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PROSTAD

Development of a Model Prostate Cancer Diagnostic Pathway

A Partnership Project between Cancer Research UK,
Hywel Dda University Health Board and Swansea University.

TRITECH Sefydliad Institute

Acknowledgments

The project team would like to acknowledge the support of the hosting organisations Hywel Dda University Health Board and TriTech institute who have supported project governance and oversight. Thank you to Swansea University as partner organisation and Cancer Research UK as funders and advisors throughout this project. We would like to acknowledge the support of the National Strategic Clinical Network for Cancer and the West Wales Prostate Cancer Support Group for their contribution to supporting the PROSTAD implementation, evaluation and future work.

Most importantly we would like to thank all those who have been through our clinical pathways and contributed to this work. Without you this project would not have been possible, and we are eternally grateful for your input.

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PROSTAD
Prostate Cancer Diagnosis Pathway

Who We Are

In 2021 the Tritech Institute was launched. We are a team based in a bespoke facility within Hywel Dda University Health Board comprising of industry-leading engineers, scientists and clinicians.

Our Institute

Here at the TriTech Institute, we support the development of healthcare solutions on a local, national, and global level offering designers and manufacturers a single point of access to the NHS through a collaborative and agile approach.

What We Offer

The team's advanced skills in clinical and research design are combined with technical engineering expertise to manage the whole innovative pathway from early unmet need, through to concept design, prototyping, clinical investigations, and real-world service evaluations.

Our Services

We provide specific services and solutions for clinical engineering, research and innovation and Value-Based healthcare, and can also support with grant writing and submission.

Foreword

PROSTAD has provided an opportunity to demonstrate that pathway process mapping and workforce realignment can generate significant improvements in cancer diagnostic pathway times for our patients, in this case those referred as urgent suspected prostate cancer. It provides valuable insight into how cancer diagnostic pathways can be improved by establishing a resourced straight to test pathway with use of dedicated scanning slots, expedited radiology reporting and dedicated patient decision clinics, aligned to the radiology resource.

The success of PROSTAD is due to several key factors:

1. Staff stakeholder engagement across all departments involved in the process as well as patient and public involvement,
2. Comprehensive process stream mapping with a sound understanding of system capacity, demand, and variation,
3. Administrative support to coordinate clinical teams and patient communication,
4. A motivated team with relevant expertise across health board clinical, research and Swansea University academic backgrounds, together with sponsorship and resources from Cancer Research UK.

Determination of the main rate limiting step in a patient pathway, in this case MRI scanning and reporting capacity, together with measures to direct existing resources to this system bottleneck, resulted in a 28-day reduction in the time from referral to the patient being informed of diagnosis regarding prostate cancer. This reduction was achieved in the context of a radiology department under significant resource pressure, the introduction of new and more complex MRI scanning protocols, and the concomitant introduction of a new trans-perineal biopsy technique, itself requiring additional resources and staff training.

However, this study has also emphasised that:

- a) process improvements can achieve a reduction in pathway times, but this will ultimately be limited by a lack of additional resources;
- b) the pathway improvements are precarious in the context of severe resource limitations, in this case, within the radiology department. This has been experienced within weeks after the end of funding associated with the PROSTAD project.

In an age where increasing cancer diagnostic pathways require radiological cross-sectional imaging, organizational resources must be directed to allow sufficient dedicated scanning time and expedited expert reporting. The reduction in time spent at this front end of PROSTAD leads to cumulative gains in time along the pathway and optimal use of system capacity.

Executive Summary

Prostate cancer is the most common male cancer in the UK. Despite Welsh Government targets for 75% of patients to start treatment within 62 days of their referral, waiting times across Wales consistently fail to achieve these targets. Hywel Dda University Health Board (HDdUHB) covers over 25% of the area of Wales covering 10% of the Welsh population, yet annually, 14% of prostate cancers in Wales are resident in the Hywel Dda region.

The Health Board's Urology department in collaboration with the Tritech Institute & Innovation and Value Based Healthcare (VBHC) divisions conducted a process mapping exercise along the patient pathway to identify key factors that impacted failure to achieve the Welsh Government targets for time to diagnostic tests, diagnosis and commencing treatment, these included patient communications, Radiology & Pathology capacity, outpatient appointments.

The PROSTAD project introduced a workforce reorganisation to address these barriers, the pathway included straight to MRI testing, next day scan reporting and next day consultant clinics, with a pathway navigator to coordinate and support the patient through the pathway. The 'PROSTAD' pathway was established to not only reduce these systemic delays but also to include gold-standard techniques including multi-parametric MRI & local transperineal (LATP) biopsy.

Since the pathway introduction in June 2023, 127 patients have been through the new model pathway. As part of the service transformation, a parallel evaluation, funded by CRUK as part of CRUK's Test, Evidence, Transition Programme, and in collaboration with Swansea University, was undertaken to explore the impact and value of the PROSTAD pathway.

The PROSTAD pathway has demonstrated an array of different benefits to our patients and clinical teams. The time to diagnostic testing has been reduced by 12 days leading to an average 28-day saving on time from referral to diagnosis. Notably, the time from decision to biopsy, fell from 38 days to 14 days with the PROSTAD pathway: with the time between MRI and MRI reporting falling from over 7 days with the standard non-PROSTAD pathway to a single day with the PROSTAD pathway, as shown in table below. This has led to improved patient experience and better access to gold standard testing. Further work is needed to explore opportunities to reduce service costs and to investigate the diagnostic benefit of multi-parametric MRI over bi-parametric MRI, taking into context cost and workflow implications of increased scanning and reporting times.

When the PROSTAD pathway is run as it is currently, the mean overall healthcare costs were £992 (SD=£607) per patient in the PROSTAD pathway and £847 per patient (SD=£503) in the Standard care pathway. The mean healthcare cost per patient in the PROSTAD pathway was £145 more than in the comparator pathway (n=112). On average, to reduce the time to diagnosis costs £6.62 per day. The Cost utility analysis showed an incremental cost effectiveness ratio of £24,569 per QALY gained for the current configuration of PROSTAD. This is above the standard willingness-to-pay threshold of £20,000 but within the window where further consideration is required from £20,000 to £30,000.

More so, patient and staff feedback in relation to the service was positive however consideration must be given to patients who need time to consider treatment options. It was noted that some patients wanted time to consider if they would want treatment and as such if the investigations were necessary. A person-centred approach is central to delivering care to enable patient choice and enhance experience. While costs of the PROSTAD pathway were higher, this was due to use of multiparametric MRI which is being further explored to determine the real-world benefits of this compared to biparametric MRI. If limited clinical benefits are seen in terms of performance and accuracy, with multiparametric MRI then the move to bpMRI will reduce costs and enable additional sites to deliver the scans. The recommendations for sustainable adoption are:

1. Ringfencing new USC PSA prostate MRI slots
2. Providing 2 sessions of MRI prostate scan time per week for new USC referrals in conjunction with increased specialist Uro-radiologist capacity.
3. Through reviewing evidence, determine if multiparametric MRI improves accuracy, by internal studies within the health board and monitoring national/international studies and guidelines within this evolving subject.
4. Expanding Local Anaesthetic Transperineal capacity.

5. Invest further in Prostate Pathway Navigators to coordinate communication and workflow between clinical teams and to be a point of contact for patients for questions, updates and general communication.
6. Study impact of the PROSTAD pathway on radiology workload and other cancer pathways
7. Strengthen communication and collaboration across teams to reduce barriers in the pathway and improve efficiencies.
8. Evaluate service modifications and impact on pathways to ensure aligns with optimal pathway.
9. Enhance transportation infrastructure and support.

These recommendations aim to address the identified barriers while leveraging the facilitators to create a more efficient and patient-friendly prostate cancer diagnostic pathway.

The PROSTAD project has led to improved diagnosis time and patient experience with learnings, such as dedicated sessions and use of transperineal biopsies being continued within Hywel Dda University Health Board. It is anticipated that the learning gained from the PROSTAD project will be transferable nationally to enable other Health Boards to meet the ambitious targets within Wales and improve the diagnostic pathway for those with suspected prostate cancer. The learnings can also be utilised for other cancer diagnostic pathways within the Health Board, and nationally, particularly to other remote/ rural based providers.

Contents

Definitions & Abbreviations

bpMRI	Bi-parametric magnetic resonance imaging
CCA	Cost Consequence Analysis
CE	Cost-effectiveness
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness acceptability curve
CI	Confidence interval
CMO Chain	Theories or chains that shed light on the relationship between contexts mechanisms and outcomes
Context/ (C)	Contextual factors into which an intervention is placed
CUA	Cost-utility analysis
DPIA	Dat Protection Impact Assessment
Formal Theories	Broad theories that inform or underpin understandings of contexts and mechanisms – e.g. social theories, economic incentive theories, etc.
GIRFT	Get it right first time
GP	General Practitioner
HDdUHB	Hywel Dda University Health Board
HEAP	Health economic analysis plan
ICER	Incremental cost-effectiveness ratio
Initial theories	An early theory regarding what works, for whom and under which circum-stances based on available evidence
LATP biopsy	Local Anaesthetic Transperineal biopsy
MDT	Multidisciplinary team
Middle-Range Theories	An initial theory which has been refined using primary evidence collect-ed from interviews or other data sources
Mechanism/ (M)	How actors interact with or react to an intervention
mpMRI	Multi-parametric magnetic resonance imaging
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMB	Net monetary benefit
Outcomes/ (O)	The intended or unintended effects of how actors interact with an inter-vention
P	Participant (patient or carer)
PAS	Patient administration system
PCa	Prostate cancer
PET	Positron emission tomography
PICO	Population, Intervention, Comparator, Outcomes
PoS	Point of suspicion
PPI	Patient and Public Involvement
Programme Theories	An overall high-level theory based on primary and secondary data regard-ing how, for whom and under which circumstances the intervention works
PS	Participant Stakeholder (non-patient, e.g. NHS staff); we indicate stake-holder affiliation.
PSA	Prostate specific antigen
QALY	Quality-adjusted life-year
RDP	Rapid diagnostic pathway
RE	Realist evaluation
SA	Sensitivity analysis
SBUHB	Swansea Bay University Health Board
SCHE	Swansea Centre for Health Economics
SCP	Single cancer pathway
TRUS	Transrectal ultrasound scan
USC	Urgent suspected cancer
VBHC	Value based healthcare

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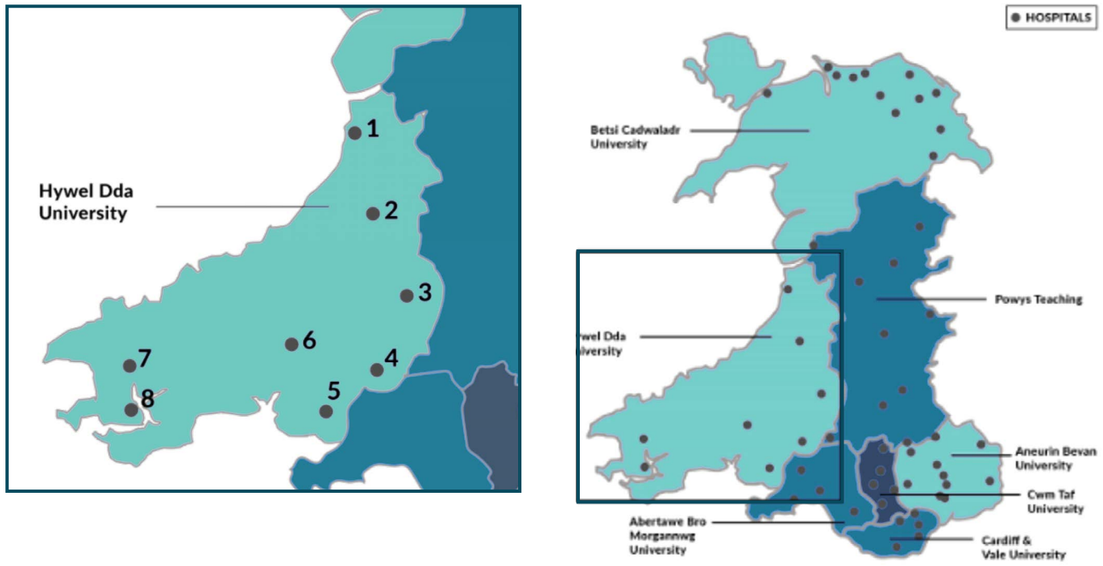
Introduction

Background

Prostate cancer is the most commonly diagnosed male cancer in the UK. Data from the National Prostate Cancer Audit 2020 shows a 23% rise in annual prostate cancer diagnoses from 2017 and Welsh Cancer Intelligence Surveillance Unit data shows that across Wales, 3,192 men were diagnosed with prostate cancer in 2018. Of these, 454 patients (14.2%) were from Hywel Dda University Health Board (HDdUHb), even though the health board represents only 10% of Wales's population (Figure 1).

Figure 1: Geographic representation of Hywel Dda University Health Board in Wales including sites of main district and community hospitals.



1. Bronglais General Hospital
2. Tregaron Community Hospital
3. Llandovery Hospital
4. Amman Valley Hospital
5. Prince Philip Hospital
6. Glangwili General Hospital
7. Withybush General Hospital
8. South Pembrokeshire Hospital

Annually in HDdUHB, approximately 600 Urgent Suspected Cancer (USC) GP referrals are made to the Urology team due to raised Prostate Specific Antigen (PSA). Approximately half of these patients will go on to have a pre-biopsy MRI. Within HDdUHB, USC referral numbers from Primary Care have now returned to pre-COVID levels and Secondary Care services are struggling to manage demand with capacity. Our current waiting times on the prostate cancer diagnostic pathway are prolonged, falling well outside the 28-day decision to treat and 62-day referral to treatment targets. StatsWales indicates that during the 12-month period December 2020 and November 2021, HDdUHB figures for the Single Cancer Pathway (SCP) were below the all-Wales average in 11 of the 12 months and it is notable that the all-Wales average is also well below Welsh Government's 75% target. Delays in diagnosis lead to delays in commencing treatment and can be associated with poorer outcomes and poorer patient experience.

Wales' National Optimal Pathway

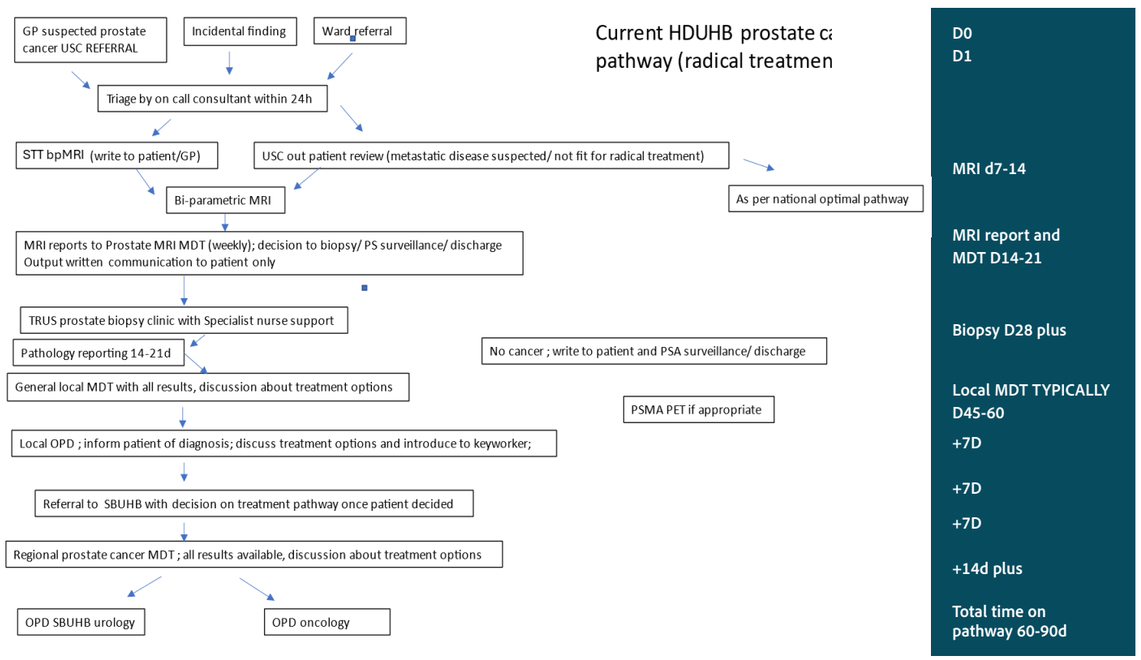
Wales' National Optimal Pathway (NHS/ Wales Executive, 2023) for prostate cancer describes good practice diagnostic and treatment pathways from the point of suspicion (PoS), stating that the diagnostic pathway, including staging, should be performed by Day 28 with MRI recommended within seven days and biopsy by Day 14. Organisational reforms and increasing demands on the service mean that the challenges of meeting these cancer targets are exacerbated by a lack of capacity and resources (Melby et al 2021). State-funded healthcare systems like the NHS are facing unprecedented demand to meet cancer targets following the Covid-19 pandemic (Aggarwal et al, 2024).

The Urology Department, working with HDdUHB's Tritech and Innovation Division conducted extensive process-mapping work to explore factors contributing to this delay, and identified deficiencies in the pathway (versus the optimal national pathway) that related to initial communications with the patient, capacity to offer and report on MRIs, capacity within Pathology, outpatient clinic waits both in HDdUHB and Swansea Bay University Health Board (SBUHB).

HDdUHB Clinical Pathway prior to PROSTAD

Prior to the introduction of PROSTAD, patients experienced delays in receiving MRI and biopsy due to the longer screening process, lack of dedicated MRI slots (bi-parametric) meaning patients were seen in general scanning clinics and only Trans-Rectal Ultrasound (TRUS) guided biopsies were available (see Figure 2).

Figure 2: The Pre-PROSTAD Process



Previous waiting times on the prostate cancer diagnostic pathway were prolonged and fell outside the 28 and 62 day decision to treat and referral to treatment targets (National data). The Urology Department within HDdUHB has undertaken multiple process mapping sessions and understands the contributory factors towards this delay, including time to scan and biopsy.

The key delays to diagnosis-day fell were identified in the pathway were time to MRI, reporting of MRI and time to biopsy. Additional diagnostic testing was also seen, and increased patient burden identified by underutilisation of gold standard testing.

Project aims and objectives

The PROSTAD project aimed to develop an optimal patient diagnostic pathway through a workforce and planning reorganisation that incorporates gold standard diagnostic and investigative techniques (multi-parametric MRI, LATP biopsy) and reduces the time spent by the patient in the pathway. We aimed to understand barriers at the front end of the pathway, including those to implementation, and identify facilitators that speed up progress, to improve patient satisfaction, communication, experience and outcomes. As part of the project, we developed training, pathway documentation and recommendations to aid the rapid roll-out of the new pathway across Wales and the UK.

The PROSTAD pathway is focused on the initial diagnostic testing, starting at time of receipt of referral for USC and continuing to MRI and biopsy. The PROSTAD pathway did not look at PSA testing prior to referral to secondary care. It is anticipated that there will be numerous benefits by reducing the time for patients to receive diagnosis. These include:

- Patient experience – patients will be kept better informed during their patient journey with timely face-to-face / telephone contact with appropriate specialists and reduced wait times.
- Patient confidence - there is an expectation of improved confidence and trust from patient groups and the wider public in the cancer diagnostic service.
- Patient outcomes - shortened diagnostic and times to treatment, reducing the risk of disease progression and supporting mental wellbeing of those being investigated by providing rapid results. In addition to improved diagnostic accuracy of staging and reduction in false negative results, evidence shows that LATP is less invasive and associated with fewer complications than TRUS biopsy (Lopez et al, 2021).
- Improved staff satisfaction

These benefits will be determined through a robust evaluation of the pathway. In addition to the clinical and patient benefits, we anticipate additional benefits stemming from the evaluation. These outputs include:

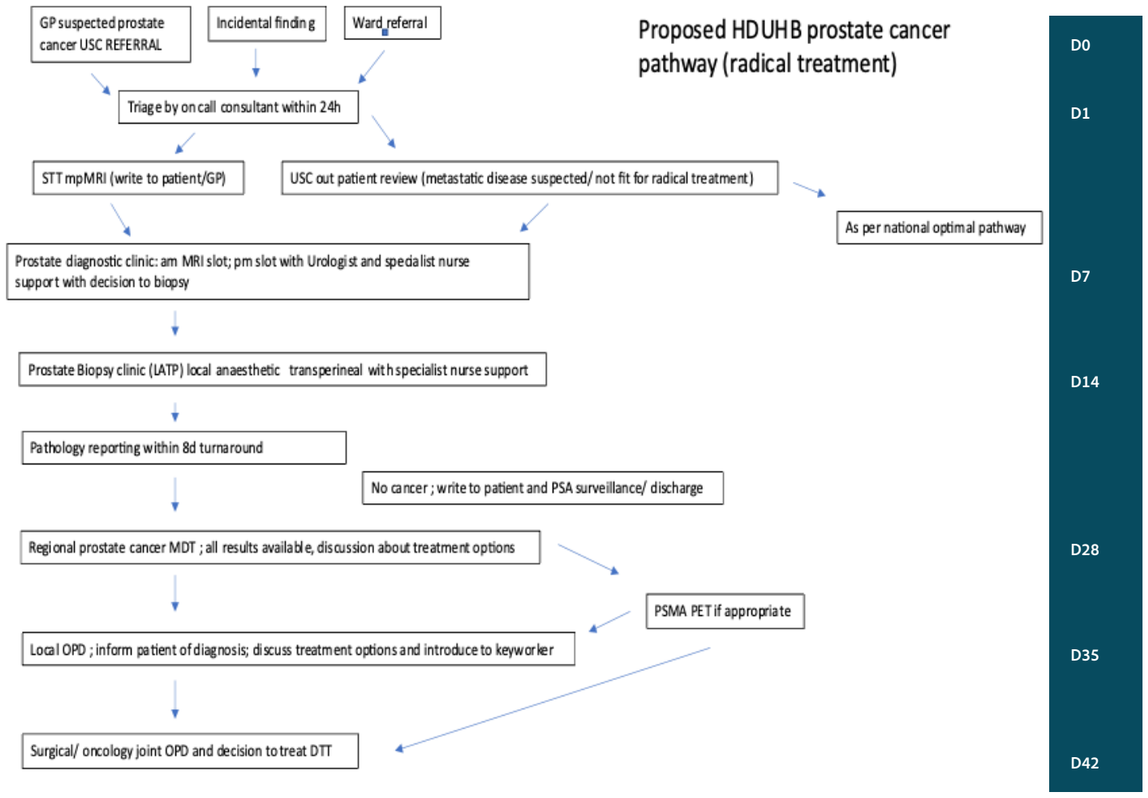
- Evidence for and preparation of a business case to extend the service on a permanent basis and support the role out to other Health Boards.
- Model pathway which can be adopted and rolled out nationally, supported through training materials and pathway specific documentation included in an implementation guide. To include advice on necessary adaptations that may be needed for sustainability and/ or roll out.
- Patient and clinician showcase events.
- Dissemination via relevant conferences, forums, journal publications and Welsh health networks.

PROSTAD Clinical Pathway

The clinical pathway redesign was supported by patient and public involvement and previous mapping of the clinical pathways.

The introduction of a weekly prostate specific MRI session (Tuesday morning) at Bronglais General Hospital, Aberystwyth, allowed up to four patients on the PROSTAD pathway (from across all parts of the Health Board) to be scanned. All eligible patients are invited onto the PROSTAD pathway, dependent upon the availability of MRI slots at Bronglais Hospital and the patient's availability to attend the MRI appointment. Reporting on scans was to be undertaken within 24 hours such that they were available on Wednesday afternoon when the patients were invited for an appointment, either face to face or by phone depending on patient preference. The biopsy was subsequently arranged at the earliest available date with a preference to LATP biopsy where possible. (See clinical pathway below, Figure 3).

Figure 3: The PROSTAD Clinical Pathway



MultiParametric MRI

This has implications on the need for unnecessary biopsies in borderline cases and therefore service capacity. The NICE guidelines are evidence based, supported by literature that suggests that due to the sensitivity of mpMRI compared to bpMRI, more prostate cancer are detected however additional studies, including meta-analysis, have shown comparable sensitivity (Alabousi et al, 2019; Bass et al, 2021; Pesapane et al, 2021; Woo et al 2018)). More recently the PRIME study provided evidence for bpMRI over mpMRI (Asif et al, 2024). Despite the growing body of evidence for bpMRI, national guidelines are unchanged. There are also delays in MRI reporting due to workforce shortages, this is exacerbated in mpMRi due to the increased reporting times.

Transperineal Biopsy

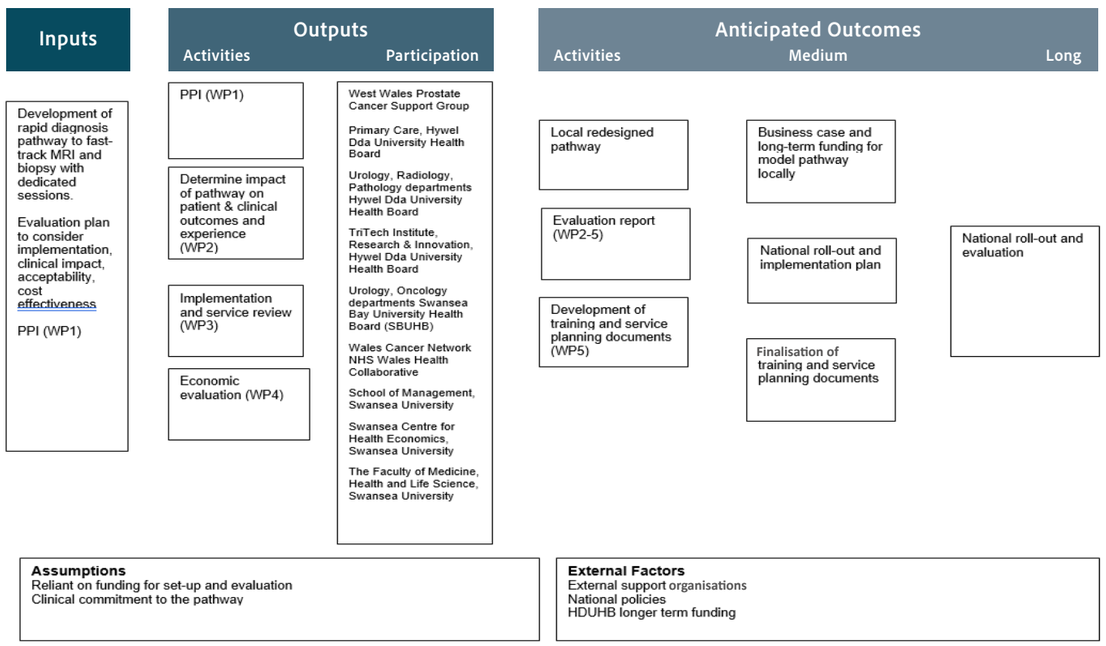
Transperineal prostate biopsies have improved patient safety with virtual elimination of septic complications and improved diagnostic accuracy over trans-rectal biopsies (Chen et al, 2022; Roberts et al, 2021) and are also less invasive (Thompson, Grumnet & Sengupta, 2020). NICE are evaluating evidence and likely to recommend transperineal biopsy with the rapid uptake of this technique in the rest of the UK. (https://www.nice.org.uk/guidance/indevelopment/gid-dg10043/documents).

There is growing professional and public drive for a phasing out of transrectal biopsies as demonstrated by the "TRexit" movement (Grummet et al, 2020). The use of transperineal biopsies would provide patient confidence and minimise patient anxiety with regards to them receiving the safest and most accurate diagnostic biopsies.

The PROSTAD Evaluation

As part of the service development and implementation, a robust real-world evaluation was derived to focus on five work packages and inform service development and roll out. And provide recommendations for transition including adaptations needed to local contexts. Full details can be found in the published protocol (Jones et al, 2024) in Appendix 1 and summarised in the following evaluation framework (Figure 4). All those eligible for the pathway were invited to provide feedback and clinical data was collected to support outcome measures.

Figure 4: Evaluation Framework



The real-world evaluation was designed to allow flexibility to adapt with the service. During the evaluation the protocol was a live document, updated as and when required to ensure it met the requirements of the project team.

To achieve the PROSTAD aims and objectives five work packages were developed:

- **Work package 1**: Patient and Public Involvement (PPI) in the evaluation
- **Work package 2**: Evaluation including Patient Experience & Outcomes, Clinical Impact
- **Work package 3**: Implementation and service review
- **Work package 4**: Health economic evaluation
- **Work package 5**: Learnings from implementation & preparation for adoption as appropriate based on outcomes of WP2-4

Work package 1: Patient and Public Involvement (PPI) in the evaluation

The aim was to involve patients and the public with experiential knowledge of the service in several ways:

- Contributing to formulation of evaluation questions.
- Helping shape emergent findings.
- Refining final programme theory.
- Disseminating evaluation findings.

Work package 2: Evaluation inc. Patient Experience & Outcomes, Clinical Impact

A Realist Evaluation (RE) approach (e.g. Pawson and Tilley, 1997) was adopted to understand how contextual factors and related mechanisms interact to produce the outcomes for the PROSTAD pathway. The RE utilised a combination of both qualitative and quantitative methods to address the evaluation questions.

Work Package 3: Implementation and service review

This work package assessed service aims to reduce overall time on pathway, identify and reduce any unnecessary activities and improve efficiencies within the service by identifying pinch points and real time solutions.

Work Package 4: Economic evaluation

The economic evaluation considered resource use and cost differences between the pilot pathway and current pathways (based on matched controls) and patient outcomes (using data obtained from work package 2, relevant literature and Patient Reported Experience/ Outcome Measures, where available) as part of a cost-consequences analysis. Specific objectives of the health economic evaluation are:

- to map out the PROSTAD pathway.
- to understand the impact of the service when compared to 'standard clinical practice' (i.e., with the pre-PROSTAD Standard pathway) on key descriptives such as referrals patterns and time to event across the diagnosis pathway.
- to identify key resource drivers and costs associated with the PROSTAD pathway service and subsequent impact on other NHS resources.
- to investigate the impact of the PROSTAD pathway on for example, cancers detected, stage of diagnoses.
- to assess short-term outcomes for patients in terms of diagnosis and to explore the cost-consequences of the PROSTAD pathway (should data allow) in improving outcomes.

Work Package 5: Learnings from implementation & preparation for adoption

This supports the HDdUHB Urology to collate the implementation learnings and the information required for a business case for the service adoption of the new PROSTAD pathway.

In addition, the PROSTAD team with the National Strategic Clinical Network for Cancer in Wales (Cancer - NHS Wales Executive), have developed key considerations to guide and support a national roll-out.

Governance & regulatory approvals

Being a service evaluation, no NHS ethical approval was required, however the study has received Swansea University Ethics and Hywel Dda Innovation approvals. A DPIA has also been completed to accompany the collaboration agreement between the work package leads.

Project management

Steering Group meetings occurred quarterly to provide strategic oversight to the project with membership from core project team, clinical experts, patient representatives and CRUK representatives.

Project Management meetings occur monthly, along with additional internal team meetings spaced midway between.

Evaluation Outcomes

Service Implementation and patient attendance

127 patients have been through the PROSTAD pathway, compared to 112 patients on the standard pathway during the evaluation period (July 2023 to June 2024). The average time for patients in the pathways can be seen in Table 1. This clearly shows that those patients on the PROSTAD pathway have benefited from a reduction in the time of 12days between their referral and their MRI. Furthermore, the anticipated reduction in MRI reporting times can also be seen with a reduction from 8 days to 1 day. In total those on the PROSTAD Pathway received their diagnosis an average of 28 days earlier than those on the usual care pathway.

The pathway related outcomes were similar with 75 – (59%) having biopsy, 50 – (39%) going for surveillance and 2 – (2%) being discharged in PROSTAD compared to those on the non-PROSTAD pathway (112) where 64 – (57%) had biopsy, 43 – (38%) went to surveillance, 2 – (2%) were discharged. Patients received biopsy in an average of 25days on the PROSTAD pathway following decision to biopsy compared to 20days on the non-PROSTAD pathway. This difference is likely due to the initial imbedding of LATP and the early requirements to undertake in theatre under general anesthetic, once safety was confirmed within the clinical team, these biopsies moved to outpatients and time to biopsy was reduced within the pathway. Despite initial delays total time to patient being informed of diagnosis was 70days in PROSTAD compared to 98days in the non-PROSTAD pathway.

Table 1: Time (in days) between GP referral and key milestones within diagnosis pathways.

Waiting time (in days from referral)	n	PROSTAD pathway	n	Usual care pathway	Time
Mean time					
Mean time to MRI (SD)	127	13 (5)	112	25 (13)	-12 (-15 to -10; p<0.001)
Mean time to MRI reporting (SD)	127	14 (5)	112	33 (14)	-19 (-21 to -16; p<0.001)
Mean time to clinical decision whether to biopsy (SD)	127	14 (5)	111	38 (13)	-24 (-26 to -21; p<0.001)
Mean time to biopsy (SD)	66	46 (25)	57	66 (20)	-20 (-28 to -12; p<0.001)
Mean time to diagnosis (SD)	61	53 (26)	55	76 (24)	-23 (-33 to -15; p<0.001)
Mean time to outpatient appointment where patient informed of diagnosis (SD)	44	70 (24)	41	98 (25)	-28 (-39 to -17; p<0.001)
Median time					
Median time to MRI (IQR)	127	13 (3)	112	23 (15)	-10; p<0.001
Median time to MRI reporting (IQR)	127	14 (4)	112	32 (17)	-18; p<0.001
Median time to clinical decision whether to biopsy (IQR)	127	14 (4)	111	37 (15)	-23; p<0.001
Median time to biopsy (IQR)	66	38 (19)	57	62 (25)	-24; p<0.001
Median time to diagnosis (IQR)	61	45 (19)	55	75 (28)	-30; p<0.001
Median time to outpatient appointment where patient informed of diagnosis (IQR)	44	64 (18)	41	93 (21)	-29; p<0.001

CI: Confidence interval; IQR: Interquartile range; SD: Standard deviation

Work Packages 1 & 2

Authors: Prof Jaynie Rance & Dr Katie Jones, Swansea University

Introduction

This section outlines the processes and results of work packages 1 and 2 of the PROSTAD project. Work package 1 constitutes the PPI component of the project and informs the direction and concerns explored within work package 2, a realist evaluation of PROSTAD, a model prostate cancer (PCa) diagnosis pathway. The aims of the realist evaluation are to examine how, for whom and under which circumstances PROSTAD works.

Aims and Objectives

1. Explore the process of implementing PROSTAD, the new prostate cancer diagnostic pathway, and develop theories to inform guidance applicable to the implementation of similar pathways elsewhere.
2. Identify the outcomes (intended and unintended) of PROSTAD for multiple stakeholders, including staff and patients.
3. Identify the mechanisms by which PROSTAD produces outcomes for staff and patients.

4. Identify the contextual factors that impact the mechanisms by which PROSTAD produces outcomes for staff and patients.

Patient and Public Involvement

We invited members of local West Wales Prostate Cancer Support group, who were involved in the project development, group to become members of our PPI group. The numbers in attendance in the meetings varied but the attendees were representing and feeding back from the wider support group. There was funding to pay members of the group for four meetings over the course of the project, focusing on shaping evaluation questions (including scope and considerations for interviews), data analysis (involving interpretation of anonymized participant transcripts), and dissemination. There was no consistent number of attendees, but between 3 and 6 members attended each.

Key themes identified as important for exploration included: primary care and referral processes; communication; co-ordination and continuity. These points informed search processes for the rapid realist review conducted to develop initial programme theories. A full report of the rapid realist review can be found in appendix 2.

Methodology

Realist Evaluation

Particularly useful when considering the introduction of multifaceted interventions in complex environments, realist evaluation (Pawson and Tilley, 1997) holds that an intervention in and of itself does not necessarily produce change, but rather it's how individuals interact with and respond to an intervention that promotes (or fails to promote) outcomes (Jagosh et al., 2016). A realist approach aims to identify contextual factors (C) and mechanisms (M) that lead to un/intended outcomes (O). According to the realist approach, we produce theories on how, for whom, and under which circumstances PROSTAD works or fails to work. The findings are presented as theories or CMO (context/ mechanism/ outcome) chains.

We conducted a rapid realist review to develop initial programme theories that later informed interpretation of interview data and programme theory development.

Interviews

Interview data was collected, anonymized and provided by HDdUHB.

Inclusion/ Exclusion

All participants are adults (18+).

Patients referred to the PROSTAD pathway (via USC GP PSA referrals) were eligible for participation.

Partners of carers of patients referred to PROSTAD.

Stakeholders perceived to be involved with or impacted by PROSTAD's implementation were eligible for participation, these included urologists, patient navigator, service delivery managers, radiologists, and GPs.

Participants were excluded if they were not able to speak or understand English well enough to be interviewed in English.

Recruitment

Patients and partners or carers of patients referred to PROSTAD and stakeholders employed in the day-to-day running of PROSTAD were contacted by TriTech (HDdUHB) researchers (JC and AC; unaffiliated with the day-to-day running of the service) and invited to participate in interviews.

Participants' verbal consent was obtained and recorded by the interviewer, and interviews were conducted virtually, either by phone or conferencing software.

Interview Data Collection

Interviews were recorded, anonymized and transcribed by a research nurse and researcher (JC and AC). The transcripts were securely shared with independent researchers (JR and KJ) via OneDrive for analysis. Semi-structured realist interviews were conducted using an interview schedule. Initial realist interview guides for patients and carers included questions about experience of going through the Model Prostate Diagnosis Pathway, any previous experiences of similar processes, perceived benefits and barriers or the new pathway. For key stakeholders, initial topics focussed on their role in developing the pathway, their understanding of what the pathway might intend to achieve, intended outcomes for patients and staff and benefit and barriers for patients and staff. As per realist evaluation methodology, the interview questions were adapted, supplemented or reformulated as our understanding evolved through interactions with participants.

Routinely Collected Data

Work package 4 of this evaluation project describes a cost-effectiveness study based on routinely collected data (Sewell et al., 2024), the results of which also inform theory development (as indicated).

Analysis

Following other examples in realist data collection and analysis, the transcripts were examined or 'concept mined' to identify patterns and themes using NVIVO (Mukumbang et al., 2020). These were considered against and alongside normative and initial programme theories that had been developed through the rapid realist review, literature associated with the programme, and understandings developed through attending programme development meetings (See Appendix 2). We further refined key concepts, organizing themes and concepts into contexts, mechanisms and outcomes to develop middle-range theories.

Results

Interviews: Findings

Eighteen realist interviews were conducted with patients (n=15) and patients' partners/ carers (n=3). Participant demographics can be viewed in Appendix 3: Patient Participant Demographics.

Twelve realist interviews were conducted with stakeholders (GP, Urology staff, radiology staff, managers and support group leaders). We do not provide information regarding the exact role of each stakeholder as this may compromise their anonymity, however their associations are indicated throughout.

Changes to Pathway

There were some changes or challenges to the implementation of PROSTAD as initially conceived. These were documented and discussed at monthly programme development meetings; stakeholder interviewees also described some changes to the PROSTAD pathway.

See Appendix 4: Logic Model for an understanding of how the pathway was intended to operate.

Key changes were made to the pathway as initially proposed:

- mpMRI scanning occurs at one location (instead of two).*
- 4 patient MRI slots per week (instead of 8).
- MRI results within 48 hour – usually 24 hours (instead of same day).
- Not all PROSTAD patients requiring a biopsy underwent LATP biopsies.
- Phone consultation results (instead of in-person). Hybrid clinics were trialled with face-to-face or telephone clinics available. Following patient feedback, telephone only appointments were progressed. Main reason cited was excessive travel to Bronglais DGH for scan and then to Glangwili DGH for clinic appointments the following day.
- Biopsy within 7 days of MRI results.

*mpMRI requires additional scanning time, technical expertise, and availability of clincial staff to administer the intravenous injection and radiology were unable to commit the additional resource unfortunately.

It's important to note that the goal to perform the biopsy within 7 days of the MRI result remains an aim and is not regularly achieved via the PROSTAD pathway or the non-PROSTAD

pathway, as indicated by the findings presented in Work Package 4.

Interview Themes and Theory Development

We used our initial programme theories (see appendix 2) to inform theory development. We indicated contexts (C), mechanisms (M) and outcomes (O) in brackets following each statement.

It's important to note that patient participants do not have experience of the conventional PCa diagnostic pathway comparator, whereas the majority of the stakeholders interviewed have experience of both pathways.

Below we describe theories relating to how, for whom and under which circumstances PROSTAD works or doesn't work.

Intended Outcomes

The Suspected Cancer Pathway's target is for patients to have undergone diagnostic tests and begin treatment within 62 days. While variable, patients referred to the conventional PCa diagnostic pathway may wait 98 days to receive a diagnosis. PROSTAD's key normative theory is that the changes to service delivery will reduce time from referral to diagnosis. It's worth noting that ultimately the broader aim is to reduce time to treatment for patients to experience the beneficial outcomes of earlier treatment. However, the time between diagnosis and treatment is not addressed by this project; future work aims to address different parts of the pathway.

Routinely collected data demonstrates that it achieves the goal of reducing time to diagnosis, though not as dramatically as hoped for. The mean time between referral to PROSTAD and diagnosis is 64 days, compared to 93 days on the conventional pathway.

The time between referral, MRI scan and MRI scan results is on average 13 days and is arguably the most effective part of the pathway. But there are sticking points that the cost-effectiveness analysis (Work Package 4) clearly shows, namely the time between decision to biopsy and performing the biopsy, and the time between biopsy results and the appointment where patients receive their diagnosis (Sewell et al., 2024). There were also deviations from the pathway as initially conceived in other respects, such as PROSTAD patients undergoing TRUS biopsies while LATP biopsies were phased in over the duration of the project. We were able to start with 1 session LATP biopsies per week (4 patients) with expansion to 2 sessions (9 patients) by study end. This introduction was also undertaken in the non-PROSTAD pathway to ensure equity of care for patients on both pathways.

There are contextual and mechanistic factors influencing these outcomes. For example, capacity to perform LATP biopsies was low at the outset of the project, and staff needed to be trained to perform this procedure; the arrangement of this required planning and co-ordination. As these arrangements were concurrent with the evaluation, it's reasonable to assume that the low capacity for LATP biopsies impacted the time to biopsy for some patients. Additionally, when patients were waiting too long for the LATP biopsies, decisions were made to redirect these patients to undergo TRUS biopsies to reduce waiting times.

'introducing the transperineal biopsies, we had some early barriers in where we were going to locate that […]. We have now, as I say, we've relocated that over to the day surgery unit. So, we've released that capacity back, but that was something that we've had to work on over a number of months to try and get that capacity' (PS5, Urology)

The European Association for Urology (EAU) produced guidelines recommending the use of LATP biopsies (EAU 2023), and so even without adopting the PROSTAD pathway, LATP is likely to become the preferred approach in HDdUHB. Indeed, the Urology department at HDdUHB has been considering this transition since before 2019, but for various reasons has not implemented it, implying the evaluation acted as an impetus to drive or expedite this change.

'I don't know if we'd have rolled out that method [LATP] as quickly as we have if it hadn't been for the introduction of this [PROSTAD]' (PS5, Urology)

During the evaluation, PROSTAD operated with four MRI slots per week for patients, available at one location. PROSTAD as planned aimed to offer MRI scanning at two locations with availability to see eight patients per week. This was partly to cater for the expansive area covered by the health board, as the site could be up to 2-3 hours drive for some patients. With just one site providing MRI scanning, this also constitutes an unachieved output.

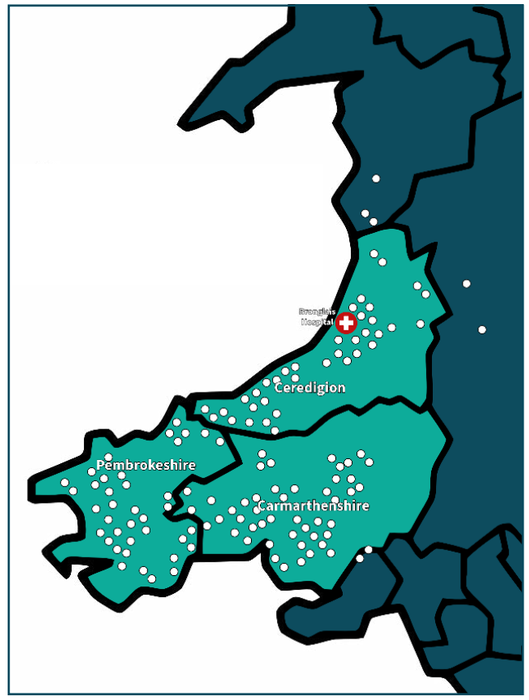
Unintended Consequences: Inequalities

During the evaluation of PROSTAD, the conventional pathway remained operational, creating a 'two-tier system' (PS6, Urology) for the evaluation's duration. A small number of patients declined the PROSTAD pathway, opting for the conventional pathway, which performs MRI scanning at multiple sites. Staff believe this was due to the increased travel distance. We did not conduct interviews with those who declined the pathway; PROSTAD patients we interviewed regularly remarked on the travelling distance – particularly those requiring multiple investigations, which took place at various hospital sites. However, a postcode scatter map highlighted that patients from across the Health Board attended Bronglais General Hospital for MRI as part of PROSTAD (Figure 5).

'I have had very, very few people refuse to go up to Bronglais because of the travel distance. But I think I would make it available at all sites because then we could fit more patients in as well. We could get more patients on this pathway if only we could have it in more sites' (PS1, Urology); 'If you're an older chap who's maybe a little bit more, you know, as it was, I just found the place to park out in someone's residential road down the road. But I think if you're an older chap, particularly relying on public or hospital transport, it could be quite a bit of a drag up there' (P12)

PROSTAD serves a rural population across three counties (C) and MRIs are available at one location (C), some patients may find it inconvenient or

Figure 5: A postcode scatter map of those patients who attended MRI scans at Bronglais General Hospital.



difficult to travel (M); patients to whom the benefits of travel are not adequately communicated (M) may not the benefits of travelling (M), leading to patients potentially declining the quicker pathway (O), in turn exacerbating inequalities with regard to access (O).

The above theory reflects some participant views, though it is not borne out by the postcode scatter map, which shows patients from all parts attended. While it would appear that for some patients travel isn't a barrier, data was not collected on those who declined and so it is not known how many decline the pathway nor their reasons for doing so. The rational for travel was explained to patients by the patient coordinator and so informed decisions could be made.

Some stakeholders remarked on the potential unfairness to patients on other pathways, as PROSTAD patients are prioritized for a day a week. This was one of the barriers to the implementation of MRI scans at two locations:

'They've wanted us to be able to undertake the full cohort to the patients. But I think it's – despite

repeatedly being asked to do that – we haven't been able to be able to so. So that is a shame really. But it is down to the waits that we have for other patients as well' (PS3, Radiology).

'it is an additional pressure in terms of we have to have like dedicated time slots available for these patients. Again, that hinders other patients who are waiting for longer than expected for their cancer diagnosis as well. So, because of the limited capacity we have, so possibly the funding should be allocated for expanding the services' (PS4, Radiology)

Pathology and Radiology staff have priorities outside of Urology (C), and, while staff within these services perceive a benefit to Urology patients, their roles mean they may be less exposed to patients individual "stories" or are exposed to a wider range of patients (M) and potentially experience a greater sensitivity to fairness and parity for patients on other pathways (M), leading to resistance to implementation on grounds of unfairness (O).

Organisational Factors: Primary Care and Referral

Primary care and referral were a common interview theme, and they constitute a point of professional tension for staff and challenge for patients. GPs and patients described general (i.e. not PROSTAD related) challenges to making/ obtaining referral; Radiology described their frustration at receiving referrals that they interpreted as below the threshold for referral. One GP described how referrals to secondary care 'bounce-back' and get 'nit-picked' (PS11, GP):

'great having ways to have a better treatment pathway from referral to diagnosis, but you can't have a referral without a GP consultation and a PSA test' (PS12, West Wales Cancer Support).

'I find them notoriously obstructive sometimes. And it's to the detriment of the patients you know, because they have had instances where I really wanted a scan done and the scan was rejected for not meeting some Radiological guidelines that they are following and I guess, yes, you have guidelines – but guidelines are just that, guidelines' (PS11, GP)

If secondary healthcare services are stretched (C), then staff feel pressure to adopt a protective approach (M) and referrals are returned (O); or GPs decision-making might be influenced (M) with them less willing to refer patients in the first place (O), leading to patients experiencing GP services as points of difficulty (O).

However, there was a perception that a dedicated pathway challenged this barrier to referral:

'I know it's difficult with the NHS at the moment and I know, you know, it's a short staff, etcetera and lack of funding. However, when things like this do come up, it is just it is well, it would help so many people. It's just it's just been so easy' (P18, carer).

'I think the benefits are much more like entry into the system' (P5).

'I do think the referral pathways, on the whole, for the specialty are great – in the sense of… you encounter a lot less obstacles' (PS11, GP).

One patient described hearing about the PROSTAD pathway via word of mouth requesting referral due to concerning symptoms:

'So, I said isn't that [the Prostad pathway] a good idea? My GP was rather against this idea actually – but in his due, he did put me through it' (P2)

If GPs and patients are aware of the availability/ existence of a dedicated pathway for PCa diagnosis (C), then GPs may perceive a dedicated PCa diagnostic centre as more "welcoming" of referrals (M) and patients may feel more empowered to request referral (M), leading to an earlier referral (O), an experience less fraught with challenge (O), shortened period of anxiety for the patient (O) and potentially greater patient/ doctor parity in referral processes and decision-making (O).

During the PROSTAD project, referrals to Radiology initially posed an issue, which was then addressed, as described in the following quote suggesting a potentially positive unintended outcome of the project:

'when we've had the electronic referral sent in, it's varying the amount of information that we have had, so I think there's been some of the back pages have been missing. So, I know that that has caused a little bit of an issue, but it's nothing that can't be that sort of thing, couldn't be ironed out. And I think these has been addressed now I think' (PS3, Radiology).

Organisational Factors: Impact of PROSTAD on Staff Adjoining Services

The PROSTAD pathway depends on multiple services – GP referral, Radiology and Pathology are all central to the running of the service. The implementation of PROSTAD impacts staff and services who have varying priorities and responsibilities beyond Urology.

'We're trying to change the workforce model trying to make it more of a sustainable service, but if all services implement changes like this then it's adding to what used to be a sort of a manageable workload – it's increasing that' (PS7, Pathology).

'the sustainability of that with the capacity and demand issues that we have in Radiology is very, very difficult' (PS3, Radiology)

PROSTAD depends on services like Radiology and Pathology (C), which are stretched with staffing issues and little capacity (C). The required change or increase to work may prompt concern regarding the impact on the service if other specialties adopt similar rapid pathway approaches (M). This may lead to tentative engagement (O) or scepticism (O), impinging on the acceptability or longevity of the pathway (O).

Radiology staff changed working practices – such as reporting on scans within 24 hours and dedicating slots on one day per week to one specialism – to participate in the evaluation of PROSTAD. Participants remarked on PROSTAD's dependence on radiology's participation:

'we need to support the Radiology department to make it work' (PS1, Urology)

Some participants described a culture where their service may not be considered, even if it will be impacted:

'we often take part in trials where the outcome could have potentially huge output impact on us but were not thought of' (PS8, Pathology)

In cases where they felt included, staff in adjoining services like radiology and pathology expressed more enthusiasm for PROSTAD, suggesting the extent to which communication has been a facilitating factor.

'there are few areas where we can increase the efficiency of our work. For example, we can change the protocols of the examination and we can slightly shorten the examination times. There is a potential possibility that, you know, we can tweak around the – the protocols of the examination to shorten and we can […] if we do that smartly, do that so that 15 minutes per patient can be saved and we can do another two patients. So that is the room for improvement is existing. So, we can work around that' (PS9, Radiology)

PROSTAD requires some changes to working practices or workload/ type in Radiology and Pathology (C). At times, staff in these areas have felt their service is not fully considered when adjoining services change pathways (C / M), but some felt more included and consulted in this particular project (M), which was a motivating factor for staff (M) to make or propose changes to their working practices (O) and express support for the PROSTAD pathway (O).

Organizational Factors: Driving Pathway Changes

Health services operate under multiple pressures. Capacity and staffing issues, as well as external or broader pressures, such as targets and public perception of sites and services:

'we're looking at this golden 62-day cancer wait target. I mean it's aspirational, but there's no reason why we shouldn't aim for it […] you know, we're getting hit with a stick about a 62-day cancer performance' (P12, Urology).

While professional tensions pre-existed PROSTAD (as described above in relation to referral processes), some required changes to working practices exacerbated friction. For example, staff

in Radiology feel the pressures they experience are not fully understood, and frustrated that the decisions they make to prioritize patients are interpreted as deliberately obstructive:

'I think some comments that have come from people outside of the health board haven't been helpful by saying there's got to be a will' (PS3, Radiology).

However, the necessary communication engendered by the project was seen as having a positive impact on challenging siloed working practices and generating mutual understanding and the explicit acknowledgment of a shared goal:

'I think the work that I've done with X on trying to establish this pathway means that we've already been working quite closely, even though sometimes that relationship was a bit fraught. It means that we've got to know each other as teams. So, when we've looked at introducing something else a bit further down the line or what things we're planning. Those relationships already exist' (PS5, Urology)

'it's just great news to hear that it's having a positive effect for the patients. That's the that's the bigger picture goal everybody sort of pulling towards' (PS7, Pathology)

In a health service context where services and teams tend to be siloed (C), service pressures may be acknowledged but misunderstandings of one another's motivations occur frequently (C). Pathway changes give rise to increased communications and opportunities to discuss points of contention (M), leading to greater understanding (O) and potentially greater flexibility and agreeability (O).

Participating in a study also acts as a motivating factor. For example, the evaluation of the PROSTAD pathway may have accelerated the transition towards LATP biopsies.

'I don't know if we'd have rolled out that method [LATP biopsies] as quickly as we have if it hadn't have been for the introduction of this, the MRI, it all sort of tied in together' (PS 5, Urology).

While opportunities for open communication were important drivers to change, recurring themes in interviews with some stakeholders imply the extent to which personalities play a part: influence, personal commitment and motivation were evidently central to the various actors' ability to persevere through, and in some cases overcome, resistance to change.

Participants expressed a sense of professional pride and a felt sense of improving care for patients:

'it's just it's just lovely knowing that you have taken that complete worry off people's shoulders because… whereas before, historically, they were waiting, they could be waiting a month to six weeks realistically' (PS1, Urology).

This professional pride and a desire for change motivated stakeholders to push through barriers and take on the burden of additional tasks in the name of achieving goals:

'there's been operational hurdles, there's been governance hurdles, but we've achieved – all of those and yeah, got to where we want to be' (PS2, Urology).

'I pushed this through. We've got colleagues trained up. I've had to, to kind of engage with colleagues, sell it to colleagues, sell it to a service, sell it to the governance' (PS2, Urology)

There was also a sense that commitment to the project generated enthusiasm and determination to implement changes:

'because I committed to do the this participated in this project, I was determined to create the space and do things on top of what we were doing already' (PS4, Radiology)

'I think it's [participation in the PROSTAD project] sort of given Urology some exposure within the health Board as well. You know, in terms of the recognition' (PS5, Urology).

Services regularly fail to meet national targets (C) and are unable to follow the gold standard of care (C), and "the system" is clunky and with many processual procedures to overcome to create change (C). Passionate and highly motivated members of staff (M), particularly those with influence (M), may be motivated to take actions (such as pathway development activities, funding applications for piloting, etc.) (M) to generate the changes required – taking on additional work/ burden (M) to (for example) organize appropriate training for colleagues (O) and driving changes to service delivery (O). Where successful, this in turn potentially leads to increased job satisfaction and maintained enthusiasm (O) related to seeing the difference made to patients (i.e. patient-facing roles) and being part of something (M).

The sustainability of the service constitutes a concern:

'I worry about what's going to happen when our projects runs out' (PS6, Urology)

Factors beyond the control of those immediately involved with the delivery of PROSTAD were identified as potential barriers to sustainability – for example, broader issues with staffing and funding:

'we have trouble, you know, recruiting doctors, you know, GP's, dentists. Anyone' (PS1, Urology.

'when you compare our health board to other health boards with the amount of consultants that we have that are able to report that's why we outsource so much' (PS3, Radiology)

Patient Experience: Rapidity

Even though the NHS Wales staff interviewed experienced the pathway differently, they believed PROSTAD to represent a significant improvement for patients referred to the new pathway as compared to the conventional pathway. The speed and reduced timescale – within the constraints mentioned above – was perceived positively:

'I think the outcomes for the patients, yes. But I think the actual – being able to have the numbers that they wanted to scan from that perspective, it hasn't been [a success]' (PS3, Radiology).

The referral to MRI and then delivery of MRI results was seen as particularly successful due to the speed.

'We're certainly getting the MRI scans done, you know, in a timely manner. It's what comes after that. That's still a bit of a sticking point' (PS1, Urology).

Patients were impressed by the rapidity of the pathway, suggesting low expectations of services:

'I had a concern, and I was basically sent to hospital to have a scan within a few well within a week or so, so I was quite impressed by it to be honest" (P3).

'they said you'll get a phone call tomorrow from the consultants with the results, which, again, you know, I mean that's something that you think's going to take a couple of months' (P7, Carer)

Some patients experienced the speed as discombobulating:

'couldn't fault it – we're just we were in a little bit of the daze because of the speed of it all to be honest' (P7, Carer)

Echoing this confusion, one patient remarked on companionship as a supportive factor in understanding and retaining information:

'if I was a single guy on my own […] then all this could easily get confusing (P8).

Some patients describe a sense of shock, implying the emotional impact of referral and some individualised the speed and mistook it as related to the seriousness of their condition as opposed to a convention of the PROSTAD pathway:

'he was making an urgent referral for the – to […] the Urology department which at that time came as a huge shock to me [...] at that time I didn't realize, you know, where what, what it was all about' (P13)

While patients described the emotional impact, they also largely expressed a desire to "know" either way as soon as possible:

'I was in within weeks. So, it's just getting the diagnostics done quickly, if there's a problem, hopefully I can do something about it' (P9).

Referral to a cancer diagnosis pathway is a distressing life event (C). The patients we interviewed had low expectations of NHS services (M), and so the speed of the pathway (M) in some cases elicited concern and exacerbated anxiety (O). However, receiving clear communication regarding the pathway's purpose at the point of referral (M) supported understanding of the pathway (O) and it's reasonable to assume that this may reduce or minimize speed-related concerns (O). While patients positively described the first part of the pathway (referral, to MRI scan and results), and were pleasantly surprised or 'impressed' (P3) by the speed at which they received their scan and results, from a pragmatic perspective, emotionally the speed may deprive patients of time to process information (M), leading to confusion and challenges retaining information (O). Having a companion to jointly receive the information (M) was described as beneficial to digesting information (O).

Staff perceived the speediness positively and made regular reference to time stamps. Some staff queried the benefit of earlier diagnosis if patients chose to "watch and wait", as opposed to 'curative' options or treatment, implying a medically-minded approach focusing on a narrow perspective of clinical outcomes, at the expense of informed decision-making:

'if he, the patient, doesn't want any radical treatment for a complete prostatectomy or any other, you know, radiotherapy or any other things, then why are we investigating so quickly?' (PS9, Radiology).

For others, knowing concretely if something is wrong, minimizing the period of uncertainty and being empowered to decide earlier was perceived positively – regardless of the decision they make:

'Rather than hanging around and dwelling on it, what – could it be this? Could it be that' (P9).

'knowledge is power' (PS1, Urology).

'because the big the biggest thing and not just for me, but for my wife as well was the waiting. They're waiting to find out things' (P11).

'if it's good news or bad news, it's nice to know as soon as possible' (P14).

Treatment options force patients to weigh up risk and 'chances' (P12), and choosing to delay the medical route might be attractive for some patients:

'it's some quite big decisions to make, you know, I'm, my gut is currently telling me to sit on a careful watch and wait, so repeat MRI and repeat biopsy before I jump down the radiotherapy or proctectomy pathway because there's implications to any of those treatments which I'm relatively young for […] I've got to live with the consequences of any treatment' (P12).

If patients receive a diagnosis quickly (C), and information is conveyed with clarity (M) they are more empowered (M) to make an informed choice as to treatment options (O), and earlier diagnosis may potentially give patients a wider range of options (O).

Patient Experience: Communication & Continuity

Patients received their MRI results by phone. Staff interviewed were unanimous regarding the convenience of phone consultations to deliver MRI results; they believe that patients also experience these as more convenient:

'they do seem to like the fact that they've, you know, they can be sitting at home in their own environment, you know, and processing it because even when we were offering the choice people were still choosing the phone call' (PS1, Urology).

Patient participants also remarked on phone consultations positively:

'It was just the speed at which it was that they were able to give me that information truthfully and it basically pushed me/that up the process rather than, you know, wait anxiously for a week or fortnight' (P13).

If patients have to travel significant distances for consultations (C) and the information conveyed is clear-cut (M) then phone consultations for the results (M) is perceived as mostly convenient (O); it's also perceived as timesaving by staff (M) suggesting that patients receive shorter consultations when delivered virtually (O).

Patient participants described caveats to the acceptability of phone consultations – for instance, not having an exact time (as you would with an in-person consultation) is inconvenient for the patient, and may impinge on their ability to co-ordinate with a loved one to be with them during that call:

'It's a very fluffy time and it's – sometimes it's like trying to make the right time. So, if I knew for a fact that Doctor Jones or whoever is going to phone me at 4:30 on the dot, I can prepare' (P12)

Staff felt that the earlier parts (MRI scan and results) worked best with regard to speed. Patients also described more challenges during later parts of the pathway. While every experience is unique, the more investigations required, the more likely patients were to describe mix-ups, confusion, and frustration. These are broadly grouped into themes relating to discontinuity, lack of clarity and patient labour, despite detailed communication regarding the pathway from the navigator.

'the fact that you deal with multiple departments, never quite sure who you are dealing with. Is it Glangwili? Is it Llanelli? Is it the waiting list people? Is it the preadmissions people? Is it the Urologists themselves? Or is it their PA? or is it just the nurse you get a little bit lost in where you are along the way' (P2).

'They needed kidney function as well which I haven't done. I literally had just the PSA reading. So… may have been a confusion that this all was happening so quickly – and to get the blood test done before I went into the MRI' (P2).

The various parts of the pathway are geographically dispersed (C), requiring patients to attend appointments at various locations for MRI scanning, LATP biopsy, bone scan, and PET scanning. Patients requiring further investigation beyond the MRI scans (C) will have experienced a steep increase in concern for their health after receiving suspicious MRI results (M), and will receive lots of information in a relatively short time frame (M). The combination of these factors was sometimes experienced as discombobulating or "convoluted", leading to confusion, poor retention or understanding (O).

It's worth noting that geographical dispersion and the receipt of a lot of information is also a feature of the conventional pathway for patients requiring investigations beyond MRI scanning, as bone and PET scanning is performed in a different health board.

Patient Emotions

A referral to a cancer diagnostic pathway is a distressing life event; staff acknowledged the impact on patients:

'they're just seeing and hearing the word cancer, you know' (PS1, Urology).

Supporting patients to process the information and the emotional response to this information was not a particularly prevalent theme for staff interviewed; this may be due to lack of time or a focus on medical outcomes.

The patient participants expressed stoic sentiments, which may reflect the population, i.e. older males in a rural, farming area. These socio-cultural factors were remarked upon:

'men will put it off and if they knew that they could get it done as quickly as that within a week, speak to the consultant, all the better' (P7, carer).

While gender "norms" may be a factor in the exploration of emotional impact, frustration, vulnerability and fear were notable themes and were often connected to waiting. Patients found to be cancer-free post-MRI, and therefore discharged early from the pathway, reported minimized anxiety and PROSTAD worked very well for these patients.

Patients who required further investigations, described a positive experience related to communication and timely interventions:

'I had an appointment at [hospital] for the MRI and then within 48 hours, I believe I had a phone call from the specialist to say "Yes, we need to give you a biopsy." So, within three weeks I had the biopsy. And within three weeks after that, I

had the results. So, I got to say, it was really sort of speedy and positive, and I was well looked after' (P9).

They also valued empathic and "human" interactions with staff, which they differentiated from counselling:

'the other thing I think has been absolutely amazing is as soon as it was confirmed to be prostate cancer, the support I've had from Hywel Dda. The Urology team has been fantastic because within a week I had a phone call from one of your Urology nurses – like a clinical one, like, she was like a specialist. And then that opened up a whole avenue of support from them … no, I wouldn't say counselling. I have had counselling that was provided. There was a support' (P13).

'You sometimes want a bit of reassurance again, but then we're making the final decision about what I'm planning on doing when I see them next' (P12).

Referral to a cancer diagnostic pathway can cause anxiety (C). If the pathway works as it should (or close to as it should) (C), then the shorter waiting periods of the pathway (M) leave less time for speculation regarding what's going on in the body (M) and the various communications are experienced by the patient as regular and consistent (M), leading to a sense of being looked after or contained by a steadily moving process (O).

As seen in WP4, at times PROSTAD patients experienced longer waiting times for biopsy (although the overall time to biopsy from referral was shorter). Patients were also by administrative errors or lack of communication expressed distress, loneliness and feelings of disempowerment – frustrated by bureaucratic processes, inconsistent communication and periods of waiting:

'right now, I am alone […] what is my case? I have no idea. I called in one hospital, Urology department. I called last week, the Urology department, and nurse only promises to call you, they inform you. but they call, open my case in computer and say no result and stop' (P1).

'It's just the way the systems are, bureaucracy going from department to department' (P8)

One patient described a mix up in which he attended an appointment for his LATP biopsy but was booked on a TRUS biopsy clinic, and so he left without receiving any biopsy. A few weeks later, he called to check the status of his appointment for a LATP biopsy:

*'I was told "' you are not on the list", and I said what do you mean I'm not on the list and she said "well we only get a certain amount sent through to us and there's no sign of your name being on the list". And I said when does it come on the list? "Oh, it could be about 3 months" […] I had to ring again because they never came back to me, but they eventually did get through after a week and they sorted it within a few days and I have this appointment which I am attending tomorrow. Clearly there is a problem with the administration, I think. It doesn't help the anxiety of the patient, having to make these phone calls and find out that you are no longer on the lis*t' (P6).

If patients experience long waiting periods (C), or do not know who to contact (C), repeated frustrated attempts (M) or periods of wondering what's happening and not knowing when or who to call (M) leads to exacerbated distress and disempowerment (O).

Discussion: Theories in Context

This evaluation explores the contextual and mechanistic factors influencing how, for whom, and under which circumstances PROSTAD works or doesn't work. Above, we've suggested key themes and posited a number of middle-range theories in relation to this topic.

Intended Outcomes and Unintended Consequences

The findings of this realist evaluation accord with our rapid realist review, which also found that implementing a rapid diagnostic pathway or centre is likely to reduce pathway time to some degree (Shah et al., 2016). However, Sewell et al.'s cost-benefit analysis (work package 4) using routinely collected data showed that the time between decision to biopsy and the biopsy taking place took longer on the PROSTAD pathway compared to the conventional pathway. However, this was not strongly reflected in the interview data, where non-patient stakeholders focus on the time to MRI and then to MRI results.

Important unintended consequences, such as impact on non-Urology patients (Broe et al., 2018) and Radiology services (Oon et al., 2014), were also identified through the rapid review.

Organisational Factors

Similar to research exploring pathway change in other areas (Jabbour et al., 2018), we have also identified at least three levels across which organizational factors operate: individual, organizational and socio-cultural. This evaluation highlights the dependence on a small number of highly individuals, who take on the burden of change to implement the desired changes – e.g. coordinating LATP biopsy training or creating time to change scanning working practices. This aligns with the findings of a systematic review that identifies "champions" for a service as a key driver of change (Cowie et al., 2020).

Interdependencies and the impact of PROSTAD on other service areas.

PROSTAD is dependent on multiple services working towards a goal; however, some services have broader priorities, which – without investment or expansion of the service – commitment must be weighed against. While a theme of this evaluation, it should be noted that this is not a feature unique to PROSTAD. Inter-specialty tensions within health services are well-known features of health services, and this evaluation accords with extant explorations of this topic. Radiology referral processes constitute a prominent theme, with some patients, GPs and Urology staff frustrated at perceived gatekeeping behaviour at varying stages; contrastingly, Radiology staff report suboptimal referrals or concerns for over-investigation in the context of a limited capacity service. This point of contention is commonly identified in the research literature (Oswal et al., 2009; Martins et al., 2020).

Staff stakeholders who were interviewed reported improved communication and mutual understanding as it necessitated meeting and discussing issues – rather than simply sending a more bureaucratic letter or email referring or declining a referral.

Participating in the trialling of PROSTAD had what we're calling "the trial effect", namely that the act of committing to a project creates a shared goal for a limited period, constituting a driving factor for change (at least in the short term). Individuals felt committed to trying something different, potentially engaging in activities for the duration, though raised concerns regarding long-term sustainability both due to dependence on continued engagement from disciplines with commitments beyond Urology patients and due to broader factors. For example, funding concerns, a UK-wide staffing crisis, and aging population all impact the service – as they do every service. However, there's confidence that trialling and evaluating PROSTAD may give exposure to the dependence on other services and the strains they operate under, thereby adding leverage to make a case for further investment for services like Radiology or Pathology to support PROSTAD – or indeed similar service changes.

Patient Experience

Shortening the waiting period between steps of the PCa diagnostic pathway was viewed positively by staff and patients. Staff tended to focus on the extent to which reducing waiting periods may improve clinical outcomes; patients were also concerned with clinical outcomes but also emphasized the emotional impact of waiting. Reduced waiting periods and improved communication has benefits beyond clinical outcomes and reduction of anxiety. PCa is an existential issue and raises questions of life and death that are unsolvable. However, experience of diagnosis and care can exacerbate or minimize the emotional impact of a health scare or diagnosis.

Longer waiting periods – particularly if there was little information or contact during these periods – exacerbated feelings of disempowerment and vulnerability. In contrast, shorter waiting periods and consistent communication potentially offer an experience of predictability. This might be

particularly important for people with a PCa diagnosis, which can be experienced as a loss of control and an assault on normative markers of masculinity (Salifu et al., 2023). Explorations of this topic suggest that retaining or experiencing forms of control – whether through knowledge or other assertions of agency – constitute mitigating factors or coping strategies for people with PCa (Langelier et al., 2022).

Virtual consultations are often viewed as more convenient to both staff and patients (Lawford et al., 2018; Campbell et al., 2023). However, while staff and patient satisfaction is recognized, Walthall et al., (2022) point out that satisfaction and experience are not synonymous; while satisfaction is high, there may be a diminishing in experience in the sense of time spent discussing concerns and procedures or the clinician's ability to recognize visual cues that indicate understanding or lack thereof. This is of particularly importance in non-English speakers and those with poor health literacy.

Summary and Recommendations

This realist evaluation proposes theories regarding the implementation of a PCa cancer RDP, PROSTAD. It explores the challenges and facilitators to the implementation process, including the types of compromises made, the mechanisms driving the pathway forward and unintended consequences. We also propose theories regarding how PROSTAD works, for whom and under which circumstances.

While the pathway faces challenges – predominantly with regard to capacity within Radiology and Pathology – this evaluation suggests a positive improvement for patients who value prompt investigations and results. Staff perceive the reduction of time between referral and MRI, and time between the MRI scan and results, positively. For patients who require further investigation, such as LATP biopsies, the pathway requires further optimisation before it reaches its intended outcomes. This suggests a perverse effect, namely: potentially sicker or riskier patients are experiencing more challenges; based on routinely collected data (presented in Sewell et al., 2024), this may also be a characteristic of the conventional pathway.

Recommendation 1:
The sustainability of PROSTAD depends on other specialties – particularly Radiology and Pathology. As a key driver for cooperativeness and mutual understanding between services, communication should begin early and be maintained. This will enable relationship building early on in the process and knowledge sharing which could contribute to less siloed services.

Recommendation 2:
To understand unintended consequences, it's vital to explore and identify if/ to what extent PROSTAD impacts other diagnostic pathways and ways to mitigate negative effects and determine the benefit of PROSTAD vs the cost to other pathways.

Recommendation 3:
Some patients describe confusion related to the PROSTAD pathway – which may in some cases be a feature of referral to any cancer diagnostic pathway. As PROSTAD has multiple steps across multiple locations, we recommend developing means to support patients whose journey goes beyond MRI scanning to keep on top of their care – for example, folders with dividers for each stage, an app for patient access to appointments or something similar. Increasing the information that patients get when they enter the service about what they can expect, what tests they might receive, where the tests may occur, etc. may dispel confusion as they go through the pathway and improve experience.

Recommendation 4:
Improve patient communication such that patients clearly know who they can call for updates or have the key care coordinator take the initiative in providing regular updates (e.g. a phone call at each 3-4-week mark). While there is a key care coordinator for PROSTAD patients, some patients do not seem to know this , although this is highlighted to them during the initial conversation.

Recommendation 5:
Give patients a choice between phone or in-person consultations, and give patients a narrow time slot to receive a call to allow them to plan or to ask for a companion to support them if they wish.

Recommendation 6:
Sense check during consultations, particularly if a patient's visual or other cues are diminished; encourage patients to write information down and give them an opportunity to check that information and understanding at the end of the call.

Recommendation 7:
Patients noted delays to biopsy and further delays to results. This part of the pathway was out of scope for this evaluation, but further work should be considered to address this.

Strengths and Limitations

To our knowledge, this is the first realist evaluation of a PCa RDP or indeed cancer diagnosis RDP generally. It brings together interview data with patients and staff in multiple specialties to examine the mechanisms by which PROSTAD produces intended and unintended outcomes.

As PROSTAD focuses on one element of the pathway, information regarding its impact on time to treatment falls outside the remit of this evaluation. This is a known limitation of the project.

We only interviewed patients referred to PROSTAD; we do not have interview data exploring patient experience of the conventional pathway, or those who declined a referral to PROSTAD. A cohort of participants were invited to participate by the health board by phone, potentially introducing bias. There may also be selection bias, due to limited capacity to undertake interviews, random sampling was utilised. However, those who could not speak English were excluded as previously noted.

With regard to the realist approach, the transition of interview data meant that there were limited iterations of interview questions over the course of data collection, resulting in limited development of interview schedules. Transcripts were sent to the evaluation team in bulk, limiting opportunities to refine or expand the scope of the interviews. Further collaborations will look to address this.

Work Package 3: Implementation and Service Review (I&SR)

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Introduction

This section focuses on visualising the prostate cancer pathway journey and the flow of male patients through this service to reach a diagnosis and then to a care destination of their choice. The scope of this service review concerns the 'front end' of the process – from GP suspicion to a diagnosis. The review does cover the longer process, but focuses on the 'suspicion to outcome' loop to ensure that bottlenecks and inhibitors to the loop could be detected. No such limiting factors were detected.

The organisations involved with the work package include the staff of the prostate pathway and supporting functions of Hywel Dda University Health Board in primary and secondary care services (direct patient facing and support functions).

The review employed the methods of process mapping (visualisation) with staff service reviews to establish the flow of patients and was conducted during the implementation period. The informants and participants included professional health and care staff from all the major stages of the pathway. These staff took part in interviews to explain the intricacies of the pathway, its decision points and its issues/areas of improvement. The objective of this section is to profile the pathway and to present a service review of the current state performance of the pathway as a means of benchmarking the projects that are introduced to improve service experience, services flow and ultimately costs per patient.

The Research Process

The following is a synopsis of the methods and process undertaken by the research team:

- The Project Activities: The major activities of this work package included a qualitative analysis of patient flows involving:
- Mapping the 'current state' prostate cancer pathway (Swim Lane Mapping as per its use by Prof Nick Rich).
- Understanding any issues with the current-state ways of working that inhibit patient flow (the compression of time as per 'best practice' professional guidelines and Government policies).
- The identification of corrective actions (if necessary) to restore instabilities/delays in the flow of patients.

The scope and focus of the work package (aka 'the System') and mapping started at the point of General Practitioner "suspicion of prostate cancer" to a negative or confirmatory diagnosis.

The Stakeholders Involved:
10 representatives of key stakeholders in the pathway were drawn from:

- **General practice**
- **Urology clinical teams**
- **Patient Management**
- **Radiology**
- **Pathology**
- **Surgical specialists**

Systems Thinking:

The purpose of the PROSTAD pathway is to provide safe, high-quality services which result in a confirmation/rejection of GP suspicion of prostate cancer for males in the HDdUHB region.

Table 2: The major Elements of the Suspected Prostate Pathway

There are 3 key loops in the prostate pathway system.

Elements	Connectors	Purpose
Patient		
General practitioners		
Urologists	Clinical Handovers	
Cancer Administration and Case work	Quality Management Resource scheduling	Deliver Pathway Objectives Meet Protocols and Guideline
Blood Specialists	Communication Systems	Deliver National Targets
MRI Radiologists	Teamwork (MDT)	
Surgeons		

The 'old' way of working was a disjointed process of teams and queues that added to the stop-go patient experience. The system did not continuously flow nor work effectively for any given team in the pathway (interview data). The process was also variable and resulted in a typical throughput time of between 45 to 60 days 'in the system'. The combined actual processing activities (patient touch points where the professionals are diagnosing or communicating with the patient) is between 3 – 4 hours – in an ideal world - and comprises of actual MRI scanning time, reporting, communication and decision making.

If the midpoint between 45 days and 60 days is taken (52.5 days) and converted into 8-hour working days, then the throughput is 420 elapsed hours from GP suspicion. 4 hours / 420 elapsed hours is a value adding ration of 0.95% of the wait time or 99.05% of time spend waiting, delayed and in queues.

The referral rate (demand for the service – hence the heart image) is determined by the General Practice appointments (which yield around 8 to 10 Urology referrals per week). Based on Systems Thinking and theory, the patients who are static in the system and not being processed towards an outcome diagnosis which are the 'Stock' or 'root cause' issue. The stock (or queue for the PROSTAD service) is influenced by the speed of our key (automated) machine cycle times (supported by very competent and professionally skilled staff). There is currently one bottleneck (shown by a time and a bottle) and this is the flow limiting step. The cause of this limitation is capacity, however increased capacity could lead to backlog due to a rate limiting step in the LATP biopsy stage. There are two system bottlenecks (a main one of the highest importance) and then would be LATP biopsy process (not automated but requiring specialist skills) and then (if they had endless capacity) the bottleneck would move to the Pathology team.

The PROSTAD pathway demonstrates flow, and the rate of this is determined by the MRI speciality teams and their cycle times of the machinery and a demand rate (the heartbeat) which is higher than their capacity. The move to PROSTAD was enabled by the MRI team allocating protected slots.

This single change in the conventional to PROSTAD pathway unlocked significant levels of flow.

The Research Methods to Map and Visualise Flows (constraints)

- The Methods Used: The methods employed, to investigate the suspected prostate cancer pathway, included:
- Interviews with stakeholders to assess (duration of 1 hour):
- The "voice of the patient", any typologies of patient (profiles) and any issues that impacted on the performance of the individual or their team when being safe, effective, efficient or timely in:
- Collecting process sequence and timing information.
- Collecting information on measures, targets and 'silly rules' (rules that cause problems and/or issues with the way a team or handovers between teams e.g. meeting turnaround times as a result of compromising the completeness of information at the point of handover of responsibility).
- Review of standard letters and documents (for completeness of data needed to ensure effective and efficient transmission of data between professional teams of booking of a service).

The patient pathway was mapped in terms of:

- Demand profile and any seasonality (VALSAT methodology with Demand amplification)
- Quality issues at each stage (data completeness, timeliness of data, access to appropriate data)
- Triage and the routing of patients based on clinical need, selection by the patient or a processing constraint in the pathway (skills availability or machine cycle times).
- Pathway shape analysis using the service variety funnel (VALSAT methodology) and the Flow Characteristics model (Rich, 2012).
- Cycle time analysis and an analysis of buffering (push and pull of patients into process stages) to determine the shortest possible time a patient can flow (safely) through the pathway.
- A swim lane map to visualise the flow of the patient and responsibilities undertaken by each department or specialist involved. The use of the map to identify improvements to improve efficiency at points in the pathway and the effective and uninterrupted flow through the pathway.
- Use of the FMEA (Failure Mode and Effects Analysis) risk analysis tool to determine the severity and frequency of failures and delays in the pathway.

Patient Profiles

The analyses, based on interviews with each stakeholder (early-stage stakeholders with closest proximity to the patient were prioritised) led to the identification of two basic profiles of male patients:

- Male patients who prioritised 'speed' as key to their needs and wished to access the prostate cancer pathway service as soon as possible.
- Male patients who wished to take 'time out' to consider their options and sometimes would leave the pathway temporarily to have a holiday in order to cope with the stress resulting from the suspicion or a confirmatory result. This is a "delayed start" patient.

The splits of profiles is a ratio of 90%+ of male patients that recognise the importance of speed in the pathway and less than 10% who wish to delay at periods during the pathway. The presence of a split in demand profiles is not significant but the design of a pathway for speed does not suit all of the patient demand profiles. In reality, one male patient per week will not wish to start the process immediately.

Learning Point:

There is much commonality in the expectations of patients, patient objectives and a lower variety of issues that would influence Patient Reported Experience outcomes with this pathway than other typical secondary care diagnosis pathways. The pathway and its demand may be classified as 'Low Volume and Low Variety'. This terminology may sound foreign to some clinical professionals, but this will be explained later. The pathway shares similar characteristics to cataract operations, vasectomies, and general surgery but with much lower volumes of patient referrals.

The "voice of the patient" analysis is a total quality management methodology (Kano, 1994) that investigates three levels of quality:

- Basic elements of a service that are largely unsaid, implicit and expected – such as the service is safe.
- Performance elements of service – that the service is delivered in a consistent and timely manner.
- Excitement elements of a service – the service can be provided after working hours or in the patient's house for example.

The research, for this work package, did not draw directly from patient interviews or Delphi/ panel groups but relied on staff perceptions and expertise in what patients had asked for or queried about the service they were about to receive or the reflections of patients that had used the service.

A safe service was considered a basic level of quality, a good quality and timely service based on an efficient and effective communication support process was considered the next level of quality that would yield time compression and reduce backlogs (performance level) and 'delighters' or excitement factors were drawn from being able to book slots ahead of time or understand patient wishes in a timely manner so that capacity could be booked with key professional teams.

The voice of the patient (from the staff perspective) also unearthed a set of desires:

- To be communicated with constantly to allay fears that increased when communication was slower or intermittent.
- To have clear communication for patients and clear setting of standards to reduce variability on professional practice.
- To understand system bottlenecks and queues.
- To know "what happens next" and when the likely activity will occur.

Learning Point:

Most prostate pathway errors/delays (at the stages of the pathway) will cost very little money or effort to address and prevent reoccurrence as they mainly concern standardisation and education of all stakeholders. Reducing these "process issues" supports the major investments (in the technology and availability of professional skills) needed to support more effective pathway-level flows. The voice of the patients (both forms) value good communication and timely delivery of any promise made to the patient.

The research team reviewed the 'visibility' of the patient in the process of their care, and this was determined to be low to medium. The rating is applied to services where the patient is largely the recipient of a set of processes rather than engaged in coproduction of their care pathway. At very few points in the pathway can or will the patient decide what happens to them. In effect, the patient is passive in the process pathway.

Learning Point:

The patient profiles reveal two key types of service demand. Type 1: An immediate service delivered in the shortest possible time to increase favourable outcomes. Type 2: A patient with a need to delay and "take stock of life" and delay treatment or decide not to progress. The finding means that a highly time compressed service is not needed by all patients – a minority need time to think and consider all options (deal with the cognitive exhaustion of the suspicion and process options.

The demand for the service was also reviewed and established to be a rate of 10 referrals per week. This is the rhythm of the service and to ensure a smooth flow of patients, this is the number of patients that would need to leave the service or enter a surveillance stage each week. This actual number may seem low but in comparative terms for the pathway it is a reasonable rate of referral and a constant demand for the service.

The demand pattern is not seasonal, and the demand is constant and flat in nature for the short term (1 to 3 years but generally rising as detection processes and male awareness has risen) – so the research team deemed the referral demand pattern as 'Low in Variation'.

Learning Point:

The variability of demand (short term within a month) and seasonally show low variability and a constant level of demand for the prostate service.

Vulnerability of the patient was rated on a low to high scale and prostate pathway patients were considered to be low in terms of vulnerability with most capable of an independent life during the course of treatment.

Learning Point:

The low vulnerability of the patient implies that a same-day admission policy could be enacted if needed and that as much effort and communication should be invested to keep the patient well at home, prior to, during and post intervention.

The combination of Vs (volume, variety, variation and visibility) makes this pathway suitable for time compression (compressing the time taken from referral to diagnosis) but not through the dedication of assets to the pathway e.g. there is insufficient volume to occupy 80%+ of an MRI machine capacity in 1 week or over a year to warrant asset dedication. However, ringfencing timeslots to support the flow of patients is a good investment of Health Board assets that have a finite operating capacity in the hours they are available to use.

Demand Patterns

The second analysis of demand concerned the presence of 'failure demand'. Failure demand is the amount of demand placed on a professional or their team which results from inconsistency of the process itself and/or failure to meet promises given to the patient. In this manner, if a patient is seen and promised a diagnosis within one week (and it is not provided in that week period) then phone calls from the patient to the department or General Practitioner would be determined to be Failure demand as the system has failed to deliver against an expectation. There were very few reported instances of failure demand (interviews with stakeholders) across the pathway and very few examples raised by the professional stakeholders during the interview process. The key points where failure demand reduced the capacity or flows of process stages was for the General Practitioner, Urology and surgical specialists, and MRI teams and well as the high dependency of the patient on their care worker for support.

It is important to note that the national targets in this professional setting are directional rather than absolute measures. If such targets were not aspirational and achievable they would incur the dysfunctions of a 'silly rule'. There was no evidence that this is a 'silly rule'. A silly rule is a goal which causes dysfunctions in a system and is often indirectly the source of failure. With no seasonality and other negative influences on process management, the lack of failure demand confirms the PROSTAD pathway is efficient and effective for both forms of patient (speed focus) and 'time out' focus.

Learning Point:

The demand for the service is flat and constant but there are also low levels of failure demand. The service is low volume, low variety of patient types, low variation in demand and low visibility of the patient in designing their care pathway. These characteristics make the pathway a context that is suitable to 're-engineering' of flows to eliminate unnecessary delays. These 5Vs show that the system is inherently stable, but that failure demand must be addressed to release capacity to flow patients through this safe and quality assured process. The review findings show that a redesigned and proactively managed pathway is capable and that it would the meet national targets for referral to detection times.

Low levels of failure demand generally supports higher levels of patient flow. There is some failure demand (presently and historically) at the beginning of the process. The source of the failure demand (and return, questioning or rejection of referrals) concerns issues with the standardisation of the referral process and compliance with the needs of the "referral and information receiving" teams.

Learning Point:

There were no silly rules impacting on this care pathway. The system is undistorted by any overarching rules or national targets. Even though the historic pathway performance may have lagged national indicators the clinical and management teams have followed the right path of improving the constantly and incrementally improving the system rather than adopting a 'knee jerk' approach based on chasing measures. The latter methodology is fool hardy and incurs the dysfunctions of the 'silly rule' syndrome.

Documentation

In health and care processes, documentation triggers action by care teams and it also causes delays when information is incomplete, suffers from poor timeliness of handover or is illegible. The documents in the system are largely automated (the PAS system) or in the form of standardised proforma. The proforma use forcing functions for key data such that the data must be entered before a document can be completed and saved. The electronic and manual documents used by professionals were reviewed during the interviews and were found to contain no omissions. The processes of data exchange were therefore considered robust and reliable. The Welsh PAS system was rarely unavailable to staff.

Comparing the Standard Pathway and PROSTAD

The two process pathways were reviewed and the PROSTAD pathway was, primarily through the effectiveness of MDTs and the high levels of support provided by the Radiology teams, significantly shorter with much better patient flows. The focus of the Swim Lane mapping was the new PROSTAD process.

Swim Lane analysis

Swim lane mapping was conducted to depict the flow of patients (Shostack, 1984). The symbol icons are shown in Table 3 and the scope of the project is shown in Table 4.

Table 3: Icons

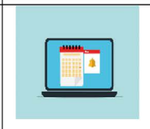
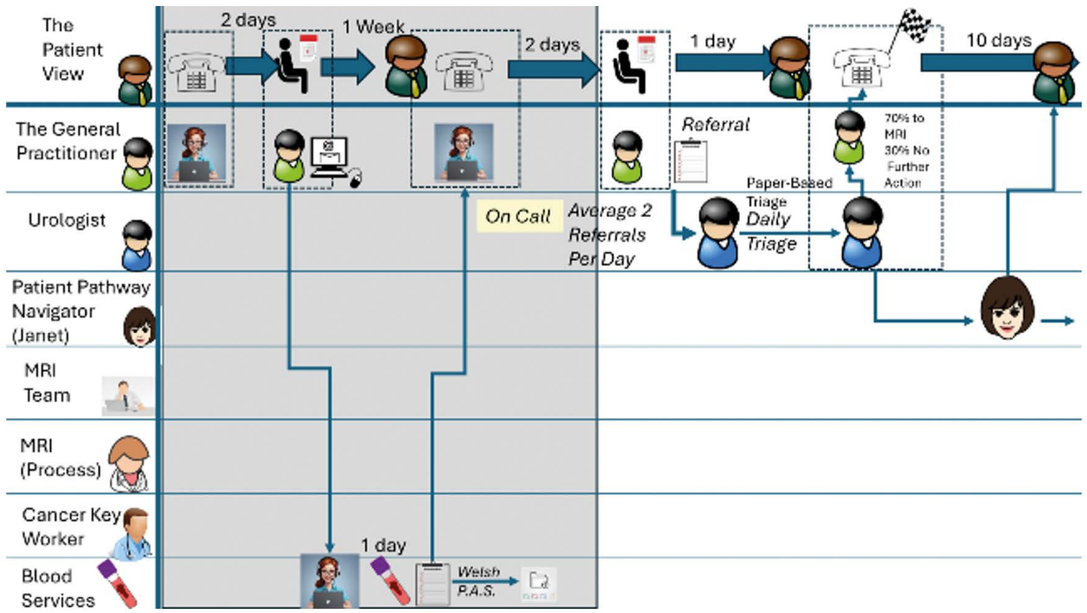
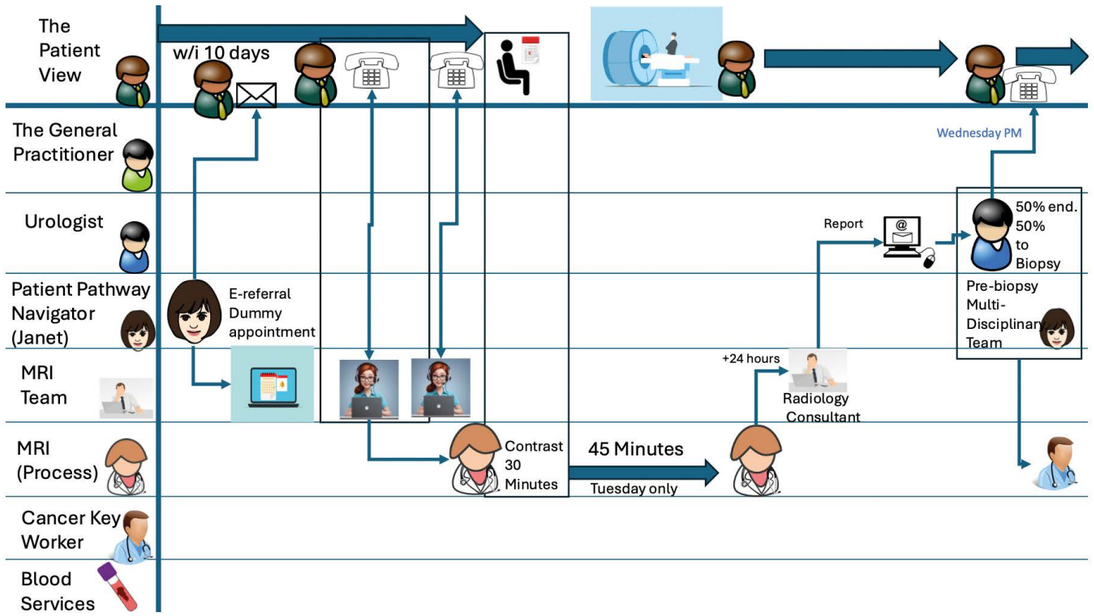
The Patient		The General Practitioner		Urologist	
Patient Pathway Navigator		MRI Team		MRI Process Team	
Cancer Key Worker		Blood Services		Front Desk and Reception (inc. records)	
MRI Scanner		Waiting		Appointment Booking	
LATP Biopsy		Decision and choice		Patient Exit Point	
Email		IT System Record		Letter	
Phone call		Manual Record		Out of Scope Section	

Table 4: The Process (Start and End Points), with Grey shading is out of scope

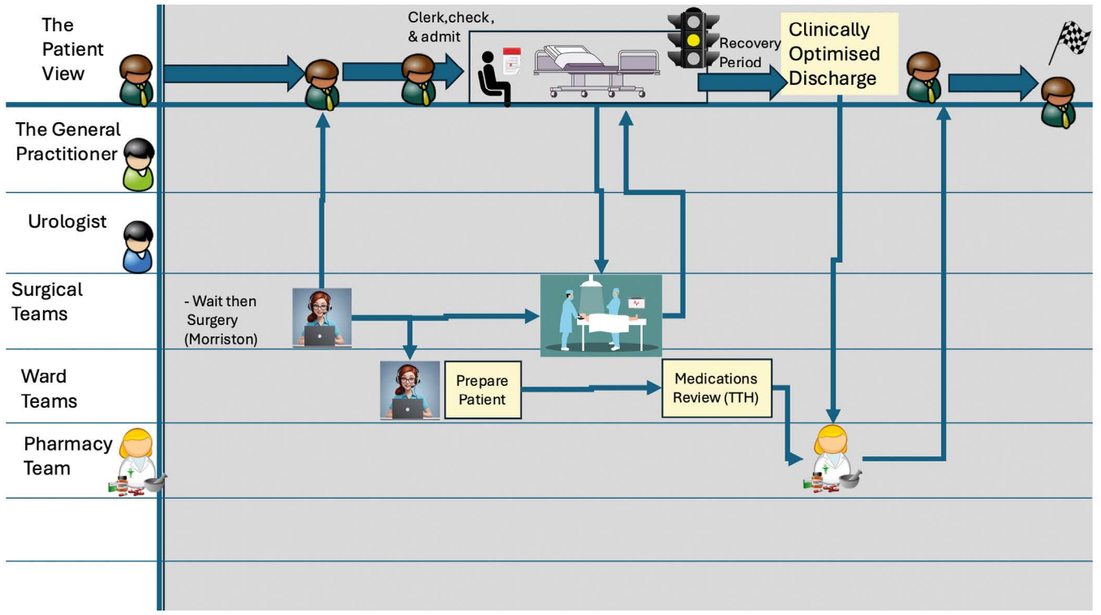
Loop 1



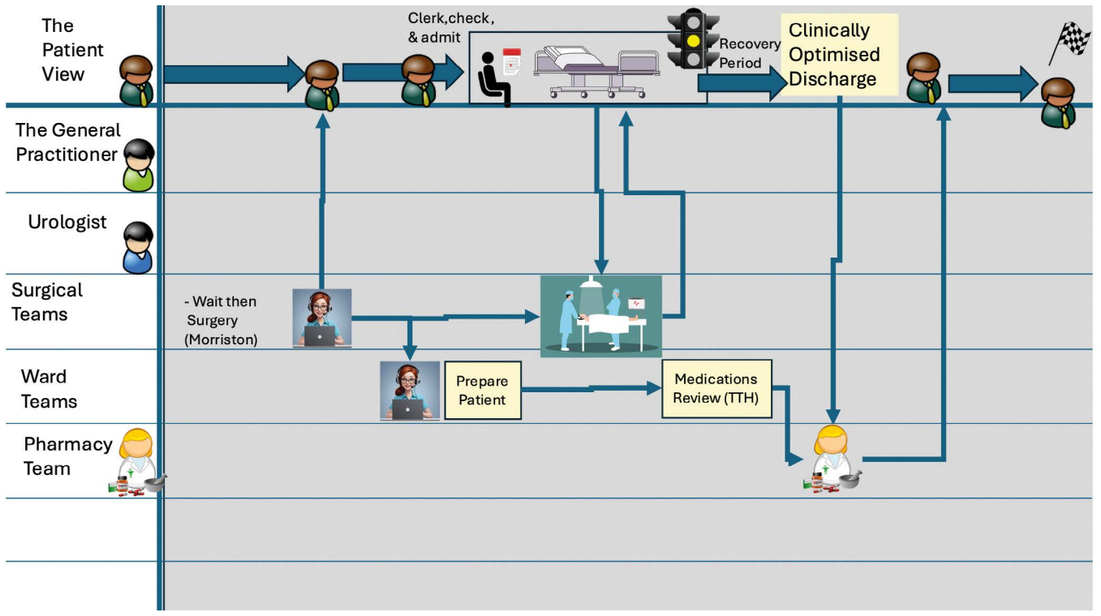
Loop 2



Loop 3



Loop 4



The following ‘swim lanes’ show the new PROSTAD Process as it is working currently (Figures 6-9).

Figure 6: Loop 1 from GP to Urology Triage

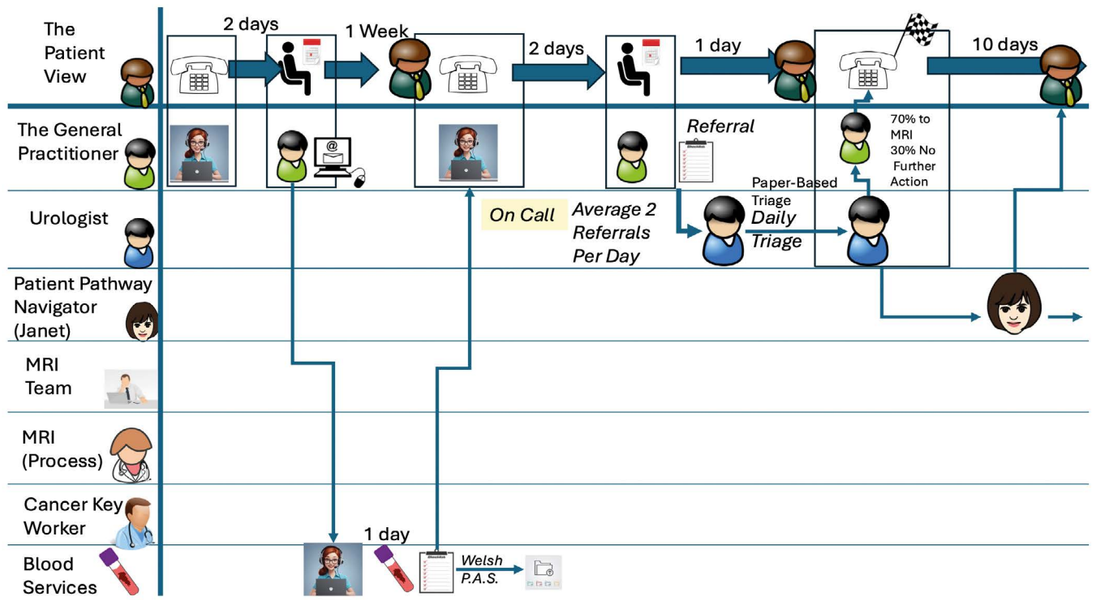


Figure 7: Loop 2 from Urology Triage to Biopsy MDT

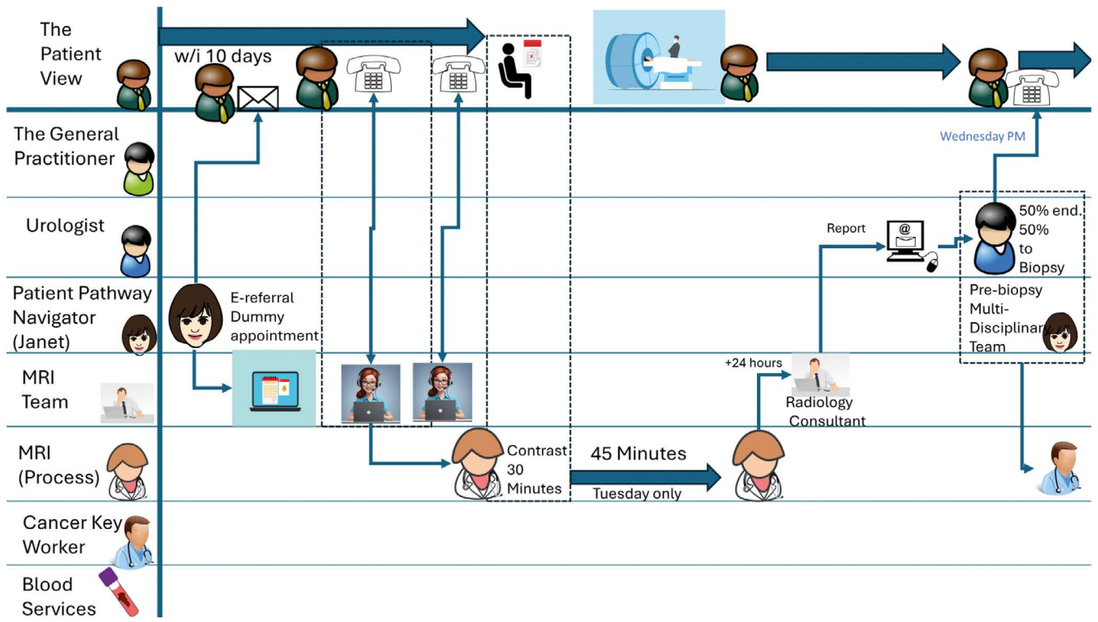


Figure 8: Loop 3 from Biopsy to Treatment Decision (out of scope)

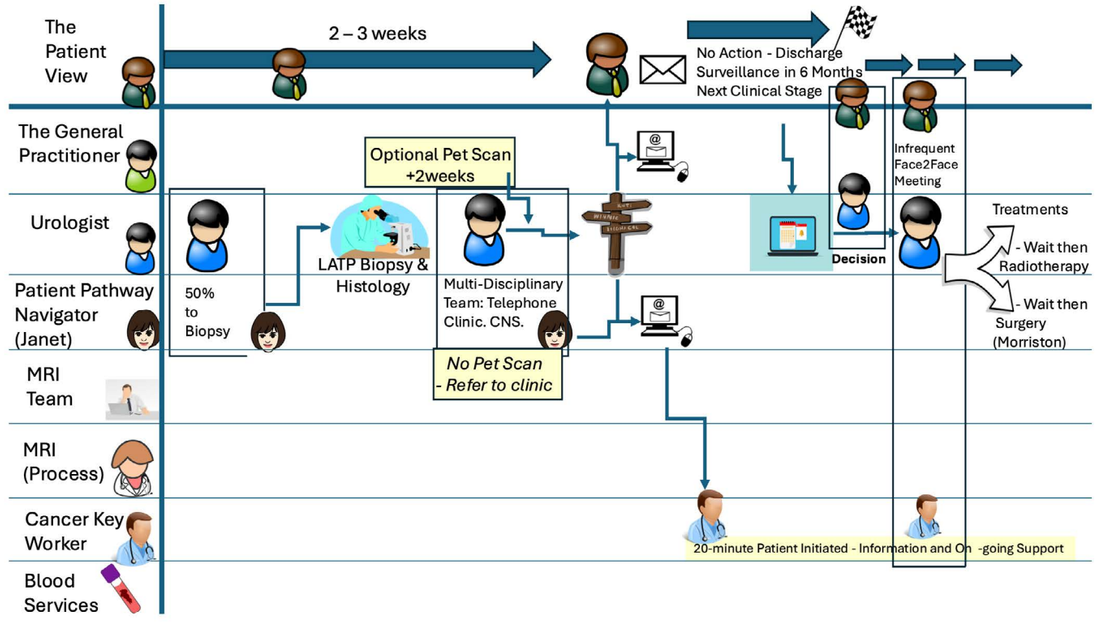
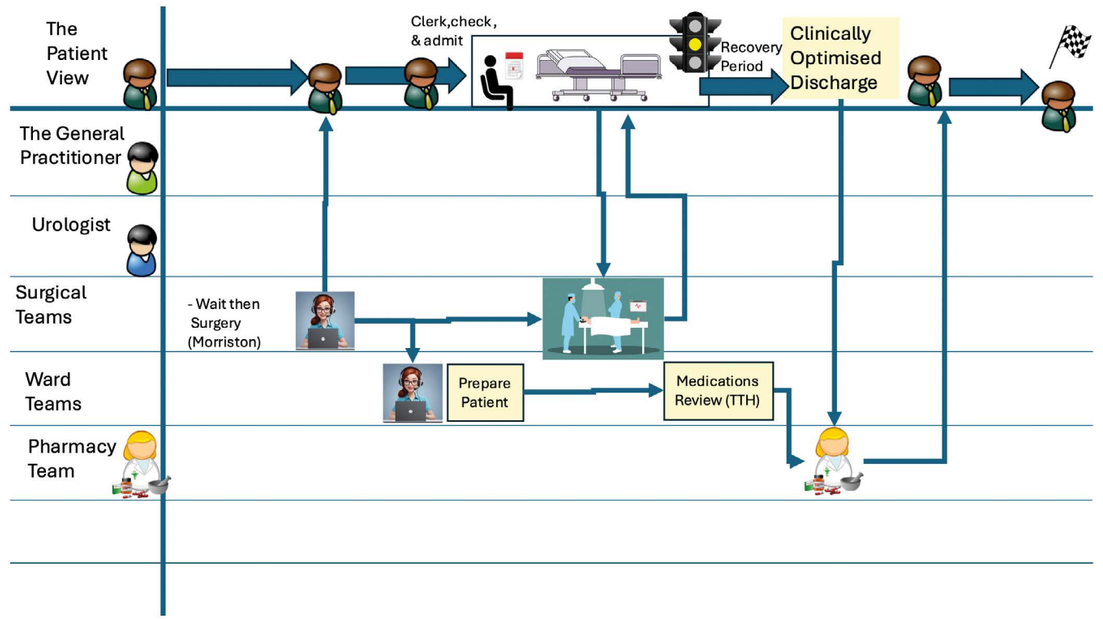


Figure 9: Loop 4 from Treatment Decision to Post Surgery (out of scope)



The process has very few decision points and flows well for the PROSTAD pathway. The conventional pathway has a longer and growing wait for patients as the MRI process has less capacity than the demand placed on it by all referrers (not just Prostate referrals).

In summary, the demand rate is higher than the bottleneck process. For the purpose of this review – the bottleneck is the wait time and processing speed of the slowest stage. The bottleneck is the MRI team stage and the Radiology process. The cycle time for the MRI machine is 45 minutes plus 30 minutes for the administration of contrast (a machine bottleneck of 45 minutes as the patient is brought in before the machine has completed its cycle of the previous patient). The cycle time for Pathology is less than 30 minutes.

The wait time for the MRI machine is around 10 days and the Pathology is 1 day. The typical throughput time that can be achieved by the PROSTAD system is therefore 3 days at the GP stage, 10 days of waiting, 1 day of MRI time and the wait for biopsy and the results of 5 days then a final conclusion of the suspicion (19 days at the steady state). The conventional and non-PROSTAD pathway is much longer due to a longer delay when awaiting the MRI process. The author would like to acknowledge the process efficiency and proactive support of the Radiology team.

The rhythm of the system is 8 to 10 referrals a week to the prostate service. At 10 referrals a week this equates to 1 male patient every 4 hours of the working week. The current backlog of patients is circa 40 males (monitored during the project with staff). The backlog is therefore 4 - 5 weeks. The backlog is unlikely to reduce and will grow even with the PROSTAD pathway in place. The question is whether the MRI teams could process at the rate of referral – this will stabilise the flow of prostate patients but would lengthen the other demand queues for the MRI service. The current way of working is stabilising flows, and the conventional pathway demand is being processed so the pathway queue is not lengthening dramatically. If the MRI slots were to match the demand rate, then this would necessitate 450 minutes of machine time or one shift per week (7.5 hours). The best way of working would be to reserve 2 'slots' for patients each week (4 hours duration) to spread the load and go from one batch of patients and results per week to 2 smaller sessions (batches) to allow one release of results every 3 days (based on engineering and demand calculations by the author).

The MRI process has good uptime and availability. Rarely is the machine unavailable for use and the maintenance schedules are very effective (HDdUHB maintenance and the maintenance/audits/ calibrations conducted provided by the machine provider). The MRI team has a good coverage of skilled staff and reporting processes are efficient and without delays. Turnaround time reduction at blood processing, MRI and biopsy stages are good and would require furthermore capacity and team improvements to compress time at these stages and to improve flow.

Current State Swim Lane delays and errors that are not designed-in do however result from variations in practice and ineffective communication of needs between teams. There is much confusion about what is best practice and also what is expected of a 'supplier' team in the process. The standardisation and promotion of a 'one best way' was supported by all professionals and this would include:

- The Pathology team face significant demand from a variety of referrers but could potentially create a prostate pathway or dedicate assets to reduce turnaround times but – operating a one-day turnaround service is not holding the flow of patients back.

- A "one best" way for General Practice and clarity on the data needed for an effective referral (especially as the Get It Right First Time (GIRFT)) organisation has made recommendations in this area of the process and variation at this stage is impacting on the right first-time handovers/referrals to the Urology teams (NHS England, 2024). At present the lost time of the Urology team has not been identified as being in the region of £2000 annually of lost Urology specialist time.

- The MDTs, at each stage of the process, work well and are well attended.

- The biopsy process faces some delays in terms of histology reporting from the process and a 'one best way' may help these professionals in terms of the prostate specimens are one of the top specimens by weekly, monthly and annual volumes. It is also a relatively fast process in comparison to fatty tissue processing and reporting. This process can be improved but histology is not the system bottleneck.

Waiting times (and rework waiting = failure demand) that are key to the flow of patients (the queues around each process) therefore include:

- Requests from Urology to the general practitioners for more information or to complete the standard process of an effective standardised referral (completeness of the referral)

- Time delays from referral to MRI and any reporting delay (the latter is small in events of delay but the queue for MRI is the most important target for pathway improvement).

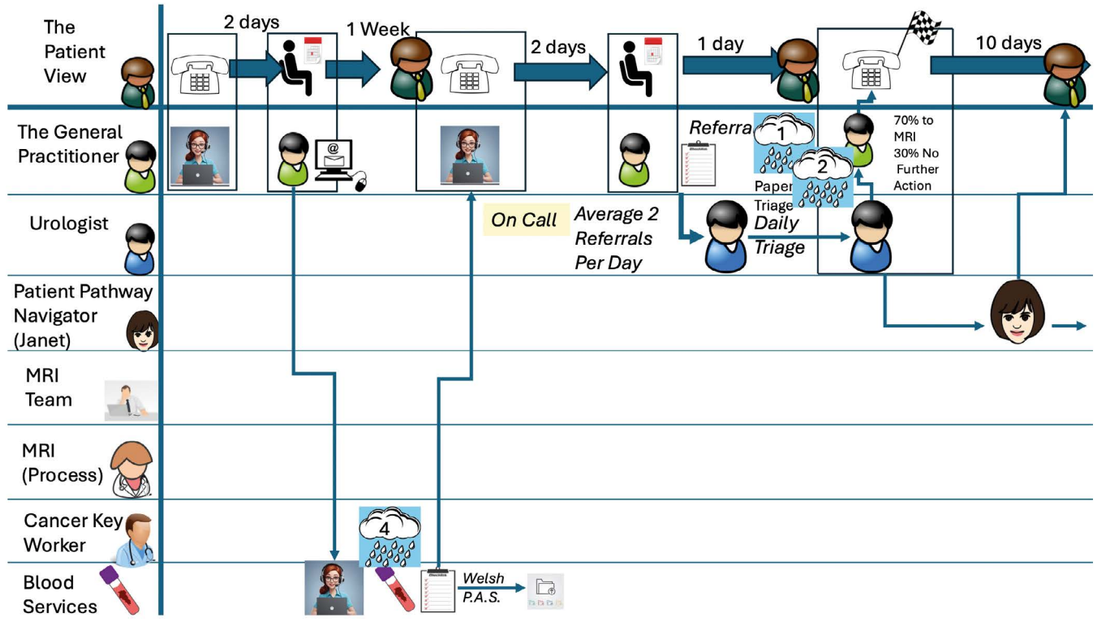
- Time delays from referral to clinical decision to biopsy and reporting (the latter has some delays and issues which could be improved by quality teams in the Pathology process)

- Time from referral to outpatient appointment/ virtual discussion with the patient.

The Addition of Cloud Bursts to the Swim Lane Map

The initial Swim Lane map was reviewed by the mapping team and 'rain cloud' icons are added to the stages where issues or potentials for improvement exist. The following shows the re-worked Swim Lane for the PROSTAD pathway (Figures 10 & 11).

Figure 10: Loop 1 from GP to Urology triage



The following Clouds are noted:

1. Lack of standardised handover from GPs to Urology team (delay of process, costs to GP in time lost and costs to Urologist in lost time). The introduction of a standard protocol and flow chart decision-making would enhance the flow performance of the prostate pathway.

2. Clarity of the GIRFT and Urologist standard documentation would support the new 'one best way' to meet published guidelines and these documents should be written with GPS to ensure they are concise and provide all the correct information at referral.

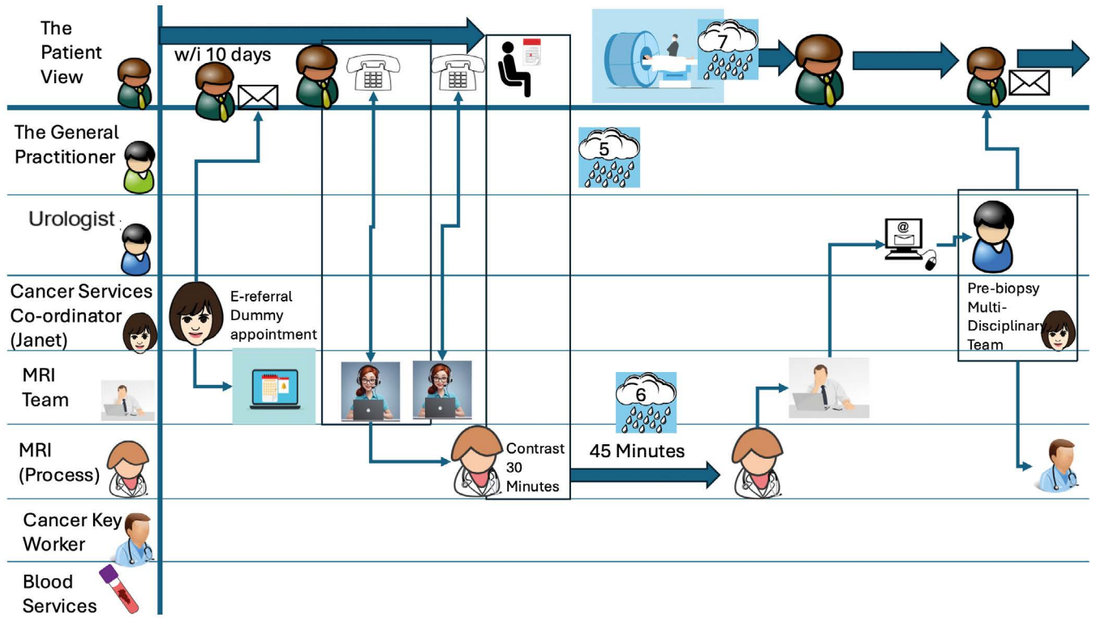
3. GP lost time as patients chase for information about progress. The patent is in an emotional state and therefore needs greater awareness of the process and their expectations need "to be set" to avoid unnecessary calls to the General Practice.

4. The Pathology team have significant demand on them. An improvement project to understand all the demand and its referrer would help establish the business case for dedication of assets to reduce time here or an exercise in set up and changeover time reduction may save time and result in a quicker diagnosis for the General Practitioners. The current time to achieve an appointment slot is around 1 week of delay with a process of short duration for blood taking and analysis. The taking and processing of blood results is a stage in the pathway that faces significant service service demand which makes it another bottleneck to patient flow. Any improvement in turnaround times at this point will be time saved to the pathway and have benefits beyond the blood processing and results stage.

From the second loop of the prostate pathway, we can determine areas for potential improvement which include:

5. Updating of the GPs on progress through the MRI process bottleneck and results.

Figure 11: Loop 2 from Urology to Biopsy



6. The MRI process is the "pathway bottleneck" and must be protected at all times. A slot missed here will never be recovered. As such the availability and quality of imaging/timely update of results are key to patient flow. This includes patients arriving on time and the availability of staff in the MRI imaging department. The severity of a lost slot in this part of the pathway is very high in cost (to the system and not the actual cost of conducting the service at this point). Such slots would be made available at predetermined times each week and 'ringfenced' only for suspected prostate cancer patients.

7. Any increase to the number of patients that are processed here (each week) is key to the whole system flow and increased numbers will reduce waiting times for patients who prefer speed over time to come to terms with their 'speculative' suspicion. Any project and investment here will release great benefits for staff, patients and flow. It must also be suspected that such an investment will benefit a range of planned and urgent slot requirements for the MRI team.

Additional 'rain clouds' were identified in Loop 3 from biopsy to decision to treat and Loop 4 from treatment decision onwards. These can be seen in Appendix 5.

The PROSTAD Pathway for the Male Patient Requiring Immediate Action (Speed Focus)

The "before" and "after" analysis of the PROSTAD process shows significant savings (see work packages 2 and 4). The success has brought the pathway to claim to be a 'best' current practice. The value-adding of the pathway (the amount of time when the patient is being diagnosed relative to the total pathway time) has increased as a result of compressing time from referral to diagnosis and decision and reducing the unnecessary time spent waiting for patients. The changes in system performance have not resulted from staff working harder but from a realignment of processing with demand on a service and the reduction in queue and delay time. To make further progress the teams will need to cut delays further and invest in additional MRI time by using dedicated and ringfenced slots for prostate pathway patients each or multiple times each week. The process of ringfencing would need to be negotiated with the radiology senior management team.

Acknowledged Limitations (Methodology)

The methodology for this work package was designed to engage with pathway professional staff staff and to gain their perspective of patient flows, cycle times and delays. The research did not conduct secondary data analysis of recorded information (this is covered by other work packages) and the field research did not include direct patient involvement and their reflective accounts of the pathway.

Conclusion

The investment in protected MRI slots has enabled much greater system flow for suspected prostate cancer patients. The detailed analyses show that the pathway is stable, manageable and free of major catastrophic failures and excess failure demand. The standardisation of the pathway has greatly enabled flow but there still remains more to do. For standardisation to work effectively and efficiently there must be widespread understandings and a common approach to the service. The latter necessitates mass-education for all key stakeholders and especially to heighten the situational awareness of all in terms of handovers and their completeness. Delays are being caused by incomplete handovers and referrals and, to a lesser extent, untimely reporting (generally as opposed to being from a particular stage or group). The most meaningful next step projects would be to ensure that the bottleneck remains protected and to seek a higher rate of weekly slots (when the MRI slots available meet the demand rate from GPs there will be a stable backlog and standard waiting time for PROSTAD and less conventional pathway patients). This would be the ideal goal of the system. The matching of the demand and process rates would reduce throughput time but allow men wanting to 'think about' the suspicion of cancer to do so.

Work Package 4: Health Economic evaluation

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Introduction

This section reports on Work Package 4 of the PROSTAD evaluation and describes the health economic component of the evaluation. The health economic evaluation was undertaken with regard to current recommendations for evaluating cost-effectiveness of health technologies within a UK NHS context (NICE, 2023; NICE 2024). A health economics analysis plan was written as a supplement to the study protocol and signed off by the study team prior to analysis. The HEAP was followed without deviation. The health economic evaluation is reported using key sections of the Consolidated Health Economic Evaluation Reporting Standards 2022 checklist (Husereau et al. 2022).

Methods of the health economic evaluation

Aim and objectives

The aim of the health economic evaluation was to assess the costs and consequences of the PROSTAD pathway for men with suspicion of prostate cancer compared to Standard care.

The economic evaluation considered resource use and cost differences between the PROSTAD pathway and Standard pathway and patient outcomes (using data obtained from pathway records and relevant literature) as part of a cost-consequences analysis. Specific objectives of the health economic evaluation were to:

- Map out the PROSTAD pathway.
- Understand the impact of the service when compared to 'standard clinical practice' (i.e., with no PROSTAD pathway) on key descriptives such as referral patterns and time to event across the diagnosis pathway.
- Identify key resource drivers and costs associated with the PROSTAD pathway service and subsequent impact on other NHS resources.
- Investigate the impact of the PROSTAD pathway on for example, cancers detected, stage of diagnosis (if available).
- Assess short-term outcomes for patients (up to diagnosis) and to explore the cost-effectiveness of the PROSTAD pathway.
- Estimate the budget impact of the PROSTAD pathway on NHS Wales in case of a national roll-out.

Table 5 summarises the PICO that guided the health economic evaluation.

Please see full report in Appendix 6 for detailed methodology.

Results of the health economic evaluation

Two base cases were considered during this analysis. Firstly, the analysis was run with the 80:20 split base case. This base case considered that, in both arms, for patients requiring a biopsy, 80% of had an TRUS biopsy and 20% had a LATP biopsy. This is what is currently happening in HDdUHB for both PROSTAD and non-PROSTAD arms. No data was collected on which biopsy patients had therefore this was estimated by expert opinion. The second base case, per protocol, considered that patients followed the protocol as laid out in Figure 1 and Figure 2. This means that all patients in the PROSTAD arm requiring a biopsy have an LATP biopsy and all patients in the standard arm requiring a biopsy have a TRUS biopsy.

Implementation Costs

After consultation with the HDdUHB project team it was decided that the cost of the pathway coordinator would not be considered in the overall cost analysis. This was due to the fact that the PROSTAD pathway only sped up the pathway rather than changed the pathway itself and therefore the costs would be equal in both arms.

Table 5. PICO (Population, Intervention, Comparator, Outcomes) framework of the health economic evaluation alongside the PROSTAD pathway in HDdUHB.

Population	Intervention	Comparison	Outcomes
Men with suspicion of prostate cancer re-ferred by their GP or consultant to the pros-tate cancer diagnosis services No subgroups will be analysed	PROSTAD – New Model Prostate Cancer Diag-nostic Pathway	Standard pathway (Standard care)	Time to diagnosis Cancers detected Other significant diagno-ses Health-related quality of life Pathway costs Healthcare resource use between referral and di-agnosis Patient experience and satisfaction (analysed separately if available)

Healthcare Costs and Total Costs 80:20 split base case

In the first, 80:20 'base case' scenario, costs during the diagnosis stage (including mpMRI, biopsies, outpatient appointments, MDTs and other tests and healthcare contacts) in the PROSTAD group (n=127) amounted to a mean £992.43 (standard deviation, SD=£607.74) per patient. The Standard care diagnosis pathway in the parallel comparator group (n=112) cost a mean £847.05 per patient (SD=£503.29), including bpMRI, biopsies, outpatient appointments, MDTs and other secondary care costs.

The overall cost difference of £145.38 (95% CI: £2.09 to £288.71), compared to the comparator pathway was statistically significant in both t-tests and Mann-Whitney U tests.

The total per patient cost for PROSTAD patients compared to Standard care patients are summarised in Table 6.

The total costs from referral to diagnosis were statistically significantly higher in the PROSTAD pathway compared to Standard care for the cancer diagnosis patients, but not for the other groups. Statistical significance remained (p=0.017) following Bonferroni correction for multiple comparisons among means (Dunn, 1961) due to the model looking at different time periods within the overall time to diagnosis (e.g. time from referral to MRI, time from MRI to decision to biopsy, etc.). The difference is cost was mainly driven by the higher cost of the mpMRI compared to bpMRI.

Table 6. Per patient cost for PROSTAD patients compared to parallel Standard care patients.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	**-**
Mean cost (SD)	£992.43 (£607.74)	£847.05 (£503.29)	£145.38 (£2.06 to £288.71; p<0.001))
Median cost	£1,160.50	£828.64	331.86; p<0.001
Minimum cost	£367.87	£316.26	
Maximum cost	£2,445.74	£2,206.54	

CI: Confidence interval; SD: Standard deviation

Total mean costs for individual outcome groups can be found in Table 7. Mean costs were presented here to provide more information on variance.

Table 7. Mean total cost per patient for different outcome groups.

Outcome group	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
No biopsy (surveillance only) (SD)	52	£402.83 (79.45)	49	£382.70 (£126.09)	£20.13 (-£-21.23 to £61.49; p=0.337)
Biopsy – cancer diag-nosis (SD)	50	£1,568.14 (£473.06)	43	£1,337.79 (£363.88)	£230. 35 (£54.29 to £406.40; p = 0.01)
Biopsy – other or no diagnosis (SD)	8	£869.547 (£11.44)	12	£818.16 (£179.37)	£51.38 (-£83.25 to £186.02; p=0.433)

CI: Confidence interval; SD: Standard deviation

statistically significantly higher in the PROSTAD pathway compared to Standard care for the cancer diagnosis patients, but not for the other groups. Statistical significance remained (p=0.017) following Bonferroni correction for multiple comparisons among means (Dunn, 1961) due to the model looking at different time periods within the overall time to diagnosis (e.g. time from referral to MRI, time from MRI to decision to biopsy, etc.). The difference is cost was mainly driven by the higher cost of the mpMRI compared to bpMRI.

In the per protocol scenario, costs during the diagnosis stage (including mpMRI, biopsies, outpatient appointments, MDTs and other tests and healthcare contacts) in the PROSTAD group (n=127) amounted to a mean £1,165.71 (standard deviation, SD=£730.73) per patient. The Standard care diagnosis pathway in the parallel comparator group (n=112) cost a mean £814.30 per patient (SD=£486.42), including bpMRI, biopsies, outpatient appointments, MDTs and other secondary care costs.

The overall cost difference of £351.41 (95% CI: £2190.98 to £511.84), compared to the comparator pathway was statistically significant in both t-tests and Mann-Whitney U tests.

The total per patient cost for PROSTAD patients compared to Standard care patients are summarised in Table 8.

Table 8. Per patient cost for PROSTAD patients compared to parallel Standard care patients.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	**-**
Mean cost (SD)	£1,165.71 (£730.73)	£814.30 (£486.42)	£351.41 (£190.98 to £511.84; p<0.001)
Median cost	£1442.63	£758.11	684.52; p<0.001
Minimum cost	£367.87	£316.26	
Maximum cost	£2,727.87	£2,316.41	

CI: Confidence interval; SD: Standard deviation

Total mean costs for individual outcome groups can be found in Table 9. Mean costs were presented here to provide more information on variance.

Table 9. Mean total cost per patient for different outcome groups.

Outcome group	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
No biopsy (surveillance only) (SD)	52	£408.25 (£111.22)	49	£378.38 (£112.23)	£29.87 (-£14.26 to £74.00; p=0.09)
Biopsy – cancer diag-nosis (SD)	50	£1,861.56 (£480.15)	43	£1,280.38 (£386.29)	£581.18 (£399.68 to £762.67; p < 0.001)
Biopsy – other or no diagnosis (SD)	8	£1,151.68 (£11.44)	12	£782.90 (£180.85)	£368.78 (£233.04 to £504.52; p<0.001)

CI: Confidence interval; SD: Standard deviation

The total costs from referral to diagnosis were statistically significantly higher in the PROSTAD pathway compared to Standard care for everyone following biopsy, but not for the surveillance group. Statistical significance remained (p=0.017) following Bonferroni correction for multiple comparisons among means (Dunn, 1961) due to the model looking at different time periods within the overall time to diagnosis (e.g. time from referral to MRI, time from MRI to decision to biopsy, etc.). The difference in cost was mainly driven by the higher cost of the LATP biopsy compared to TRUS.

Pathway Outcomes – for all scenarios

Of the 127 patients going through the PROSTAD pathway, diagnosis information was available for 110. Of these, 50 were diagnosed with cancer (adenocarcinoma of the prostate), which represents a cancer conversion rate of 45.45%. Of these patients (staging information was available for 41), 2 presented with metastasised cancer (4.8%). Of the remaining patients, 52 were put on surveillance (47.27%), seven were discharged with no serious Pathology found (6.36%) and one received another (unknown) diagnosis (0.90%). In the Standard care pathway, 43 (out of 104 with available diagnosis information) were diagnosed with cancer (41.35%) with 4 (of 40 with available staging information) diagnosed with metastasised cancer (10.0%), 49 were assigned to surveillance (47.11%), 6 had another diagnosis (5.77%) and 6 were discharged (5.77%).

Time between Referral and Key Pathway Milestones

The mean and median times from referral to key milestones within the diagnosis pathway (e.g. MRI, decision to biopsy, biopsy, etc.) were overall shorter in the PROSTAD pathway (see Table 10). However, within the pathway, time from decision to biopsy to biopsy taking place was shorter in the Standard care pathway (26 days) than the PROSTAD pathway (32 days). This difference is due to patient choice to delay biopsy for personal reasons as evidenced by comparing median days where time from decision to biopsy to biopsy taking place was similar in the PROSTAD pathway (24 days) than the Standard care pathway (25 days). Reasons for delay included wanting to think about having a biopsy and pre-booked holidays. The waiting time from referral to the date when the patient was told about the diagnosis was considerably reduced from 98 days (SD=25 days) in the comparator group to 70 days (SD=24 days) in the PROSTAD pathway (p<0.001). These differences were statistically significant.

Times to key milestones between referral and diagnosis were reduced across all individual outcome groups (see Table 11), with time from decision of biopsy to biopsy again longer in the PROSTAD pathway. Time to MRI was reduced between 10 and 15 days, with a decrease in time to decision to biopsy between 21 and 26 days. The highest reduction in waiting times was found in patients who eventually were diagnosed with prostate cancer, with time to biopsy decreasing from 66 days to 41 days (p<0.001) and time to cancer diagnosis significantly reduced from 77 days to 49 days in the PROSTAD pathway patients (p<0.001) when compared to the Standard care pathway.

Table 10. Time (in days) between GP referral and key milestones within diagnosis pathways.

Waiting time (in days from referral)	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
Mean time					
Mean time to MRI (SD)	127	13 (5)	112	25 (13)	-12 (-15 to -10; p<0.001)
Mean time to MRI reporting (SD)	127	14 (5)	112	33 (14)	-19 (-21 to -16; p<0.001)
Mean time to clinical decision whether to biopsy (SD)	127	14 (5)	111	38 (13)	-24 (-26 to -21; p<0.001)
Mean time to biopsy (SD)	66	46 (25)	57	66 (20)	-20 (-28 to -12; p<0.001)
Mean time to diagnosis (SD)	61	53 (26)	55	76 (24)	-23 (-33 to -15; p<0.001)
Mean time to outpatient appointment where patient informed of diagnosis (SD)	44	70 (24)	41	98 (25)	-28 (-39 to -17; p<0.001)
Median time					
Median time to MRI (IQR)	127	13 (3)	112	23 (15)	-10; p<0.001
Median time to MRI reporting (IQR)	127	14 (4)	112	32 (17)	-18; p<0.001
Median time to clinical decision whether to biopsy (IQR)	127	14 (4)	111	37 (15)	-23; p<0.001
Median time to biopsy (IQR)	66	38 (19)	57	62 (25)	-24; p<0.001
Median time to diagnosis (IQR)	61	45 (19)	55	75 (28)	-30; p<0.001
Median time to outpatient appointment where patient informed of diagnosis (IQR)	44	64 (18)	41	93 (21)	-29; p<0.001

CI: Confidence interval; IQR: Interquartile range; SD: Standard deviation

Table 11. Mean waiting times within diagnosis pathways (in days from referral) for different outcome groups.

Outcome group	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
Mean time to MRI (in days from referral)					
No biopsy (surveillance only) (SD)	52	14 (5)	49	24 (12)	-10 (-15 to -7; p<0.001)
Biopsy – cancer diag-nosis (SD)	50	12 (4)	43	27 (12)	-15 (-18 to -11; p<0.001)
Biopsy – other or no diagnosis (SD)	8	14 (4)	12	26 (18)	-12 (-24 to -1; p=0.041)
Mean time to MRI reporting (in days from referral)					
No biopsy (surveillance only) (SD)	52	15 (5)	49	31 (13)	-16 (-21 to -13; p<0.001)
Biopsy – cancer diag-nosis (SD)	50	14 (5)	43	36 (13)	-22 (-26 to -18; p<0.001)
Biopsy – other or no diagnosis (SD)	8	16 (4)	12	33 (18)	-17 (-29 to -6; p=0.007)
Mean time to clinical decision whether to biopsy (in days from referral)					
No biopsy (surveillance only) (SD)	52	15 (5)	49	36 (13)	-21 (-26 to -18; p<0.001)
Biopsy – cancer diag-nosis (SD)	50	14 (5)	42	40 (13)	-26 (-31 to -22; p<0.001)
Biopsy – other or no diagnosis (SD)	8	16 (4)	12	39 (19)	-23 (-35 to -11; p=0.001)
Mean time to biopsy (in days from referral)					
No biopsy (surveillance only) (SD)	N/A	N/A	N/A	N/A	N/A
Biopsy – cancer diag-nosis (SD)	50	41 (22)	43	66 (20)	-25 (-34 to -17; p<0.001)
Biopsy – other or no diagnosis (SD)	8	41 (18)	11	65 (22)	-24 (-44 to -5; p=0.017)
Mean time to diagnosis (in days from referral)					
No biopsy (surveillance only) (SD)	N/A	N/A	N/A	N/A	N/A
Biopsy – cancer diag-nosis (SD)	50	49 (22)	43	77 (24)	-28 (-38 to -18; p<0.001)
Biopsy – other or no diagnosis (SD)	8	58 (29)	11	74 (25)	-16 (-43 to 11; p=0.230)
Mean time to outpatient appointment where patient informed of diagnosis (in days from referral)					
No biopsy (surveillance only) (SD)	N/A	N/A	N/A	N/A	N/A
Biopsy – cancer diag-nosis (SD)	44	70 (24)	39	96 (24)	-26 (-37 to -16; p<0.001)
Biopsy – other or no diagnosis (SD)	N/A	N/A	N/A	N/A	N/A

CI: Confidence interval; IQR: Interquartile range; SD: Standard deviation

Cost-effectiveness of the PROSTAD pathway

Cost-consequences analysis

80:20 split base case

base case

The main costs and consequences of the PROSTAD pathway are summarised in Table 12. Overall, the PROSTAD pathway increases per patient cost by £145, but the PROSTAD pathway is on average 28 days shorter than the Standard care pathway.

Per protocol base case

The main costs and consequences of the PROSTAD pathway are summarised in Table 13. Overall, the PROSTAD pathway increases per patient cost by £351, but the PROSTAD pathway is on average 28 days shorter than the Standard care pathway.

Cost-effectiveness of the PROSTAD pathway

Cost-consequences analysis

80:20 split base case

base case

The main costs and consequences of the PROSTAD pathway are summarised in Table 12. Overall, the PROSTAD pathway increases per patient cost by £145, but the PROSTAD pathway is on average 28 days shorter than the Standard care pathway.

Table 12. Costs and consequences of the PROSTAD pathway between referral and diagnosis.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	**-**
Mean total cost (SD)	£992.43	£814.30 (£486.42)	£ 351.41 (£190.98 to £511.84; p<0.001)
Median total cost	£1,160.50	£828.64	331.86; p<0.001
Cancer conversion rate	45.45%	41.35%	4.1%
Mean time to MRI (SD)	13 (5)	25 (13)	-12 (-15 to -10; p<0.001)
Mean time to MRI reporting (SD)	14 (5)	33 (14)	-19 (-21 to -16; p<0.001)
Mean time to clinical decision whether to biopsy (SD)	14 (5)	38 (13)	-24 (-26 to -21; p<0.001)
Mean time to biopsy (SD)	46 (25)	66 (20)	-20 (-28 to -12; p<0.001)
Mean time to diagnosis (SD)	53 (26)	76 (24)	-23 (-33 to -15; p<0.001)
Mean time to out-patient appointment where patient informed of diagnosis (SD)	70 (24)	98 (25)	-28 (-39 to -17; p<0.001)

CI: Confidence interval; SD: Standard deviation

Per protocol base case

The main costs and consequences of the PROSTAD pathway are summarised in Table 13. Overall, the PROSTAD pathway increases per patient cost by £351, but the PROSTAD pathway is on average 28 days shorter than the Standard care pathway.

Table 13. Costs and consequences of the PROSTAD pathway between referral and diagnosis.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	**-**
Mean total cost (SD)	£1,165.71 (£730.73)	£814.30 (£486.42)	£ 351.41 (£190.98 to £511.84; p<0.001)
Median total cost	£1442.63	£758.11	684.52; p<0.001
Cancer conversion rate	45.45%	41.35%	4.1%
Mean time to MRI (SD)	13 (5)	25 (13)	-12 (-15 to -10; p<0.001)
Mean time to MRI reporting (SD)	14 (5)	33 (14)	-19 (-21 to -16; p<0.001)
Mean time to clinical decision whether to biopsy (SD)	14 (5)	38 (13)	-24 (-26 to -21; p<0.001)
Mean time to biopsy (SD)	46 (25)	66 (20)	-20 (-28 to -12; p<0.001)
Mean time to diagnosis (SD)	53 (26)	76 (24)	-23 (-33 to -15; p<0.001)
Mean time to outpatient appointment where patient informed of diagnosis (SD)	70 (24)	98 (25)	-28 (-39 to -17; p<0.001)

CI: Confidence interval; SD: Standard deviation

Cost-utility and cost-effectiveness analysis

80:20 split base case

The results of the cost-effectiveness and cost-utility analyses are summarised in Table 14. Please note that the QALYs obtained in Table 14 were derived from the literature and agreed upon by the PROSTAD study team. No utility data were collected.

Table 14. Base case total cost and outcomes for PROSTAD and comparator cohorts (based on 127 patients in each group).

	PROSTAD pathway	Standard care pathway	Difference
Total cost	£122,740	£105,135	£17,605
Total QALYs	120.75	120.03	0.72
Total time to diagnosis (years)	15.55	22.83	-7.28
Total time to diagnosis (days)	5,680	8,339	-2,659

Based on these results, the ICER for the CEA was calculated as £6.62 per one less day to diagnosis for the PROSTAD pathway compared to Standard care. CUA showed an ICER of £24,569 per QALY gained. This is within the maximum acceptable willingness-to-pay threshold of between £20,000 and £30,000, generally accepted by NICE although this should be considered alongside the decision of certainty around the ICER (NICE, 2023, section 6.3.7). This is explored in our sensitivity analyses presented.

Net monetary benefit was calculated as -£3,205 at the £20,000 willingness-to-pay threshold and £3,995 at the £30,000 threshold.

Per protocol base case

The results of the cost-effectiveness and cost-utility analyses are summarised in Table 15.

Table 15. Base case total cost and outcomes for PROSTAD and comparator cohorts (based on 127 patients in each group).

	PROSTAD pathway	Standard care pathway	Difference
Total cost	£142,610	£101,346	£41,264
Total QALYs	120.75	120.03	0.72
Total time to diagnosis (years)	15.55	22.83	-7.28
Total time to diagnosis (days)	5,680	8,339	-2,659

Based on these results, the ICER for the CEA was calculated as £15.52 per one less day to diagnosis for the PROSTAD pathway compared to Standard care. CUA showed an ICER of £57,587 per QALY gained. This ICER is above an ICER of £30,000 per QALY gained which NICE would consider in making recommendations whether this is an effective use of NHS resources, again with uncertainty in findings requiring assessment via sensitivity analysis and/or aspects not captured in the analysis such as uncaptured benefits and non-health factors (NHS 2023, section 6.3.8.)

Net monetary benefit was calculated as -£26,864 at the £20,000 willingness-to-pay threshold and -£19,664 at the £30,000 threshold.

Sensitivity analyses

Please see Appendix 6 for full sensitivity analysis.

Scenario Analysis

Results of the scenario analyses are summarised in Table 16. SA-ID A refers to the scenario whereby all patients requiring a biopsy, in both arms, receive the LATP biopsy. SA-ID B is the same as SA-ID A but utilities in the cancer outcome group are changed to be equal in both arms. SA-ID C is SA-ID A but with the rate for each outcome group the same in both arms. SA-ID D is a combination of SA-ID A, SA-ID B and SA-ID C.

The PROSTAD pathway was found to be not cost-effective in scenarios where LATP was assumed for all PROSTAD patients and TRUS guided biopsy for all Standard care patients (per protocol scenario above). Critically in scenario 1 where LATP was assumed for all patients regardless of pathway the PROSTAD pathway was found to be cost-effective. Given the new draft National optimal pathway and GIRFT recommendations, universal LATP biopsies will be the norm moving forwards.

Table 16. Results of scenario analyses.

SA-ID	Parameter	Change	Optimal strategy
SCENARIO 1 – LATP biopsy assumed for all patients			
A	Costing for biopsy	Change costing for biopsy from 80:20 to LATP for all	PROSTAD (ICER = £24,569)
B	Cancer Utility	Scenario 1 costs, SA1 utilities	No PROSTAD (ICER = £46,168)
C	Outcome group rates	Scenario 1 costs, SA2 rates	PROSTAD (ICER = £17,663)
D	Outcome group rates & Cancer utility	Scenario 1 costs, SA1 utilities, SA2 rates	No PROSTAD (ICER = £29,772)

Since the cost is the same for both arms for the biopsy, the results are identical to the 80:20 split base case results.

Plausibility of Considered Scenarios

The sensitivity analysis shows considerable uncertainty around the results mainly based on the small differences in waiting time to diagnosis and consequently small QALY differences.

While all scenarios may be considered plausible based on clinical opinion and predictions of what may be the future of the pathways (e.g. all patients receiving LATP biopsies), changes to biopsy type did not considerably affect cost-effectiveness of the PROSTAD pathway.

Discussion

Our findings are based on an economic analysis undertaken alongside the development and roll-out of the PROSTAD pathway for eligible men with suspicion of prostate cancer living within the HDdUHB area compared to current pathway (Standard care). The findings reflect the time-horizon from referral to diagnosis over a 10-month evaluation period.

Summary of key results

The health economic evaluation of the PROSTAD pathway found the following key results:

- Between July 2023 and June 2024, the PROSTAD pathway offered 172 mpMRI slots with 127 patients seen in 43 sessions.
- For the 80:20 split base case analysis, the mean overall healthcare costs were £992.43 (SD=£607) per patient in the PROSTAD pathway and £847 per patient (SD=£503) in the Standard care pathway. The mean healthcare cost per patient in the PROSTAD pathway was £145 more than in the comparator pathway (n=112).
- For the per protocol analysis, the mean overall healthcare costs were £1,166 (SD=£730) per patient in the PROSTAD pathway and £814 per patient (SD=£486) in the Standard care pathway. The mean healthcare cost per patient in the PROSTAD pathway was £351 more than in the comparator pathway (n=112).
- Of the 127 patients going through the PROSTAD pathway, 50 were diagnosed with cancer (adenocarcinoma of the prostate), which represents a cancer conversion rate of 45.45%. In the Standard care pathway, 43 (out of 104 with available diagnosis information) were diagnosed with cancer (41.35%). The rate of metastasised cancers was higher in the Standard care group (10% compared to 4.8% in the PROSTAD pathway).
- The mean time from referral to MRI was 12 days shorter per patient in the PROSTAD pathway, with a reduction of 24 days between referral and time of decision to biopsy. pathway.
- The mean time from referral to diagnosis was 28 days shorter per patient in the PROSTAD pathway.
- The ICER for the CEA was calculated as £6.62 per one less day to diagnosis with the 80:20 split base case.
- The ICER for the CEA was calculated as £15.52 per one less day to diagnosis with the per protocol scenario.
- CUA showed an ICER of £24,569 per QALY gained for the 80:20 split base case. This is above the standard willingness-to-pay threshold of £20,000 but within the window where further consideration is required from £20,000 to £30,000.
- CUA showed an ICER of £57,587 per QALY gained for the per protocol scenario. This is above the standard willingness-to-pay threshold of between £20,000 and £30,000.
- Net monetary benefit was calculated as -£3,205 at the £20,000 willingness-to-pay threshold and £3,995 at the £30,000 threshold, based on the 80:20 split base-case.
- Net monetary benefit was calculated as -£26,864 at the £20,000 willingness-to-pay threshold and -£19,664 at the £30,000 threshold in the per protocol scenario.
- The probability of the PROSTAD pathway being the most cost-effective option at the £20,000 and £30,000 thresholds is 36% and 37%, respectively for the 80:20 split base case.

The probability of the PROSTAD pathway being the most cost-effective option at the £20,000 and £30,000 thresholds is 30% and 32%, respectively for the per protocol scenario. In summary, the 80/20 split scenario used indicated that PROSTAD costs £145 per patient more and resulted in 28 days less waiting for patients from referral to diagnosis compared to Standard care. The incremental cost to achieve a reduction of one day to diagnosis was £6.62. In a cost-utility analysis, the incremental cost per QALY gain was £24,569 falling within the NICE £20,000-£300,000 threshold for further consideration with the NMB also reflecting this. Sensitivity analysis indicates uncertainty in these estimates. The per-protocol scenario estimated that PROSTAD cost £351 more than Standard care, with an incremental cost to achieve a reduction of one day to diagnosis estimated at £15.52. The incremental cost-utility analyses produced an ICER of £57,8587 and negative NMB suggesting this is unlikely to be cost-effective, again with similar uncertainty presented.

Strengths and limitations

To our knowledge, this is the first health economic evaluation of a novel prostate cancer diagnosis pathway using mpMRI to accelerate diagnosis in Wales. The evaluation was undertaken and reported following current best practice recommendations (Husereau et al. 2022; NICE, 2023; NICE 2024) and similar methods and modelling approaches were used successfully in the past for comparable evaluations (Sewell et al., 2020). We used routine data and the highest quality literature inputs available to ensure a robust real-world economic evaluation, using transparent methods.

Our evaluation reflects the challenges in balancing the need for real-world, rapid, responsive service innovation alongside the demand for rigorously designed economic evaluations. Several limitations are evident. While every effort was made by the team to gather the most complete routine data set possible, sample size was small in both comparator groups due to the novelty and immaturity of the service. There were data gaps (e.g. in types of biopsies received) and thus, key assumptions (e.g. in producing the 80/20 split to reflect a real-world base-case of actual implementation of PROSTAD) had to be made based on the clinical opinion from the PROSTAD team.

Another key limitation is the timeline for evaluation of the PROSTAD innovation precluded time to collect fuller, longer-term outcomes to reflect the full cancer pathway for people diagnosed with -prostate cancer including treatment and follow up. This restriction of the model time horizon until diagnosis will inevitably miss costs and benefits accrued in the treatment stages of the pathways and cannot be considered a true reflection of the cost-effectiveness of the PROSTAD pathway in its entirety. A longer-term analysis including all potential costs and outcomes once the PROSTAD pathway matures is highly recommended, ideally to capture a life-time horizon as recommended by NICE.

Whilst the current PROSTAD innovation enabled a natural comparator cohort to be prospectively included, selection was based on the real-world decisions of the PROSTAD clinical team and thus bias cannot be ruled out. Careful checks were made throughout the design, conduct and reporting of our analyses (see section 2.6), to ensure every effort was made to reflect the real-world, local context of PROSTAD, however data challenges were evident. Whilst we mitigated where possible (e.g. through using published national unit costs, agreed with the PROSTAD team), the question of whether these findings could be generalised to other settings need to be carefully considered by the PROSTAD team, stakeholders and decision makers.

No data on the nature of biopsy undertaken on an individual patient level was available for the analysis and a best estimate from the PROSTAD team was used in the 80:20 base case. This may lead to bias in the results due to the cost difference for LATP and TRUS guided biopsies. However, according to clinical opinion from the PROSTAD team, the proportion of LATP biopsies was comparable in both pathways and any potential impact on difference in biopsy type was explored in scenario analyses.

A driver of the model results is the utility post-diagnosis (derived from literature inputs not specific to our population) which is lower for

the Standard care arm as more patients in this pathway were diagnosed with higher stage cancers and metastases. The reasons for this are unknown but could be related to demographic differences (e.g. potentially higher deprivation in the Standard care pathway as the travel required for the PROSTAD pathway may deter people living in more deprived areas) or chance due to the small sample size. However, selection bias cannot be excluded. The prospective collection of patient-reported outcomes, particularly in enabling robust calculation of utilities should be considered, alongside the collection of longer-term consequences to capture the full range of costs and effects, to avoid compounding the issues faced when quantifying a value (based on economic methods) to derive value for money estimates. Whilst we employed standard methods of sensitivity analyses to quantify the uncertainty in our estimations of cost-effectiveness (cost per QALY), caution must be applied in using our findings as a proxy of value alone without considering the strength of evidence from the other components of the PROSTAD evaluation.

Our findings warrant careful and cautious interpretation. Our 80:20 base case, based on the ICER suggests that if the PROSTAD pathway continues to be delivered as 'current' it would potentially fall into the NICE threshold where decisions about the acceptability of the PROSTAD pathway may be considered an effective use of NHS resources. The NMB for at a willingness to pay threshold of £20,000 was negative, whereas at a willingness to pay threshold of £30,000 was positive. Uncertainty was seen across our sensitivity analyses. The deviations from the protocol made were deemed by the PROSTAD team to reflect patient need and circumstances, and thus the challenges of delivering a person-centred pathway in an area where equity challenge could be a key issue (e.g. in accessing care), may need to balance alongside an aggregated analysis of costs and outcome, focused on efficiency which is presented in this economic analysis.

We would advocate that our cost-consequence analysis (CCA) alongside careful assessment of CEA should be used in reporting our findings to stakeholders, to reflect the complexity, challenges and uncertainty seen in our findings. Our CCA provides a disaggregated picture of costs and outcomes, and alongside our CEA and CUA analyses, provides decision makers with a comprehensive, transparent account of the health economic impact of PROSTAD, which in turn could be used as part of a fuller discussion of the value of PROSTAD aligned to the NHS Wales principles of value-based health care. We would encourage this evaluation to be used as part of a 'roundtable' discussion with key stakeholders on the methodological, analytical and practical challenges of undertaking economic evaluations of models/pathways of care which aim to provide faster diagnosis for people who have symptoms suspicious of cancer.

Results in context

Prostate cancer poses a significant burden on the population, the health service and the economy (Roehrborn and Black, 2011; Smith-Palmer et al., 2019). Faster diagnosis has the potential to improve patient outcomes, remove the need for more intensive and more costly treatment options, and to improve patient experience as anxiety is usually high in patients waiting for diagnosis (Awsare et al., 2008; Dillard et al., 2017). Yet, many diagnosis services fall short of the National Optimal Pathway (NOP) for Prostate Cancer which recommends a time from point of suspicion to first definitive treatment of less than 62 days (NHS Wales, 2023).

Our results for the Standard care pathway in HDdUHB suggest a mean time from referral to outpatient appointment to discuss diagnosis and treatment options with the patient of 98 days (SD=25 days). While no data to calculate time to first definitive treatment was available for our analysis, the evaluation confirms that the Standard care pathway is considerably longer than the NOP. One-stop pathways (which provide mpMRI, clinic and biopsy in one day) were shown to reduce time to diagnosis to a median of 8 days (Bass et al., 2018). However, they were suggested to be too high a burden for patients (Lopez and Bryant, 2023). Alternatively, the use of rapid imaging and diagnosis pathways including mpMRI as part of the 'Rapid Access Prostate Imaging and Diagnosis' (RAPID) pathway has previously been shown to reduce time to diagnosis by 16.25 days (Eldred-Evans et al., 2023), which is comparable to the improvement in waiting time of 23 days found in our evaluation using the PROSTAD pathway. However, while it has been suggested that mpMRI is cost-effective as a first test in the diagnosis of prostate cancer (Faria et al., 2018; Giganti and Moore, 2019), no published evidence on the cost-effectiveness of rapid prostate cancer diagnosis pathways is available, which has been a source of criticism in the past (Lopez and Bryant, 2023). We have assumed that NICE recommendation on using mpMRI was informed by a robust health economic assessment (NICE, 2019). Our evaluation found that the PROSTAD pathway, while reducing the waiting time to diagnosis of prostate cancer in HDdUHB, still does not meet the NOP recommendations of <21 days for decision to treat.

The use of a standard ICER- value framework allows a consistent and transparent comparison of these findings with other health technologies and interventions (including complex interventions) and we have also presented NMB as a cleaner (simpler) presentation of whether or not PROSTAD could be considered cost-effective, alongside detailed examination of the uncertainty in our findings.

The best-case scenario from our findings (based on the 80/20 split) is that there may be some consideration as to whether or not PROSTAD falls within an acceptable boundary of cost-effectiveness (£20,000-£30,000 per QALY gained), alongside other considerations (including full consideration of the uncertainty and limitations presented), if the NICE reference standard is used. The per protocol scenario is unlikely to fall within 'accepted' cost-effectiveness thresholds, again with uncertainty in our findings. It is a matter for the PROSTAD clinical team and decision makers to appropriately interpret the evidence presented from our analysis to inform recommendations. Our focus has been on presenting as robust, comprehensive and transparent analysis as possible within the context and challenge of undertaking economic evaluation in this setting.

This could also raises questions as to whether this framework (focused on QALYs as a measure of benefit which was not captured directly in our evaluation and relied on published data not directly applicable to the PROSTAD pathway) is capturing the full extent of value for patients, professional and policy makers, in an evolving service innovation in a local setting. We suggest that our findings from the economic evaluation (both CCA and CEA/CUA) are a starting point in discussing what patients, public (and professionals) need and want in making resource allocation decisions regarding PROSTAD. Drawing upon the rich evidence provided through the PROSTAD evaluation, rather than in silo will enable HDdUHB to meet public expectations and achieve the outcomes that matter most to people whilst reducing waste, harm and variation.

Since the initial study concept, the landscape around LATP v TRUS biopsy has shifted. Whilst LATP was more widely adopted in England , the publication of the 2024 Urology GIRFT report has prompted a widespread adoption and standardisation of LATP throughout Wales, supported by central funding. Therefore a cost comparison of PROSTAD v standard pathway with LATP biopsy in both arms is the cost comparison that is relevant in practice today.

Work Package 5: Learnings from implementation & preparation for adoption

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This package was designed to support the HDdUHB Urology team develop a business case for the service adoption of the new PROSTAD pathway and develop associated documents to aid national rollout, including implementation service guides. A key aspect of service implementation is understanding the barriers and mitigators to implementing and running the service. It is also crucial to understand the facilitators of the service to enable adoption and support for the pathway.

Key barriers and facilitators of the PROSTAD service

The implementation of the PROSTAD service, aimed at creating a rapid access prostate cancer pathway, revealed several barriers and facilitators crucial to the setup and roll-out of this innovative service. Some of which are unique to HDdUHB as a rural health board. These barriers and facilitators have been identified throughout the work packages and reported by the clinical and management teams through management and steering group meetings.

Barriers and mitigation

Pathway development: Developing a new pathway that specified rapid MRI required close collaboration between the Urology and Radiology teams. This necessitated additional coordination and alignment between departments in order to sequentially plan scanning, reporting, and patient clinics within a 2 working day window The availability of the MRI scanner was the centre point around which activities were then planned. Realignment of clinicians' clinical duties/ job plans enabled success. Communication and joint planning are essential to development and undertaking of pathway changes.

Organisational challenges: Establishing a secondary care rapid access pathway for suspected prostate cancer presented several organisational hurdles including allocation of resources (time, space and staffing) and service planning. Coordination of planning and resourcing requires strong communication, compromise and full understanding of services. To ensure the change is supported, buy-in is required across the pathway including from patients, Urology, Radiology, primary care and finance. Continued communication and presentation of evidence is vital at all stages to enable this support at all levels.

Practicalities of patient flow: The need for administrative support (pathway navigator) was critical for liaising with Radiology to schedule MRIs and inform patients about their appointments. 0.4 WTE was required for the role. We were fortunate that additional training was not required due to our navigator's experience as a Macmillan cancer support worker and medical secretary. Clear communication ensured appointments were not missed and all slots were utilised where possible. Where slots were not filled, this was largely due to patient choice with some patients electing to wait for a slot at a more local scanner despite counselling regarding waiting times and scan quality.

Rurality: The distribution of hospitals in geographically vast areas and rural health boards often experience challenges to adequately and equitably cater to the population's needs. In regions with limited hospital coverage, patients may have to travel significant distances to access specialised diagnostic services for prostate cancer. This leads to increased travel times, financial burdens, and potential delays in diagnosis and treatment initiation. Moreover, as experienced in this project, inadequate transportation infrastructure exacerbates these challenges, particularly for elderly or medically compromised individuals.

Limited Radiology capacity, particularly in rural health boards, poses a significant barrier to the rapid diagnosis of prostate cancer. The availability of advanced imaging modalities, for straight to test like magnetic resonance imaging (MRI), is crucial for accurate diagnosis. However, the travelling time to reach the dedicated MRI session can result in patients not accepting the rapid access pathway. This results in exacerbated waiting times for patients requiring MRI, which is integral in the assessment of prostate cancer. While the location of the health board cannot be mitigated, close monitoring and understanding of these challenges is key to supporting patient attendance and assessing need for additional sites.

In addition, the geographical spread of the four district general hospitals within Hywel Dda University Health Board (HDdUHB) posed logistical challenges. The MRI site identified as being most appropriate for the service was in the northern part of the Health Board, at Bronglais General Hospital. This created a travel time of over two hours one way for patients from the eastern side of the county. While an additional MRI session in the eastern part of the health board would have reduced travel time, the available machines were either used for acute services or staffing capacity was limited at these sites.

Time challenges: The Radiology team needed to undertake multiparametric MRI (mpMRI) scans, which required additional scanning time compared to bi-parametric scans. This adjustment in workflow posed time management challenges within the department. However, the recently published PRIME study has suggested good quality bi-parametric is adequate for pre-biopsy straight to test assessment, which could mitigate this challenge (Asif et al, 2023).

Staff capacity (Radiographers): Despite repeated discussions, securing a second dedicated MRI session was unattainable due to a lack of MRI radiographer capacity in the Radiology team. As a result, less than half the projected number of patients could undergo mpMRI via the new PROSTAD pathway. Moving forward there are plans in discussion to secure a dedicated Urology Radiologist to support dedicated expert reporting.

Staff capacity (Consultant Radiologist): As a result of external funding, the project has enabled the Radiologists in our health board to upskill in reporting mpMRI scans. The time taken to reporting the scans will reduce as the confidence builds by undertaking more scans. Multi-parametric MRI needs specialist Uro-radiologist to report these scans, the skill mix in some health boards might not have enough cross-cover for annual and sick leave. It might be prudent to consider reporting of specialist mpMRI scans at a regional level to enable colleagues from neighbouring health boards to cross cover. Further discussions regarding job planning needs to be taken into consideration for this.

Primary care concerns: Primary care colleagues expressed concerns about increased workload due to MRI reports being sent directly to GPs. This issue arose because the Urology team initially sent MRI requests to Radiology via email without using a separate MRI form, leading to reports being sent to primary care, who were unprepared to interpret them. This was quickly mitigated by changing to electronic MRI requests generated by the triaging consultant urologist, ensuring that MRI reports were sent only to Urology.

Patient concerns about communication: This was identified a concern by the PPI group (WWPCSG) before the project commenced. To enable improved communication, a patient pathway navigator was assigned the role of communicating with patients on PROSTAD pathway. The role included informing them about date and time of MRI scan, booking and confirming follow up appointment and sending them relevant documentation to prepare them for MRI. They also ensured that the patients understood the pathway and were prepared to attend.

Facilitators:

Evidence-based practice: Learning from teams in London regarding mpMRI specifications provided a strong foundation for developing local Radiology specifications. Setting up the machine for dedicated sessions to perform uniform scans for all patients increased the system's efficiency by reducing time between patients.

Financial support: Securing funding from Cancer Research UK (CRUK) was pivotal in planning, launching, and delivering the PROSTAD service. This financial backing ensured that the necessary

resources were available for the project to be piloted. The evidence showing substantial pathway time savings and improved patient experience are hoped to lead to sustainable health board investments into the wider health systems raised.

Clinical expertise: The involvement of a Urology Consultant who saw PROSTAD patients for clinical review and was able to read MRI scans significantly aided decision-making. This dual expertise was reflected positively in patient feedback.

Utilising technology: Patients were happy to receive the results of MRI and decision for biopsy over the telephone or via virtual clinics. This aided speeding up the pathway as no clinical space was needed. It was also a sustainable option by reducing carbon footprint.

Collaboration: The success of the PROSTAD project heavily relied on excellent collaboration among the PROSTAD project team, primary and secondary care colleagues, Radiology teams, administrative staff, and cancer tracking teams within HDdUHB. This multidisciplinary cooperation was crucial for the project's implementation and operation and was enabled by interviews carried out as part of WP1/2 and by monthly project meetings with invited participation from all stakeholder groups.

Clinical Communications: Effective communication was facilitated by a joint letter from the PROSTAD project lead and the GP Cancer Lead to primary care teams, keeping them informed about the rapid access pathway. Additionally, information about PROSTAD was disseminated to HDdUHB colleagues through the HDdUHB Medical Director's newsletter in May 2024.

Patient Choice: As noted in interviews and within the swim lane mapping, not all patients wanted to be seen quickly and offering the choice was advantageous to patients and their attendance to the service.

Patient Communication: The patient navigator was able to support patients in making decisions and alleviating concerns, for example patients being concerned on why they were being contacted for a next day appointment. This feedback was also important in communications and patient facing materials and utilised by GPs when explaining the 'what will happen next' scenario to patients.

Achievements, national adoption and scale plans:

Following PROSTAD pilot and the success at the NHS Awards, the team are looking to take forward recommendations set out in this report in order to refine and optimise the service within HDdUHB. Discussions around a second dedicated MRI session are ongoing but is limited by capacity at present for scanning time and within the workforce. Sharing of the learning from PROSTAD to support national rollout is being g supported by the National Strategic Clinical Network for Cancer (part of NHS Wales). To support national adoption, an implementation guide for PROSTAD and a Service Guide have been developed (See Appendix 7 and 8). The ambition is that the learnings and best practice from PROSTAD will be introduced across Wales.

In addition to this the following activities have been undertaken to increase awareness of PROSTAD:

Presentations to support adoption and scaling:

The pathway model was presented for adoption and scaling to key stakeholders, including Mr. Nick Gill, Urology CSG Lead; Prof. Tom Crosby, National Cancer Clinical Director for Wales; and Dr Jeff Turner, Consultant Gastroenterologist at the NHS Wales Executive Cancer Network. Ongoing discussions continue to look at national adoption of learnings from this project.

The team was invited to present at the Urology Clinical Site Group (CSG) meeting in September 2024 which prompted national support and discussions around opportunities to scale

Meeting with Tom Howson, Bevan Commission for exploring the support for adopt and scale of the model (17 July 2024) and understand national opportunities to aid this.

Dissemination

The team presented PROSTAD at the MediWales Conference on 26 June 2024 to raise awareness within the innovation community, particularly focusing on the transformation pathway.

The health economic model and patient experience has been presented at CRUK Early diagnosis conference June 2024.

The results from PROSTAD were presented at the National Urology Cancer Network Meeting September 2024.

Publication in: Jones, K. R., Rees, S., Chandran, A., Erdem, E., Jones, M., Farrington, S., ... & Gemine, R. (2024). Prostad: The development and evaluation of a prostate cancer rapid diagnostic pathway, a protocol. medRxiv, 2024-05.

An abstract has been submitted to the IHI /BMJ Group International forum on Quality and Safety in Healthcare Utrecht May 25.

Training and development:

Discussions have been initiated with the Health Education and Improvement Wales (HEIW) team regarding the development of a training package for Local Anaesthetic Transperineal (LATP) biopsy for Urologists in Wales. The ambition is for a national programme to be established.

The NHS Wales cancer recovery programme is currently looking at variation across health boards in use of diagnostics to support spread and scale of the learning by HDdUHB as part of the PROSTAD project. This task, once completed, has the potential to support opportunities to embed this best practice with the aim of reducing waiting times for people with suspected prostate cancer across Wales.

Awards:

- The team has been shortlisted as a finalist for the Moondance Cancer Award 2024
- The team was awarded NHS Wales Award 2024 for efficient care.

Recommendations

Based on the barriers and facilitators identified during the implementation of the PROSTAD service, we have noted nine recommendations to improve the effectiveness and accessibility of the service within HDdUHB:

1. Ringfencing new USC PSA prostate MRI slots.
2. Providing 2 sessions of MRI prostate scan time per week for new USC referrals in conjunction with increased specialist Uro-radiologist capacity.
3. Through reviewing evidence, determine if multiparametric MRI improves accuracy, by internal studies within the health board and monitoring national/international studies and guidelines within this evolving subject.
4. Expanding Local Anaesthetic Transperineal capacity.
5. Invest further in Prostate Pathway Navigators to coordinate communication and workflow between clinical teams and to be a point of contact for patients for questions, updates and general communication.
6. Study impact of the PROSTAD pathway on radiology workload and other cancer pathways
7. Strengthen communication and collaboration across teams to reduce barriers in the pathway and improve efficiencies.
8. Evaluate service modifications and impact on pathways to ensure aligns with optimal pathway.
9. Enhance transportation infrastructure and support.

Radiology

1. Ringfencing MRI slots

Stakeholder discussion has identified the lack of MRI specialist radiographer capacity particularly at Withybush Hospital as well as pressures on Radiology reporting capacity as being the main barriers to achieving this change. As evidenced below:

"The move to PROSTAD was enabled by the MRI team allocating protected slots. This single change in the conventional to PROSTAD pathway unlocked significant levels of flow."

"Ringfencing (MRI) timeslots to support the flow of patients is a good investment of Health Board assets that have a finite operating capacity in the hours they are available to use."

"the queue for MRI is the most important target for pathway improvement."

2. Providing 2 sessions of MRI prostate scan time per week for new USC referrals

"The most meaningful next step projects would be to ensure that the bottleneck remains protected and to seek a higher rate of weekly slots (when the MRI slots available meet the demand rate from GPs there will be a stable backlog and standard waiting time for PROSTAD and less conventional pathway patients)."

A lack of specialist Uro-Radiologist resource is an organisational constraint, both in terms of prostate MRI expertise, reporting capacity and for the wider diagnostic and interventional Uro-Radiology service. Resourcing for additional consultant sessions, preferably as part of a new substantive post has been identified as a priority moving forwards.

Standardisation and optimising MRI Protocols in dedicated prostate MRI sessions could reduce scan times without compromising diagnostic accuracy. A dedicated session of 4 patients being scanned could be achieved in 3 hours and mitigate time management challenges within Radiology departments. Ensuring that these protocols are evidence-based and standardized can help maintain diagnostic efficacy while improving workflow efficiency.

An alternative to local reporting could be introducing regional or All Wales prostate MRI reporting services. Implementing regional prostate MRI reporting services for PROSTAD would be a strategic investment in patient care and diagnostic excellence. A dedicated session of reporting 6 prostate MRI scans could be achieved in 2 hours.

Consideration must be given to how this might impact other pathways and radiology workload and mitigating any negative impacts.

3. Determine if multiparametric MRI improves accuracy compared to bpMRI

The guidelines versus current literature are divided on whether mpMRI improves accuracy of diagnosis substantially compared to bpMRI. Given the increased cost of mpMRI compared to bpMRI, and increased scanner and reporting time, further work is needed to identify if mpMRI is required in the pathway as a standard option or should be used in specific cases. The PROSTAD team are working with Health Technology Wales to review the evidence and to look to potentially establish national guidelines on this, if evidence supports. There are likely to be multiple teams contributing to the world literature around this subject in the next couple of years.

Urology

4. Expanding LATP capacity

After Radiology capacity, this was found to be the next bottleneck. The department has established a site at Price Phillip Hospital which is carrying out LATP biopsies 2 days a week. A second biopsy machine is being procured and the department actively exploring candidate locations for the set-up of a second LATP biopsy service, likely to be at Withybush Hospital, Haverfordwest. The department has now trained a core of 6 doctors to carry out LATP biopsies with 4 of these doing regular weekly lists currently and training others in line with GIRFT recommendations (NHS England, 2024)

5. Invest in Prostate Pathway Coordinators

Implement additional dedicated prostate pathway navigators to further streamline patient communication and aid with scheduling Radiology and clinical appointments, ensuring timely access to diagnostic services. The initial success seen with the Macmillan Band 4 pathway navigator highlights the critical role of administrative support in managing patient appointments and coordinating with Radiology. Patient interviews have highlighted the importance of this role being a contact point for those going through the diagnostic pathway. Investing in these roles across all regions can significantly reduce organisational challenges and enhance patient experience. The role is also crucial for supporting patients (and their carers) in the cancer at a difficult time in their lives. Further investment in these roles will ensure adequate support and reduce the confusion noted in WP2.

General

6. Study impact of the PROSTAD pathway on radiology workload and other cancer pathways

From the outset of the project it is apparent that Radiology is a constrained service in HDUHB . Furthermore, clinical stakeholders in the department have highlighted concerns with potential impact on other pathways. Whilst the project has primarily emphasised optimisation of work flow rather than increasing capacity, it is acknowledged that this could create pressure on other pathways where there is little or no spare capacity within the radiology service. A detailed understanding of radiology service capacity, demand and resources would be beneficial in planning future services at HB level.

7. Strengthen communication and collaboration across teams to reduce barriers in the pathway and improve efficiencies

Foster continuous communication and collaboration between primary care, secondary care, Radiology, and administrative teams through regular meetings and updates. The success of the PROSTAD project relied heavily on multidisciplinary cooperation. By fostering strong communication and collaborative efforts, teams can address emerging issues promptly and ensure the smooth operation of the rapid access pathway. Regular updates and shared insights can keep all stakeholders aligned and informed. Involving radiology and pathology teams early

on in the process of setting up the service can enable their support and encourage relationship building through knowledge sharing between specialities working together on the service.

8. Continue to evaluate service modifications and impact on pathways to ensure alignments with the Wales optimal pathway

The proposed changes to the service following the above recommendations require implementation and evaluation to look at how we can further improve the pathway to meet the ambitious targets within Wales. Funding will be sought to support the next phase of evaluation.

These recommendations aim to address the identified barriers while leveraging the facilitators to create a more efficient and patient-friendly prostate cancer diagnostic pathway.

9. Enhance transportation infrastructure and support

Develop solutions to improve transportation infrastructure and provide logistical support for patients traveling long distances for diagnostic services. Geographical barriers and inadequate transportation significantly impact patient access to specialised services. Enhancing transportation options can alleviate these challenges, particularly for elderly or medically compromised individuals. An additional option would be making MRI slots available at other sites.

Barriers and Facilitators to the Evaluation

In addition to the service implementation challenges, the evaluation also faced barriers and facilitators as detailed below:

Barriers

- There were delays in securing additional approvals required to initiate the project, specifically linking to data protection and information governance.
- We experienced delays in contracting with partners, model agreements are now in place to minimise this moving forward.
- There were delays in appointment of staff to the project linked to the delays in agreements.
- Data availability was challenging however the team put in place strategies to mitigate this.
- As seen in qualitative interviews, access to patients for interviews was a challenge however a collaborative approach within the teams supported invites to interview.
- There was a change in team members during the project which led to disruption, however the work package leads were consistent across the project duration.

Facilitators

- NHS Ethics was not required as this project was a service evaluation, this was supported by a clear Innovation pathway in TriTech Institute and HDdUHB.
- The TriTech Institute and Swansea University Teams have vast experience in undertaking service reviews and redesign and of working together.
- There were existing relationships with Urology and the evaluation leads which aided communications and knowledge exchange.
- Strong PPI was evident throughout the evaluation and the team ensured this was a priority throughout the evaluation and service design.
- Alignment of work packages to ensure comprehensive evaluation was needed to reduce duplication and maximise outcomes.
- There was extensive support for the project across the Health Board, within Wales and particularly from CRUK.

These barriers and facilitators to the evaluation are useful learning points in supporting future evaluations. Not only did PROSTAD enable us to test a model prostate diagnostic pathway, but it allowed us to develop a model innovation pathway for service development:

1. Form a skill diverse team to enable clinical change and rigorous evaluation.
2. Ensure correct approvals are in place.
3. Understand baseline pathway through mapping and exploration of pinch points.
4. Understand literature and theory applicable to the pathway and redesigning.
5. Involve stakeholders including patients, clinical experts and national leads.
6. Utilise a variety of measures to monitor implementation:
    a. Patient outcomes
    b. Patient experience
    c. Staff experience
    d. System changes and response
    e. Economic and value assessment
7. Log learnings of service and evaluation
8. Communication is central to ensuring aims and objectives are met.

Discussion

PROSTAD has enabled a redesign of the prostate cancer pathway from receipt of referral to biopsy. Through evaluating our changes, understanding pinch points and areas of waste, time to MRI from point of suspicion was reduced from 25 days to 13 days. A reduction in the reporting time reduced time to diagnosis by 28 days versus the existing pathway taking us closer to the ambitious Wales' National Optimal Pathway targets. This shows not just faster but more efficient care. Shortened diagnostic and therefore time to treatment reduced the risk of disease progression and anxiety to patients. A small change in work practice at the front end of the diagnostic pathway led to a significant improvement.

Through PROSTAD, HDdUHB has introduced local anaesthetic trans-perineal prostate biopsy (LATP) across both pathways as a much safer and more accurate method of prostate cancer detection. This has proven to be the correct decision in light of the GIRFT 2024 report recommendations which have brought a national transition over to LATP biopsy. The project has shown that such a transition needs to be planned carefully to prevent delays and the build up of waiting times. WP3 has demonstrated that elimination of one critical bottleneck (tim to MRI report) can create downstream issues (time from decision to biopsy to actual biopsy). We have sought to manage this by increasing staff training and resource capacity with a phased approach incorporating spare TRUS biopsy capacity preventing excessive waiting times.

Multi-parametric prostate MRIs have been introduced as part of the PROSTAD project in line with best evidence and guidelines at time of concept. However, we may be seeing the beginning of a paradigm shift back to bpMRI with the publication of the PRIME study. The extended scanning and reporting time and cost may not be beneficial compared to bi-parametric MRIs for a marginal gain in diagnostic accuracy. Further health board and national work is needed to explore the cost and clinical implications, and for this to be cross-referenced against an evolving evidence base and any change in guidelines.

Patient experience was prioritised with patients reporting they were being kept more informed during their patient journey with timely face-to-face/ telephone contact with appropriate specialists. We expect to see improved confidence and trust from patient groups and the wider public in the cancer diagnostic service. There is also a reduction in anxiety for patients who are waiting to be seen and reassurance for those who do not have prostate cancer. However increased travel time was cited as a barrier to the service. The provision of prostate MRI and biopsy at dual sites within the health board will reduce this barrier and the risk of access inequality. Work is already underway to achieve this by Q1 2025.

PROSTAD also resulted in benefits to the clinical teams. We saw a reported increase in refined workforce skill base and expertise through training in gold standard techniques. The clinical team were able to see patients faster in dedicated clinics with streamlined pathways. Efficiencies were further seen in Radiology where MRI scanners set up in sessions rather than on individual basis and reporting by prostate specialist in dedicated session. As seen in work package 2, we also noted an increase in communication and stronger relationships between teams.

Work is needed to identify further opportunities to meet the Wales' National Optimal Pathway targets. Efficiencies from time of biopsy diagnosis to time of treatment offer the largest potential for time savings with a streamlining of local and regional MDT processes perhaps offering the greatest opportunity. Efficiency in progression to final staging PET scans have also been identified. The use of a "high risk protocol" MRI scan including lower spine MRI for patients with a PSA>20 has been rolled out in other Welsh HBs obviating the ned for a bone scan. Finally, potential time savings with histology processing of biopsy specimens should be explored.

Moving forward, aspects of the PROSTAD pathway have the potential to be replicated across and beyond Wales to improve outcomes and experience for those with suspected prostate cancer. To aid this, PROSTAD documentation will be shared with clinical networks and Health Boards. Within Hywel Dda, learnings from PROSTAD will be taken forward to revise, optimise and test the service further with the aim to meet the Wales' National Optimal Pathway targets in the future. This includes continuing straight to MRI where appropriate, rapid reporting where possible and use of LATP biopsies as outlined in Figure 13.

Figure 12: Schematic outline of proposed model prostate cancer pathway

References

Aggarwal, A., Choudhury, A., Fearnhead, N., Kearns, P., Kirby, A., Lawler, M., ... & Sullivan, R. (2024). The future of cancer care in the UK—time for a radical and sustainable National Cancer Plan. The Lancet Oncology, 25(1), e6-e17.

Alabousi, M., Salameh, J. P., Gusenbauer, K., Samoilov, L., Jafri, A., Yu, H., & Alabousi, A. (2019). Biparametric vs multiparametric prostate magnetic resonance imaging for the detection of prostate cancer in treatment-naïve patients: a diagnostic test accuracy systematic review and meta-analysis. BJU international, 124(2), 209-220.

Asif, A., Nathan, A., Ng, A., Khetrapal, P., Chan, V. W. S., Giganti, F., ... & Kasivisvanathan, V. (2023). Comparing biparametric to multiparametric MRI in the diagnosis of clinically significant prostate cancer in biopsy-naive men (PRIME): a prospective, international, multicentre, non-inferiority within-patient, diagnostic yield trial protocol. BMJ open, 13(4), e070280.

Awsare, N. S., Green, J. S. A., Aldwinckle, B., Hanbury, D. C., Boustead, G. B., & McNicholas, T. A. (2008). The measurement of psychological distress in men being investigated for the presence of prostate cancer. Prostate Cancer and Prostatic Diseases, 11, 384–389.

Bass EJ, Freeman A, Jameson C, Punwani S, Moore CM, Arya M, Emberton M, Ahmed HU. Prostate cancer diagnostic pathway: Is a one-stop cognitive MRI targeted biopsy service a realistic goal in everyday practice? A pilot cohort in a tertiary referral centre in the UK. BMJ Open. 2018 Oct 24;8(10):e024941.

Bass, E. J., Pantovic, A., Connor, M., Gabe, R., Padhani, A. R., Rockall, A., ... & Ahmed, H. U. (2021). A systematic review and meta-analysis of the diagnostic accuracy of biparametric prostate MRI for prostate cancer in men at risk. Prostate Cancer and Prostatic Diseases, 24(3), 596-611.

Broe M, Matanhelia M, O'Kelly F, et al. The hidden workload and cost of a rapid access prostate cancer clinic: Patients with no prostate cancer. Journal of Clinical Urology. 2018;11(6):409-413. doi:10.1177/2051415818788986

Campbell, K., Greenfield, G., Li, E., O'Brien, N., Hayhoe, B., Beaney, T., Majeed, A., & Neves, A. L. (2023). The Impact of Virtual Consultations on the Quality of Primary Care: Systematic Review. Journal of medical Internet research, 25, e48920. https://doi.org/10.2196/48920

Cancer Research UK (CRUK)(2024). Prostate cancer incidence statistics. Available at: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer/incidence#heading-Zero (last accessed 12/07/2024).

Chen, KW, Pek, G, Yufei, Q, Toh, PC, Kuek, N, Lee, JKC, et al. Comparing outcomes of transperineal to transrectal prostate biopsies performed under local anaesthesia. BJUI Compass. 2022; 3(3): 197– 204. https://doi.org/10.1002/bco2.112

Cowie, J., Nicoll, A., Dimova, E. D., Campbell, P., & Duncan, E. A. (2020). The barriers and facilitators influencing the sustainability of hospital-based interventions: a systematic review. BMC health services research, 20(1), 588. https://doi.org/10.1186/s12913-020-05434-9

Dillard AJ, Scherer LD, Ubel PA, Alexander S, Fagerlin A. Anxiety symptoms prior to a prostate cancer diagnosis: Associations with knowledge and openness to treatment. Br J Health Psychol. 2017 Feb;22(1):151-168.

Dugle, G., Wulifan, J.K., Tanyeh, J.P. et al. A critical realist synthesis of cross-disciplinary health policy and systems research: defining characteristic features, developing an evaluation framework and identifying challenges. Health Res Policy Sys 18, 79 (2020). https://doi.org/10.1186/s12961-020-00556-2

Dunn OJ (1961). Multiple comparison among means. J Amer Stat Assoc. 56 (293), 52-64.

Eldred-Evans, D., Connor, M. J., Bertoncelli Tanaka, M., Bass, E., Reddy, D., Walters, U., Stroman, L., Espinosa, E., Das, R., Khosla, N., Tam, H., Pegers, E., Qazi, H., Gordon, S., Winkler, M., & Ahmed, H. U. (2023). The rapid assessment for prostate imaging and diagnosis (RAPID) prostate cancer diagnostic pathway. BJU international, 131(4), 461–470. https://doi.org/10.1111/bju.15899

Faria R, Soares MO, Spackman E, Ahmed HU, Brown LC, Kaplan R, Emberton M, Sculpher MJ. Optimising the Diagnosis of Prostate Cancer in the Era of Multiparametric Magnetic Resonance Imaging: A Cost-effectiveness Analysis Based on the Prostate MR Imaging Study (PROMIS). Eur Urol. 2018 Jan;73(1):23-30.

Forde, J. C., O'Connor, K. M., Casey, L., O'Brien, M., Bowen, S., Casey, R. G., Ahmed, I., McDermott, T. E., Grainger, R., & Lynch, T. H. (2011). A rapid access diagnostic clinic for prostate cancer: the experience after one year. Irish journal of medical science, 180(2), 505–508. https://doi.org/10.1007/s11845-011-0695-3

Giganti F, Moore CM. MRI in early detection of prostate cancer. Curr Opin Urol. 2019 Nov;29(6):563-568.

GIRFT Urology: Towards Better Diagnosis & Management of Suspected Prostate Cancer; April 2024; GIRFT-Urology-Towards-Better-Diagnosis-Management-of-Suspected-Prostate-Cancer-FINAL-V1-April-2024-1.pdf

Groarke, A., Curtis, R., Walsh, D. M. J., & Sullivan, F. J. (2018). What predicts emotional response in men awaiting prostate biopsy? BMC Urology, 18(1), 27. https://doi.org/10.1186/s12894-018-0340-9

Grummet, J., Gorin, M.A., Popert, R. et al. “TREXIT 2020”: why the time to abandon transrectal prostate biopsy starts now. Prostate Cancer Prostatic Dis 23, 62–65 (2020). https://doi.org/10.1038/s41391-020-0204-8

Hall PS, Hamilton P, Hulme CT, Meads DM, Jones H, Newsham A, Marti J, Smith AF, Mason H, Velikova G, Ashley L, Wright P. Costs of cancer care for use in economic evaluation: a UK analysis of patient-level routine health system data. Br J Cancer. 2015 Mar 3;112(5):948-56.

Hawks, C., Moe, A., McCombie, S., Hamid, A., Brown, M., & Hayne, D. (2021). 'One Stop Prostate Clinic': prospective analysis of 1000 men attending a public same-day prostate cancer assessment and/or diagnostic clinic. ANZ journal of surgery, 91(4), 558–564. https://doi.org/10.1111/ans.16329

Hawks, C., Viswambaram, P., Cloney, C., Botha, E., Brown, M., Chambers, S., Paterson, C., & Hayne, D. (2021). Nurse-led telephone notification of a prostate cancer diagnosis: Prospective analysis of men's preferences for and experiences of a same-day assessment and diagnostic clinic. European journal of cancer care, 30(6), e13493. https://doi.org/10.1111/ecc.13493

Hawks, C., Al-Zubaidi, M., Viswambaram, P., Gonsalves, J., Brown, M., Byrnes, J., & Hayne, D. (2023). Analysis of the financial impact and efficiency of the One Stop Prostate Clinic: A same day prostate cancer diagnostic clinic in the Australian public health system. Journal of public health research, 12(1), 22799036221146882. https://doi.org/10.1177/22799036221146882

Hernández Alava M, Pudney S, Wailoo A (2022). Estimating EQ-5D by age and sex for the UK. NICE Decision Support Unit, University of Sheffield. Available at : https://www.sheffield.ac.uk/nice-dsu/methods-development/estimating-eq-5d (last accessed 03/07/2024).

Hines, P & Rich, N (1997)," The seven value stream mapping tools", International Journal of Operations & Production Management, Vol. 17 Iss 1 pp. 46-64. Management, 17(1), 46-64

Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) statement: updated reporting guidance for health economic evaluations. BMJ. 2022;376.

Jagosh, J., Tilley, N., & Stern, E. Realist evaluation at 25: Cumulating knowledge, advancing debates and innovating methods. Evaluation, 2016; 22(3): 267–269. https://doi.org/10.1177/1356389016656502

Jones, K. R., Rees, S., Chandran, A., Erdem, E., Jones, M., Farrington, S., ... & Gemine, R. (2024). Prostad: The development and evaluation of a prostate cancer rapid diagnostic pathway, a protocol. medRxiv, 2024-05.

Jones, K.C., Weatherly, H., Birch, S., Castelli, A., Chalkley, M., Dargan, A., Forder, J.E., Gao, J., Hinde, S., Markham, S. et al. (2023). Unit Costs of Health and Social Care 2022 Manual. Technical report. Personal Social Services Research Unit (University of Kent) & Centre for Health Economics (University of York), Kent, UK.

Kano, N., Seraku, N., Takahashi, F. and Tsuji, S. (1984), “Attractive quality and must-be quality “, Hinshitsu, The Journal of the Japanese Society for Quality Control, April, pp. 39 – 48

Krahn M, Bremner KE, Tomlinson G, Ritvo P, Irvine J, Naglie G. Responsiveness of disease-specific and generic utility instruments in prostate cancer patients. Qual Life Res. 2007 Apr;16(3):509-22.

Kuppen MCP, Westgeest HM, van den Eertwegh AJM, Coenen JLLM, van Moorselaar RJA, van den Berg P, Geenen MM, Mehra N, Hendriks MP, Lampe MI, van de Luijtgaarden ACM, Peters FPJ, Roeleveld TA, Smilde TJ, de Wit R, van Oort IM, Gerritsen WR, Uyl-de Groot CA. Health-related Quality of Life and Pain in a Real-world Castration-resistant Prostate Cancer Population: Results From the PRO-CAPRI Study in the Netherlands. Clin Genitourin Cancer. 2020 Jun;18(3): e233-e253.

Langelier, D. M., Jackson, C., Bridel, W., Grant, C., & Culos-Reed, S. N. (2022). Coping strategies in active and inactive men with prostate cancer: a qualitative study. Journal of cancer survivorship: research and practice, 16(2), 421–431. https://doi.org/10.1007/s11764-021-01037-3

Lopez, J.F., Bryant, R.J. The 'Rapid Access Prostate Imaging and Diagnosis' (RAPID) diagnostic pathway: what is the rush? BJU Int. 2023 Apr;131(4):377-379.

Lopez, J. F., Campbell, A., Omer, A., Stroman, L., Bondad, J., Austin, T., ... & Lamb, A. D. (2021). Local anaesthetic transperineal (LATP) prostate biopsy using a probe-mounted transperineal access system: a multicentre prospective outcome analysis. BJU international, 128(3), 311-318.

Martins R, Raimundo P, Alves P (2020). Appropriateness of Radiology test requests by an emergency department: a retrospective study. Acta Med Port 2020;33(1):7–14.doi:10.20344/amp.12075

McCombie, S. P., Hawks, C., Emery, J. D., & Hayne, D. (2015). A 'One Stop' Prostate Clinic for rural and remote men: a report on the first 200 patients. BJU

international, 116 Suppl 3, 11–17. https://doi.org/10.1111/bju.13100

Melby, L., & Håland, E. (2021). When time matters: a qualitative study on hospital staff's strategies for meeting the target times in cancer patient pathways. BMC health services research, 21, 1-12.

Merriel, S. W. D., Archer, S., Forster, A. S., Eldred-Evans, D., McGrath, J., Ahmed, H. U., Hamilton, W., & Walter, F. M. (2022). Experiences of 'traditional' and 'one-stop' MRI-based prostate cancer diagnostic pathways in England: a qualitative study with patients and GPs. BMJ open, 12(7), e054045. https://doi.org/10.1136/bmjopen-2021-054045

Mukumbang FC, Marchal B, Van Belle S, van Wyk B. Using the realist interview approach to maintain theoretical awareness in realist studies. Qualitative Research. 2020 Aug;20(4):485-515.

Netsey-Afedo, M. M. L., Ammentorp, J., Osther, P. J. S., & Birkelund, R. (2020). No time for reflection: Patient experiences with treatment-related decision-making in advanced prostate cancer. Scandinavian journal of caring sciences, 34(4), 880–888. https://doi.org/10.1111/scs.12794

National Institute for Health and Care Excellence (NICE), 2014. Prostate cancer diagnosis and treatment (CG175). Available at: https://www.nice.org.uk/guidance/ng131/evidence (last accessed 03/07/2024).

National Institute for Health and Care Excellence (NICE), 2023. NICE health technology evaluations: the manual. Available at: https://www.nice.org.uk/process/pmg36/chapter/economic-evaluation (last accessed 23/04/2024).

National Institute for Health and Care Excellence (NICE), 2024. Developing NICE guidelines: the manual (PMG20). Available at: https://www.nice.org.uk/process/pmg20/chapter/introduction (last accessed 23/04/2024).

National Institute for Health and Care Excellence (NICE), 2019. Prostate Cancer Diagnosis and Management. Available at: https://www.nice.org.uk/guidance/ng131/chapter/recommendations#mri-and-biopsy (last accessed 23/09/2024).

National Institute for Health and Care Excellence (NICE), 2023. Transperineal Biopsy for diagnosing Prostate Cancer Diagnosis. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-dg10043/documents

NHS England (2024). GIRFT Urology: Towards better diagnosis management of suspected prostate cancer. Available at: GIRFT-Urology-Towards-Better-Diagnosis-Management-of-Suspected-Prostate-Cancer-FINAL-V1-April-2024-1.pdf (last accessed 21/11/2024).

NHS Improvement (2023): 2021/22 National cost collection data publication. Available at: https://www.england.nhs.uk/publication/2021-22-national-cost-collection-data-publication/ (last accessed 21/03/2024).

NHS Wales (2023): National Optimal Pathway for Prostate Cancer: 2nd Edition. Available at: https://executive.nhs.wales/functions/networks-and-planning/cancer/workstreams/suspected-cancer-pathway/scp-accordion/nopccprostate2020206/#:~:text=Meet%20the%20SCP%20cancer%20waiting,the%20best%20outcomes%20in%20Europe. (last accessed 17/07/2024).

Office of National Statistics (ONS, 2023). Population estimates for England and Wales: mid-2022. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/populationestimatesforenglandandwales/mid2022 (last accessed 21/03/2024).

Oon, S. F., Cullen, I. M., Moran, D., Bolton, E. M., McDermott, T., Grainger, R., & Lynch, T. H. (2014). The effect of a Rapid Access Prostate Cancer Clinic on prostate cancer patient and disease characteristics, primary treatment and surgical workload. Irish journal of medical science, 183(2), 241–247. https://doi.org/10.1007/s11845-013-0997-8

Oswal D, Sapherson D, Rehman, A. (2009). A study of adequacy of completion of Radiology Request forms. Radiography;15 (3): 209–13.doi:10.1016/j.radi.2008.05.003

Pawson, R. and Tilley, N. (1997). Realistic Evaluation. SAGE Publications.

Pesapane, F., Acquasanta, M., Meo, R. D., Agazzi, G. M., Tantrige, P., Codari, M., ... & Sardanelli, F. (2021). Comparison of sensitivity and specificity of biparametric versus multiparametric prostate MRI in the detection of prostate cancer in 431 men with elevated prostate-specific antigen levels. Diagnostics, 11(7), 1223.

Comparison of Biparametric and Multiparametric MRI for Prostate Cancer Detection: The PRIME Study; https://www.urotoday.com/conference-highlights/eau-2024/eau-2024-prostate-cancer/150992-eau-2024-comparison-of-biparametric-and-multiparametric-mri-for-prostate-cancer-detection-the-prime-study.html

Prostate Cancer UK. https://prostatecanceruk.org/media/jobjikpi/mpmri-imaging-guidance-document-final.pdf

Rich, N. & Malik, T. (2019) "International Standards for Design and Manufacturing: Quality Management and International Best Practice", Kogan Page Publishing, London. https://www.koganpage.com/logistics-supplychain-operations/international-standards-for-design-and-manufacturing-9781789660425

Rycroft-Malone, J., McCormack, B., Hutchinson, A. M., DeCorby, K., Bucknall, T. K., Kent, B., Schultz, A., Snelgrove-Clarke, E., Stetler, C. B., Titler, M., Wallin, L., & Wilson, V. (2012). Realist synthesis: illustrating the method for implementation research. Implementation science: IS, 7, 33. https://doi.org/10.1186/1748-5908-7-33

Roberts, M.J., Macdonald, A., Ranasinghe, S. et al. Transrectal versus transperineal prostate biopsy under intravenous anaesthesia: a clinical, microbiological and cost analysis of 2048 cases over 11 years at a tertiary institution. Prostate Cancer Prostatic Dis 24, 169–176 (2021). https://doi.org/10.1038/s41391-020-0263-x

Roehrborn CG, Black LK. The economic burden of prostate cancer. BJU Int. 2011 Sep;108(6):806-13.

Saad F, Cella D, Basch E, Hadaschik BA, Mainwaring PN, Oudard S, Graff JN, McQuarrie K, Li S, Hudgens S, Lawson J, Lopez-Gitlitz A, Yu MK, Smith MR, Small EJ. Effect of apalutamide on health-related quality of life in patients with non-metastatic castration-resistant prostate cancer: an analysis of the SPARTAN randomised, placebo-controlled, phase 3 trial. Lancet Oncol. 2018 Oct;19(10):1404-1416.

Salifu, Y., Almack, K., & Caswell, G. (2023). 'Out of the frying pan into the fire': a qualitative study of the impact on masculinity for men living with advanced prostate cancer. Palliative care and social practice, 17, 26323524231176829. https://doi.org/10.1177/26323524231176829

Sewell, B., Jones, M., Gray, H., Wilkes, H., Lloyd-Bennett, C., Beddow, K., Bevan, M., & Fitzsimmons, D. (2020). Rapid cancer diagnosis for patients with vague symptoms: a cost-effectiveness study. The British journal of general practice: the journal of the Royal College of General Practitioners, 70(692), e186–e192. https://doi.org/10.3399/bjgp20X708077

Sewell B, Jones M, Davies M, Erdem, E. and Fitzsimmons, D. (2024, unpublished). PROSTAD: Health Economic Report.

Shah J. Assessment of activity and outcome from a one-stop clinic for men with suspected prostate cancer: Five years' experience. Journal of Clinical Urology. 2016;9(1):5-10. doi:10.1177/2051415815590527

Smith-Palmer J, Takizawa C, Valentine W. Literature review of the burden of prostate cancer in Germany, France, the United Kingdom and Canada. BMC Urol. 2019 Mar 18;19(1):19.

Solbjør, M., Sand, K., Ervik, B. et al. Patient experiences of waiting times in standardised cancer patient pathways in Norway – a qualitative interview study. BMC Health Serv Res 21, 651 (2021). https://doi.org/10.1186/s12913-021-06679-8

Tafuri, A., Ashrafi, A. N., Palmer, S., Shakir, A., Cacciamani, G. E., Iwata, A., Iwata, T., Cai, J., Sali, A., Gupta, C., Medina, L. G., Stern, M. C., Duddalwar, V., Aron, M., Gill, I. S., & Abreu, A. (2020). One-Stop MRI and MRI/transrectal ultrasound fusion-guided biopsy: an expedited pathway for prostate cancer diagnosis. World journal of Urology, 38(4), 949–956. https://doi.org/10.1007/s00345-019-02835-2

Thomson, A., Li, M., Grummet, J., & Sengupta, S. (2020). Transperineal prostate biopsy: a review of technique. Translational andrology and urology, 9(6), 3009.

Tobore T. O. (2019). On the need for the development of a cancer early detection, diagnostic, prognosis, and treatment response system. Future science OA, 6(2), FSO439. https://doi.org/10.2144/fsoa-2019-0028

Walthall, H., Schutz, S., Snowball, J., Vagner, R., Fernandez, N., & Bartram, E. (2022). Patients' and clinicians' experiences of remote consultation? A narrative synthesis. Journal of advanced nursing, 78(7), 1954–1967. https://doi.org/10.1111/jan.15230

Woo, S., Suh, C. H., Kim, S. Y., Cho, J. Y., Kim, S. H., & Moon, M. H. (2018). Head-to-head comparison between biparametric and multiparametric MRI for the diagnosis of prostate cancer: a systematic review and meta-analysis. American Journal of Roentgenology, W226-W241.

Zhu, J., Chen, R., Davidsson, S., Carlsson, J., Messing-Eriksson, A., Fridfeldt, J., Andrén, O., Andersson, S. O., Valdimarsdóttir, U., Fang, F., & Fall, K. (2020). Psychological and physiological impacts of a fast-track diagnostic workup for men with suspected prostate cancer: Preliminary report from a randomized clinical trial. Cancer communications (London, England), 40(5), 239–242. https://doi.org/10.1002/cac2.12021

Appendix 1
PROSTAD Evaluation Protocol

Title: Development of a Model Prostate Cancer Diagnostic Pathway

Acronym/Short Title: PROSTAD

Version Number: 0.2 Date: 4th October 2023

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Summary

Outline

Prostate cancer is the most common male cancer in the UK. Despite Welsh Government targets for 75% of suspected cancer patients to commence definitive treatment within 62 days of the point of suspicion and Wales' National Optimal Pathway for prostate cancer, waiting times on the prostate cancer diagnostic pathway in our health board and across Wales, fall well outside the 28-day decision to treat target.

HDUHB's Urology department, in collaboration with the R, I and VBHC department, have identified factors that contribute to this delay and are implementing a new diagnostic pathway that incorporates gold-standard techniques and reduces the time spent by the patient in the pathway.

This evaluation will be guided and developed by a dedicated patient and public involvement (PPI) group, and through a number of work packages, will aim to identify and understand factors that affect patient and clini-cian acceptability of the pathway, (including satisfaction, communica-tion, experience, and outcomes), impact on the service by assessing overall patient times on pathway, activities and efficiencies within the pathway and finally, considering resource use, cost differences and patient outcomes, between the new and current pathways.

Lay Summary

Prostate cancer is the most common cancer affecting men in the UK. Welsh Government targets state that people with suspected cancer should receive a decision on whether treatment is required within 28 days of the first suspicion of cancer by a healthcare professional. In Hy-wel Dda University Health Board (HDUHB) and across Wales, this target is not being met and waiting times for patients awaiting a diagnosis are long.

Within Hywel Dda, a new pathway has been developed and will be introduced. The new pathway includes recommended techniques for biopsy and will help patients to move through the pathway more quickly.

This evaluation is being planned and carried out in with people who have experience of prostate cancer and similar pathways of care. It will try to understand what can speed up or slow a person's journey through these pathways and look at how this affects their experience. It will also study the new pathway in detail and look for places within the pathway where patients may move more quickly or may experience delays. Final-ly, the evaluation will compare the resources and costs of the new pathway with the current pathway.

Keywords

cancer, prostate, pathway, patient experience, outcomes

Objectives

To evaluate, in close collaboration with a dedicated project PPI group, the new Model Prostate Cancer Diagnostic Pathway (PROSTAD) within the service, in terms of patient and clinician acceptability, clinical outcomes, impact on service efficiency and resource use and cost implications.

Duration/Target | 18 months

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Introduction

1.1 Background

Prostate cancer is the most commonly diagnosed male cancer in the UK. Data from the National Prostate Cancer Audit 2020 shows a 23% rise in annual prostate cancer diagnoses from 2017 and Welsh Cancer Intelligence Surveillance Unit data shows that across Wales, 3,192 men were diagnosed with prostate cancer in 2018. Of these, 454 patients (14.2%) were from Hywel Dda University Health Board (HDUHB), even though the health board represents only 10% of Wales' population.

Wales' National Optimal Pathway for prostate cancer describes good practice diagnostic and treatment pathways from the point of suspicion (PoS), stating that the diagnostic pathway, including staging, should be performed by Day 28 with Magnetic Resonance Imaging (MRI) recommended within seven days and biopsy by Day 14. Organisational reforms and increasing demands on the service mean that the challenges of meeting these cancer targets are exacerbated by a lack of capacity and resources (Melby et al 2021). State-funded healthcare systems like the NHS are facing unprecedented demand to meet cancer targets following the Covid-19 pandemic (WHO, 2022).

Annually in HDUHB, approximately 600 Urgent Suspected Cancer (USC) GP referrals are made to the Urology team. Approximately half of these patients will go on to have a pre-biopsy MRI. Within HDUHB, USC referral numbers from Primary Care have now returned to pre-COVID levels and Secondary Care services are struggling to manage demand with capacity. Our current waiting times on the prostate cancer diagnostic pathway are prolonged, falling well outside the 28-day decision to treat and 62-day referral to treatment targets. StatsWales indicates that during the 12-month period December 2020 and November 2021, HDUHB figures for the Single Cancer Pathway (SCP) were below the all-Wales average in 11 of the 12 months and it is notable that the all-Wales average is also well below Welsh Government's 75% target.

The Urology Department, working with HDUHB's Research and Innovation department conducted extensive process-mapping work to explore factors contributing to this delay, and identified deficiencies in the pathway (versus the optimal national pathway) that related to initial communications with the patient, capacity to offer and report on MRIs, capacity within Pathology, outpatient clinic waits both in HDUHB and SBUHB.

NHS England's National Cancer Programme focuses on accelerated diagnosis pathways to ensure patients with suspected cancer receive diagnostic tests to confirm or refute their suspicion within 28 days of referral. There is positive evidence for rapid access one-stop prostate clinics, which have been shown to shorten the diagnostic pathway (McCombie et al, 2015; Kavanagh et al, 2008; Bolton et al, 2014). Sundi et al (2015) found that clinical assessment followed by same-day evaluation of prostate cancer patients' imaging and biopsy results, by a MDT, led to critical changes in management plans for one in four patients. Manchester's RAPID programme for Lung Cancer, launched in 2016, has successfully addressed delays at the front end of suspected lung cancer pathway, through workforce reorganisation (Evison et al, 2020).

NICE guidelines for prostate cancer diagnosis recommend a full multi-parametric scan including contrast enhanced imaging and Prostate Cancer UK have supported this by publishing an imaging technical guidance document. Currently our service, and others nationally are only able to offer a bi-parametric scan without contrast. This has implications on the need for unnecessary biopsies in borderline cases and therefore service capacity.

Transperineal prostate biopsies have improved patient safety with virtual elimination of septic complications and improved diagnostic accuracy over transrectal (TRUS) biopsies (Chen et al, 2022; Roberts et al, 2021). NICE

are evaluating evidence and are likely to recommend transperineal biopsy with the rapid uptake of this technique in the rest of the UK. There is a UK 'TREXIT' movement led by leading UK urologists driving a move away from TRUS biopsies, supported by an increasing patient lobby (Grummet et al 2020). The use of transperineal biopsies would provide patient confidence and minimise patient anxiety with regards to them receiving the safest and most accurate diagnostic biopsies. The risk of infection and sepsis from TRUS is the most feared complication and is being compounded by increasing quinolone antibiotic resistant E. coli. The contemporary post procedure infection rate after TRUS biopsy is between 6-10%, and the sepsis related mortality rate has calculated at 0.13% (Joshi, 2020). The hospitalisation rate for infection may be rising due to antimicrobial resistance and is between 1-4% (Williamson et al 2013). Transperineal biopsy is associated with a far lower sepsis rate of around 0.1%, a post procedure hospitalisation rate of 0.13%, and an infection rate of 0.11% (Castellani et al, 2022). The introduction of local anaesthetic transperineal (LATP) biopsy will reduce the need for inpatient beds and anaesthetic input, therefore, reducing waiting times and risk for patients (Hogan et al, 2021). This in turn will improve the Single Cancer Pathway performance due to reduced delays in this part of the pathway. There is also a cost benefit of £461.75p per patient to carrying this procedure out under local anaesthetic.

The most stressful time in a patient's life seems to be waiting for biopsy findings, so reducing this wait should contribute to improving patient care (Awsare et al, 2008). Meta-analysis and systematic review by Gorin et al (2017) found that co-ordinating care for cancer patients improved 81% of outcomes, including patient experience. Solbjør et al (2021) found that the patient's experience of waiting times was affected both by the duration of their wait and by their expectations. Four of the 19 patients interviewed for this study had prostate cancer. In Denmark, patient dissatisfaction with long waits after initial referral reduced following the implementation of standardised cancer patient pathways (Dahl, 2017).

1.2 Current Situation

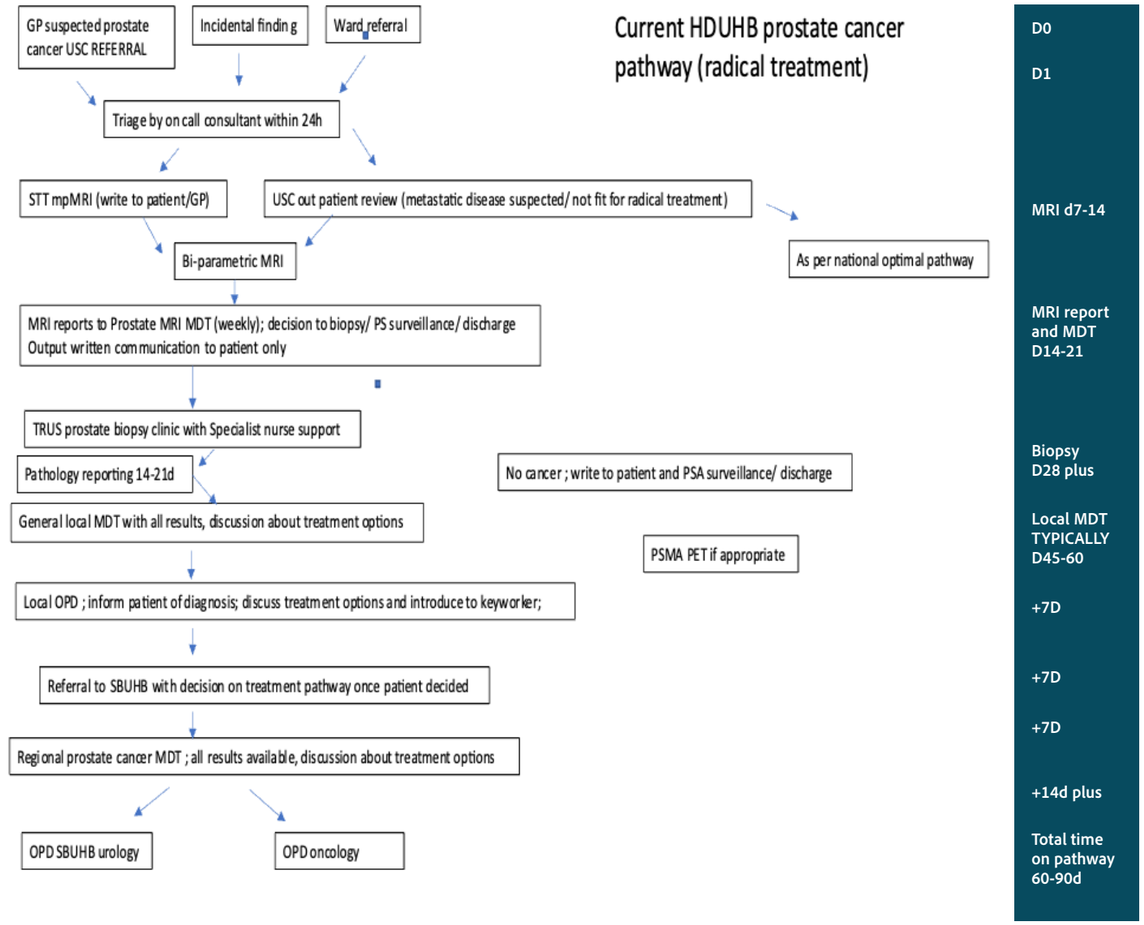
HDUHB has a large widespread ageing population with a high incidence of prostate cancer versus the rest of Wales and the UK. There is a prolonged diagnostic pathway, partially due to the need to refer to a neighbouring health board for definitive treatment. Currently diagnostic resources and capacity is spread over multiple sites each with their own limitations. This is illustrated in figure 1 (right).

The PROSTAD project has developed and is piloting a new Model Prostate Cancer Diagnostic Pathway within the service. This is illustrated in Figure 2 below. The project will aim to embed gold standard techniques and a dedicated pathway coordinator within a new diagnostic pathway, with the intention of shortening time from referral to diagnosis, reducing the overall time spent by patients on the pathway and improving outcomes and experiences.

Developing the new pathway will involve the introduction of dedicated multi-parametric MRI slots with next day reporting and follow-up appointment with urologist and specialist nurse support. There will be shared decision-making in relation to diagnostic plans, considering patient and clinical factors, patient expectations, PSA and MRI results. A LATP biopsy appointment with specialist nurse support, will follow if required. Patients will be supported through the pathway by a dedicated pathway coordinator.

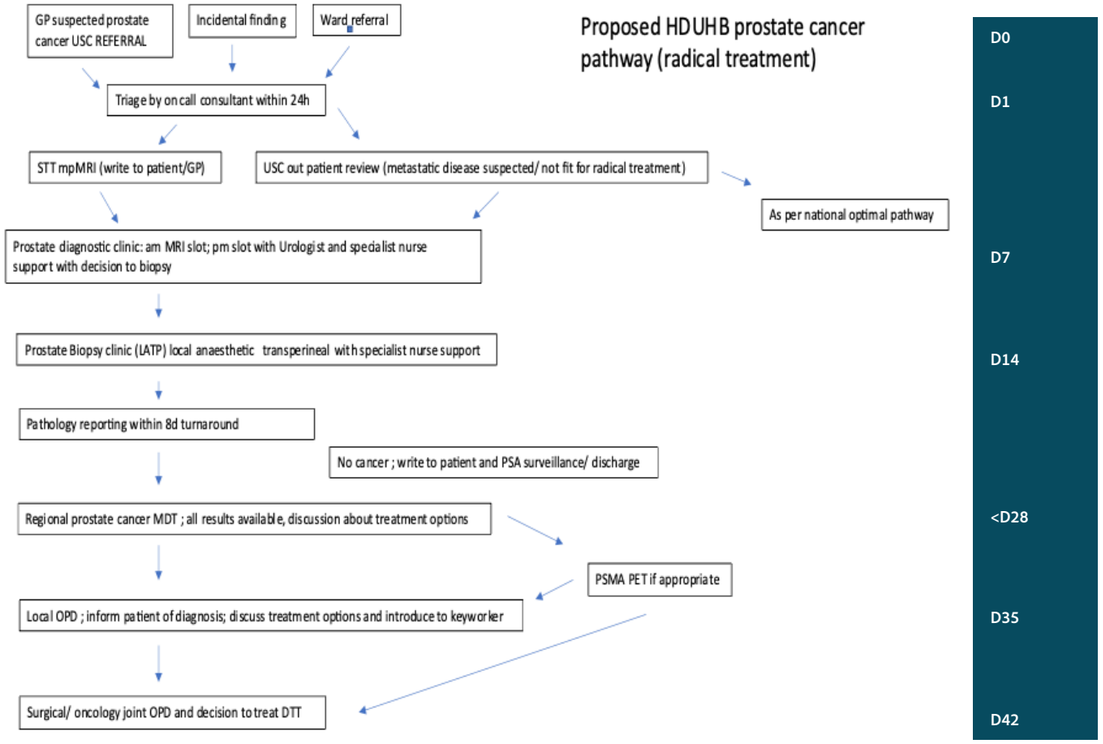
This is being launched as a pilot service in HDUHB, initially with four dedicated PROSTAD MRI slots per week, as part of a phased evaluation.

Figure 1 Standard HDUHB prostate pathway



1.2.1 Innovation Development/Evaluation

Figure 2 - New model prostate cancer pathway



Implementing the new model pathway will involve a whole systems co-produced approach. We will seek to understand the factors required to enable long-term sustainability and wider adoption and spread, including identifying risks within the pathway and possible mitigations. The evaluation will enable an understanding of the resources needed to implement, run and facilitate longer-term sustainability, by evidencing the pathway and its associated clinical and patient benefits.

1.3 Objectives

The project's main objective will be to evaluate the new PROSTAD pathway within the service and understand factors required to enable long-term sustainability and wider adoption and spread. This will include identifying risks within the pathway and possible mitigations. The evaluation will enable an understanding of the resources needed to implement, run and facilitate longer-term sustainability, by evidencing the pathway and its associated clinical and patient benefits.

Specific objectives to be addressed through the different work packages will be:

Work package 1 – to involve patients and members of the public in developing the evaluation, shaping findings and theory and dissemination activities.

Work package 2 – to assess the acceptability of the new pathway to patients and clinical team through qualitative exploration.

Work package 3 – to assess service aims to reduce overall time on pathway, reduce unnecessary activities and improve efficiencies within the service by identifying pinch points and identifying real time solutions.

Work package 4 – to consider resource use and cost differences between the pilot pathway and current pathways and patient outcomes as part of a cost-consequences analysis.

Work package 5 – to develop pathway specific documentation and training resources to enable scale-up and adoption on a national basis.

1.4 Justification for the Evaluation

As a clinical service evaluation, NHS ethical approval will not be required for any elements of the work. Swansea University ethics will be sought for evaluation aspects as appropriate.

1.5 Approvals

The evaluation has been approved by the Research, Innovation and VBHC Department at Hywel Dda UHB. No Research ethics approval is required as this does not meet the HRA requirements for NHS ethics.

Evaluation Outline

2.1 Aims and Objectives

The evaluation will aim to understand and analyse real and perceived barriers causing delays at the front end of the prostate cancer pathway and to identify facilitators that reduce these delays. We will involve members of the prostate cancer multi-disciplinary team (MDT) and patients to better understand these factors. It will incorporate the development of an implementation and service guide to support rapid wider national roll-out, once successful.

2.2 Work Plan

We will pilot and evaluate the pathway via five work packages, as detailed in the evaluation framework provided at Appendix 1a.

Work package 1: Patient and Public Involvement (PPI) in the evaluation

Patients and members of the public will be involved in developing the evaluation, shaping findings and theory and dissemination activities.

Work package 2: Evaluation including Patient Experience and Outcomes, Clinical Impact

The acceptability of the new pathway to patients and clinical team will be assessed through qualitative exploration.

Work package 3: Implementation and service review

This will assess service aims to reduce overall time on pathway, reduce unnecessary activities and improve efficiencies within the service by identifying pinch points and identifying real time solutions.

Work package 4: Economic evaluation

The economic evaluation will consider resource use and cost differences between the pilot pathway and current pathways (based on historic matched controls) and patient outcomes (using data obtained from study records, relevant literature and Patient Reported Experience/ Outcome Measures, where available) as part of a cost-consequences analysis.

Work package 5: Resources to support wider adoption

Pathway specific documentation and training resources will be developed to enable scale-up and adoption on a national basis. Evidence and data generated will be targeted to a range of audiences such as clinicians, commissioners, service managers and policymakers.

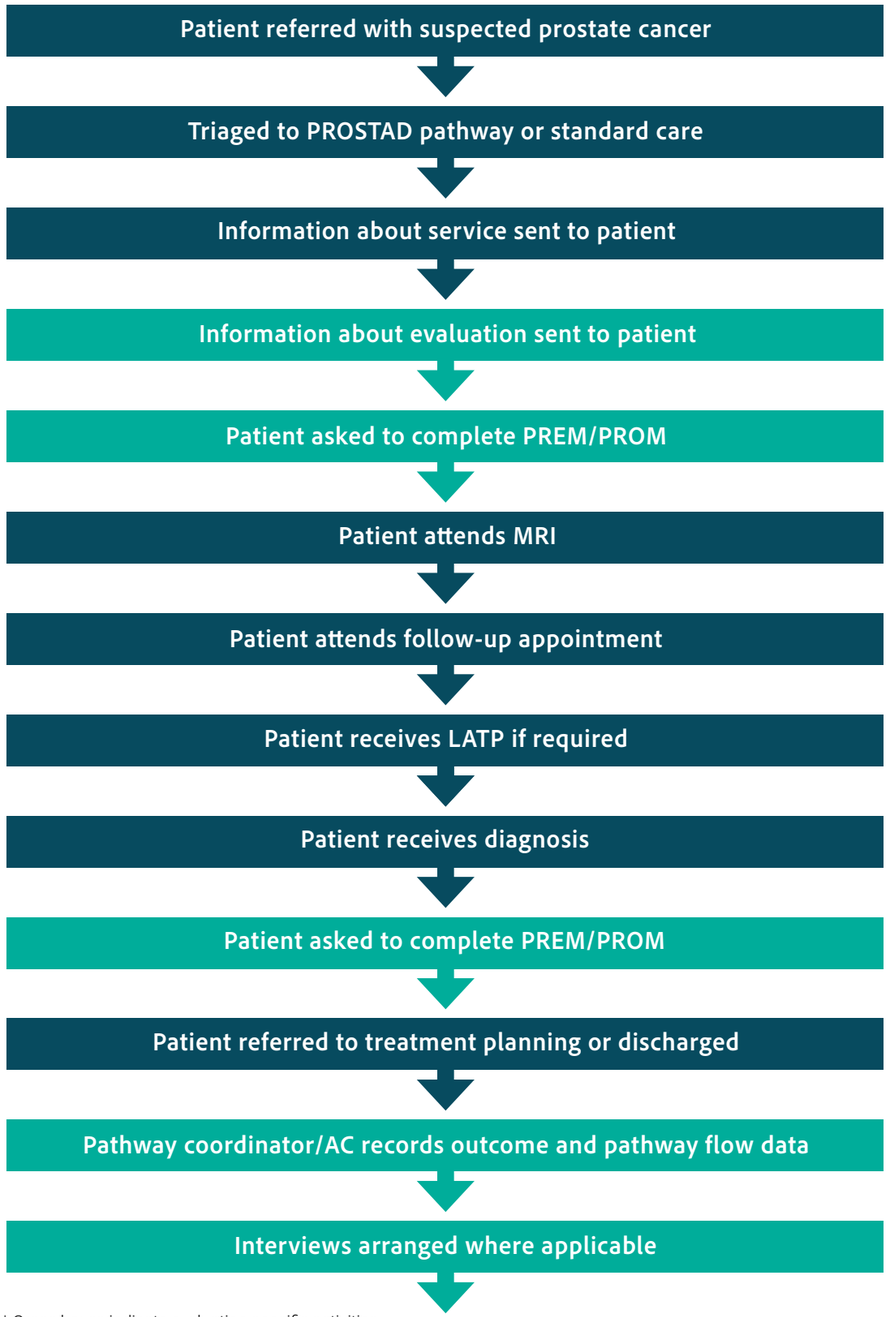
2.2.1 Study Type

Service innovation and evaluation.

2.2.2 Study Design

Patient journey and data collection flow chart

We will closely monitor data collection as part of the new pathway as the evaluation



* Green boxes indicate evaluation specific activities

Work package 1: Patient and Public Involvement (PPI) in the evaluation

(Lead Prof Jaynie Rance)

A PPI group of up to ten members, drawn from prostate cancer support groups (including the West Wales Prostate Support Group), local patient and public involvement panels, and interested patients will be established. This work package will ensure that the experiences of patients, carers and members of the public with experiential knowledge of the service will guide the evaluation by contributing to the formulation of evaluation questions, helping to shape emergent findings, refining final programme theory and disseminating findings.

Work package 2: Evaluation including Patient Experience and Outcomes, Clinical Impact

(Lead Prof Jaynie Rance)

A Realist Evaluation (RE) approach (e.g. Pawson and Tilley, 1997) will be adopted to understand how contextual factors and related mechanisms interact to produce the outcomes for the PROSTAD pathway. The RE will utilise a combination of both qualitative and quantitative methods to address the evaluation questions and support all other work packages, as appropriate. As part of this, our logic model will be used to define the data to be collected, Initial Programme Theory will be developed, defined and refined, and measures to capture perceptions of effectiveness and implementation will be agreed. Realist interviews will be conducted with key stakeholders including staff involved across the pathway (n=10) and with patients and carers (n=25). A series of four PPI group sessions will be held at different points within the work package timeline to support the delivery of these activities.

Work package 3: Implementation and service review

(Lead Prof Nick Rich)

An implementation review will be conducted to consider the barriers and facilitators to implementation. In line with Lean Development, a real time plan-do-study-act cycle will be adopted with scientific methods applied on a continuous basis to formulate a plan, implement the plan, and analyse and interpret the results, followed by development of any required changes (Langley et al, 2009). This will be conducted through a mixed methods approach, providing a practical way to understand the multiple perspectives, causal pathways, and multiple types of outcomes and to compare current state and future state of the process including safety, staff morale, quality, delivery dependability and costs. Focusing on the pathway, this work package will support optimisation. Discussions with staff involved in the pathway twill aid understanding of barriers and facilitators to implementation. Continuous data review will be undertaken to identify pinch points and modify the pathway to make as efficient as possible. An implementation plan will be constructed to focus on outcomes including acceptability to patients, staff and clinical services, wider-adoption, appropriateness and feasibility of the pathway (linked to work package 2), fidelity and applicability outside of the evaluation and to other organisations, implementation costs (linked to work package) and sustainability in the medium and long-term and in the event of critical disruption.

Work package 4: Health economic evaluation

(Co-Leads Dr Bernadette Sewell/Dr Mari Jones)

Within this work package, a health economic service evaluation of the pilot pathway compared to the current pathway will be undertaken, using resource use and cost data, literature-derived inputs and PREM/PROM data (where available). Potential costs and consequences (including health outcomes should data be available) of introducing the PROSTAD pathway and whether this could be considered value for money for HDUHB will be explored. Whilst the work package will focus on the delivery of the model pathway within the HDUHB context, it will also consider how the findings can be benefit and inform other organisations, including health boards/ Trusts and wider stakeholders such as Cancer Research UK. As part of this work package, a health economic analysis plan, detailing the data to be collected will be developed and agreed with the HDUHB team and CRUK prior to the analysis.

Specific objectives of the health economic evaluation will be to map out the PROSTAD pathway in an agreed specific patient population, to understand the impact of the service when compared to 'standard clinical practice' (i.e., with no PROSTAD pathway) on key descriptives such as referrals patterns and time to event across the diagnosis pathway; to identify key resource drivers and costs associated with the PROSTAD pathway service and subsequent impact on other NHS resources; to investigate the impact of the PROSTAD pathway on for example, cancers detected, stage of diagnoses; to assess short-term outcomes for patients and to explore the cost-consequences of the PROSTAD pathway (should data allow) in improving outcomes.

The following PICO will guide the health economic evaluation:

Population	Intervention	Comparison	Outcomes
Men with suspicion of prostate cancer referred by their GP or consultant to the prostate cancer diagnosis services • Intervention group: men going through the new pathway • Comparator group: men who have gone through the standard pathway No subgroups will be analysed.	PROSTAD - Model Prostate Cancer Diagnostic Pathway	Standard pathway in HDUHB (base case)	1. Time to diagnosis 2. Cancers detected 3. Other significant diagno-ses 4. Anxiety and depression scores 5. Health-related quality of life 6. Pathway costs 7. Healthcare resource use between referral and di-agnosis 8. Patient experience and satisfaction

As the new pathway undergoes continuous development, we will work with all relevant stakeholders to clearly define the new pathway, and update the patient population, relevant comparator and outcomes of interest (the PICO) as appropriate.

The health economic service evaluation will be undertaken in five steps to address the health economic objectives:

1. Mapping out the PROSTAD pathway

Discussions with the clinical and study teams, and data collected as part of work packages 1, 2 and 3, will aid mapping of the patient journey on the PROSTAD pathway and the standard pathway in HDUHB. This will include a graphic representation of the different stages of the patient journey (e.g., outpatient appointment, USC, MRI, MDT) and timings of the different stages, taken over the course of a selection of clinics by AC. Pathway maps will be reviewed and signed off by the project management group (including PPI representatives) before it is used to develop a patient simulation model aimed at comparing costs and outcomes (until diagnosis) of the two different diagnostic pathways.

2. Identifying the key resource drivers and costs associated with the PROSTAD pathway service and subsequent impact on other NHS resources

Resource use and costs will be assessed from a UK NHS perspective with costs expressed in 2023/24 £ sterling. No discounting will be applied as the model time horizon does not exceed one year. The cost of the PROSTAD pathway service (including oncosts and overheads) will be sourced from the HDUHB finance department and supplemented by discussions with the project and clinical team where required. Local costs will be used where possible to reflect the local scope of the evaluation. Where no local costs are available, healthcare resource use for intervention and comparator patients will be valued using published unit costs with older costs inflated using relevant price indices (if required). The impact of using national standard unit costs will be examined during sensitivity analysis. Use of healthcare resources, including outpatient appointments, inpatient admissions, diagnostic tests and imaging, will be collected through retrospective review of patient data by AC.

3. To investigate the impact of the PROSTAD pathway, for example, on cancers detected, stage of diagnoses (if available)

Patients going through diagnostic services in either the new or existing pathway, will be divided into different outcome groups, depending on the clinical outcome at diagnosis, including cancer detected, other significant diagnosis, further investigation required and discharge back to GP. These outcomes will be collected through retrospective review of patient files and service notes by AC for both the intervention and comparator groups. If possible and available, cancer stage at diagnosis will also be recorded for both groups.

4. To assess the short-term outcomes for patients

In addition to clinical outcome at diagnosis, short-term outcomes for patients will include:

- Time from referral to diagnosis obtained from patient records and service files.
- Patient quality of life/utility as assessed using the EuroQol EQ-5D-5L questionnaire routinely collected as part of the diagnostic pathway.
- Anxiety experienced as the patient goes through the pathways using the Hospital Anxiety and Depression Scale (HADS) routinely collected as part of the diagnostic pathway.
- Patient experience and satisfaction using the Wales Cancer Network Patient Experience Measure (PREM) routinely collected as part of the diagnostic pathway.

Outcomes will be collected and recorded as part of the routine service delivery to enable service evaluation and continuous improvement. Anonymised data will be shared with the Swansea University team enable the health economic service evaluation.

5. To explore the cost-consequences of the PROSTAD pathway (should data allow) in improving outcomes for people.

An economic model will be developed, to estimate the costs and consequences of the PROSTAD pathway compared to the standard pathway. We expect that a de novo model will need to be constructed. Based on data availability, an appropriate model type and structure will be developed to reflect the patient pathway, ensuring that all relevant aspects are captured (including 'downstream' consequences of initial decisions) to the point where the 'assessment' of effectiveness is agreed. Due to time and budget constraints and the novelty of the pathway, it is not likely that a full 'life-time horizon' will be considered in our model, but it will focus on the shorter-term impact of the PROSTAD pathway on cancer or other diagnoses detected, based on achieving a timelier diagnosis that would be deemed of high value to HDUHB.

The model will be informed by the implementation costs for the PROSTAD pathway, healthcare costs for both comparator pathways and outcomes collected in previous steps of the health economic service evaluation. To avoid over-complexity, aggregate costs may be

appropriate when trying to capture the overall cost associated with downstream events. Where local data sources are insufficient, unavailable or unfeasible for collection by HDUHB, the literature or UK sources will be used to identify suitable data inputs. Where this cannot be obtained, appropriate assumptions will be made in conjunction with the HDUHB project team. All inputs will be agreed prior to analysis and the sources of information will be fully referenced. A descriptive summary of the resources and costs associated with the PROSTAD pathway compared to the standard pathway will be provided. The costs of the pilot pathway and comparator will then be compared to relevant outcomes as part of a cost-consequences analysis. If data availability allows, we will also undertake an exploratory cost-utility analysis using quality-adjusted life years (QALYs) obtained from EQ-5D-5L responses.

Sensitivity analyses

Probabilistic and deterministic sensitivity analyses will be undertaken to estimate the uncertainty around results. Scenario analyses will be agreed and undertaken with the HDUHB team to address 'What If?' questions based on the impact of changing key parameters within the pathway on patient outcomes and waiting times and time within the pathway. Based on data availability, scenarios including longer-term extrapolations and agreed upon in advance with HDUHB and CRUK, may be considered.

Work package 5: Development of implementation and service guide

(Lead Dr Savita Shanbhag)

Working with SR/SF and AC, the implementation team will support the HDUHB Urology team and the Wales Cancer Network (WCN) in the development of implementation and service guides for national roll-out utilising the TIDieR framework (Hoffman et al, 2014). Information on facilitators and barriers to change, and lessons learnt, will enable other clinical teams to bring about change across the UK.

The WCN team will support the organisation of a pan-Wales workshop to support information sharing with Urology teams across Welsh health boards. To facilitate training for Urologists (from Wales and the UK) in LATP techniques, the HDUHB Urology team, working alongside WCN colleagues, will explore the feasibility of developing a training package.

The outputs of work package will be implementation and service guides for use in roll-out, and a supporting business case, which will include sustainability planning.

2.2.3 Eligibility Criteria and Subject Selection

Participants will be patients living within the HDUHB area, referred with possible prostate cancer.

2.2.4 Duration and Timescales

The service evaluation will run over 12 months, allowing a 3-month set up phase and 3-month analysis and write up phase. Based on HDUHB data, we anticipate six patients every week will need an MRI. In line with this, six dedicated MRI slots a week will be available, allowing up to 312 patients to pass through the pathway during the pilot.

2.2.5 Milestones

The figure below provides an overview of the project's core milestones. A detailed Gantt chart is available as a separate project document.

⬇ Activity / Month ➡	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Service set up	■	■	■															
Pathway running – P1				■	■	■	■	■	■	■	■	■	■	■	■			
Pathway running – P2											■	■	■	■	■			
Clinical data collection				■	■	■	■	■	■	■	■	■	■	■	■	■		
University ethics obtained								■										
Interviews								■	■	■	■	■	■	■	■			
Questionnaires								■	■	■	■	■	■	■	■			
Data analysis								■	■	■	■	■	■	■	■	■	■	
Interim reports											■							
Full review															■	■	■	■
Final reports																■	■	■
Publications										■				■				■
Dissemination event																	■	
Business case prep															■	■	■	■
Training materials prep								■	■	■	■	■	■	■	■	■	■	
Implementation review		■	■	■	■	■	■	■	■	■	■							
Service documents prep															■	■	■	■
PPI	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Project team mtgs	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Steering group mtgs									■			■			■			■

2.2.6 Data Sources

Data (as detailed in each work package) will be collected directly from patients and professionals via questionnaires and interviews. Clinical outcomes and pathway flow will be recorded from patient records and pathway management.

2.2.8 Outputs

Evaluation outputs include:

Project report capturing key TET objectives and economic evaluation based on:

- Time to diagnosis
- Cancer detected
- Other significant diagnoses
- Anxiety and depression scores
- Health-related quality of life
- Pathway costs
- Healthcare resource use between referral and diagnosis
- Patient experience and satisfaction
- Patient and clinician feedback
- Pathway specific documentation
- Training and service planning guides
- Business case for roll-out
- Implementation handbook
- Generalisable route to scale guide
- Summaries for engaging a variety of stakeholders using different media.

2.2.9 Dissemination

We will host a patient and clinician information event in partnership with WCN utilising the Urology cancer site group, to discuss and showcase the service to others. We will work with CRUK to update networks and PPI groups as appropriate. In addition, we will disseminate the outcomes through professional channels in Urology and quality/patient safety e.g. presentations at BAUS (British Association of Urological Surgeons), NHS Patient Safety Conference, International Forum on Quality and Safety, and publications in relevant journals. We will link to Bevan Commission, Life Sciences Hub Wales and Health Education and Improvement Wales to undertake preparatory work ahead of any proposed national roll-out.

Data Protection, Confidentiality and Oversight

3.1 Confidentiality

The project will be reviewed by HDUHB's Information Governance team during the set-up process to ensure that data management will be undertaken in line with local HDUHB policies and applicable national regulation e.g. GDPR. A collaboration agreement between the partner organisations will be put in place to enable anonymised data sharing. Letters of Access will be issued by HDUHB to allow access for non-HDUHB project team members, as appropriate and required. All clinical data will be stored in existing clinical databases regulated locally and nationally by Digital Health and Care Wales and monitored by HDUHB's Information Governance team. Evaluation specific data will be managed through TriTech Institute QMS in line with HDUHB's Research and Innovation procedures and shared as appropriate using the Secure File Sharing Portal.

3.2 Record Retention and Archiving

All documents relating to the evaluation will be archived in line with HDUHB archiving policies and as agreed in the collaboration agreement with Swansea University.

3.3 Oversight

Mr Yeung Ng and Mr Sohail Moosa will act as joint clinical leads to support clinical pathway implementation. Dr Rachel Gemine will act as project lead to oversee the evaluation, delegating duties to work package leads.

3.4 Reporting

The project will be monitored by the TriTech Institute and Innovation Division and reviewed at weekly meetings. The clinical project team will also meet weekly, with full evaluation team meetings (which will include CRUK representation) monthly (or more frequently as needed). Quarterly external steering group meetings will be held to monitor progress to time and target. The membership of the steering group will include the project team, key stakeholders including medical and nursing staff, service managers, Quality and Safety medical directorate representations and CRUK representatives. The steering group will receive a minimum of quarterly updates from the project team's work package leads, with each work package and its success based on individual, non-dependent, measurable outcomes, which benefit the overall project to ensure that maximum impact is generated from the project, in supporting the transition element of CRUK TET programme.

3.5 Risks and Benefits

As part of the set-up process a full risk assessment will be conducted with mitigation planning. The risk register will be reviewed by the steering group at each meeting and monitored throughout the project. It will also be linked to the service and corporate risk register as appropriate.

Infrastructure

MRI scanning time: There are four MRI scanners within the health board which can be utilised. Collectively, there is sufficient capacity but currently allocation of time slots is scattered across time and location.

Staff time: Urology, Radiology and Pathology: there is engagement across all disciplines conditional on adequate staff resourcing which mitigates against this risk. There is also sufficient cross-cover to allow for sickness and annual leave.

Staff engagement: wide consultation with staff groups around pathway issues indicates consensus around the need to redesign and implement the proposed changes. Allocation and funding of staff time is seen as a limiting step currently.

Management buy-in and continuation of service: We have discussed the project with service and directorate management who are fully supportive, and we expect continuation of funding at the end of the study.

Alignment of work packages: risk that multiple workstreams and investigators may overlap or miss important information. This will be mitigated through a comprehensive evaluation plan and regular meetings.

Patients

It is critical that the views of patients and carers are not forgotten when this work is taken forward. The West Wales Prostate Support Group, whose members' views have informed and supported the development of the project to date, will play an integral part in the project going forward to ensure continued co-production in the future.

Finance

Funding: the project is not dependent on funding for all elements to achieve results and can proceed with focus on specific areas with proportional improvement anticipated.

Risk of overspend: the budget has been costed using standard costing templates and agreed with finance in partner organisations, based on experience we anticipate this to be correct.

Benefits

This proposed pathway will improve optimal cancer pathway arrangements by shortening time to diagnosis and time to treatment of prostate cancer. This will also positively benefit people who do not have cancer as they will be reassured sooner that they do not have cancer. Patients will be kept better informed during their patient journey with timely face-to-face/ telephone contact with appropriate specialists.

References

Awsare, N., Green, J., Aldwinckle, B. et al. The measurement of psychological distress in men being investigated for the presence of prostate cancer. Prostate Cancer Prostatic Dis 11, 384–389 (2008). https://doi.org/10.1038/pcan.2008.21

Bolton EM, Kelly BD, Quinlan MR, D'Arcy FT, Azar M, Dowling CM, Power M, McCarthy P, Roche C, Walsh K, Rogers E, Durkan GC. (2014) Irish Journal of Medical Science. 183(2):173-9

Castellani, D., Pirola, G. M., Law, Y. X. T., Gubbiotti, M., Giulioni, C., Scarcella, S., ... & Rubilotta, E. (2022). Infection rate after transperineal prostate biopsy with and without prophylactic antibiotics: results from a systematic review and meta-analysis of comparative studies. The Journal of Urology, 207(1), 25-34.

Chen, KW, Pek, G, Yufei, Q, Toh, PC, Kuek, N, Lee, JKC, et al. Comparing outcomes of transperineal to transrectal prostate biopsies performed under local anaesthesia. BJUI Compass. 2022; 3(3): 197– 204. https://doi.org/10.1002/bco2.112

Dahl TL, Vedsted P, Jensen H. The effect of standardised cancer pathways on Danish cancer patients' dissatisfaction with waiting time. Dan Med J. 2017 Jan;64(1) A5322. PMID: 28007051.

Evison M, Hewitt K, Lyons J, Crosbie P, Balata H, Gee C, Duerden R, Greaves M, Sharman A, Booton R. (2020) Implementation and outcomes of the RAPID programme: Addressing the front end of the lung cancer pathway in Manchester Clinical Medicine Jul 2020, 20 (4) 401-405; DOI: 10.7861/clinmed.2019-0218

Gorin SS, Haggstrom D, Han PKJ, Fairfield KM, Krebs P, Clauser SB. Cancer Care Coordination: a Systematic Review and Meta-Analysis of Over 30 Years of Empirical Studies. Ann Behav Med. 2017 Aug;51(4):532-546. doi: 10.1007/s12160-017-9876-2. PMID: 28685390.

Grummet, J., Gorin, M.A., Popert, R. et al. "TREXIT 2020": why the time to abandon transrectal prostate biopsy starts now. Prostate Cancer Prostatic Dis 23, 62–65 (2020). https://doi.org/10.1038/s41391-020-0204-8

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... & Michie, S. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. Bmj, 348.

Hogan, D., Kanagarajah, A., Yao, H. H., Wetherell, D., Dias, B., Dundee, P., Chu, K., Zargar, H., & O'Connell, H. E. (2021). Local versus general anesthesia transperineal prostate biopsy: Tolerability, cancer detection, and complications. BJUI compass, 2(6), 428–435. https://doi.org/10.1002/bco2.106

Hopkins, C.L., Gemine, R.E., Woods, B. & Moosa, S. (2022). Acceptability of the use of AI in prostate cancer diagnosis. In preparation.

Joshi, R. (2020). Transrectal ultrasound guided prostatic biopsy and its complications: a descriptive cross-sectional study. JNMA: Journal of the Nepal Medical Association, 58(221), 44.

Kavanagh AG, Lee JC, Donnelly B. (2008) Time to treatment of prostate cancer through the Calgary Prostate Institute rapid access clinic. Canadian Journal of Urology. 15(2):3975-9

Langley, G. J., Moen, R. D., Nolan, K. M., Nolan, T. W., Norman, C. L., & Provost, L. P. (2009). The improvement guide: a practical approach to enhancing organizational performance. John Wiley & Sons.

McCombie SP, Hawks C, Emery JD, Hayne D. (2015) A 'One Stop' Prostate Clinic for rural and remote men: a report on the first 200 patients BJU International. 116 Suppl 3:11-7

Melby L, Håland E. When time matters: a qualitative study on hospital staff's strategies for meeting the target times in cancer patient pathways. BMC Health Serv Res. 2021 Mar 9;21(1):210. doi: 10.1186/s12913-021-06224-7. PMID: 33750379; PMCID: PMC7941937.

NHS England Achieving world-class cancer outcomes: Taking the strategy forward. NHS, 2016. www.england.nhs.uk/wp-content/uploads/2016/05/cancer-strategy.pdf

National Optimal Pathway https://collaborative.nhs.wales/networks/wales-cancer-network/wcn-documents/clinician-hub/csg-pathways-and-associated-documents/national-optimal-pathway-for-prostate-cancer/

NICE. https://www.nice.org.uk/guidance/ng131/chapter/recommendations#mri-and-biopsy

NICE. https://www.nice.org.uk/guidance/indevelopment/gid-dg10043/documents

Pawson, R., & Tilley, N. (1997). An introduction to scientific realist evaluation. In E. Chelimsky & W. R. Shadish (Eds.), Evaluation for the 21st century: A handbook (pp. 405–418). Sage Publications, Inc. https://doi.org/10.4135/9781483348896.n29

Prostate Cancer UK. https://prostatecanceruk.org/media/jobjikpi/mpmri-imaging-guidance-document-final.pdf

Roberts, M.J., Macdonald, A., Ranasinghe, S. et al. Transrectal versus transperineal prostate biopsy under intravenous anaesthesia: a clinical, microbiological and cost analysis of 2048 cases over 11 years at a tertiary institution. Prostate Cancer Prostatic Dis 24, 169–176 (2021). https://doi.org/10.1038/s41391-020-0263-x

Sewell, B., Jones, M., Gray, H., Wilkes, H., Lloyd-Bennett, C., Beddow, K., ... & Fitzsimmons, D. (2020). Rapid cancer diagnosis for patients with vague symptoms: a cost-effectiveness study. British Journal of General Practice, 70(692), e186-e192.

Solbjør M, Sand K, Ervik B, Melby L. Patient experiences of waiting times in standardised cancer patient pathways in Norway - a qualitative interview study. BMC Health Serv Res. 2021 Jul 5;21(1):651. doi: 10.1186/s12913-021-06679-8. PMID: 34225705; PMCID: PMC8256611.

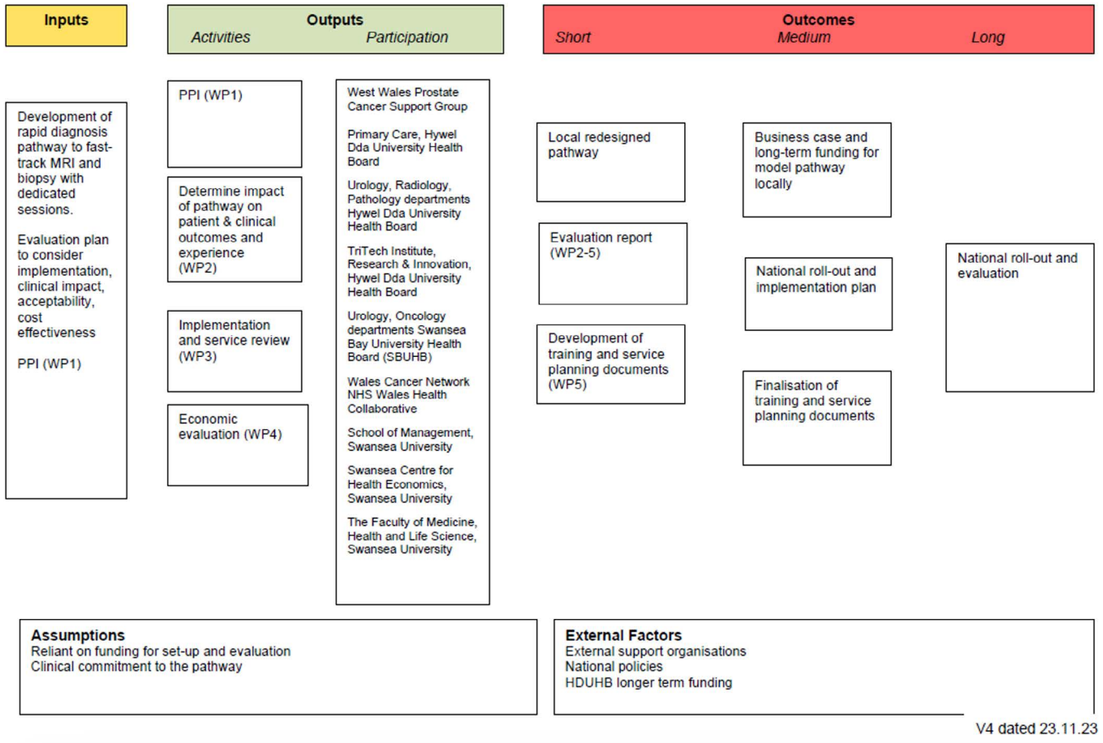
Sundi D, Cohen JE, Cole AP, Neuman BP, Cooper J, Faisal FA, Ross AE, Schaeffer EM. (2015) Establishment of a new prostate cancer multidisciplinary clinic: Format and initial experience. Prostate. 75(2):191-9 Audit of rapid access introduction reveals high prevalence of prostate cancer in Western Region.

Van Booven, D. J., Kucha Ulla, M., Pai, R., Frech, F. S., Ramasahayam, R., Reddy, P., ... & Arora, H. (2021). A systematic review of artificial intelligence in prostate cancer. Research and reports in Urology, 13, 31.

Welsh Government, 2022. https://gov.wales/suspected-cancer-pathway-waiting-times-interactive-dashboard

Appendix 1a
Logic Model

Developing a Model Prostate Cancer Pathway



Appendix 2
Rapid Realist Review

KJ, AC, JR conducted a rapid realist review of RDPs for PCa to generate initial programme theories; the questions and concepts which informed this review were developed with PPI.

Scoping the literature

We began the iterative process of reviewing and synthesizing the literature to generate theories as to how the new rapid diagnosis pathway might work, for whom and under which circumstances. As this synthesis is in the service of a realist evaluation of a real-world PCa RDP, we began by identifying normative programme theories derived from:

- Informal literature searches
- Analysis of the differences between PROSTAD PCa RDP and the Conventional Pathway.
- Information provided by those who developed the PROSTAD pathway.

Scoping Review: RDP Search 1:

We focused on “one-stop” and rapid pathways for the initial scoping review. Our scoping review – RDP Search 1 – started with an exploration of “barriers” or “facilitators” to the use of one-stop clinics on cancer diagnostic pathways. We used MeSH Terms to identify terms akin to “diagnostic pathway” and searched PubMed and Embase.

RDP Search 2

Having generated key concepts, we narrowed our field of interest to only include articles focusing on prostate cancer diagnosis, however we broadened our search by searching additional databases and forgoing the implementation-oriented terms. As well as developing new theories, we used our initial programme theories developed through scoping to guide and inform data extraction.

RDP Searches 1 and 2: Selection and Appraisal of Documents

Realist evaluation recognises the value of various types of sources and does not necessarily instate a hierarchy of evidence types – RCTs might be very useful for understanding if something works based on a series of pre-emptive (researcher-decided) parameters, but qualitative research might better inform how or for whom an intervention works or fails to work based on potentially unexpected factors. Realist evaluation also values atypical, non-peer reviewed grey literature, which can also inform theory development. For this reason, we adopted the following appraisal criteria, which has been used by others in realist evaluation (Dugle et al., 2020):

‘Does the research address the theory under test?’

‘Is this study good enough to provide some evidence that will contribute to the synthesis?’

Data Extraction

We used Covidence software to manage the review and developed tables into which we extracted data that responded to any component of the question how, for whom and under which circumstances do RDPs work or fail to work. Our first iteration extracted all results/ findings, before two researchers independently identified contexts, mechanisms or outcomes. The researchers collaborated and checked for correspondence (KJ & AC).

Analysis and synthesis processes

Realist evaluation views an intervention as a theory, and therefore our analysis and synthesis aims to discern the concepts and beliefs underpinning the intervention (Rycroft-Malone et al., 2012). We iteratively developed theories through knowledge of the PROSTAD pathway, conversations with key stakeholders, and our initial scoping searches. When analysing the data, two reviewers separately reviewed extracted data, identifying themes and concepts to inform theory generation.

Data Collection

We use interviews and pathway documentation to refine initial theories. The collection processes are described below.

Pathway Documentation Data

We attended monthly programme development meetings, where the pathway (including challenges to implementation and changes to the pathway as originally conceived) was discussed alongside evaluation. Notes were taken by a researcher (KJ) by hand; the accuracy of these notes were verified through conversations with the programme lead and against available documentation – e.g. original project funding bids.

We also use literature related to the development of the pathway (e.g. bid applications composed during the development phase) to inform our understanding of how PROSTAD is intended to work, as well as to document any changes to the pathway during the implementation process.

Results

Rapid Realist Review: Findings

Scoping Review: RDP Search 1

See Appendix 2a. Scoping PRISMA & Appendix 2b. Document Characteristics

We developed six CMO chains based on the literature searches; insights from the PPI group, information gathered from management meetings discussing a PCa RDP, and available guidelines and recommendations (e.g. NICE) also informed our understanding and interpretation of the literature. Some of these CMOs are contradictory, indicating how the same intervention may be interpreted or interacted with differently by different stakeholders or in response to different contextual factors.

RDP Search 2,

See Appendix 2c. RDP Search PRISMA

There are a number of approaches to PCa rapid diagnosis pathways. These include "one-stop" approaches (McCrombie et al., 2015; Tafuri et al., 2020; Hawks et al., 2021; Withington et al., 2021; Eldred-Evans et al., 2023), which generally aim toward MRI scan and results provided on the same day and potentially offering a biopsy that day, if necessary. Most of the one-stop clinics identified through this review incorporate a transrectal (TRUS) biopsy (where necessary); one incorporated a transperineal (TRANS) biopsy/ LATP (Eldred-Evans et al., 2023). Some pathways and centres do not include an MRI, instead taking a digital rectal examination (DRE) and TRUS biopsy (Forde et al., 2011; Oon et al., 2014; Shah et al., 2016; Withington et al., 2021).

We derived eight programme theories from our rapid synthesis. These are divided into the following interlinking themes; the number of papers with relevant findings is indicated in brackets: Primary Care (5); Organizational Factors (9); Patient Experience (9). The results of RDP Search 1 also inform our programme theories outlines below.

Primary Care 1: Referral Norms and Practices

If primary care constitutes the gateway to diagnostic pathways and health services are over-stretched (C), then a tendency to "protect" secondary services combined with a distrust of PSA testing (M), may lead to delayed referrals and patient frustration, particularly for those found to have PCa (O).

The referral process from primary care into a rapid diagnosis pathway constitutes a contextual factor in a number of articles, some of which identify "gatekeeping" tendencies (Emery et al., 2013; Shah et al., 2016; Harrison et al., 2019; Solbjør et al., 2021). While beyond the scope of this review, the prevalence of references to PSA testing in the articles selected for this review is striking: one Irish study noted that wider PSA testing may account for an increase in referrals and speculated this may be the reason for seeing patients at an earlier disease stage (Oon et al., 2014). Authors of a pilot-study in the UK remarked that they were 'disappointed' in the number of patients referred to their PCa RDC based on a PSA test performed with an active urinary tract infection; while the authors don't elaborate this suggests a potential for over-referral and unsuitability for the same-day biopsy provided by the RDC in question (Shah et al., 2016). The GPs interviewed in a qualitative study tended towards scepticism with regard to PSA testing (Merriel et al., 2022), suggesting a potential mechanism for delays to referral. While the scope of an RDC or RDP tends to exclude primary care, this finding does suggest considerable merit in collaborating with GPs with regards to referral norms.

Primary Care 2: Timely Referral and Access to Secondary Care

If primary care is the gateway to diagnostic services in the context of an overstretched NHS system with long waiting lists (C), a PCa-specific pathway may be perceived as more "welcoming" than a general Radiology referral (M), leading to a reduction in delays to referral (O); though, conversely, potentially also leading to "over" referral or overwhelming of the service (O).

Cancer-specific rapid diagnosis pathways may improve accessibility to PCa diagnostic pathways. In Merriel et al., 2022, GPs were more positive about the use of MRI scanning for PCa diagnosis, comparing this approach to diagnosis positively in relation to PSA testing. There is also evidence to suggest that the presence of rapid diagnosis pathways improved primary care access to secondary PCa diagnostic services (Oon et al., 2014; Shah et al., 2016). In a questionnaire with a very small sample (n=10), GPs rated the rapid diagnosis pathway a 7/10 for accessibility and in free-text comments expressed a need for more "one-stop" slots each week (Shah et al., 2016). While we note the above-mentioned preference among GPs for MRI scanning for PCa diagnosis when compared to PSA testing, no papers identified in this search explicitly explored how or why perceptions of accessibility may be impacted by rapid diagnosis pathways. We hypothesize that the implementation of a rapid diagnosis pathways for PCa and the associated engagement with primary care this involves, may engender a perception of this pathway as more "welcoming" or bespoke and so referral to this service may be more forthcoming when compared to a general referral to Radiology. This may lead to earlier diagnosis of PCa (Shah et al., 2016), however it may also lead to overwhelming of the service. Health professionals working on a PCa RDP in Ireland described reviewing the same patients a number of times, which was not the original intention of the service, suggesting the way contextual pressures may impinge upon or stretch the service's scope (Broe et al., 2018).

Organisational Factors 1: Staff Experience and Workload

If health care services are seen to be stretched as service capacity does not increase relative to patient need, with many staff vacancies and burnout common (C), then decreasing the number of steps in a PCa pathway and sooner patient discharge may decrease workload for some staff (M) and in turn lead to increased staff satisfaction and enthusiasm (O).

Conversely, changing procedures to accelerate some processes may feel like additional workload (M) leading to the staff responsible for producing MRI reports, results and other service-related tasks feeling more stressed or lose enthusiasm for the new pathway (O).

The main aim of rapid diagnostic centres is to perform and produce results of diagnostic tests within a shorter time frame than conventional pathways. This has been shown to result in sooner diagnosis or discharge for patients (Tafuri et al., 2020; Hawks et al., 2021; Eldred-Evans et al., 2023). Our first theory is that this may produce greater satisfaction in staff who, in the course of potentially as little as 24 hours, can see a patient through from suspicion of PCa, to discharge or referral to treatment, offering the possibility of greater continuity and engagement with the patient (Shah 2016).

However, our second theory highlights potential challenges, which may be more prominent in the piloting or implementation stages which may be determining stages for the success or acceptance of a service change. Radiologists are required to adapt and distinguish scans produced as part of a rapid pathway from other scans, which may add confusion to working practices, especially at the beginning (Tafuri et al., 2020; Allgood et al., 2021). One article described the challenges faced by urologists and Urology surgeons prior to the

introduction of a rapid access prostate clinic, noting that the introduction of the clinic then added to this workload in a service already struggling to meet patient needs according to guidelines and recommendations set out by the Association of Urological Surgeons (Broe et al., 2018). The introduction of a new pathway (particularly in instances where the piloting takes place concurrently with the conventional pathway) may lead to increased stress for staff, which in turn may result in reduced enthusiasm and / or "buy-in".

Organisational Factors 2: Impact on Adjoining Services

If health care services are seen to be stretched as service capacity does not increase relative to patient need with many staff vacancies and burnout common (C), then changes to services that may increase referrals for treatment or require changes to working practice (M) may lead to increased demand in at-capacity services and / or conflict over resources (O).

This theory highlights the impact service change in one area may have elsewhere. The introduction of a PCa rapid access clinic in Ireland led to a sudden increase in surgical workload, which later plateaued (Oon et al., 2014). A single surgeon-led service provided consistency for a rapid diagnostic service in the UK, but fluctuations in Histopathology staff created less certainty regarding the time frame for producing and sharing results (Shah et al., 2016).

There's some evidence that PCa presentations increased after the introduction of a PCa rapid diagnosis pathway, though it is unclear whether is due to a greater number of referrals to the pathway or a general population trend that coincided with its introduction (Oon et al., 2014). While the diagnosis of a greater number of people with PCa constitutes a success in terms of identifying PCa cases in the community, if adjacent services are unprepared for a greater number of referrals, then delays may simply be displaced to treatment, as opposed to diagnosis. There's also potential for conflict as finite and potentially over-stretched resources, such as MRI equipment and appropriately trained staff, are reserved for PCa services, potentially leading to staff challenging resource use (Withington et al, 2021). Further, other specialties also rely on the use of this equipment and expertise, and so conflict may arise as patients undergoing MRI scans for other purposes may be negatively impacted (Brice et al., 2021).

Organisational Factors 3: Costs, Efficiency and Value

If health care services are politicised and viewed as overburdened / cost inefficient with near-constant pressure to improve services and reduce expenditure (C), then the reduced pathway steps and greater continuity of care may reduce costs and increase efficiencies (M), leading to a greater likelihood of sustained investment and broader organisational (e.g. managerial) buy-in (O).

With staff and organizational buy-in (M), rapid diagnostic pathways are more likely to produce the intended outcomes of reduced costs and increased efficiency (O).

One normative programme theory underpinning PROSTAD (and many RDPs generally) is that fewer steps in a pathway will enhance efficiency and reduce chances for confusion in a complex and busy system. In turn, this is expected to minimize chances of patients getting "lost in the system" – particularly between procedures, such as MRI scans and biopsy (Tafuri et al., 2020). Generally, the rapid pathways for suspected PCa patients produced the intended outcomes in the papers identified in this review, namely cost-effectiveness and a more efficient pathway with fewer steps and quicker discharge for patients without PCa (Shah et al., 2016; Hawks et al., 2021; Eldred-Evans et al., 2023). While challenges to implementation can be expected, organizational buy-in can help smooth the path to successful piloting and embedding a service change. In this programme theory, we posit that should a rapid diagnosis pathway demonstrate some of the intended affects organizational buy-in may be more likely and allow for the service's sustainability post-piloting. In a circular fashion, we also suggest that greater organizational buy-in and support may increase the likelihood of rapid pathways producing these intended effects.

Patient Experience 1: Communication and Differing Experiences

If "Cancer" constitutes a frightening word that potentially engenders an existential confrontation with mortality (C), then a pathway with fewer steps (e.g. phone call consultations, rather than in-person) and materials that assuage anxiety (M) will lead to relief and reassurance, minimizing the amount of time spent in an anxious waiting phase for cancer-free patients (O).

Conversely, patients who receive a PCa diagnosis will have undergone diagnostic tests and received a worrisome result in a short period (M) potentially leading to greater shock, poor absorption of information and diminished decision-making capabilities (O).

Telephone and virtual consultations are viewed as convenient and cost-efficient ways to deliver results (Shah et al., 2016; Hawks et al., 2021). A UK-based clinic provided biopsy results by phone to cancer-free patients and in-person clinics to those with a PCa diagnosis; this was seen as convenient by staff and patients (Shah et al., 2016). In one PCa RDC, a nurse provided biopsy results by telephone, which the majority of patients (71% of 132) accepted, identifying no disadvantages (Hawks et al., 2021). Patients for whom this approach did not work well were those receiving a PCa diagnosis or with unclear results. This group of patients felt that the nurse delivering the results had limited information, reporting feeling overwhelmed and describing an anxious period of waiting for a consultation with the Urology consultant after receiving the results from the nurse (Hawks et al., 2021). Patients receiving a PCa diagnosis generally appreciated direct communication, but also require time to ask questions; where such opportunities for clarification are absent, some patients felt dissatisfied or dismissed (Netsey-Afedo et al., 2020). Some of those who received a PCa diagnosis described not feeling prepared by the literature they were given; efforts to minimize panic or distress for the majority of rapid diagnosis pathway patients who will not have PCa may inadequately prepare those who do, resulting in a greater degree of shock (Merriel et al., 2022; Solbjør et al., 2021). These points inform our programme theories which emphasize the differing experience of RDCs depending on outcome.

Patient Experience 2: Rapidity and Anxiety

If "Cancer" constitutes a frightening disease and is a word that potentially engenders a confrontation with mortality (C), then patients who receive the all-clear (M) may experience reduced anxiety or a shorter anxious period (O)

Conversely, patients may experience the speed as disorientating, related to severity (even in cases where they receive the all-clear) and sudden with less time to digest important information (M), which may lead to longer lasting psychological symptoms (e.g. anxiety or depression) in the case of those receiving a PCa diagnosis and/ or diminished decision-making abilities (O).

Cancer is a frightening disease that elicits understandable and unavoidable anxiety in patients who are referred to any PCa diagnostic pathway. In a survey of 136 patients referred to a PCa RDC, 96% rated their experience as 'good' or 'very good', with 57% reporting that they received their results faster than expected (Eldred-Evans et al., 2023). Patients referred to a rapid diagnosis pathway who receive an "all-clear", and who also constitute the majority of patients, experience reduced anxiety earlier than those on a traditional pathway due to the earlier receipt of results (Brocken et al., 2011). A randomized control trial echoes these findings, suggesting that patients' self-reported sleep quality and depressive symptoms diminished soon after receiving results indicating they are cancer-free from a PCa RDC / rapid diagnosis pathway (Zhu et al., 2022).

However, there is some evidence that patients referred to a PCa rapid diagnosis pathway may experience the speediness of the pathway as concerning as they misinterpret the speed as a sign that they have been expedited due to potential seriousness (Brocken et al., 2011; Netsey-Afedo et al., 2020; Solbjør et al., 2021). Further, 8% of patients who were recommended for a biopsy at a one-stop PCa diagnostic centre refused this procedure (Lopez et al., 2023; Eldred-Evans et al., 2023); while the reasons for this were not known, it is a concerning finding. Here we posit that speed of results may put additional pressure on patients to process information and make decisions quickly. Patients

are required to make important decisions such as consenting to biopsy or regarding receipt of results (e.g. by phone or in person where choice is given). In cases where further investigations are required, the process of booking, scheduling and making arrangements within a rapid timeframe may prove challenging for the patient under stressful circumstances.

It seems intuitive that patients receiving a cancer diagnosis will have a different experience of rapid diagnosis pathways and mechanisms for sharing bad news compared to patients found to be cancer-free. What may be more surprising is evidence to suggest that patients receiving a PCa diagnosis via an RDC / rapid diagnosis pathways were more likely to experience depression for longer post-diagnosis when compared with patients who received a PCa diagnosis on a traditional diagnostic pathway (Brocken et al., 2011). While in Brocken et al's systematic review this finding was unexplained, Groarke et al., suggest that perceived stress levels (based on general lifestyle factors) can be used to predict the emotional impact of referral to a PCa diagnostic pathway and men's ability to cope with waiting for biopsy results and the result itself (Groarke et al., 2018); the same paper suggests offering counselling services to patients with suspected PCa (Groarke et al., 2018).

Patient Experience 3: Convenience

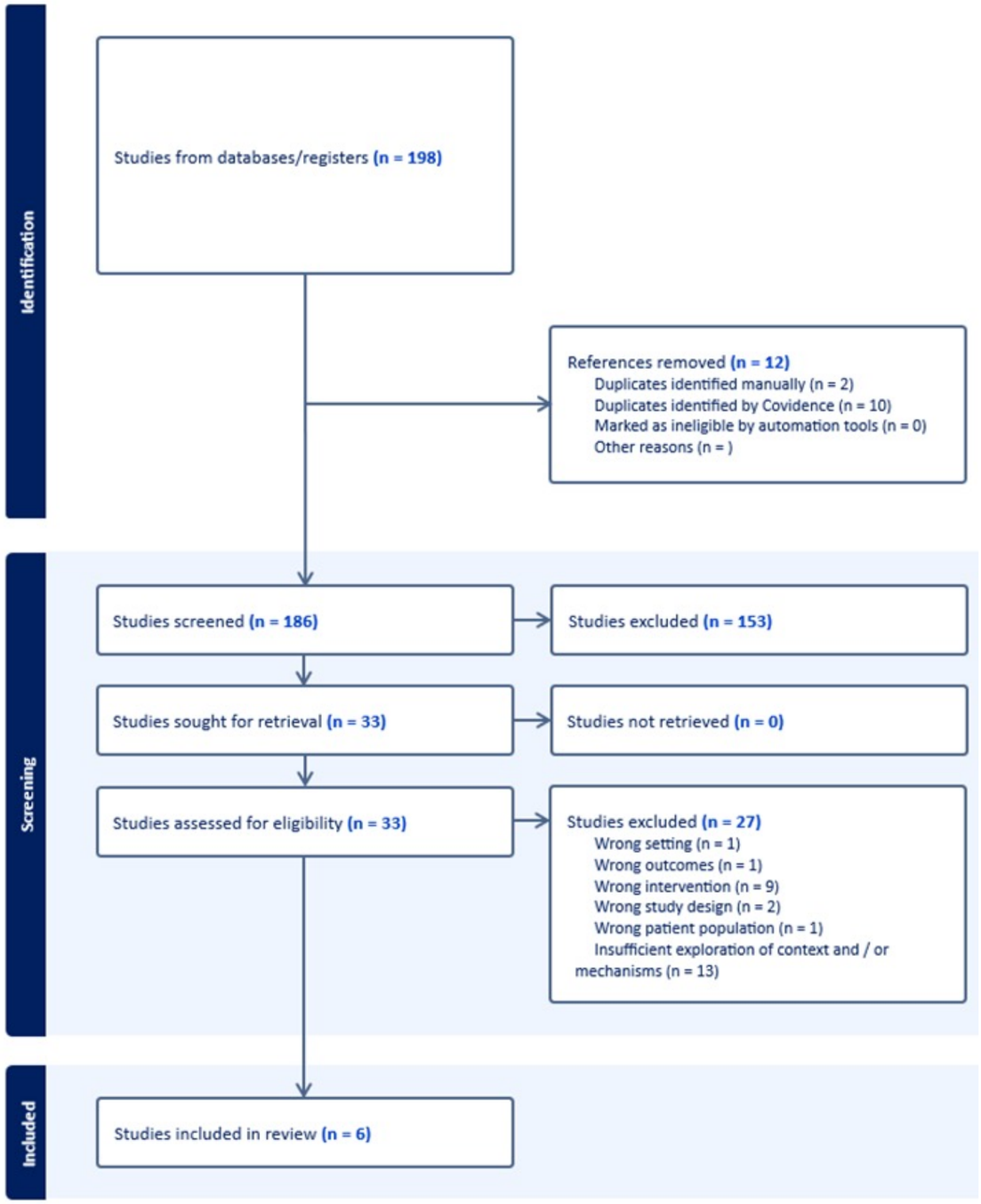
If a PCa rapid pathway is implemented in a remote area (C), then patients may find it more convenient due to the fewer hospital appointments required (M) leading to greater engagement with the service (O).

RDCs (or similar) that aim to perform multiple diagnostic tests in one visit are seen as more convenient for patients, particularly those living in rural areas (McCrombie et al., 2016; Hawks et al., 2023). Fewer appointments may be achieved by providing results virtually or a "one-stop" clinic. Using virtual or phone consultations is largely viewed positively, and we have already described some of the potential disadvantages above (Shah et al., 2016; Hawks et al., 2021). As noted above, the "one-stop" approach may also negatively impact engagement with RDCs or similar services as patients may be unprepared for further investigations, such as post-MRI biopsy (Eldred-Evans et al., 2023; Lopez et al., 2023). Nonetheless, overall speed and convenience were treated as positive indications in the articles identified in this synthesis, accounting for this programme theory.

Summary of Realist Review Findings

It is clear that there are a number of approaches to, and growing interest in, RDPs / RDCs for various cancers and that, broadly, they deliver their objective of speeding up time to diagnosis (Dolly et al., 2021). It's also clear that there are a range of approaches to PCa RDPs and, while there may be key differences, RDPs face similar challenges upon implementation. This review identifies three broad themes of the literature, namely: primary care; organizational factors; patient experience. The theories generated here align with research that recognizes the complicated nature of change in an interconnected health system. The 'primary care' and 'organisational factors' themes underline the myriad ways in which pathway change is in part dependent on adjoining pathways and specialisms.

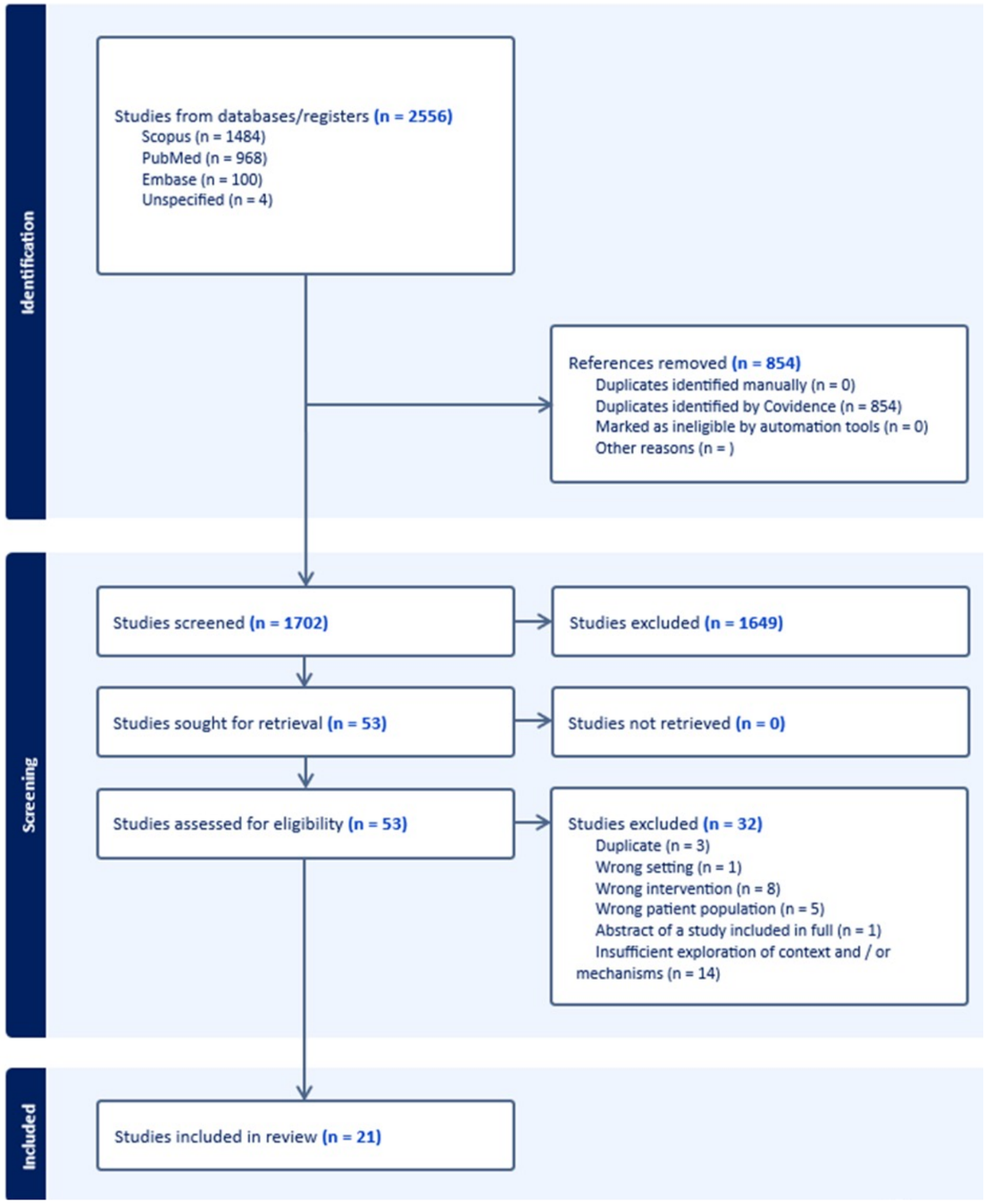
Appendix 2a
Scoping PRISMA



Appendix 2b
Scoping Review Document Characteristics

First Author	Year	Title	Type of Study	Rapid diagnosis pathway Type
Withington	2021	Putting clinical assessment and patient experience at the centre of prostate cancer diagnostics: The superior prostate experience and efficient diagnos-tics (SPEED) pathway	Non-randomised experimental study	Prostate Cancer - 1 with "straight to MRI" approach; the other without.
Spiegler	2013	The effect of the national lung cancer awareness campaign on referrals to the rapid access lung clinic	Prevalence Study	Rapid Access Lung Cancer Diagnosis
Sewell	2020	Rapid cancer diagnosis for patients with vague symptoms	Cost-effectiveness study	RDC for vague symp-toms
Merriel	2022	Experiences of 'traditional' and 'one-stop' MRI-based prostate cancer diag-nostic pathways in England: A qualita-tive study with patients and GPs	Qualitative	Prostate Cancer – "one Stop" diagnos-tic centre
Harrison	2019	Transforming cancer outcomes in Eng-land: earlier and faster diagnoses, pathways to success, and empowering alliances	Review	Multiple cancer Rap-id diagnostic cen-tres/ pathways
Brice & Harper	2021	Factors influencing the delivery of can-cer pathways: a summary of the litera-ture	Systematic Review	Multiple cancer di-agnostic centres/ pathways

Appendix 2c
RDP Search PRISMA



Appendix 3
Patient Participant Demographics

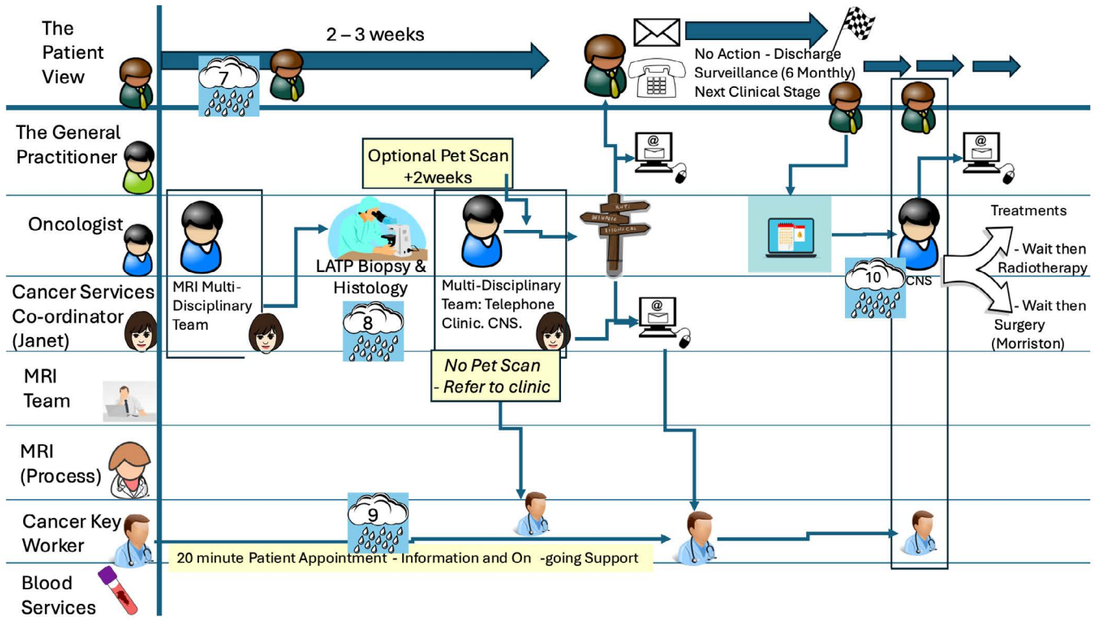
Participant Reference	Age	Marital Status	Date of Referral to the Pathway	Date of Interview
P1	67	Single/ lives alone	8.11.23	27.2.24
P2	63	Not known / Not provided	28.11.23	27.2.24
P3	54	Married	16.11.23	28.2.24
P4 Wife/ carer	not known/ not provided	Not known / Not provided	not known/ not provided	28.2.24
P5	67	Married	08.11.2024	28.2.24
P6	77	not known; lives with son	17.11.2024	28.2.24
P7 - partner/ carer	62	Married	8.11.2024	29.2.24
P8	77	Married	31.10.2024	29.2.24
P9	56	Married	29.11.2023	2.3.34
P10	69	Divorced	30.10.2023	4.3.24
P11	62	Married	27.10.2023	4.3.24
P12	49	Married	01/12//2023	9.4.24
P13	63	Married	20/10/2023	12.4.24
P14	63	Divorced	16/10/2023	30.4.24
P15	80	Widowed	08.03.2024	22.5.24
P16	59	divorced	26.10.2023	4.6.24
P17	59	engaged	17.10.2023	4.6.24
P18 - part-ner/carer	60	divorced	not known/ not provided	4.6.24

Appendix 4
Logic Model: PROSTAD as initially conceived

Context	Inputs	Outputs	Short-Term Outcomes	Longer-Term Outcomes
Delays to MRI scans and re-sults, caused by: Radiology referrals "bouncing back" to GP due to unful-filled referral criteria Radiology reporting (due to re-sources and efficiency issues) Rural and older population. Positive experiences in pathway reform for lung and breast cancer diagnosis	Evidence and guidelines, e.g. NICE, evi-dence relating to efficacy of multi-parametric MRI scanning, evidence suggesting reduced risk of infection for LATP biopsies compared to TRUS. Process mapping, including: • Formal & informal conversations between Urology, general practitioners, Radiology and service improvement leads; SBUHB & HDdUHB • MSc dissertations on following topics: 1. PCa diagnosis delays (e.g. bottlenecks in process); 2. Role of patient navigators; 3. Patient experience of RDPs. LATP Training for staff	Workforce trained in LATP biopsies. Redesigned PCa diag-nostic pathway, PROS-TAD: • Refined and mutually agreed referral processes; • 8 dedicated MRI slots at two locations (Bronglais & Withybush) • Multiparametric MRI scanning; • MRI results within 48 hours of scan; • LATP biopsy same day as MRI results if appropriate Routine adoption of gold standard diagnostics of multiparametric MRI and local anaesthetic transperineal biopsy (LATP) into the diagnostic pathway. Training and pathway documentation to aid role out across Wales and the UK	Improving patient communication, experience, and outcomes during and beyond their time on the pathway Reduced time to PCa diagnosis or discharge for patients referred to PROSTAD compared to conventional pathway. Improved efficiency, e.g. fewer referrals "bouncing back" Fewer complications and infections at biopsy stage	Better outcomes for patients receiving a PCa diagnosis. Improved integration between health boards (SBUHB & HDdUHB) Cost benefit of fewer infections/ hospital stays at biopsy stage

Appendix 5
Rain clouds identified in Loops 3 & 4

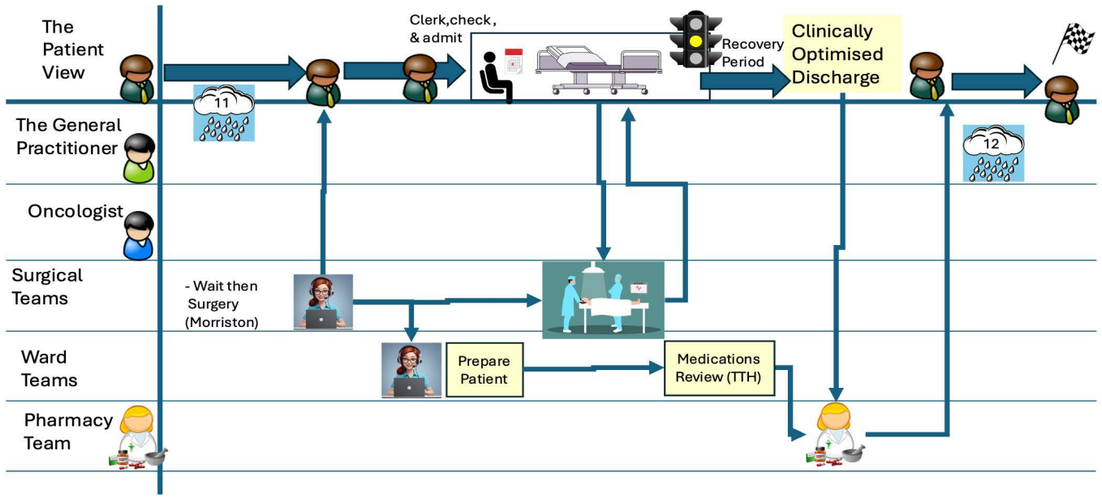
Loop 3 from Biopsy to Treatment Decision



The potentials for improvement in loop 3 include:

1. Greater understanding of the process of LATP and how results can be communicated more quickly as well as constraints that the team face (this could be numbers of staff, technology, and any other factor that would improve the speed of information to improve the speed of patient flow. Patient availability for biopsy and skills available (including holiday cover) will be important parts of the planning and service delivery process here.
2. The ongoing role of the case worker and what information is delivered and at what time in the journal (as well as numbers of interactions with patients) along the journey should be collected and reviewed in terms of information that can be provided of 'self-served' via an online portal or YouTube channel for prostate pathway males.
3. The decision on what route to follow (surgical intervention or radiotherapy) will incur time delays and this adds to the lead time for the next stages in the process.

Loop 4 from Treatment Decision to Post Surgery (Out of Scope)



Loop four is technically outside of the scope of the project but is part of the patient's journey. This part is similar to others and information is key to flow. The updating of the patient/primary care is critical to a good overall experience for the pathway (as opposed to good experiences at each previous stage – the patient only remembers everything that happened rather than the steps in the journey.

4. Updating for the GP/patient and potentially the General Practice Nurse on the process and timings would be beneficial and pick up on any issues priori to committing assets and staff for surgery.

5. Closing down the pathway and placing the patient into surveillance mode is important and could trigger feedback for Patient Reported Experience Measures of the PROSTAD system.

The research did not permit the review of the prostate system prior to PROSTAD nor were group meetings held to establish the 'gold standard' and ideal swim lane (where there are no constraints, and all IT systems seamlessly interact etc.). However, notwithstanding this drawback, the other work packages have collected actual and synthetic times and flows for these pre-PROSTAD and post-PROSTAD conditions. The cycle times and deviations reinforce what was detected in this work package event though both were conducted separately.

Appendix 6
Health Economic Analysis Full Report

SCHE Swansea Centre for Health Economics

Research led, Analysis Driven, Real World Perspective

HEALTH ECONOMIC REPORT

Study Title

Development of a Model Prostate Cancer Diagnostic Pathway (PROSTAD)

Version 1.4. Dated: 01 October 2024

Authors: Jones M, Sewell B, Davies M, Erdem E and Fitzsimmons D

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List of Abbreviations

Abbreviation	Full term
CE	Cost-effectiveness
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness acceptability curve
CI	Confidence interval
CUA	Cost-utility analysis
GP	General Practitioner
HDdUHB	Hywel-Dda University Health Board
HEAP	Health economic analysis plan
ICER	Incremental cost-effectiveness ratio
LATP biopsy	local anaesthetic transperineal prostate biopsy
MDT	Multidisciplinary team
bpMRI	Bi-parametric magnetic resonance imaging
mpMRI	Multi-parametric magnetic resonance imaging
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMB	Net monetary benefit
PSA	Probabilistic sensitivity analysis
QALY	Quality-adjusted life-year
SA	Sensitivity analysis
SCHE	Swansea Centre for Health Economics
TRUS	Transrectal ultrasound scan
UK	United Kingdom

PROSTAD pathway evaluation - Health Economic Report

1. Introduction

This section reports on Work Package 4 of the PROSTAD evaluation and describes the health economic component of the evaluation. The health economic evaluation was undertaken with regard to current recommendations for evaluating cost-effectiveness of health technologies within a UK NHS context (NICE, 2023; NICE 2024). A health economics analysis plan (HEAP; version 1.2, dated June 2024) was written as a supplement to the study protocol (version 0.3, dated 23/11/2023) and signed off by the study team prior to analysis. The HEAP was followed without deviation. The health economic evaluation is reported using key sections of the Consolidated Health Economic Evaluation Reporting Standards 2022 checklist (Husereau et al. 2022).

2. Methods of the health economic evaluation

2.1. Aim and objectives

The aim of the health economic evaluation was to assess the costs and consequences of the PROSTAD pathway for men with suspicion of prostate cancer compared to Standard care.

The economic evaluation considered resource use and cost differences between the pilot pathway and current pathway and patient outcomes (using data obtained from pathway records and relevant literature) as part of a cost-consequences analysis. Specific objectives of the health economic evaluation were to:

- Map out the PROSTAD pathway.
- Understand the impact of the service when compared to 'standard clinical practice' (i.e., with no PROSTAD pathway) on key descriptives such as referral patterns and time to event across the diagnosis pathway.
- Identify key resource drivers and costs associated with the PROSTAD pathway service and subsequent impact on other NHS resources.
- Investigate the impact of the PROSTAD pathway on for example, cancers detected, stage of diagnosis (if available).
- Assess short-term outcomes for patients (up to diagnosis) and to explore the cost-effectiveness of the PROSTAD pathway.
- Estimate the budget impact of the PROSTAD pathway on NHS Wales in case of a national roll-out.

Table 1 summarises the PICO that guided the health economic evaluation.

Table 1. PICO (Population, Intervention, Comparator, Outcomes) framework of the health economic evaluation alongside the PROSTAD pathway in HDdUHB.

2.2. Description of Control and Intervention Pathway

The control group of the health economic evaluation included patients who received Standard care, i.e. who went through the current standard prostate cancer pathway at Hywel Dda University Health Board (HDdUHB) (see Figure 1) between June 2023 and April 2024. Per pathway description (see Figure 1), patients received a bi-parametric magnetic resonance imaging (bpMRI) followed up by a multidisciplinary team (MDT) meeting and transrectal ultrasound-guided (TRUS) biopsy, if required. The intervention (PROSTAD pathway) involved the introduction of dedicated multi-parametric magnetic resonance imaging (mpMRI) slots with next day reporting and follow-up appointment with a consultant urologist. A local anaesthetic transperineal prostate (LATP) biopsy appointment with specialist nurse support was supposed to follow if required (see Figure 2). Patients were supported through both pathways by a dedicated pathway navigator who arranged patient appointments. Selection of pathways for each patient was undertaken by the clinical team and reflects a real-world setting without manipulation of selection or adjustments by the evaluation team.

Table 1. PICO (Population, Intervention, Comparator, Outcomes) framework of the health economic evaluation alongside the PROSTAD pathway in HDdUHB.

Population	Intervention	Comparison	Outcomes
Men with suspicion of prostate cancer referred by their GP or consultant to the prostate cancer diagnosis services No subgroups will be analysed	PROSTAD – New Model Prostate Cancer Diagnostic Pathway	Standard pathway (Standard care)	Time to diagnosis Cancers detected Other significant diagnoses Health-related quality of life Pathway costs Healthcare resource use between referral and diagnosis Patient experience and satisfaction (analysed separately if available)

Figure 1: Standard HDdUHB prostate pathway (Standard care/control)

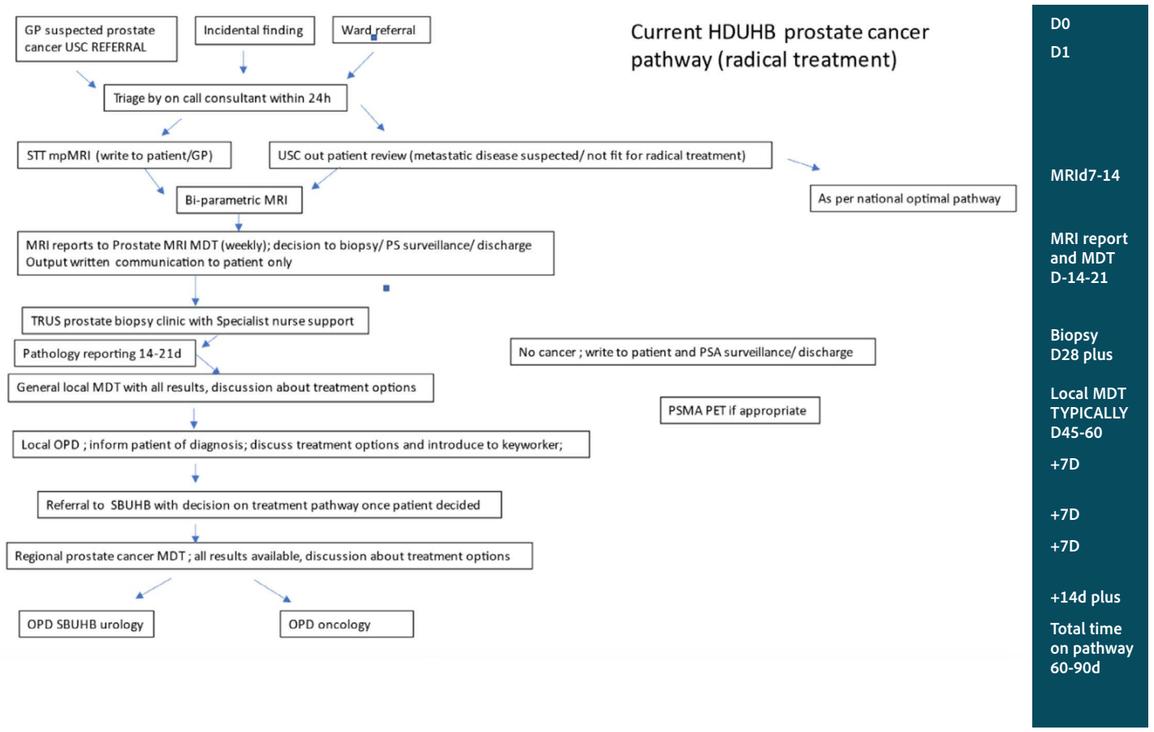
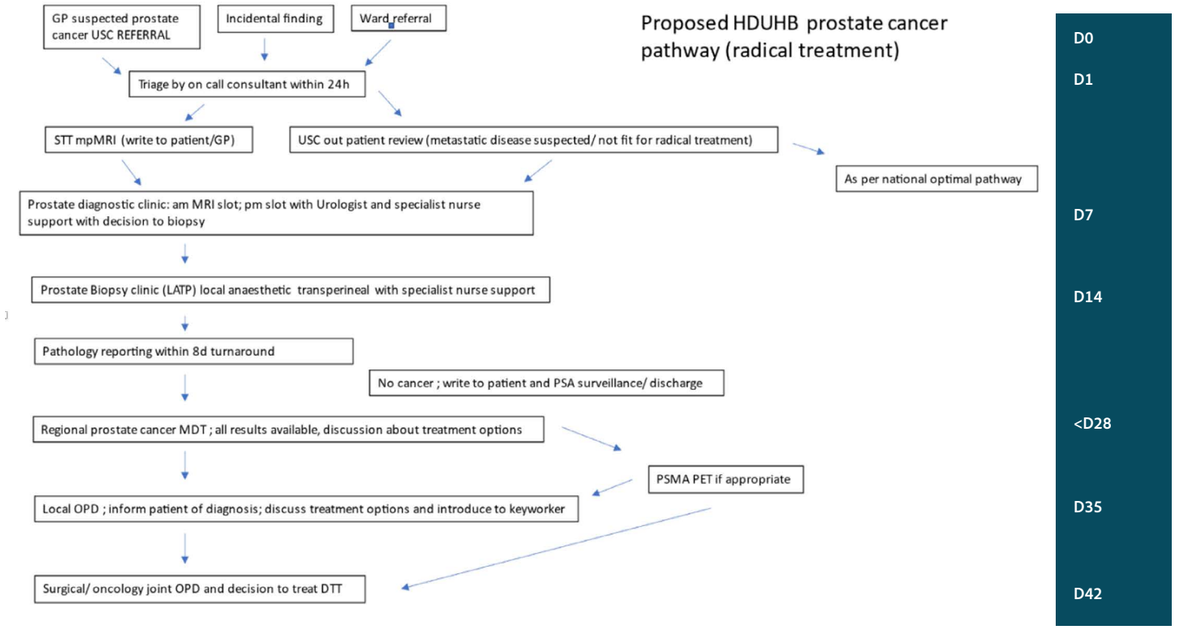


Figure 2: New model prostate cancer pathway (PROSTAD) (Intervention).



2.3. Evaluation Setting and Perspective

The evaluation followed the pilot service of the newly established PROSTAD pathway for men with suspicion of prostate cancer in HDdUHB, Wales, United Kingdom (UK). A UK National Health Service (NHS) perspective was adopted, in line with National Institute for Health and Care Excellence (NICE) methodological recommendations (NICE, 2024).

Due to data availability limitations, pathway-related secondary care resources only were included in the evaluation. All costs were expressed in 2023/24 UK pound (£) sterling to reflect year of data collection.

2.4. Time Horizon and Discounting

The time horizon of the evaluation was from point of referral of the patient (by their GP to the Urgent Suspected Cancer Pathway) to the PROSTAD pathway and Standard care pathway, respectively to diagnosis. Longer term outcomes (e.g. to consider the full cancer pathway for people diagnosed, including treatment and follow-up) were not evaluated as more time will be required for the PROSTAD pathway to be established before a longer (e.g. 'life-time') analysis can be conducted. No discounting was applied as the time horizon of the analysis did not exceed one year.

2.5. Health Economic Analysis

A decision-analytical model was developed in Microsoft Excel 2016 and Visual Basics for Applications (VBA) for Excel (version 365). The decision tree model structure followed the PROSTAD pathway (Figure 1) and was based on routinely collected service data to evaluate the effects of the PROSTAD pathway on health-related quality of life, resource use and costs, as well as time to diagnosis and other milestones within the pathway. The model schematic can be found in Appendix A, Figure A1. Data analysis was undertaken in Excel 16 (Microsoft, 2016) and RStudio 2024.4.2.764 (Posit Team, 2024).

The model-based health economic analysis framework included:

- A cost-consequence analysis (CCA) summarising all relevant costs and outcomes of the PROSTAD pathway in tabular balance sheet to provide an overview of the impact of the PROSTAD pathway on clinical and service outcomes.
- A cost-effectiveness analysis (CEA) to estimate the incremental cost per reduction in time to diagnosis.
- A cost-utility analysis (CUA) using utilities from published literature to estimate the incremental cost per quality adjusted life year (QALY) gained (if data availability allows).
- Net monetary benefit (NMB) was calculated to represent the value of the PROSTAD pathway in monetary terms at different willingness to pay thresholds.

Furthermore, a budget impact analysis (BIA) was developed to extrapolate the cost of the PROSTAD and comparator pathways to the Welsh context based on published prostate cancer incidence numbers to estimate the full-scale cost impact of the new pathway to NHS Wales.

2.6. Model validation

Quality assurance steps were conducted throughout the evaluation period to ensure the model produces transparent, accurate and reproducible outputs and functions appropriately in line with theoretical expectations and the modification of key parameters. Steps of this process included:

- Review of structural assumptions and modelling techniques, technical implementation, formulae and functionality: Technical validation by internal and external modelling experts were sought to validate the model structure, coding and input processing and ensure structural validity and integrity. Upon completion, the model underwent quality assurance by an internal colleague, independent of the work and with expertise in economic modelling at Swansea University.
- Review of data inputs and sources and clinical assumptions: For clinical validation of the model, the model structure, clinical assumptions and all model inputs were reviewed by the PROSTAD team, the CRUK TET steering group panel and clinicians involved to ensure the model accurately reflects the patient pathway and flow through the model. Assumptions were discussed and signed off in a PROSTAD meeting prior to analysis. A review was undertaken of the draft health economics report (including findings) with a final round of analyses and revision of the health economics report undertaken based on feedback/comments from the PROSTAD team. An audit trail of feedback/changes is available on request.
- Sensitivity and scenario analyses and validation of results: Extensive sensitivity and scenario analyses were undertaken to test the robustness of the results to changes in key parameters and to assess the impact of parameter uncertainty and changes in service provision on the results.
- On review of the provisional health economic findings, the PROSTAD team asked for the model to use published national unit costs (taken from NHS/Health related group (HRG) costs and from published NICE guidance, as reported in supplementary table A1, appendix A and reflected in table 2 below.

2.7. Model inputs

The health economic model required the data inputs summarised in Table 2, with a summary of unit costs used presented in supplementary table A1.

2.8. PROSTAD pathway cost

The cost of running the PROSTAD pathway service was sourced from the HDdUHB finance department and supplemented by discussions with the project and clinical team where required, Staff costs were converted into monthly costs and the incremental costs of the PROSTAD pathway was calculated (20% of monthly salary). The monthly incremental staff cost for the PROSTAD pathway was then divided by the mean number of patients seen per month to arrive at a per patient cost. Pathway development/service set-up cost was not taken into account for this analysis as the main focus of the evaluation was to estimate the ongoing costs and consequences to inform a potential larger roll-out of the PROSTAD pathway within

Table 2. Model inputs and data sources for the PROSTAD pathway evaluation.

Parameter	Data source
PROSTAD pathway implementation costs	HDdUHB Finance Department records, NHS HRG/reference costs and NICE guidance as set out in table supplementary table A1, appendix A
Healthcare resource use for PROSTAD and Standard care pathways	HDdUHB/pathway records, NHS HRG/ reference costs and NICE guidance as set out in table supplementary table A1.
Diagnosis outcomes for PROSTAD and Standard care pathways	HDdUHB/pathway records
Time to diagnosis and other key pathway mile-stones for PROSTAD and Standard care path-ways	HDdUHB/pathway records
Health utilities	Published literature

HDdUHB. Healthcare resource use and costs

Data routinely collected for patients referred to the PROSTAD pathway between 19th June 2023 and 16th April 2024 was compared to routine data for patients going through the Standard care pathway between 15th May 2023 and 26th March 2024. The fully anonymised data included dates of key events and milestones throughout the pathway (e.g. referral, MRI, clinic, biopsy, MDT) and information on any tests and investigation received between referral and diagnosis. Primary care resource use was not available for this evaluation. Healthcare resource use was costed using most current standard published unit costs (NHS Improvement, 2023) and inflated to 2023/24 prices using the NHS cost inflation index (NHSCII) as published by the Personal Social Services Research Unit (University of Kent) and the Centre for Health Economics (University of York) (Jones et al., 2023) where necessary. Where no national unit costs were available (e.g. for bpMRI, mpMRI and MRI reporting), local costs were sought from HDdUHB finance . A summary of all unit costs applied can be found in Table A1, Appendix A.

While the pathway descriptions (Figures 1 and 2) stipulated TRUS guided biopsy for the Standard care pathway and LATP biopsy for the PROSTAD pathway, in reality, biopsies were assigned based on individual patient needs and circumstances regardless of the pathway. No data were made available on the type of biopsy received for individual patients during the evaluation phase. Therefore, following the direction from the PROSTAD team, an assumption was made that 80% of patients received TRUS guided biopsy and 20% would receive LATP biopsy for both pathways. The PROSTAD team advised that this should be used as the 'base-case scenario'. Thus, the two main scenarios considered in our analyses were:

1. Twenty percent of patients received LATP and 80% received TRUS guided biopsies in both arms, which reflects the pathways delivered during the PROSTAD evaluation phase, in order to preserve the 'reality' of how PROSTAD was actually implemented in practice, based on patient need and circumstances.
2. Per protocol analysis, where PROSTAD patients received LATP and Standard care received TRUS, reflecting the pathways that would be delivered, if the PROSTAD protocol was implemented in practice, without deviation.

A final scenario (assuming all patients received LATP biopsy as the gold standard) was tested in sensitivity analysis.

Following valuation of resources, subsequent pathway costs including tests and investigations and any other secondary care costs between referral and diagnosis were added up to provide a total cost, which was subsequently divided by the number of patients in each arm to arrive at a mean cost per patient (including standard deviation). Mean and median costs as well as 95% confidence intervals and interquartile ranges were calculated and tabulated for both pathways. Differences between the intervention and control pathways were analysed with 95% confidence intervals and p-values reported. Differences with p-values at and below 0.05 were considered statistically significant.

2.9. Pathway outcomes

Clinical and service outcomes were collected and recorded as part of the routine pathway delivery to enable service evaluation and continuous improvement. Anonymised data was shared with the Swansea University team to enable the health economic service evaluation.

Patients going through diagnostic services in either the new or existing pathway, were divided into different diagnosis outcome groups, depending on the decision at clinic/MDT and the outcome at diagnosis. Following MRI, patients were divided into those moving forwards to biopsy and those who do not (most of which will receive prostate-specific antigen surveillance). Patients going through biopsy were then receiving an outcome of either a cancer diagnosis or no cancer diagnosis (either no Pathology found or other diagnosis). These outcomes were collected through retrospective review of patient files and service notes by the HDdUHB team for both the intervention and Standard care pathways. If possible and available, cancer stage at diagnosis was recorded for both groups.

Cancer conversion rates were calculated for both pathways by dividing the number of patients diagnosed with cancer by the number of patients with an available decision to biopsy and/or diagnosis. Furthermore, cancer staging information was reviewed and compared descriptively between pathways.

2.10. Pathway Waiting Times

Pathway waiting times were expressed as the number of whole days between referral by GP (to either PROSTAD or comparator pathway) and diagnosis or other relevant key milestones. Date of Pathology report was considered as the date of diagnosis.

Waiting times were calculated for different milestones within the pathway, including:

- Time (in days) from referral to MRI
- Time (in days) from referral to MRI reporting
- Time (in days) from referral to clinical decision to biopsy
- Time (in days) from referral to biopsy
- Time (in days) from referral to diagnosis (Pathology report)
- Time (in days) from referral to outpatient appointment (where results are discussed with patient)

To fit appropriate distributions to the wait time data and allow sampling of times for each individual in the model, the waiting times for each section of the pathway were compared with standard statistical distributions and the distributions with the best fit (according to Chi square, Akaike Information Criterion and Bayesian Information Criterion) were chosen. For each waiting time section (pre-MRI report and from MRI report to biopsy) for both intervention and control arms the log normal distribution provided the best fit. In probabilistic analysis, the waiting times were sampled directly from the appropriate log normal distribution.

2.11. Statistical analysis

For costs and outcomes, descriptive statistics were calculated, including mean, median, standard deviation, minimum and maximum values. Mean per patient healthcare costs

(including cost of pathway coordinator), times to key milestones and diagnosis between PROSTAD and Standard care pathways were compared using Mann-Whitney U tests (to account for the skewness of the data). Mean differences, 95% confidence intervals (CI) and p-values were reported, with a significance level of $p<0.05$.

2.12. Health-related quality of life and other health outcomes

It is well established that the diagnostic phase is a source of high anxiety for patients (Awsare et al., 2008; Dillard et al., 2017). The model therefore required health utilities before and following diagnosis. No utility data was collected routinely as part of the pathways. A rapid literature search was undertaken in Medline and Embase to derive the required utility inputs. After searching for key words including "prostate cancer", "cancer", "quality of life", and "diagnosis", five relevant publications were identified (Krahn et al. 2007, NICE 2014, Hall et al. 2015, Saad et al. 2018, Kuppen et al. 2020). The utilities for prostate cancer (and metastasised disease) reported in Krahn et al. (2007), Hall et al. (2015), Saad et al. (2018) and Kuppen et al.(2020) were higher or very similar to the utility of the general population of people older than 60 years in the UK (Hernández Alava et al. 2022) which was considered inappropriate. It was therefore decided to use the utility decrements reported in the NICE Clinical Guideline on prostate cancer diagnosis and management (NICE, 2014) update health economic model report of 0.027 for localised prostate cancer and 0.137 for metastatic disease. These decrements were deducted from the utility for the general population of men of an average age of 66 years (Hernández Alava et al. 2022) which was the mean age used in the NICE guideline and validated by our clinical experts. Using the decrements and general population utility, utilities for prostate cancer diagnosis and metastatic disease were calculated (see Table 3). To establish pre-diagnosis utility, data from Moseholm et al. (2016), which reports pre-and post-diagnosis quality of life based on the EORTC QLQ-C30 questionnaire in a vague RDC setting was used. The authors found a 3% improvement in quality of life following cancer diagnosis and a 7% improvement for patients with a non-cancer diagnosis for patients presenting with vague symptoms in the Global Health scale (Moseholm et al., 2016). Considering that biopsy will reduce quality of life in the short-term and based on expert opinion, a reduction of 5% from a cancer diagnosis was assumed for the pre-diagnosis stage. And a 7% improvement was added for a non-cancer diagnosis. All utility inputs and required assumptions were reviewed and agreed by the PROSTAD team before analysis.

2.13. Missing Data

Missing data were discussed with the PROSTAD team and assessed on a case-by-case basis. Analysis was undertaken on an available case basis. For patients who were still on the pathway at the end of the data collection period, data relating to the completed sections of their pathway were included in the evaluation while those censored due to the end of data collection were deemed missing.

2.14. Health economic analyses

A cost-consequences analysis visually compared all relevant outcomes and costs of intervention and control in tabular form.

Furthermore, a cost-effectiveness analysis compared the incremental cost of the PROSTAD pathway to Standard care regarding the changes in waiting time to diagnosis and other key milestones within the pathways to derive an incremental cost per day reduction in waiting time.

Cost-utility analysis was used to estimate cost per QALY between intervention and control groups. Incremental costs and effects were presented with 95% confidence intervals. Costs and effects of the PROSTAD pathway were then compared with Standard care and presented as incremental cost-effectiveness ratios (ICERs). An ICER can be represented as:

$$ICER = \frac{C_1 - C_0}{E_1 - E_0} = \frac{\Delta C}{\Delta E}$$

Where C_1 and E_1 are the costs and effects of the intervention arm and C_0 and E_0 are the cost and effects of the control arm with ΔC and ΔE the incremental costs and effects of the intervention compared to control. The ratio allows for assessment of the cost-effectiveness of the intervention.

Table 3. Utilities used in the health economic model.

Data item	Value	Source	Notes
Utility general pop-ulation (men, 66 years)	0.8313	Hernández Alava et al. 2022	Mean age (66 years) based on NICE guideline HE mod-elling
Utility during wait-ing time to diagno-sis	0.7641	Moseholm et al., 2016	3% improvement com-pared to pre-diagnosis based on EORTC-QLQ results (+ extra 2% deduction accounting for decrement of biopsy and possible AEs)
Utility surveillance only/discharged	0.8176	Moseholm et al., 2016	based on 7% improvement following non-cancer diagnosis
Utility prostate cancer (no metastases)	0.8043	NICE guideline, HE model report, Table HE14	deducted decrement of 0.027 from general popu-lation
Utility metastases	0.6943	NICE guideline, HE model report, Table HE14	deducted decrement of 0.137 from general population

For CUA, QALYs incorporate quantity of life (additional life years) and health-related quality of life in one health outcome measure and are typically derived from health utilities generated by responses to the EQ-5D-5L questionnaires. Generally, the UK National Institute for Health and Care Excellence (NICE, 2023) considers an intervention cost-effective if one of the following applies:

- The intervention is less costly and more clinically effective compared with all other relevant alternatives. In this case, no ICER is calculated as the strategy in question dominates the alternatives.
- The intervention has an ICER of less than £20,000 per QALY compared to the next best alternative. This means that an investment of up to £20,000 to achieve an additional QALY is considered cost-effective.
- The intervention is between £20,000 and £30,000 per QALY gained and the decision committee is confident about its value for money based on the certainty of the evaluation results and/or additional benefits that may not be captured in the evaluation.

The ICER is reported to determine the cost-effectiveness of the intervention compared to competing alternatives and aid decision-making but is not an absolute statement on whether the intervention can be deemed cost-effective. The ICER resulting from the CUA was compared to the willingness to pay thresholds of £20,000 and £30,000 per QALY gained as standardised by NICE.

Outputs were also used to estimate the incremental net monetary benefit (NMB) at the standard willingness to pay thresholds as suggested by NICE of both £20,000 and £30,000 per QALY using the formula NMB = (incremental benefit x threshold) – incremental cost. NMB gives an indication of whether an intervention provides more benefit than investment required (if the NMB value is positive) or requires more inputs than it produces benefits (if the NMB is negative). A positive NMB is generally considered good value for money, while a negative NMB indicates that an intervention may not be cost-effective.

2.15. Sensitivity analyses

A series of sensitivity analyses (SA) were undertaken to test the robustness of the results considering the uncertainty in input parameters such as costs and outcomes and in different scenarios.

2.15.1. One-way Sensitivity Analysis

Deterministic one-way SA were conducted, whereby a key input parameter was changed, the model re-run and the new ICER recorded. This analysis is a useful way of estimating uncertainty and determining the key drivers of the model result. Parameter changes for deterministic SA included changes to RDC and comparator total costs, time from referral to diagnosis and utilities (+/- 10%, 20%, 50%).

2.15.2. Probabilistic Sensitivity Analysis

Probabilistic sensitivity analysis (PSA) was performed to test the robustness of the modelling conclusions in the face of uncertainty surrounding the choice of all modelling inputs. In this analysis, the mean values that were utilised in both base cases were replaced with values drawn from distributions around the mean values with the results presented of the average across 30,000 simulations. Costs were sampled from gamma distributions, and utilities and probabilities from beta distributions. The standard error of the mean was assumed to be 10% of the mean for all parameters where no uncertainty data (standard error, standard deviation, sample size, 95% confidence intervals) could be obtained. The results of the PSA were presented on a cost-effectiveness (CE) plane and as cost-effectiveness acceptability curves (CEAC). The CE plane is a scatter plot of the point estimates obtained from the 30,000 simulations depicted in four quadrants representing the probability of the intervention being more/less costly and more/less effective compared to Standard care. A CEAC is a curve that describes the probability of the intervention being cost-effective at different willingness-to-pay-thresholds based on the results of the PSA and helps decision makers understand the uncertainty with making a decision based on cost-effectiveness findings.

2.15.3. Scenario Analyses

Scenario analyses were undertaken to investigate the impact of key structural assumptions focusing on use of biopsies (where no routine data was available for the analysis) and staff costs of the PROSTAD pathway on the cost-effectiveness results. Scenario 1 assessed the impact of all patients receiving LATP biopsies as the gold standard in both pathways.

2.16. Budget impact analysis

A budget impact analysis based on the PROSTAD evaluation was undertaken to estimate the potential investment or resource/cost impact of secondary/tertiary healthcare resulting from the provision of the PROSTAD pathway across NHS Wales over a predicted 5-year time horizon.

Published annual incidence of new prostate cancer diagnoses in Wales (CRUK, 2024) was used to estimate the number of newly diagnosed prostate cancers in Wales per year. Since cancer diagnoses only account for a proportion of the PROSTAD pathway diagnoses, the cancer conversion rate of the PROSTAD pathway was used to calculate the total number of people accessing the PROSTAD pathway with cancer diagnoses, and other/no diagnoses, respectively. The resulting number of people potentially going through the PROSTAD pathway across Wales was then used to calculate total PROSTAD cost and net cost of healthcare resource use between referral and diagnosis based on evaluation cost data for both the PROSTAD and the comparator patients. Finally, the change in healthcare resource use and the PROSTAD implementation costs were combined to arrive at a total net budget impact of the PROSTAD pathway over the next five years. Sensitivity analyses were undertaken to estimate the budget impact based on different use of biopsies.

3. Results of the health economic evaluation

3.1. Implementation Costs

After consultation with the HDdUHB project team it was decided that the cost of the pathway coordinator would not be considered in the overall cost analysis. This was due to the fact that the PROSTAD pathway only sped up the pathways rather than changed the pathway itself and therefore the costs would be equal in both arms.

3.2. Healthcare Costs and Total Costs

80:20 split base case

In the first, 80:20 'base case' scenario, costs during the diagnosis stage (including mpMRI, biopsies, outpatient appointments, MDTs and other tests and healthcare contacts) in the PROSTAD group (n=127) amounted to a mean £992.43 (standard deviation, SD=£607.74) per patient. The Standard care diagnosis pathway in the parallel comparator group (n=112) cost a mean £847.05 per patient (SD=£503.29), including bpMRI, biopsies, outpatient appointments, MDTs and other secondary care costs.

The overall cost difference of £145.38 (95% CI: £2.09 to £288.71), compared to the comparator pathway was statistically significant in both t-tests and Mann-Whitney U tests.

The total per patient cost for PROSTAD patients compared to Standard care patients are summarised in Table 4.

Table 4. Per patient cost for PROSTAD patients compared to parallel Standard care patients.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	**-**
Mean cost (SD)	£992.43	£814.30 (£486.42)	£ 351.41 (£190.98 to £511.84; p<0.001)
Median cost	£1,160.50	£828.64	331.86; p<0.001
Minimum cost	£367.87	£316.26	-
Maximum cost	£2,445.74	£2,206.54	-

CI: Confidence interval; SD: Standard deviation

Total mean costs for individual outcome groups can be found in Table 5. Mean costs were presented here to provide more information on variance.

Table 5. Mean total cost per patient for different outcome groups.

Outcome group	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
No biopsy (surveillance only) (SD)	52	£402.83 (79.45)	49	£382.70 (£126.09)	£20.13 (-£-21.23 to £61.49; p=0.337)
Biopsy – cancer diagnosis (SD)	50	£1,568.14 (£473.06)	43	£1,337.79 (£363.88)	£230. 35 (£54.29 to £406.40; p = 0.01)
Biopsy – other or no diagnosis (SD)	8	£869.547 (£11.44)	12	£818.16 (£179.37)	£51.38 (-£83.25 to £186.02; p=0.433)

CI: Confidence interval; SD: Standard deviation

The total costs from referral to diagnosis were statistically significantly higher in the PROSTAD pathway compared to Standard care for the cancer diagnosis patients, but not for the other groups. Statistical significance remained (p=0.017) following Bonferroni correction for multiple comparisons among means (Dunn, 1961) due to the model looking at different time periods within the overall time to diagnosis (e.g. time from referral to MRI, time from MRI to decision to biopsy, etc.). The difference is cost was mainly driven by the higher cost of the mpMRI compared to bpMRI.

Per protocol scenario

In the per protocol scenario , costs during the diagnosis stage (including mpMRI, biopsies, outpatient appointments, MDTs and other tests and healthcare contacts) in the PROSTAD group (n=127) amounted to a mean £1,165.71 (standard deviation, SD=£730.73) per patient. The Standard care diagnosis pathway in the parallel comparator group (n=112) cost a mean £814.30 per patient (SD=£486.42), including bpMRI, biopsies, outpatient appointments, MDTs and other secondary care costs.

The overall cost difference of £351.41 (95% CI: £2190.98 to £511.84), compared to the comparator pathway was statistically significant in both t-tests and Mann-Whitney U tests.

The total per patient cost for PROSTAD patients compared to Standard care patients are summarised in Table 6.

Total mean costs for individual outcome groups can be found in Table 7.

Mean costs were presented here to provide more information on variance.

The total costs from referral to diagnosis were statistically significantly higher in the PROSTAD pathway compared to Standard care for everyone following biopsy, but not for the surveillance group. Statistical significance remained (p=0.017) following Bonferroni correction for multiple comparisons among means (Dunn, 1961) due to the model looking at different time periods within the overall time to diagnosis (e.g. time from referral to MRI, time from MRI to decision to biopsy, etc.). The difference is cost was mainly driven by the higher cost of the mpMRI compared to bpMRI.

3.3. Pathway Outcomes – for all scenarios

Of the 127 patients going through the PROSTAD pathway, diagnosis information was available for 110. Of these, 50 were diagnosed with cancer (adenocarcinoma of the prostate), which represents a cancer conversion rate of 45.45%. Of these patients (staging information was available

Table 6. Per patient cost for PROSTAD patients compared to parallel Standard care patients.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	-
Mean cost (SD)	£1,165.71	£814.30 (£486.42)	£ 351.41 (£190.98 to £511.84; p<0.001)
Median cost	£1442.63	£758.11	684.52; p<0.001
Minimum cost	£367.87	£316.26	-
Maximum cost	£2,727.87	£2,316.41	-

CI: Confidence interval; SD: Standard deviation

Table 7. Mean total cost per patient for different outcome groups.

Outcome group	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
No biopsy (surveillance only) (SD)	52	£408.25 (£111.22)	49	£378.38 (£112.23)	£29.87 (-£14.26 to £74.00; p=0.09)
Biopsy – cancer diagnosis (SD)	50	£1,861.56 (£480.15)	43	£1,280.38 (£386.29)	£581.18 (£399.68 to £762.67;
Biopsy – other or no diagnosis (SD)	8	£1,151.68 (£11.44)	12	£782.90 (£180.85)	£368.78 (£233.04 to £504.52; p<0.001)

CI: Confidence interval; SD: Standard deviation

for 41), 2 presented with metastasised cancer (4.8%). Of the remaining patients, 52 were put on surveillance (47.27%), seven were discharged with no serious Pathology found (6.36%) and one received another (unknown) diagnosis (0.90%). In the Standard care pathway, 43 (out of 104 with available diagnosis information) were diagnosed with cancer (41.35%) with 4 (of 40 with available staging information) diagnosed with metastasised cancer (10.0%), 49 were assigned to surveillance (47.11%), 6 had another diagnosis (5.77%) and 6 were discharged (5.77%).

3.4. Time between Referral and Key Pathway Milestones

The mean and median times from referral to key milestones within the diagnosis pathway (e.g. MRI, decision to biopsy, biopsy, etc.) were overall shorter in the PROSTAD pathway (see Table 8). However, within the pathway, time from decision to biopsy to biopsy taking place was shorter in the Standard care pathway (26 days) than the PROSTAD pathway (32 days). This difference is due to patient choice to delay

Table 8. Time (in days) between GP referral and key milestones within diagnosis pathways.

Waiting time (in days from referral)	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
Mean time					
Mean time to MRI (SD)	127	13 (5)	112	25 (13)	-12 (-15 to -10; p<0.001)
Mean time to MRI reporting (SD)	127	14 (5)	112	33 (14)	-19 (-21 to -16; p<0.001)
Mean time to clinical decision whether to biopsy (SD)	127	14 (5)	111	38 (13)	-24 (-26 to -21; p<0.001)
Mean time to biopsy (SD)	66	46 (25)	57	66 (20)	-20 (-28 to -12; p<0.001)
Mean time to diagnosis (SD)	61	53 (26)	55	76 (24)	-23 (-33 to -15; p<0.001)
Mean time to outpatient ap-pointment where patient in-formed of diagnosis (SD)	44	70 (24)	41	98 (25)	-28 (-39 to -17; p<0.001)
Median time					
Median time to MRI (IQR)	127	13 (3)	112	23 (15)	-10; p<0.001
Median time to MRI reporting (IQR)	127	14 (4)	112	32 (17)	-18; p<0.001
Median time to clinical decision whether to biopsy (IQR)	127	14 (4)	111	37 (15)	-23; p<0.001
Median time to biopsy (IQR)	66	38 (19)	57	62 (25)	-24; p<0.001
Median time to diagnosis (IQR)	61	45 (19)	55	75 (28)	-30; p<0.001
Median time to outpatient appointment where patient informed of diagnosis (IQR)	44	64 (18)	41	93 (21)	-29; p<0.001

CI: Confidence interval; SD: Standard deviation

Table 9. Mean waiting times within diagnosis pathways (in days from referral) for different outcome groups.

Outcome group	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
Mean time to MRI (in days from referral)					
No biopsy (surveillance only) (SD)	52	14 (5)	49	24 (12)	-10 (-15 to -7; p<0.001)
Biopsy – cancer diag-nosis (SD)	50	12 (4)	43	27 (12)	-15 (-18 to -11; p<0.001)
Biopsy – other or no diagnosis (SD)	8	14 (4)	12	26 (18)	-12 (-24 to -1; p=0.041)
Mean time to MRI reporting (in days from referral)					
No biopsy (surveillance only) (SD)	52	15 (5)	49	31 (13)	-16 (-21 to -13; p<0.001)
Biopsy – cancer diag-nosis (SD)	50	14 (5)	43	36 (13)	-22 (-26 to -18; p<0.001)
Biopsy – other or no diagnosis (SD)	8	16 (4)	12	33 (18)	-17 (-29 to -6; p=0.007)
Mean time to clinical decision whether to biopsy (in days from referral)					
No biopsy (surveillance only) (SD)	52	15 (5)	49	36 (13)	-21 (-26 to -18; p<0.001)
Biopsy – cancer diag-nosis (SD)	50	14 (5)	42	40 (13)	-26 (-31 to -22; p<0.001)
Biopsy – other or no diagnosis (SD)	8	16 (4)	12	39 (19)	-23 (-35 to -11; p=0.001)
Mean time to biopsy (in days from referral)					
No biopsy (surveillance only) (SD)	N/A	N/A	N/A	N/A	N/A
Biopsy – cancer diag-nosis (SD)	50	41 (22)	43	66 (20)	-25 (-34 to -17; p<0.001)
Biopsy – other or no diagnosis (SD)	8	41 (18)	11	65 (22)	-24 (-44 to -5; p=0.017)

CI: Confidence interval; SD: Standard deviation

Outcome group	n	PROSTAD pathway	n	Standard care pathway	Difference (95% CI)
Mean time to diagnosis (in days from referral)					
No biopsy (surveillance only) (SD)	N/A	N/A	N/A	N/A	N/A
Biopsy – cancer diag-nosis (SD)	50	49 (22)	43	77 (24)	-28 (-38 to -18; p<0.001)
Biopsy – other or no diagnosis (SD)	8	58 (29)	11	74 (25)	-16 (-43 to 11; p=0.230)
Mean time to outpatient appointment where patient informed of diagnosis (in days from referral)					
No biopsy (surveillance only) (SD)	N/A	N/A	N/A	N/A	N/A
Biopsy – cancer diag-nosis (SD)	44	70 (24)	39	96 (24)	-26 (-37 to -16; p<0.001)
Biopsy – other or no diagnosis (SD)	N/A	N/A	N/A	N/A	N/A
Mean time to clinical decision whether to biopsy (in days from referral)					
No biopsy (surveillance only) (SD)	52	15 (5)	49	36 (13)	-21 (-26 to -18; p<0.001)
Biopsy – cancer diag-nosis (SD)	50	14 (5)	42	40 (13)	-26 (-31 to -22; p<0.001)
Biopsy – other or no diagnosis (SD)	8	16 (4)	12	39 (19)	-23 (-35 to -11; p=0.001)

CI: Confidence interval; SD: Standard deviation

reasons as evidenced by comparing median days where time from decision to biopsy to biopsy taking place was similar in the PROSTAD pathway (24 days) than the Standard care pathway (25 days). The waiting time from referral to the date when the patient was told about the diagnosis was considerably reduced from 98 days (SD=25 days) in the comparator group to 70 days (SD=24 days) in the PROSTAD pathway (p<0.001). These differences were statistically significant.

Times to key milestones between referral and diagnosis were reduced across all individual outcome groups (see Table 9), with time from decision of biopsy to biopsy again longer in the PROSTAD pathway. Time to MRI was reduced between 10 and 15 days, with a decrease in time to decision to biopsy between 21 and 26 days. The highest reduction in waiting times was found in patients who eventually were diagnosed with prostate cancer, with time to biopsy decreasing from 66 days to 41 days (p<0.001) and time to cancer diagnosis significantly reduced from 77 days to 49 days in the PROSTAD pathway patients (p<0.001) when compared to the Standard care pathway.

3.5. Cost-effectiveness of the PROSTAD pathway

3.5.1. Cost-consequences analysis

80:20 split base case

base case

The main costs and consequences of the PROSTAD pathway are summarised in Table 10. Overall, the PROSTAD pathway increases per patient cost by £145, , the PROSTAD pathway is on average 28 days shorter than the Standard care pathway.

Table 10. Costs and consequences of the PROSTAD pathway between referral and diagnosis.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	**-**
Mean total cost (SD)	£992.43 (£607.74)	£847.05 (£503.29)	£145.38 (£2.06 to £ 288.71; p<0.001)
Median total cost	£1,160.50	£828.64	331.86; p<0.001
Cancer conversion rate	45.45%	41.35%	4.1%
Mean time to MRI (SD)	13 (5)	25 (13)	-12 (-15 to -10; p<0.001)
Mean time to MRI reporting (SD)	14 (5)	33 (14)	-19 (-21 to -16; p<0.001)
Mean time to clinical decision whether to biopsy (SD)	14 (5)	38 (13)	-24 (-26 to -21; p<0.001)
Mean time to biopsy (SD)	46 (25)	66 (20)	-20 (-28 to -12; p<0.001)
Mean time to diagnosis (SD)	53 (26)	76 (24)	-23 (-33 to -15; p<0.001)
Mean time to out-patient appointment where patient informed of diagnosis (SD)	70 (24)	98 (25)	-28 (-39 to -17; p<0.001)

CI: Confidence interval; SD: Standard deviation

Per protocol base case

The main costs and consequences of the PROSTAD pathway are summarised in Table 11. Overall, the PROSTAD pathway increases per patient cost by £351, the PROSTAD pathway is on average 28 days shorter than the Standard care pathway.

Table 11. Costs and consequences of the PROSTAD pathway between referral and diagnosis.

	PROSTAD pathway	Standard care pathway	Difference (95% CI)
n	**127**	**112**	**-**
Mean total cost (SD)	£1,165.71	£847.05 (£503.29)	£145.38 (£2.06 to £ 288.71; p<0.001)
Median total cost	£1442.63	£758.11	684.52; p<0.001
Cancer conversion rate	45.45%	41.35%	4.1%
Mean time to MRI (SD)	13 (5)	25 (13)	-12 (-15 to -10; p<0.001)
Mean time to MRI reporting (SD)	14 (5)	33 (14)	-19 (-21 to -16; p<0.001)
Mean time to clinical decision whether to biopsy (SD)	14 (5)	38 (13)	-24 (-26 to -21; p<0.001)
Mean time to biopsy (SD)	46 (25)	66 (20)	-20 (-28 to -12; p<0.001)
Mean time to di-agnosis (SD)	53 (26)	76 (24)	-23 (-33 to -15; p<0.001)
Mean time to out-patient appointment where patient informed of diagnosis (SD)	70 (24)	98 (25)	-28 (-39 to -17; p<0.001)

CI: Confidence interval; SD: Standard deviation

Based on these results, the ICER for the CEA was calculated as £15.52 per one less day to diagnosis for the PROSTAD pathway compared to Standard care. CUA showed an ICER of £57,587 per QALY gained. This ICER is above an ICER of £30,000 per QALY gained which NICE would consider in making recommendations whether this is an effective use of NHS resources, again with uncertainty in findings requiring assessment via sensitivity analysis and/or aspects not captured in the analysis such as uncaptured benefits and non-health factors (NHS 2023, section 6.3.8.)

Table 12. Base case total cost and outcomes for PROSTAD and comparator cohorts (based on 127 patients in each group).

	PROSTAD pathway	Standard care pathway	Difference
Total cost	£122,740	£105,135	£17,605
Total QALYs	120.75	120.03	0.72
Total time to diagnosis (years)	15.55	22.83	-7.28
Total time to diagnosis (days)	5,680	8,339	-2,659

3.5.2. Cost-utility and cost-effectiveness analysis

80:20 split base case

The results of the cost-effectiveness and cost-utility analyses are summarised in Table 12.

Table 12. Base case total cost and outcomes for PROSTAD and comparator cohorts (based on 127 patients in each group).

Based on these results, the ICER for the CEA was calculated as £6.62 per one less day to diagnosis for the PROSTAD pathway compared to Standard care. CUA showed an ICER of £24,569 per QALY gained. This is within the maximum acceptable willingness-to-pay threshold of between £20,000 and £30,000, generally accepted by NICE although this should be considered alongside the decision of certainty around the ICER (NICE, 2023, section 6.3.7). This is explored in our sensitivity analyses presented.

Net monetary benefit was calculated as -£3,205 at the £20,000 willingness-to-pay threshold and £3,995 at the £30,000 threshold.

Per protocol base case

The results of the cost-effectiveness and cost-utility analyses are summarised in Table 13.

Table 13. Base case total cost and outcomes for PROSTAD and comparator cohorts (based on 127 patients in each group).

	PROSTAD pathway	Standard care pathway	Difference
Total cost	£142,610	£101,346	£41,264
Total QALYs	120.75	120.03	0.72
Total time to diagnosis (years)	15.55	22.83	-7.28
Total time to diagnosis (days)	5,680	8,339	-2,659

Net monetary benefit was calculated as -£26,864 at the £20,000 willingness-to-pay threshold and -£19,664 at the £30,000 threshold.

Table 14. Results of the deterministic one-way sensitivity analysis (based on £30,000 per QALY gained cost-effectiveness threshold).

SA-ID	Parameter	Change	Optimal strategy
1	Cancer Utility	Use average metastases rate to change cancer utility in both groups to 0.7968	No PROSTAD (ICER = £46,168)
2	Outcome group rates	Outcome rates to average of both groups	PROSTAD (ICER = £17,663)
3	Outcome group rates + Cancer utility	Outcome rates to average of both groups, cancer utility to average (SA1)	No PROSTAD (ICER = £29,772)
4	Costs	PROSTAD increase by 20%	No PROSTAD (ICER = £58,827)
5	Costs	PROSTAD increase by 50%	No PROSTAD (ICER = £110,215)
6	Costs	PROSTAD decrease by 20%	PROSTAD dominates
7	Costs	PROSTAD decrease by 50%	PROSTAD dominates
8	Costs	Non-PROSTAD increase by 20%	PROSTAD dominates
9	Costs	Non-PROSTAD increase by 50%	PROSTAD dominates
10	Costs	Non-PROSTAD decrease by 20%	No PROSTAD (ICER = £53,913)
11	Costs	Non-PROSTAD decrease by 50%	No PROSTAD (ICER = £97,930)
12	Utilities	PROSTAD increase by 20%	PROSTAD (ICER = £497)
13	Utilities	PROSTAD decrease by 20%	PROSTAD DOMINATED
14	Utilities	PROSTAD decrease by 50%	PROSTAD DOMINATED
15	Utilities	Non-PROSTAD increase by 20%	PROSTAD DOMINATED
16	Utilities	Non-PROSTAD decrease by 20%	PROSTAD (ICER = £182)
17	Utilities	Non-PROSTAD decrease by 50%	PROSTAD (ICER = £290)
18	Wait time for MRI	PROSTAD increase by 20%	PROSTAD (ICER = £27,075)
19	Wait time for MRI	PROSTAD increase by 50%	No PROSTAD (ICER = £31,966)
20	Wait time for MRI	PROSTAD decrease by 20%	PROSTAD (ICER = £22,487)
21	Wait time for MRI	PROSTAD decrease by 50%	PROSTAD (ICER = £19,951)
22	Wait time for MRI	Non-PROSTAD increase by 20%	PROSTAD (ICER = £19,710)
23	Wait time for MRI	Non-PROSTAD increase by 50%	PROSTAD (ICER = £15,200)
24	Wait time for MRI	Non-PROSTAD decrease by 20%	No PROSTAD (ICER = £32,607)
25	Wait time for MRI	Non-PROSTAD decrease by 50%	No PROSTAD (ICER = £64,032)
26	Wait time for Biopsy (after MRI)	PROSTAD increase by 20%	No PROSTAD (ICER = £30,677)
27	Wait time for Biopsy (after MRI)	PROSTAD increase by 50%	No PROSTAD (ICER = £48,923)
28	Wait time for Biopsy (after MRI)	PROSTAD decrease by 20%	PROSTAD (ICER = £20,489)
29	Wait time for Biopsy (after MRI)	PROSTAD decrease by 50%	PROSTAD (ICER = £16,403)
30	Wait time for Biopsy (after MRI)	Non-PROSTAD increase by 20%	PROSTAD (ICER =£20,788)
31	Wait time for Biopsy (after MRI)	Non-PROSTAD increase by 50%	PROSTAD (ICER = £16,890)
32	Wait time for Biopsy (after MRI)	Non-PROSTAD decrease by 20%	No PROSTAD (ICER = £30,030)
33	Wait time for Biopsy (after MRI)	Non-PROSTAD decrease by 50%	No PROSTAD (ICER = £45,050)

ICER: incremental cost-effectiveness ratio

3.6. Sensitivity analyses

3.6.1. Deterministic Sensitivity Analysis

80:20 split base case

The results of the deterministic one-way sensitivity analysis are presented in Table 14.

Model results are sensitive to changes in pathway costs and utilities during the waiting time to diagnosis with scenarios where the PROSTAD pathway is both dominating Standard care (i.e. less costly and

Table 15. Results of the deterministic one-way sensitivity analysis (based on £30,000 per QALY gained cost-effectiveness threshold).

SA-ID	Parameter	Change	Optimal strategy
1	Cancer Utility	Use average metastases rate to change cancer utility in both groups to 0.7968	No PROSTAD (ICER = £108,214)
2	Outcome group rates	Outcome rates to average of both groups	No PROSTAD (ICER = £46,858)
3	Outcome group rates + Cancer utility	Outcome rates to average of both groups, cancer utility to average (SA1)	No PROSTAD (ICER = £78,984)
4	Costs	PROSTAD increase by 20%	No PROSTAD (ICER = £97,391)
5	Costs	PROSTAD increase by 50%	No PROSTAD (ICER = £157,098)
6	Costs	PROSTAD decrease by 20%	PROSTAD (ICER = £17,783)
7	Costs	PROSTAD decrease by 50%	PROSTAD dominates
8	Costs	Non-PROSTAD increase by 20%	PROSTAD (ICER = £29,300)
9	Costs	Non-PROSTAD increase by 50%	PROSTAD dominant
10	Costs	Non-PROSTAD decrease by 20%	No PROSTAD (ICER = £85,874)
11	Costs	Non-PROSTAD decrease by 50%	No PROSTAD (ICER = £128,304)
12	Utilities	PROSTAD increase by 20%	PROSTAD (ICER = £1,165)
13	Utilities	PROSTAD decrease by 20%	PROSTAD DOMINATED
14	Utilities	PROSTAD decrease by 50%	PROSTAD DOMINATED
15	Utilities	Non-PROSTAD increase by 20%	PROSTAD DOMINATED
16	Utilities	Non-PROSTAD decrease by 20%	PROSTAD (ICER = £1,669)
17	Utilities	Non-PROSTAD decrease by 50%	PROSTAD (ICER = £679)
18	Wait time for MRI	PROSTAD increase by 20%	No PROSTAD (ICER = £63,462)
19	Wait time for MRI	PROSTAD increase by 50%	No PROSTAD (ICER = £74,927)
20	Wait time for MRI	PROSTAD decrease by 20%	No PROSTAD (ICER = £52,708)
21	Wait time for MRI	PROSTAD decrease by 50%	No PROSTAD (ICER = £46,765)
22	Wait time for MRI	Non-PROSTAD increase by 20%	No PROSTAD (ICER = £46,198)
23	Wait time for MRI	Non-PROSTAD increase by 50%	No PROSTAD (ICER = £35,629)
24	Wait time for MRI	Non-PROSTAD decrease by 20%	No PROSTAD (ICER = £76,428)
25	Wait time for MRI	Non-PROSTAD decrease by 50%	No PROSTAD (ICER = £150,086)
26	Wait time for Biopsy (after MRI)	PROSTAD increase by 20%	No PROSTAD (ICER = £71,905)
27	Wait time for Biopsy (after MRI)	PROSTAD increase by 50%	No PROSTAD (ICER = £114,673)
28	Wait time for Biopsy (after MRI)	PROSTAD decrease by 20%	No PROSTAD (ICER = £48,024)
29	Wait time for Biopsy (after MRI)	PROSTAD decrease by 50%	No PROSTAD (ICER = £38,447)
30	Wait time for Biopsy (after MRI)	Non-PROSTAD increase by 20%	No PROSTAD (ICER = £48,726)
31	Wait time for Biopsy (after MRI)	Non-PROSTAD increase by 50%	No PROSTAD (ICER = £39,589)
32	Wait time for Biopsy (after MRI)	Non-PROSTAD decrease by 20%	No PROSTAD (ICER = £70,387)
33	Wait time for Biopsy (after MRI)	Non-PROSTAD decrease by 50%	No PROSTAD (ICER = £105,593)
34	Utility of waiting time	Utility changed to 0.7239 (10% reduction)	No PROSTAD (ICER = £40,883)
35	Utility of waiting time	Utility changed to 0.6837 (15% reduction)	No PROSTAD (ICER = £31,688)
36	Utility of waiting time	Utility changed to 0.6434 (20% reduction)	PROSTAD (ICER = £25,858)

ICER: incremental cost-effectiveness ratio

more effective) and dominated by Standard care (i.e. more costly and less effective).

Per protocol base case

The results of the deterministic one-way sensitivity analysis are presented in Table 15.

Model results are sensitive to changes in pathway costs and utilities during the waiting time to diagnosis with scenarios where the PROSTAD pathway is both dominating Standard care (i.e. less costly and more effective) and dominated by Standard care (i.e. more costly and less effective). For both base-cases, this suggests uncertainty in the base-case findings, thus the impact of joint uncertainty in costs and outcomes is presented next.

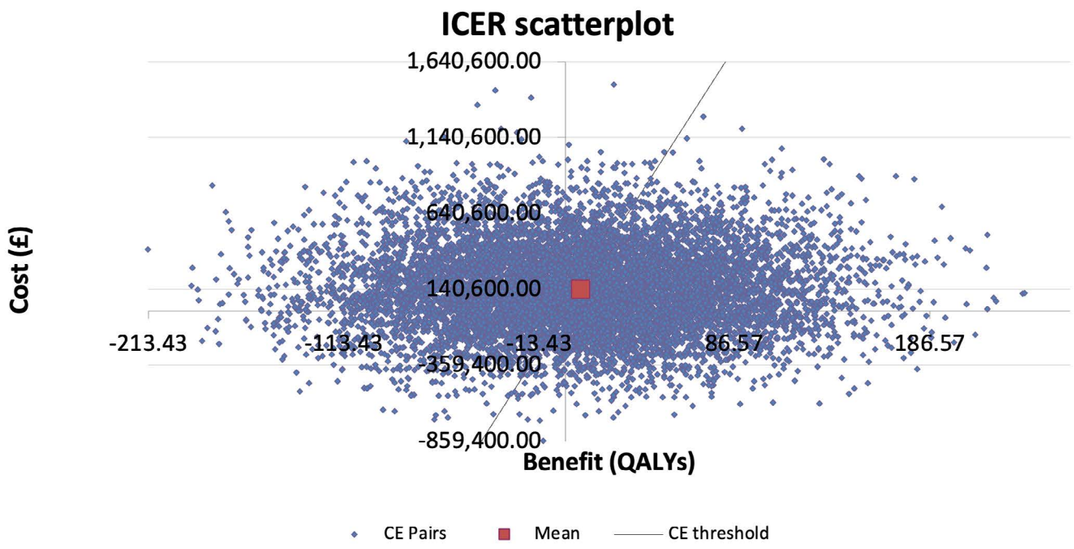
3.6.2. Probabilistic Sensitivity Analysis

80:20 split base case

Changing all parameters for the CUA based on pre-defined distributions and ranges and recalculating the ICER 30,000 times for a population of 1,000 people per cohort, resulted in an incremental cost of £142,340 (95% CI: -£382,087 to £723,093) with 7.63 (95% CI: -113.99 to 128.58) QALYs gained which results in a probabilistic ICER of £18,663 per QALY gained, with a 36% probability that the PROSTAD pathway is the most cost-effective option at the £20,000 threshold and 37% probability for PROSTAD to be cost-effective at the £30,000 threshold.

Figures 2 and 3 present the cost-effectiveness plane and cost-effectiveness acceptability curve, respectively.

Figure 3. Cost-effectiveness plane illustrating the distribution of ICERs for the PROSTAD pathway compared to Standard care resulting from the probabilistic sensitivity analysis.



Per protocol scenario

Changing all parameters for the CUA based on pre-defined distributions and ranges and recalculating the ICER 30,000 times for a population of 1,000 people per cohort, resulted in an incremental cost of £326,116 (95% CI: -£234,667 to £902,614) with 7.86 (95% CI: -112.80 to 131.11) QALYs gained which results in a probabilistic ICER of £41,474 per QALY gained, with a 30% probability that the PROSTAD pathway is the most cost-effective option at the £20,000 threshold and 32% probability for PROSTAD to be cost-effective at the £30,000 threshold.

Figures 4 and 5 present the cost-effectiveness plane and cost-effectiveness acceptability curve, respectively.

Figure 4. Cost-effectiveness acceptability curve of PROSTAD pathway based on ICERs plotted against different willingness-to-pay thresholds

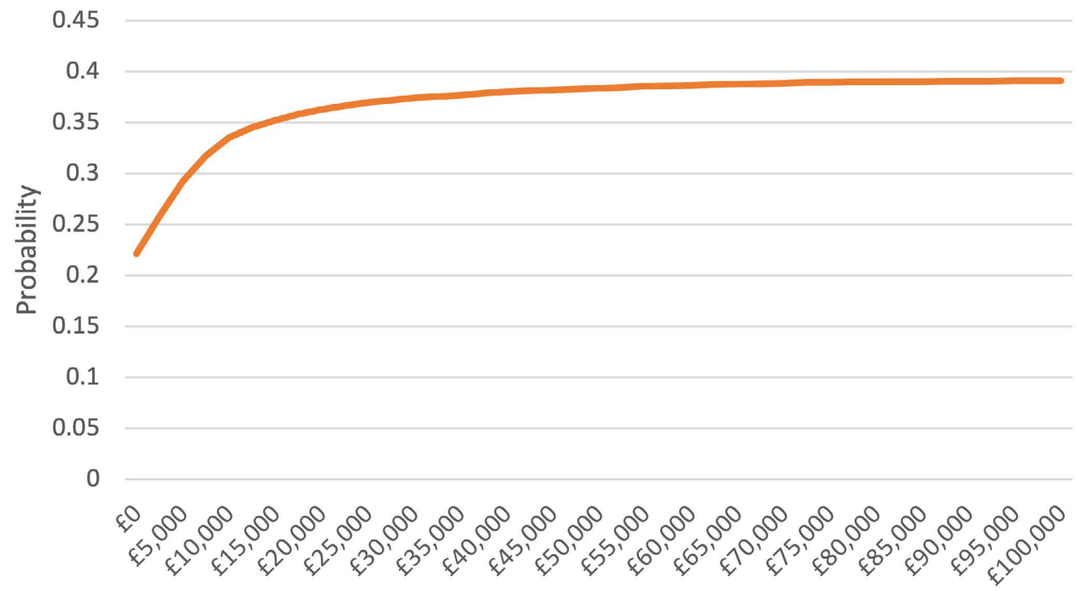


Figure 4. Cost-effectiveness plane illustrating the distribution of ICERs for the PROSTAD pathway compared to Standard care resulting from the probabilistic sensitivity analysis.

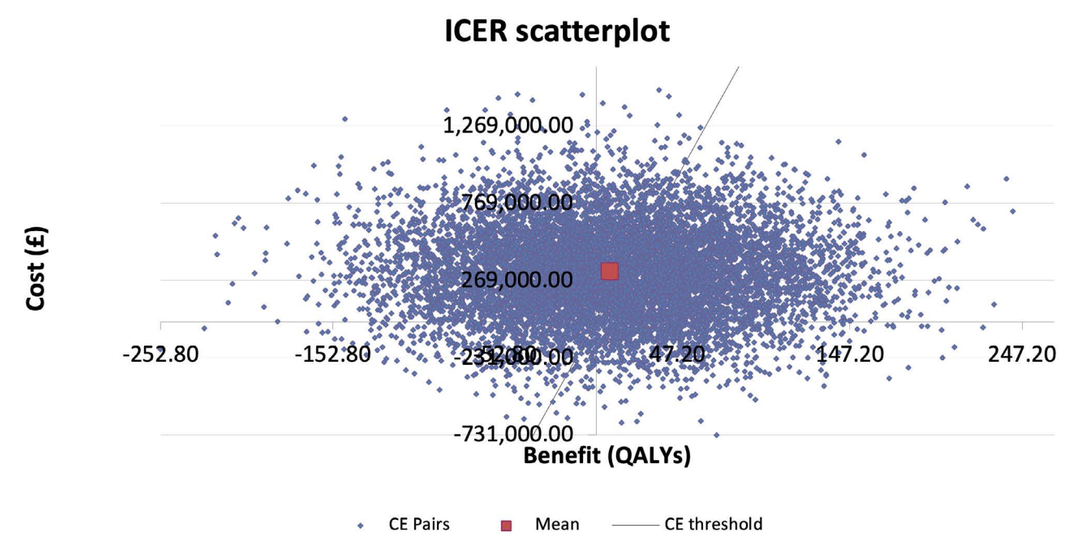
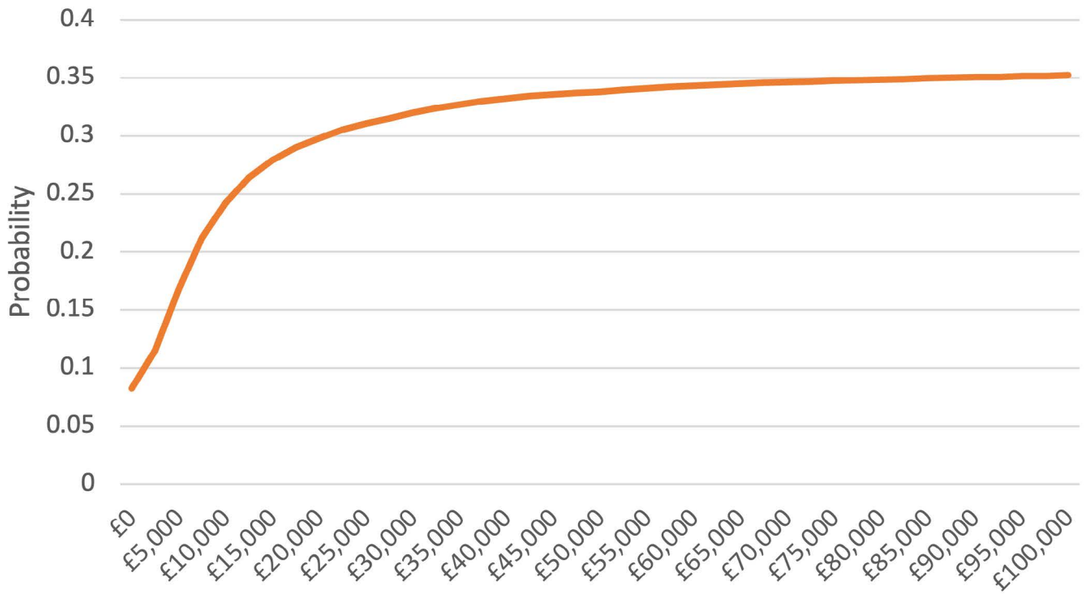


Figure 5. Cost-effectiveness acceptability curve of PROSTAD pathway based on ICERs plotted against different willingness-to-pay thresholds.



3.6.3. Scenario Analysis

Results of the scenario analyses are summarised in Table 16. The PROSTAD pathway was found to be not cost-effective in scenarios where LATP was assumed for all PROSTAD patients and TRUS guided biopsy for all Standard care patients (per protocol scenario above), however in scenario 1 where LATP was assumed for all patients regardless of pathway the PROSTAD pathway was found to be cost-effective.

Table 16. Results of scenario analyses.

SA-ID	Parameter	Change	Optimal strategy
SCENARIO 1 – LATP biopsy assumed for all patients			
A	Costing for biopsy	Change costing for biopsy from 80:20 to LATP for all	PROSTAD (ICER = £24,569)
B	Cancer Utility	Scenario 2 costs, SA1 utilities	No PROSTAD (ICER = £46,168)
C	Outcome group rates	Scenario 2 costs, SA2 rates	PROSTAD (ICER = £17,663)
D	Outcome group rates & Cancer utility	Scenario 2 costs, SA1 utilities, SA2 rates	No PROSTAD (ICER = £29,772)

Since the cost is the same for both arms for the biopsy, the results are identical to the 80:20 split base case results.

Plausibility of Considered Scenarios

The sensitivity analysis shows considerable uncertainty around the results mainly based on the small differences in waiting time to diagnosis and consequently small QALY differences.

While all scenarios may be considered plausible based on clinical opinion and predictions of what may be the future of the pathways (e.g. all patients receiving LATP biopsies), changes to biopsy type did not considerably affect cost-effectiveness of the PROSTAD pathway.

3.7. Budget Impact of the PROSTAD pathway

The budget impact for the PROSTAD pathway is summarised in Appendix B for both base cases.

80:20 split base case

The budget impact of the PROSTAD pathway is summarised in Table 17.

Taking into account 2,996 newly diagnosed prostate cancers in Wales per year (CRUK, 2024), an annual population growth of 0.80% for Wales (ONS,2023) and a cancer conversion rate within the PROSTAD pathway of 45.45% (with 54.55 % of patients going through the PROSTAD pathway being put on surveillance or discharged), 6,591 people were estimated to be eligible for the PROSTAD pathway in Wales in Year 1, increasing to 6,805 in Year 5, with a total number of 33,488 patients going through the PROSTAD pathway over the 5-year period.

Table 17. Budget impact of PROSTAD pathway, expressed as the additional cost required if the PROSTAD pathway would replace the current Standard care pathway in Wales.

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Number of eligible patients for PROSTAD pathway	6,591	6,644	6,697	6,751	6,805
Healthcare costs PROSTAD patients	£6,541,321	£6,593,651	£6,646,401	£6,699,572	£6,753,168
Healthcare costs comparator patients	£5,583,060	£5,627,724	£5,672,746	£5,718,128	£5,763,873
Net healthcare costs	£958,261	£965,927	£973,655	£981,444	£989,295

Therefore, the introduction of the PRSTAD pathway for the whole of Wales has a budget impact of £4,868,582.

Considering additional cost required to run the PROSTAD pathway and changes in healthcare resource use/cost because of the existence of the PROSTAD pathway, the total budget impact of the PROSTAD pathway over a 5-year period in Wales would be £4,868,582.

Per protocol base case

The budget impact of the PROSTAD pathway is summarised in Table 18.

Taking into account 2,996 newly diagnosed prostate cancers in Wales per year (CRUK, 2024), an annual population growth of 0.80% for Wales (ONS,2023) and a cancer conversion rate within the PROSTAD pathway of 45.45% (with 54.55 % of patients going through the PROSTAD pathway being put on surveillance or discharged), 6,591 people were

estimated to be eligible for the PROSTAD pathway in Wales in Year 1, increasing to 6,805 in Year 5, with a total number of 33,488 patients going through the PROSTAD pathway over the 5-year period.

Table 17. Budget impact of PROSTAD pathway, expressed as the additional cost required if the PROSTAD pathway would replace the current Standard care pathway in Wales.

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Number of eligible patients for PROSTAD pathway	6,591	6,644	6,697	6,751	6,805
Healthcare costs PROSTAD patients	£6,541,321	£6,593,651	£6,646,401	£6,699,572	£6,753,168
Healthcare costs comparator patients	£5,583,060	£5,627,724	£5,672,746	£5,718,128	£5,763,873
Net healthcare costs	£958,261	£965,927	£973,655	£981,444	£989,295

Table 18. Budget impact of PROSTAD pathway, expressed as the additional cost required if the PROSTAD pathway would replace the current Standard care pathway in Wales.

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Number of eligible patients for PROSTAD pathway	6,591	6,644	6,697	6,751	6,805
Healthcare costs PROSTAD patients	£7,683,429	£7,744,896	£7,806,855	£7,869,310	£7,932,265
Healthcare costs comparator patients	£5,367,215	£5,410,153	£5,453,434	£5,497,061	£5,541,038
Net healthcare costs	£2,316,214	£2,334,744	£2,353,422	£2,372,249	£2,391,227

Therefore, the introduction of the PRSTAD pathway for the whole of Wales has a budget impact of £11,767,856.

Considering additional cost required to run the PROSTAD pathway and changes in healthcare resource use/cost because of the existence of the PROSTAD pathway, the total budget impact of the PROSTAD pathway over a 5-year period in Wales would be £11,767,856.

4. Discussion

Our findings are based on an economic analysis undertaken alongside the development and roll-out of the PROSTAD pathway for eligible men with suspicion of prostate cancer living within the H-DDA UHB area compared to current pathway (Standard care). The findings reflect the time-horizon from referral to diagnosis over a 10 month evaluation period.

4.1 Summary of key results

The health economic evaluation of the PROSTAD pathway found the following key results:

- Between June 2023 and April 2024, the PROSTAD pathway offered 172 mpMRI slots with 127 patients seen in 43 sessions.
- For the 80:20 split base case analysis, the mean overall healthcare cost were £992.43 (SD=£607) per patient in the PROSTAD pathway and £847 per patient (SD=£503) in the Standard care pathway. The mean healthcare cost per patient in the PROSTAD pathway was £145 more than in the comparator pathway (n=112).
- For the per protocol analysis, the mean overall healthcare cost were £1,166 (SD=£730) per patient in the PROSTAD pathway and £814 per patient (SD=£486) in the Standard care pathway. The mean healthcare cost per patient in the PROSTAD pathway was £351 more than in the comparator pathway (n=112).
- Of the 127 patients going through the PROSTAD pathway, 50 were diagnosed with cancer (adenocarcinoma of the prostate), which represents a cancer conversion rate of 45.45%. In the Standard care pathway, 43 (out of 104 with available diagnosis information) were diagnosed with cancer (41.35%). The rate of metastasised cancers was higher in the Standard care group (10% compared to 4.8% in the PROSTAD pathway).
- The mean time from referral to MRI was 12 days shorter per patient in the PROSTAD pathway, with a reduction of 24 days between referral and time of decision to biopsy. The waiting time from referral to the date when the patient was told about the diagnosis was reduced from 98 days (SD=25 days) in the comparator pathway to 70 days (SD=24 days) in the PROSTAD. These differences were statistically significant. A bottleneck was identified in the PROSTAD pathway between time of decision to biopsy and the actual biopsy date, where patients in the PROSTAD pathway waited 6 days longer than patients in the Standard care pathway.
- The mean time from referral to diagnosis was 28 days shorter per patient in the PROSTAD pathway.
- The ICER for the CEA was calculated as £6.62 per one less day to diagnosis with the 80:20 split base case.
- The ICER for the CEA was calculated as £15.52 per one less day to diagnosis with the per protocol scenario.
- CUA showed an ICER of £24,569 per QALY gained for the 80:20 split base case. This is above the standard willingness-to-pay threshold of £20,000 but within the window where further consideration is required from £20,000 to £30,000.
- CUA showed an ICER of £57,587 per QALY gained for the per protocol scenario. This is above the standard willingness-to-pay threshold of between £20,000 and £30,000.
- Net monetary benefit was calculated as -£3,205 at the £20,000 willingness-to-pay threshold and £3,995 at the £30,000 threshold, based on the 80:20 split base-case.
- Net monetary benefit was calculated as -£26,864 at the £20,000 willingness-to-pay threshold and -£19,664 at the £30,000 threshold in the per protocol scenario.
- The probability of the PROSTAD pathway being the most cost-effective option at the £20,000 and £30,000 thresholds is 36% and 37%, respectively for the 80:20 split base case.

The probability of the PROSTAD pathway being the most cost-effective option at the £20,000 and £30,000 thresholds is 30% and 32%, respectively for the per protocol scenario. In summary, the 80/20 split scenario used indicated that PROSTAD costs

£145 per patient more and resulted in 28 days less waiting for patients from referral to diagnosis compared to Standard care. The incremental cost to achieve a reduction of one day to diagnosis was £6.62. In a cost-utility analysis, the incremental cost per QALY gain was £24,569 falling within the NICE £20,000-£300,000 threshold for further consideration with the NMB also reflecting this. Sensitivity analysis indicates uncertainty in these estimates. The per-protocol scenario estimated that PROSTAD cost £351 more than Standard care, with an incremental cost to achieve a reduction of one day to diagnosis estimated at £15.52. The incremental cost-utility analyses produced an ICER of £57,8587 and negative NMB suggesting this is unlikely to be cost-effective, again with similar uncertainty presented.

4.2 Strengths and limitations

To our knowledge, this is the first health economic evaluation of a novel prostate cancer diagnosis pathway using mpMRI and a pathway navigator to accelerate diagnosis in Wales. The evaluation was undertaken and reported following current best practice recommendations (Husereau et al. 2022; NICE, 2023; NICE 2024) and similar methods and modelling approaches were used successfully in the past for comparable evaluations (Sewell et al., 2020). We used routine data and the highest quality literature inputs available to ensure a robust real-world economic evaluation, using transparent methods.

Our evaluation reflects the challenges in balancing the need for real-world, rapid, responsive service innovation alongside the demand for rigorously designed economic evaluations. Several limitations are evident While every effort was made by the team to gather the most complete routine data set possible, sample size was small in both comparator groups due to the novelty and immaturity of the service. There were data gaps (e.g. in types of biopsies received) and thus, key assumptions (e.g. in producing the 80/20 split to reflect a real-world base-case of actual implementation of PROSTAD) had to be made based on the clinical opinion from the PROSTAD team.

Another key limitation is the timeline for evaluation of the PROSTAD innovation precluded time to collect fuller, longer-term outcomes to reflect the full cancer pathway for people diagnosed with Prostate Cancer including treatment and follow up. This restriction of the model time horizon until diagnosis will inevitably miss costs and benefits accrued in the treatment stages of the pathways and cannot be considered a true reflection of the cost-effectiveness of the PROSTAD pathway in its entirety. A longer-term analysis including all potential costs and outcomes once the PROSTAD pathway matures is highly recommended, ideally to capture a life-time horizon as recommended by NICE.

Whilst the current PROSTAD innovation enabled a natural comparator cohort to be prospectively included, selection was based on the real-world decisions of the PROSTAD clinical team and thus bias cannot be ruled out. Careful checks were made throughout the design, conduct and reporting of our analyses (see section 2.6), to ensure every effort was made to reflect the real-world, local context of PROSTAD, however data challenges were evident. Whilst we mitigated where possible (e.g. through using published national unit costs, agreed with the PROSTAD team), the question of whether these findings could be generalised to other settings need to be carefully considered by the PROSTAD team, stakeholders and decision makers.

No data on the nature of biopsy undertaken on an individual patient level was available for the analysis and a best estimate from the PROSTAD team was used in the 80:20 base case. This may lead to bias in the results due to the cost difference for LATP and TRUS guided biopsies. However, according to clinical opinion from the PROSTAD team, the proportion of LATP biopsies was comparable in both pathways and any potential impact on difference in biopsy type was explored in scenario analyses.

A driver of the model results is the utility post-diagnosis (derived from literature inputs not specific to our population) which is lower for the Standard care arm as more patients in this pathway were diagnosed with higher stage cancers and metastases. The reasons for this are unknown but could be related to demographic differences (e.g. potentially higher deprivation in the Standard care pathway as the travel required for the PROSTAD pathway may deter people living in more deprived areas) or chance due to the small sample size. However, selection bias cannot be excluded.

The prospective collection of patient-reported outcomes, particularly in enabling robust calculation of utilities should be considered, alongside the collection of longer-term consequences to capture the full range of costs and effects, to avoid compounding the issues faced when quantifying a value (based on economic methods) to derive value for money estimates. Whilst we employed standard methods of sensitivity analyses to quantify the uncertainty in our estimations of cost-effectiveness (cost per QALY), caution must be applied in using our findings as a proxy of value alone without considering the strength of evidence from the other components of the PROSTAD evaluation.

Our findings warrant careful and cautious interpretation. Our 80:20 base case, based on the ICER suggests that if the PROSTAD pathway continues to be delivered as 'current' it would potentially fall into the NICE threshold where decisions about the acceptability of the PROSTAD pathway may be considered an effective use of NHS resources. The NMB for at a willingness to pay threshold of £20,000 was negative, whereas at a willingness to pay threshold of £30,000 was positive. Uncertainty was seen across our sensitivity analyses. The deviations from the protocol made were deemed by the PROSTAD team to reflect patient need and circumstances, and thus the challenges of delivering a person-centred pathway in an area where equity challenge could be a key issue (e.g. in accessing care), may need to balance alongside an aggregated analysis of costs and outcome, focused on efficiency which is presented in this economic analysis.

We would advocate that our cost-consequence analysis (CCA) alongside careful assessment of CEA should be used in reporting our findings to stakeholders, to reflect the complexity, challenges and uncertainty seen in our findings. Our CCA provides a disaggregated picture of costs and outcomes, and alongside our CEA and CUA analyses, provides decision makers with a comprehensive, transparent account of the health economic impact of PROSTAD, which in turn could be used as part of a fuller discussion of the value of PROSTAD aligned to the NHS Wales principles of value-based health care. We would encourage this evaluation to be used by CRUK as part of a 'round-table' discussion with key stakeholders on the methodological, analytical and practical challenges of undertaking economic evaluations of models/pathways of care which aim to provide faster diagnosis for people who have symptoms suspicious of cancer.

4.3 Our results in context

Prostate cancer poses a significant burden on the population, the health service and the economy (Roehrborn and Black, 2011; Smith-Palmer et al., 2019). Faster diagnosis has the potential to improve patient outcomes, remove the need for more intensive and more costly treatment options, and to improve patient experience as anxiety is usually high in patients waiting for diagnosis (Awsare et al., 2008; Dillard et al., 2017). Yet, many diagnosis services fall short of the National Optimal Pathway (NOP) for Prostate Cancer which recommends a time from point of suspicion to first definitive treatment of less than 62 days (NHS Wales, 2023).

Our results for the Standard care pathway in HDdUHB suggest a mean time from referral to outpatient appointment to discuss diagnosis and treatment options with the patient of 98 days (SD=25 days). While no data to calculate time to first definitive treatment was available for our analysis, the evaluation confirms that the Standard care pathway is considerably longer than the NOP. One-stop pathways (which provide mpMRI, clinic and biopsy in one day) were shown to reduce time to diagnosis to a median of 8 days (Bass et al., 2018). However, they were suggested to be too high a burden for patients (Lopez and Bryant, 2023). Alternatively, the use of rapid imaging and diagnosis pathways including mpMRI as part of the 'Rapid Access Prostate Imaging and Diagnosis' (RAPID) pathway has previously been shown to reduce time to diagnosis by 16.25 days (Eldred-Evans et al., 2023), which is comparable to the improvement in waiting time of 23 days found in our evaluation using the PROSTAD pathway. However, while it has been suggested that mpMRI is cost-effective as a first test in the diagnosis of prostate cancer (Faria et al., 2018; Giganti and Moore, 2019), no published evidence on the cost-effectiveness of rapid prostate cancer diagnosis pathways is available, which has been a source of criticism in the past (Lopez and Bryant, 2023). We have assumed that NICE recommendation on using MPMRI was informed by a robust health economic assessment (NICE, 2019). Our

evaluation found that the PROSTAD pathway, while reducing the waiting time to diagnosis of prostate cancer in HDdUHB, still does not meet the NOP recommendations of <21 days for decision to treat.

The use of a standard ICER- value framework allows a consistent and transparent comparison of these findings with other health technologies and interventions (including complex interventions) and we have also presented NMB as a cleaner (simpler) presentation of whether or not PROSTAD could be considered cost-effective, alongside detailed examination of the uncertainty in our findings.

The best-case scenario from our findings (based on the 80/20 split) is that there may be some consideration as to whether or not PROSTAD falls within an acceptable boundary of cost-effectiveness (£20,000-£30,000 per QALY gained), alongside other considerations (including full consideration of the uncertainty and limitations presented), if the NICE reference standard is used. The per protocol scenario is unlikely to fall within 'accepted' cost-effectiveness thresholds, again with uncertainty in our findings. It is a matter for the PROSTAD clinical team and decision makers to appropriately interpret the evidence presented from our analysis to inform recommendations. Our focus has been on presenting as robust, comprehensive and transparent analysis as possible within the context and challenge of undertaking economic evaluation in this setting.

This could also raises questions as to whether this framework (focused on QALYs as a measure of benefit which was not captured directly in our evaluation and relied on published data not directly applicable to the PROSTAD pathway) is capturing the full extent of value for patients, professional and policy makers, in an evolving service innovation in a local setting. We suggest that our findings from the economic evaluation (both CCA and CEA/CUA) are a starting point in discussing what patients, public (and professionals) need and want in making resource allocation decisions regarding PROSTAD. Drawing upon the rich evidence provided through the PROSTAD evaluation as a whole, rather than in silo will enable HDdUHB to meet public expectations and achieve the outcomes that matter most to people whilst reducing waste, harm and variation.

References

Awsare, N. S., Green, J. S. A., Aldwinckle, B., Hanbury, D. C., Boustead, G. B., & McNicholas, T. A. (2008). The measurement of psychological distress in men being investigated for the presence of prostate cancer. Prostate Cancer and Prostatic Diseases, 11, 384–389.

Bass EJ, Freeman A, Jameson C, Punwani S, Moore CM, Arya M, Emberton M, Ahmed HU. Prostate cancer diagnostic pathway: Is a one-stop cognitive MRI targeted biopsy service a realistic goal in everyday practice? A pilot cohort in a tertiary referral centre in the UK. BMJ Open. 2018 Oct 24;8(10):e024941.

Cancer Research UK (CRUK)(2024). Prostate cancer incidence statistics. Available at: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer/incidence#heading-Zero (last accessed 12/07/2024).

Dillard AJ, Scherer LD, Ubel PA, Alexander S, Fagerlin A. Anxiety symptoms prior to a prostate cancer diagnosis: Associations with knowledge and openness to treatment. Br J Health Psychol. 2017 Feb;22(1):151-168.

Dunn OJ (1961). Multiple comparison among means. J Amer Stat Assoc. 56 (293), 52-64.

Eldred-Evans D, Connor MJ, Bertoncelli Tanaka M, Bass E, Reddy D, Walters U, Stroman L, Espinosa E, Das R, Khosla N, Tam H, Pegers E, Qazi H, Gordon S, Winkler M, Ahmed HU. The rapid assessment for prostate imaging and diagnosis (RAPID) prostate cancer diagnostic pathway. BJU Int. 2023 Apr;131(4):461-470.

Faria R, Soares MO, Spackman E, Ahmed HU, Brown LC, Kaplan R, Emberton M, Sculpher MJ. Optimising the Diagnosis of Prostate Cancer in the Era of Multiparametric Magnetic Resonance Imaging: A Cost-effectiveness Analysis Based on the Prostate MR Imaging Study (PROMIS). Eur Urol. 2018 Jan;73(1):23-30.

Giganti F, Moore CM. MRI in early detection of prostate cancer. Curr Opin Urol. 2019 Nov;29(6):563-568.

Hall PS, Hamilton P, Hulme CT, Meads DM, Jones H, Newsham A, Marti J, Smith AF, Mason H, Velikova G, Ashley L, Wright P. Costs of cancer care for use in economic evaluation: a UK analysis of patient-level routine health system data. Br J Cancer. 2015 Mar 3;112(5):948-56.

Hernández Alava M, Pudney S, Wailoo A (2022). Estimating EQ-5D by age and sex for the UK. NICE Decision Support Unit, University of Sheffield. Available at : https://www.sheffield.ac.uk/nice-dsu/methods-development/estimating-eq-5d (last accessed 03/07/2024).

Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) statement: updated reporting guidance for health economic evaluations. BMJ. 2022;376.

Jones, K.C., Weatherly, H., Birch, S., Castelli, A., Chalkley, M., Dargan, A., Forder, J.E., Gao, J., Hinde, S., Markham, S. et al. (2023). Unit Costs of Health and Social Care 2022 Manual. Technical report. Personal Social Services Research Unit (University of Kent) & Centre for Health Economics (University of York), Kent, UK.

Krahn M, Bremner KE, Tomlinson G, Ritvo P, Irvine J, Naglie G. Responsiveness of disease-specific and generic utility instruments in prostate cancer patients. Qual Life Res. 2007 Apr;16(3):509-22.

Kuppen MCP, Westgeest HM, van den Eertwegh AJM, Coenen JLLM, van Moorselaar RJA, van den Berg P, Geenen MM, Mehra N, Hendriks MP, Lampe MI, van de Luijtgaarden ACM, Peters FPJ, Roeleveld TA, Smilde TJ, de Wit R, van Oort IM, Gerritsen WR, Uyl-de Groot CA. Health-related Quality of Life and Pain in a Real-world Castration-resistant Prostate Cancer Population: Results From the PRO-CAPRI Study in the Netherlands. Clin Genitourin Cancer. 2020 Jun;18(3):e233-e253.

Lopez JF, Bryant RJ. The 'Rapid Access Prostate Imaging and Diagnosis' (RAPID) diagnostic pathway: what is the rush? BJU Int. 2023 Apr;131(4):377-379.

National Institute for Health and Care Excellence (NICE), 2014. Prostate cancer diagnosis and treatment (CG175). Available at: https://www.nice.org.uk/guidance/ng131/evidence (last accessed 03/07/2024).

National Institute for Health and Care Excellence (NICE), 2023. NICE health technology evaluations: the manual. Available at: https://www.nice.org.uk/process/pmg36/chapter/economic-evaluation (last accessed 23/04/2024).

National Institute for Health and Care Excellence (NICE), 2024. Developing NICE guidelines: the manual (PMG20). Available at: https://www.nice.org.uk/process/pmg20/chapter/introduction (last accessed 23/04/2024).

National Institute for Health and Care Excellence (NICE), 2023. Transperineal biopsy for diagnosing prostate cancer (DG54) Available at: https://www.nice.org.uk/guidance/dg54 (last accessed 23/09/2024).

NHS Improvement (2023): 2021/22 National cost collection data publication. Available at: https://www.england.nhs.uk/publication/2021-22-national-cost-collection-data-publication/ (last accessed 21/03/2024).

NHS Wales (2023): National Optimal Pathway for Prostate Cancer: 2nd Edition. Available at: https://executive.nhs.wales/functions/networks-and-planning/cancer/workstreams/suspected-cancer-pathway/scp-accordion/nopccprostate2020206/#:~:text=Meet%20the%20SCP%20cancer%20waiting,the%20best%20outcomes%20in%20Europe. (last accessed 17/07/2024).

Office of National Statistics (ONS, 2023). Population estimates for England and Wales: mid-2022. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/populationestimatesforenglandandwales/mid2022 (last accessed 21/03/2024).

Roehrborn CG, Black LK. The economic burden of prostate cancer. BJU Int. 2011 Sep;108(6):806-13.

Saad F, Cella D, Basch E, Hadaschik BA, Mainwaring PN, Oudard S, Graff JN, McQuarrie K, Li S, Hudgens S, Lawson J, Lopez-Gitlitz A, Yu MK, Smith MR, Small EJ. Effect of apalutamide on health-related quality of life in patients with non-metastatic castration-resistant prostate cancer: an analysis of the SPARTAN randomised, placebo-controlled, phase 3 trial. Lancet Oncol. 2018 Oct;19(10):1404-1416.

Sewell B, Jones M, Gray H, Wilkes H, Lloyd-Bennett C, Beddow K, Bevan M, and Fitzsimmons D (2020). Rapid cancer diagnosis for patients with vague symptoms: a cost-effectiveness study. British Journal of General Practice, 70 (692), e186-e192.

Smith-Palmer J, Takizawa C, Valentine W. Literature review of the burden of prostate cancer in Germany, France, the United Kingdom and Canada. BMC Urol. 2019 Mar 18;19(1):19.

APPENDIX A:
Health Economic Analysis – Supplementary Materials

Figure A1. Model schematic of the health economic model to assess the cost-effectiveness of the PROSTAD pathway compared to Standard care.

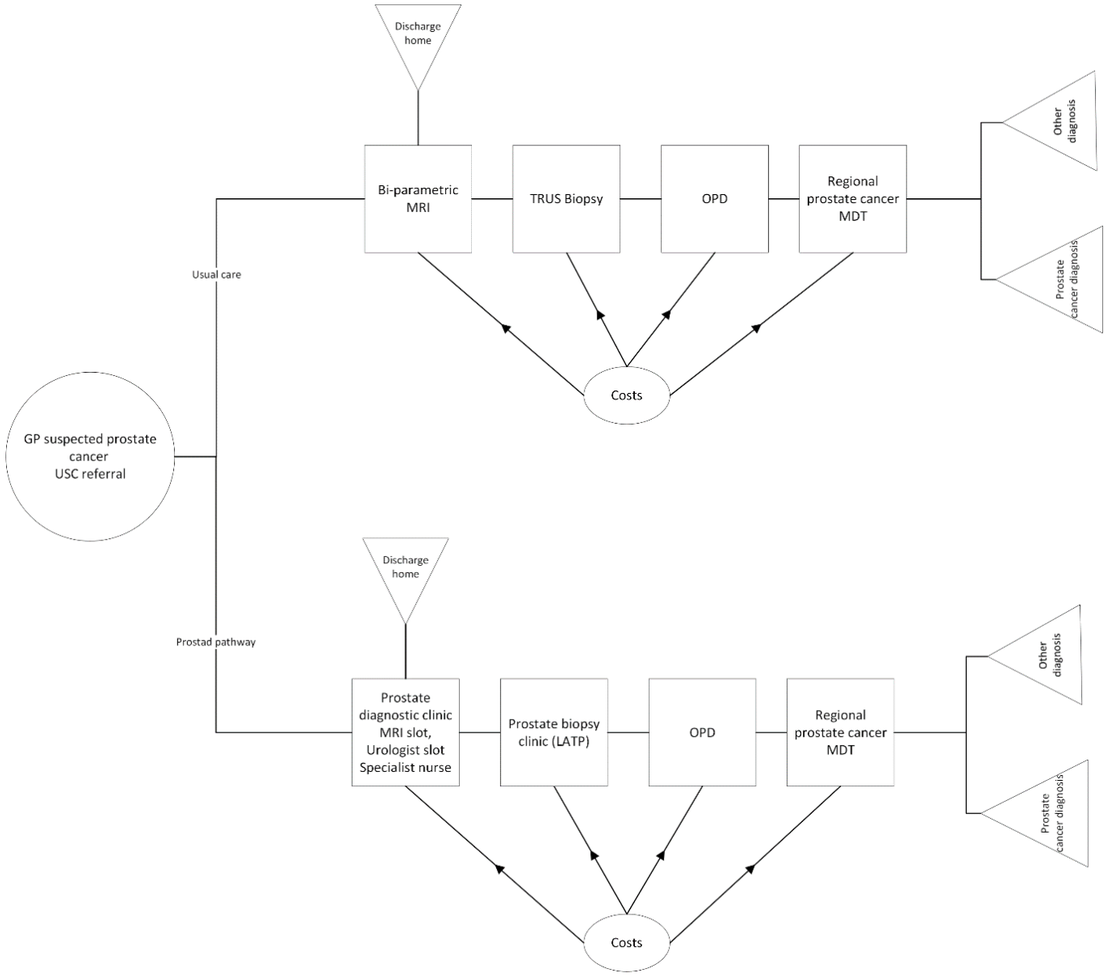


Table A1. Unit costs used to value health and care resource use for health economic evaluation.

Resource	Unit Cost (£)	Source of Cost
Multiparametric MRI	£176.65	NICE Diagnostics Guidance DG54
Bi-parametric MRI	£128.27	NICE Diagnostics Guidance DG54
Transrectal ultrasound scan (TRUS) prostate biopsy	£373.55	NICE Diagnostics Guidance DG54
Local anaesthetic transperineal prostate biopsy (LATP)	£726.21	NICE Diagnostics Guidance DG54
Prostate-specific antigen (PSA) sur-veillance	£22.50	NICE guideline NG131: https://www.nice.org.uk/guidance/ng131
Prostate cancer MDT	£149.22	NHS Reference Costs 2021/22: Other Cancer MDT Meetings
Pathology	£46.89	NHS Reference Costs 2021/22: Histopathology and histology
Urology outpatient appointment	£152.45	NHS Reference costs 2021/22 (weighted across all options)
Bone scan	£380.04	NHS Reference costs 2021/22 (weighted across all options)
Positron emission tomography (PET) scan	£717.61	NHS Reference costs 2021/22 (Positron Emission Tomography (PET), 19 years and over; RN07A)
Diagnostic Flexible Cystoscopy, 19 years and over	£256.54	NHS Reference costs 2021/22 (weighted across all options)
CT (unspecified)	£145.33	NHS Reference costs 2021/22 (weighted across all options)
Blood test	£8.98	NHS Reference costs 2021/22 (Phlebotomy + Cy-tology; DAPS08 + DAPS01)
MRI (unspecified)	£221.99	NHS Reference costs 2021/22 (weighted across all options)
Bone marrow biopsy	£555.35	NHS Reference Costs 2021/22: Diagnostic Bone Marrow Extraction
ENT OPA	£167.32	NHS Reference costs 2021/22 (weighted across all options)
General surgery OPA	£187.58	NHS Reference costs 2021/22 (weighted across all options)
Trauma and Orthopaedic Service OPA	£174.70	NHS Reference costs 2021/22 (weighted across all options)
Ophthalmology Service OPA	£156.70	NHS Reference costs 2021/22 (weighted across all options)
Colorectal Surgery Service OPA	£140.61	NHS Reference costs 2021/22 (weighted across all options)
Clinical Haematology Service OPA	£213.01	NHS Reference costs 2021/22 (weighted across all options)
Anticoagulant nurse OPA	£54.02	NHS Reference costs 2021/22 (weighted across all options)
Physiotherapy	£94.58	NHS Reference costs 2021/22 (weighted across all options)
Ultrasound	£76.31	NHS Reference costs 2021/22 (weighted across all options)
Rehabilitation services	£179.93	NHS Reference costs 2021/22 (weighted across all options)
Dermatology Service OPA	£166.03	NHS Reference costs 2021/22 (weighted across all options)
A&E attendance	£300.34	NHS Reference costs 2021/22 (weighted across all options)
Vascular Surgery Service OPA	£177.40	NHS Reference costs 2021/22 (weighted across all options)
Respiratory Medicine Service OPA	£204.66	NHS Reference costs 2021/22 (weighted across all options)
Consultant radiologist	£231.09	NHS Reference costs 2021/22 (weighted across all options)
MRI reporting	£38.78	HDdUHB Finance information

All costs were inflated to 2023/24 prices.

APPENDIX B
Budget impact analysis

80:20 split base case

The budget impact of the PROSTAD pathway is summarised in Table B1.

Taking into account 2,996 newly diagnosed prostate cancers in Wales per year (CRUK, 2024), an annual population growth of 0.80% for Wales (ONS,2023) and a cancer conversion rate within the PROSTAD pathway of 45.45% (with 54.55 % of patients going through the PROSTAD pathway being put on surveillance or discharged), 6,591 people were estimated to be eligible for the PROSTAD pathway in Wales in Year 1, increasing to 6,805 in Year 5, with a total number of 33,488 patients going through the PROSTAD pathway over the 5-year period.

Table B1. Budget impact of PROSTAD pathway, expressed as the additional cost required if the PROSTAD pathway would replace the current Standard care pathway in Wales.

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Number of eligible patients for PROSTAD pathway	6,591	6,644	6,697	6,751	6,805
Healthcare costs PROSTAD patients	£6,541,321	£6,593,651	£6,646,401	£6,699,572	£6,753,168
Healthcare costs comparator patients	£5,583,060	£5,627,724	£5,672,746	£5,718,128	£5,763,873
Net healthcare costs	£958,261	£965,927	£973,655	£981,444	£989,295

Per protocol base case

The budget impact of the PROSTAD pathway is summarised in Table B2.

Taking into account 2,996 newly diagnosed prostate cancers in Wales per year (CRUK, 2024), an annual population growth of 0.80% for Wales (ONS,2023) and a cancer conversion rate within the PROSTAD pathway of 45.45% (with 54.55 % of patients going through the PROSTAD pathway being put on surveillance or discharged), 6,591 people were estimated to be eligible for the PROSTAD pathway in Wales in Year 1, increasing to 6,805 in Year 5, with a total number of 33,488 patients going through the PROSTAD pathway over the 5-year period.

Table B2. Budget impact of PROSTAD pathway, expressed as the additional cost required if the PROSTAD pathway would replace the current Standard care pathway in Wales.

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Number of eligible patients for PROSTAD pathway	6,591	6,644	6,697	6,751	6,805
Healthcare costs PROSTAD patients	£7,683,429	£7,744,896	£7,806,855	£7,869,310	£7,932,265
Healthcare costs comparator patients	£5,367,215	£5,410,153	£5,453,434	£5,497,061	£5,541,038
Net healthcare costs	£2,316,214	£2,334,744	£2,353,422	£2,372,249	£2,391,227

Appendix 7
Implementation guide for PROSTAD rapid prostate cancer diagnosis pathway

Introduction

The PROSTAD pathway aims to streamline prostate cancer diagnosis by reducing time from point of suspicion to diagnosis and improving patient outcomes through advanced diagnostic techniques, multidisciplinary collaboration, and patient-centred care. This guide provides a step-by-step overview for other teams to adopt and implement the PROSTAD pathway effectively.

Project Planning and Preparation

Formulate the Project team

- Identify key stakeholders, including urologists, radiologists, pathologists, GPs, hospital administrators, cancer tracking team, sponsor (like the Medical Director) and patient representatives.
- Establish governance structures, including a project manager and working groups.

Primary Objectives:

1. Decrease the average time from initial GP urgent suspected cancer (USC) referral (Point of suspicion) to confirmed prostate cancer diagnosis in line with national targets.
2. Enhance the detection rate of clinically significant prostate cancers through advanced imaging (bi-parametric or multi-parametric MRI) and local anaesthetic transperineal biopsy (LATP).
3. Achieve an improved patient satisfaction rate with the PROSTAD pathway.

Secondary Objectives:

1. Develop and implement standardised diagnostic protocols across all participating hospitals to streamline workflow.
2. Enhance collaboration among urologists, oncologists, radiologists, pathologists, and GPs.

Planning and Preparation (minimum timeframe 3 – 6 months)

- Establish project team to include key members of the multi- disciplinary team. It is also advisable to appoint a project manager to oversee the implementation. Implementation/ Innovation leads should also be invited to support the evaluation framework development.
- Detailed project plan and timeline including Gantt chart. This should cover the service plan and evaluation plan utilising PROSTAD documentation as a guide.
- Baseline data collection report highlighting current situation to support understanding of pathway and pinch points in this that could be improved.
- Procurement and maintenance plan for diagnostic equipment (if needed).
- Appoint a patient pathway navigator or identify resources to undertake this role.

Develop a detailed project plan

- Process map the current pathway to identify pinch points that cause delay.
- Ensure all GP referrals are triaged electronically.
- Check if there is a failsafe mechanism to communicate patient list to pathway navigator.
- Identify Radiology capacity to undertake dedicated MRI sessions (MRI radiographers) and rapid reporting same or next day (consultant radiologist).

Communication

- Communication between Urology and Radiology can be speeded up with electronic Radiology request forms that has adequate information so patient can go straight to test.
- Have the pathway navigator to inform patients every step of the way and guide them from referral to MRI and outpatient appointment to discuss whether biopsy is needed or not.
- Ensure any changes in pathway are communicated to primary care teams.

Urology clinic to discuss MRI results and make decision for biopsy

Identify Urology capacity to deliver the clinical review 1 days after the MRI.

- Identify if clinic space is needed for the above clinical review. In our experience most patients were happy with a telephone call.

LATP

- Training of Urologists in LATP techniques. LATP training costs
- Identify a dedicated space for undertaking LATP procedures.
- Identify how many sessions are needed each week and how many patients can undergo LATP in one session.
- LATP equipment costs – has it already been provided to all health boards via Welsh Government.
- Ensure adequate nursing support for LATP.
- Ensure communication between admin teams so patients on the biopsy list (identified by the consultant in the step above) are booked seamlessly into the biopsy clinic.
- Check who is responsible for giving information to the patient regarding medication changes (e.g. blood thinners)

Resources

- Consider sourcing funding for Band 4 pathway navigator.
- Radiology sessions and Urology follow up clinics are reallocation of existing work so no additional costs incurred.
- Identify if additional training needed for Radiologists if using multi-parametric MRI with contrast enhanced images.

Conduct baseline assessments

- Gather baseline data on current diagnostic timelines, patient satisfaction, and existing resources.
- Identify potential barriers and develop strategies to address them.

Implementation and initial rollout

- Instal and test diagnostic LATP equipment in pilot site.
- Standardized diagnostic protocols for MRI.
- Pilot PROSTAD pathway for 3 months.
- Data collection and initial performance reports.
- PDSA cycle to analyse deficiencies in pathway.
- Feedback session reports.

Long term

- Conduct comprehensive evaluation, prepare final reports.
- Business case to develop sustainability plan.

Additional personnel:

- Consider if you need Project Manager to oversee the project implementation and coordination. Could this be the Urology manager or cancer services manager?
- Administrative Staff: Support project logistics and data collection.
- Pathway navigator (see details above)

Equipment:

- LATP biopsy kit and probes
- Set up database for ongoing data collection for monitoring and evaluation.

Facilities:

- Dedicated spaces within hospital for LATP
- Consider if you need outpatient clinic space.

Funding:

- Initial funding to cover project setup, training, and equipment procurement (if needed).
- Ongoing funding for continuous operation, maintenance, and potential scaling.

Stakeholder engagement:

- Regular meetings with patient groups.
- Communication with primary care colleagues
- Feedback sessions to ensure continuous stakeholder involvement.

Training

- Enable training opportunities for urologists focused on advanced diagnostic techniques LATP.
- Ongoing audit of procedures, adverse events and patient satisfaction.
- Create Urology mentor roles to train Specialist trainees and provide continuous support.
- Create Radiology mentor roles to train other radiologists in reporting prostate MRI scans.

Allocate physical space (see above)

- Identify and allocate dedicated spaces within hospitals for clinics.

Procure and install equipment

- Procure advanced imaging and biopsy equipment (e.g., multiparametric MRI machines, LATP).
- Ensure proper installation, testing, and training on the use of new equipment.
- Create and standardize diagnostic protocols and guidelines to ensure consistency across all sites.

Patient and Stakeholder Engagement

- Inform patients about the new pathway, utilise the PROSTAD patient information leaflet.
- Provide appropriate educational materials and resources to patients and caregivers, based on their feedback.
- Establish patient advisory panels and regular feedback mechanisms.
- Hold co-creation workshops with patients, carers, and healthcare providers.

Ongoing monitoring

- Compare outcomes with baseline data and project goals.
- Implement improvements based on evaluation findings and stakeholder feedback.
- Prepare detailed reports on the project's outcomes, challenges, and successes.
- Share insights and best practices with other teams and healthcare organizations.

Appendix 8
Service Guide PROSTAD

This service ensures timely diagnosis and treatment, improving patient outcomes and reducing anxiety. The following are key considerations required:

Objectives

- Ensure patients receive a prompt diagnosis.
- Provide quick access to appropriate diagnostic options.
- Offer comprehensive support throughout the diagnostic process.

Eligibility criteria

- Patients referred by their General Practitioner (GP) with urgent suspected prostate cancer (refer to local guidance for PSA levels or clinical features for suspected prostate cancer).

Initial GP Consultation:

- Evaluation of symptoms and medical history.
- PSA test and Digital Rectal Examination (DRE).

Referral Submission:

- GP completes and submits the electronic referral form via Welsh Clinical Communications Gateway (WCCG) as urgent suspected cancer (USC) to the PROSTAD Pathway.
- Include patient details, symptoms, PSA levels, and DRE findings.
- Add information on Urine dipstick results.

Clinical triage by Urology team

- Electronic triage.
- Referral for straight to test MRI (magnetic resonance imaging).
- Triaging clinician to complete electronic Radiology request form.
- Triaging clinician to inform PROSTAD pathway navigator.

Pathway navigator

- to liaise with Radiology to book MRI.
- inform patient of the MRI appointment and location.
- Book patient to consultant follow up to discuss MRI results next working day after the MRI.
- Send PROSTAD leaflet and MRI Radiology leaflet to patient.

Radiology team

- Undertake MRI.
- Rapid reporting (same or next day) within 24 hours.

Clinical review (telephone or virtual appointment)

- Consultant urologist to review MRI/ report and clinical details.
- Make decision regarding biopsy.
- Inform Urology clerk to book patient for biopsy appointment.
- If patient does not ned biopsy options are discharge or active surveillance.

Diagnosis

- If the MRI indicates potential malignancy, a prostate biopsy will be scheduled within seven days.
- Types of biopsy: Transrectal Ultrasound (TRUS) biopsy or local anaesthetic Transperineal (LATP) biopsy.

Contact information

- PROSTAD Rapid Access Pathway Navigator/Clinic
- Phone: [Clinic Phone Number]
- Email: [Clinic Email Address]
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