting that nurse-led diagnostic pathways can be a useful way of maximizing efficiencies, whilst maintaining clinical standards and patient experience. A key component of this project that appeared to contribute to improvements was having advanced specialist nurses involved from the start of the pathway through to the decision to treat. This helped to ensure good communication, information sharing and patient experience. However, evidence from this case study also suggested that where nurse-led clinics are small-scale, added on to (rather than replacing) traditional clinics, and insufficiently supported with secretarial staff, the outcomes are minimal in comparison to the costs. Since the new pathway in Fife was an 'add on', it risked leading to unintended consequences, such as confusion about its role and purpose, and wasted resources due to inappropriate or insufficient referrals. Where nurse-led diagnostic pathways for prostate cancer referrals have been implemented elsewhere, they have tended to replace the consultant-led pathways entirely (including biopsies) and are appropriately resourced. Operationally, these appear to be well established, for example in Grampian and Highlands. As far as we are aware, formal comparisons with consultant-led pathways in terms of clinical outcomes and cost have not been conducted.

Evidence from this case study highlighted that improvements to the diagnostic pathway need to consider the whole pathway, from referral to initiating treatment. This is important since improvements at the start of the pathway (e.g., dealing with a long referral list) may introduce bottlenecks later in the pathway (e.g., for imaging, biopsy or treatment). Improvements also need to consider the importance of prioritisation within that initial referral list, to ensure optimal pathways for patients based on individual factors. Given the high numbers of referrals to prostate clinics, vetting processes need to enable potential higher risk cancers to be prioritised over others, and to prevent over-investigation and over-diagnosis of lower risk cancers. A key aspect in achieving impact appears to be the confidence and experience of the ACNS leading the pathway.

5.2 Working towards diagnostic pathway improvements that could be transferable across the UK

The improvement project in NHS Fife showed the potential to be effective in terms of maximising efficiencies and potentially addressing delays at the very start of the diagnostic pathway, without compromising quality of care or patient experience. Since nurse-led diagnostic clinics for

prostate cancer appear to be highly acceptable to patients and generally acceptable to clinicians, the improvement project has the potential for scale up. However, a scaled-up improvement project should learn from both this case study and from nurse-led prostate diagnostic clinics that have been implemented in other Boards already. In transferring learning from this case study, other contexts should further explore how key components of the improvement project (particularly the vetting of the referrals and the staffing of the clinics) might best work in their setting. It seems important to decide whether *all* prostate cancer referrals go through this pathway (as an alternative to the consultant-led pathway), or whether *a sub-set* of referrals go through it (as an addition to the consultant-led pathway). The former model is already used elsewhere, and the implementation infrastructure requirements are proven to be feasible. The latter model, tried here in NHS Fife, generated lack of agreement and inconsistency regarding how to define that sub-set. Urology consultants would need to be satisfied that the potential risk of over-investigation amongst a cohort of patients that would not benefit from a prostate cancer diagnosis is monitored and either outweighed by the benefits, or mitigated (e.g., by the level of experience and confidence of the ACNS, and/or by robust training and supervision arrangements).

In NHS Fife, the ACNS was supported by PNs who extended their roles as a part of this improvement project. This raises questions around 'job creep' (where lower-banded staff take on additional duties because of work pressures), and associated training and support needs, and potential reviews of pay scales. Experience in NHS Fife suggested that an important issue in either scaling up or transferring this model is to detail the administrative tasks involved in the pathway and to ensure they are delegated/allocated to a specific and sufficient resource.

Sustainable implementation at scale would rely on a cohort of experienced advanced nurse specialists to ensure diagnostic clinics can be suitably and consistently delivered. We are not aware of the extent to which that cohort is currently available, or whether it would require an additional investment. Since in some cases a nurse-led service may well be replacing a junior doctor-led service, it should perhaps not be seen as an opportunity to save on costs, but rather as an opportunity to increase the capacity within the workforce in order to meet growing demand.

5.3 Methodological reflections

In the first phase of this project, we collaboratively developed a theory of change for the improvement, which helped us to refine our evaluation framework and data collection tools. We also conducted an evaluability assessment, which was helpful in identifying the necessary data and resources required to conduct a meaningful evaluation. Identifying specific data for analysis relied upon an extensive conversation between NHS health care staff, NHS administration and analysts, and the University of Stirling evaluation team. It was decided during these conversations that we would not be given access to data for the consultant pathway which continued to run alongside the nurse-led pathway. This meant we were unable to compare data from the nurse-led clinics and from the consultant-led clinics during the same time period.

A key challenge in data access and sharing has been different understandings of what information about data items is needed (e.g., metadata, such as the specific categories and data formats) which is made more difficult by governance preventing the University evaluation team seeing the original data in-situ. The purpose of this governance is to protect patients, but it can be a barrier to this type of evaluation. Another challenge has been limited access to some data because it is not in digital form, or because access requires gatekeeper permissions. A key challenge was the lack of access to data from the consultant-led pathway which ran parallel to the nurse-led pathway. This limited interpretation of system level effects upon the nurse-led pathway and meant we could not confidently attribute changes to the nurse-led pathway. These challenges are likely to affect other evaluations. One of the facilitators has been the responsiveness of NHS administration and analytical staff to specific data queries, despite their limited time capacity.

The data collection depended on the meaningful relationship between the research team and the clinical team. PT (the researcher) was embedded in the urology department throughout the project with regular working patterns there. This allowed the researchers to establish connections with the clinical team who were involved in the implementation of the intervention. That relationship was essential to facilitate participant recruitment, and for observations and informal discussions both within the urology team and amongst others (including SPOCH and radiologists), to understand broader system impact.

6 Reflections and key points

KEY POINTS

- A nurse-led model for prostate cancer diagnosis was developed and implemented in NHS Fife for the assessment and management of a sub-set of suspected prostate cancer referrals. In a 12-month period, 315 patients were seen in nurse-led clinics (between one and three clinics per week at different time points). The model was easily adjusted in response to learning and changes in context.
- The nurse-led clinics were run in addition to the usual consultant-led clinics; all referrals were vetted (usually by a consultant), and patients deemed appropriate for nurse-led assessment were allocated to nurse-led clinics until those clinic spaces were full.
- The patient criteria for the nurse-led clinic evolved during the implementation. It depended on the experience and competence of the nurse specialist running the clinic. In general, it was felt that older patients and patients with multi-morbidities should be seen by the consultants. These patients were likely to be more complex with more limited treatment options.
- It was not possible to directly compare the quality of care or the time to diagnosis/treatment for the nurse-led model and the traditional consultant-led model due to a lack of access to routine data for the consultant-led clinics. However, the experience of patients going through the nurse-led pathway was positive, with patients reporting their care to be patient-centred and professional.
- There appears to be value in having advanced clinical nurse specialists involved in direct patient care from the start of the diagnostic journey to diagnosis, particularly in relation to communication and patient experience.
- The nurse-led pathway was seen to accrue lower costs than the consultant-led pathway up to the first MDT meeting (£1049.00 vs £1417.00 per patient).
- As far as we were able to compare using available data, the nurse-led model did not appear to reduce delays in the pathway. This might be because patients like those seen in the nurse-led clinic (younger men presenting with abnormal age-specific PSA levels) would already have been 'fast-tracked' for a clinic appointment at the vetting stage.

The NHS Fife project has shown that the nurse-led pathway demonstrates potential to improve efficiency by streamlining diagnostic processes whilst maintaining high quality patient care and experience. While the time to diagnosis increased slightly, it is unclear whether this was due to the new pathway or broader healthcare system factors. Patients reported high levels of satisfaction and felt informed and supported throughout the nurse-led diagnostic process. Staff emphasised the importance of consistent communication, mentorship and iterative learning during implementation, which enhanced the new pathway's acceptability.

There were administrative challenges throughout implementation, including inconsistent application of referral criteria at vetting stage, and increased workload demands on staff involved.

Concerns about role clarity and potential over-investigation of some patients highlighted the need for careful vetting of referrals and robust clinic criteria. The nurse-led pathway was associated with lower costs (£1049.00 vs £1417.00 per patient up to the point of the first MDT meeting) than the consultant-led model but required adequate investment in advanced specialist nurse training and resources (including secretarial and pathway navigator support) to ensure effectiveness and sustainability. The risk of 'job creep' for lower-banded staff highlighted the need for appropriate remuneration and role definition. Fully integrated nurse-led pathways in other regions, such as Grampian and the Highlands, have demonstrated feasibility when replacing traditional consultant-led pathways entirely. The NHS Fife approach, which added the pathway alongside existing services, faced challenges related to resource allocation and role alignment.

For successful implementation and scaling up of the nurse-led diagnostic pathway, careful consideration of its design and integration within existing healthcare systems is required. One key decision is whether the pathway should fully replace the traditional consultant-led approach or operate alongside it. Fully integrated nurse-led pathways, as seen in other regions, have demonstrated greater efficiency by reducing ambiguity and streamlining processes. To ensure the pathway operates effectively, robust criteria and processes for referral vetting are essential. Improvements to the clinical referral triage process, as recently implemented in NHS Lanarkshire for example, could help prioritise high risk patients, prevent unnecessary investigations and optimise resource use.

Staffing and training are central to the nurse-led pathway's success. A well-supported cohort of advanced nurse specialists is needed, as their confidence and experience are vital for achieving desired outcomes. Providing comprehensive training, mentorship and supervision will further ensure that clinical decisions remain of a high standard. The administrative workload associated with the pathway also requires sufficient support, as this will reduce the pressure on clinical staff and allow them to focus on patient care.

The nurse-led pathway has important implications for person-centred care. When specialist nurses are involved consistently throughout the diagnostic process, they can build rapport with patients, improve communication and enhance the overall experience. Patients value this continuity of care, which fosters trust and a better understanding of their diagnosis and treatment options.

Regular monitoring and evaluation are also necessary to ensure that the pathway achieves its intended outcomes. This includes assessing time to diagnosis, maintaining clinical standards, and collecting feedback on patient and staff experiences. It is important to address potential bottlenecks in downstream services, such as imaging or biopsies, to prevent delays further along the diagnostic journey.

Ultimately, nurse-led diagnostic pathways offer a promising opportunity to enhance prostate cancer care and meet growing demand by improving efficiency and delivering a high-quality patient experience, provided the necessary support and resources are in place.

7 Recommendations

Based on the experience of NHS Fife, we have noted the following recommendations to maximise the effectiveness and acceptability of the improvement project:

- Different NHS Boards have different skill mixes, roles and ways of working within their urology teams. Where clinical teams wish to employ nurse specialists to lead the diagnostic process (in the place of consultants), they need to adapt the nurse-led model to suit their own current workforce (including the training and experience of the nurse specialists). Consultant mentorship is a good way to support nurse specialists who are developing their experience. Sustainability must be built into any model so that diagnostic assessments can continue if staff members are absent.
- Proposals for changing the operational delivery of the diagnostic pathway must be 'bottom up', driven by the clinical team, and designed to address the specific bottlenecks or delays in that particular Board/area.
- Nurse-led clinics should be resourced in a similar manner to consultant-led clinics in terms of staffing and clinic space. Patient pathway navigators can be useful support staff to nurse specialists within a diagnostic clinic setting and can provide continuity along the diagnostic pathway. However, their role in the pathway needs to be clearly understood, and they may require additional training and remuneration if their role expands.
- Where clinical teams are wishing to address the problem of growing demand and long waiting lists for prostate cancer diagnosis and treatment, they should examine waits and delays at every stage of the journey (i.e., from referral to start of treatment). Seeing more patients in diagnostic clinics will only reduce waits overall if patients don't subsequently have a longer wait for imaging or biopsy, or for surgery.
- If nurse-led clinics are implemented to 'free up' consultants' time, it needs to be clear that that time can be used effectively. For example, they will only be able to use that freed-up time for treating more patients if there are no other constraining factors (e.g., in theatre space, surgical robot, anaesthetist, theatre nursing).

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List of appendices

Full documents are provided in a supplementary folder.