

Rapid Diagnostic Pathways for Prostate Cancer: A Realist Synthesis

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Summary / Abstract

Introduction: The NHS Long-term Plan outlines a number of approaches to address delays and diagnose three out of four cancers at an early stage, and yet patients regularly experience delays to diagnosis, potentially leading to poorer outcomes for those receiving a diagnosis. Attempts to address such delays include the implementation of a number of rapid diagnosis pathways (RDPs). This realist review explores rapid diagnosis pathways for prostate cancer, identifying approaches to RDPs, as well as generating theories regarding what works, for whom and under which circumstances.

Methods: This is a realist evidence synthesis. The questions and approach are informed by patient and public involvement (PPI). We conducted a scoping review to generate initial programme theories and then refined these through further search processes. As a realist review, we do not focus on a specific data type or outcome, rather we include qualitative and quantitative data to inform theories comprised of contexts, mechanisms, and outcomes (CMO chains).

Results: Six studies were included in our scoping review; twenty studies were included in the second review. The studies include qualitative and quantitative data. We identified three broad themes: Primary care, organizational factors, and patient experience.

Conclusions/ Recommendations: We recommend the involvement of adjoining services (e.g. general practice and radiology) in the planning of prostate cancer RDPs and emphasize the importance of clear communication with patients.

Introduction

Rationale for review

Delays in the diagnosis of cancer are associated with poorer outcomes [1], with earlier diagnosis and detection constituting an important factor in reducing chance of metastases [2]. Cancer Research UK (CRUK) reports that the survival rate for cancer in the UK is lower than that of comparable countries, and that this is partly due to delays to diagnosis [3]. According to 2014's English National Cancer Diagnosis Audit, 24% of patients experienced avoidable delays to diagnosis, with around 38% of these delays occurring within secondary care [4].

Responding to these issues, the UK's NHS long-term plan describes overhauling diagnostic services and the goal to diagnose three out of four cancers at an early stage by 2028 [5]. A number of Rapid Diagnosis Centres (RDCs), Multi-Disciplinary Centres (MDCs) and other rapid pathway

types have been piloted and implemented in recent years, many under the Accelerate, Co-ordinate, Evaluate (ACE) programme [6]. In this review, we use the term Rapid Diagnostic Pathway (RDP) (except when citing works that specify the term RDC) as some approaches span across multiple centres. All of the RDPs identified in this review are located within secondary care services and require referral by a GP or other primary health care professional (HCP). Based on a Danish model of care [7], RDPs aim to expedite diagnosis often using a “one-stop”, single-centre approach – i.e. performing multiple diagnostic procedures and providing the results sometimes all in one day. Some adopt a generalized approach and target people with vague but concerning symptoms [8, 9, 10], while others focus on rapid diagnosis of specific cancers [11, 12]. Some are mobile and community based [12], whereas others are hospital-based and share resources [10].

Prostate cancer (PCa) is the most common cancer affecting men and people assigned “male” at birth [13] and 22% of those who received a PCa diagnosis experienced an avoidable delay [4]. Since 2018, NICE have recommended the use of MRI scanning in PCa diagnosis [14]. Multiple studies have demonstrated the efficacy of MRI scans that are validated (where necessary) with local anesthetic transperineal prostate (LAMP) biopsies [15, 16]. However, the implementation of these changes remains an under-explored topic.

Evaluation Objectives

This realist evidence synthesis aims to explore PCa RDPs; here, we generate and test theories regarding how, for whom and under which circumstances PCa RDPs might work. We look at existing evidence to:

- identify varying approaches to PCa RDPs;
- produce theories relating to the contextual and mechanistic factors that cause intended or unintended outcomes in the implementation and running of PCa RDPs;
- generate theories regarding the experience of varying actors impacted by PCa RDPs (e.g. patients, clinical staff, clinical staff in adjoining services, etc.)

This is the first stage of a realist evaluation of a PCa RDP in Wales (UK); the pathway is known as Prostad (Welsh for *prostate*). Information about Prostad can be seen in *Figure 1. Prostad*.

Patient and Public Involvement

This is the first stage of a realist evaluation which incorporates patient and public involvement (PPI) at each stage. The PPI group is comprised of people who have experienced PCa diagnostic pathways and received a PCa diagnosis; they were invited to describe elements of the diagnostic process that were important to them, which in turn inform the evaluation approach. Important concepts include care co-ordination, patient labour, and the referral process from primary care.

Methods

We used Covidence to manage the review process collaboratively. Two reviewers agreed on search terms and approaches (JR & KJ); one reviewer performed initial scoping search and screening (KJ) with two researchers performing full-text review (KJ & JR). For the second round of searching, three reviewers screened and extracted data (KJ, JR, AR).

Realist Evaluation

Realist evaluation [17] is a widely used mixed-methods approach which aims to generate theories to establish the relationship between the context (C) in which an intervention is placed and the mechanisms (M) by which an intervention produces outcomes (O). A realist approach holds that, while the intervention may remain the same, contextual factors and the way people interact with an intervention influence the mechanisms by which it may work for some people. Particularly useful when considering the introduction of multifaceted interventions in complex environments, realist evaluation holds that it is not the intervention on its own that produces outcomes, rather it is the way actors respond to and interact with an intervention [18].

Changes to the Review Process

There were no changes to the review process.

Scoping the literature

We began the iterative process of reviewing and synthesizing the literature to generate theories as to how, for whom and under which circumstances RDPs might work. 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 Figure 1: Prostad PCa RDP and Figure 2: Conventional Pathway.
- Information provided by those who developed the Prostad pathway.

Scoping Review: RDP Search 1:

We focused on the “one-stop” element of the pathway 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 [19]:

‘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 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.

Analysis and synthesis processes

Realist evaluation views an intervention as a theory; realist synthesis aims to discern the concepts and beliefs underpinning the intervention [20]. We iteratively developed theories through knowledge of the Prostad pathway, conversations with key stakeholders, and our initial scoping searches. When analyzing the data, two reviewers (KJ, AC) separately reviewed extracted data, identifying themes and concepts to inform theory generation.

Results

Scoping Review: RDP Search 1

RDP Search 1: Prisma (Appendix 1)

RDP Search 1: Document Characteristics (Appendix 2)

We developed six CMO chains, utilizing knowledge produced via the scoping review (Appendix 3. RDP Search 1: Initial Theories), PPI group, information and feedback gathered from management meetings discussing a PCa RDP, and available guidelines and recommendations (e.g. NICE). Some of these CMOs are contradictory, indicating how the same intervention may be interpreted or interacted with variously by different stakeholders or in response to contextual factors.

RDP Search 2

RDP Search 2: Prisma (Appendix 4)

RDP Search 2: Document Characteristics (Appendix 5)

There are a number of approaches to PCa rapid diagnosis pathways. These include “one-stop” approaches [21, 22, 23, 24, 25], 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 LATP biopsy [25]. Some pathways and centres do not include an MRI, instead taking a digital rectal examination (DRE) and TRUS biopsy [11, 26, 27, 24].

RDP Search 2: Programme Theories

We derived eight programme theories from our rapid realist synthesis. These are divided into the following interlinking themes: Primary Care; Organizational Factors; Patient Experience. The results of RDP Search 1 also inform the theories outlined 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 an RDP constitutes a contextual and mechanistic factor in a number of articles, some of which identify “gatekeeping” tendencies among GPs [28, 27, 29],

chiming with the views of our PPI group. While beyond the scope of this review, the prevalence of references to PSA testing in the articles selected for this review is striking, and also constitutes a concern raised in PPI meetings. Wider PSA testing may account for an increase in referrals, and this may be the reason for seeing patients at an earlier disease stage [26]. 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 [27]. While the authors don’t elaborate, this suggests a potential for over-referral and the risk of referring unsuitable patients as they would be unable to undergo the same-day biopsy provided by the RDC in question [27]. The GPs interviewed in a qualitative study tended towards skepticism regarding PSA testing [30], suggesting a potential mechanism for delays to referral. While the scope of an RDC or RDP tends to begin at the point of referral, thereby excluding the processes leading to GP (or other primary care) referral, this finding does suggest the merit of collaborating with GPs when implementing an RDP.

Primary Care 2: Timely Referral and Access to Secondary Care

Primary care is the gateway to diagnostic services (C). If general radiology services have long waiting lists (C), then a PCa-specific pathway may be perceived as more “welcoming” (M), leading to GPs feeling empowered to make the decision to refer earlier (O1); though, conversely, potentially also leading to “over” referral or overwhelming of the service (O2)

Cancer-specific RDPs may improve accessibility to PCa diagnostic facilities. In Merriel *et al.* 2022 [30], GPs spoke positively about the use of MRI scanning for PCa diagnosis, comparing this approach with PSA testing. There is also evidence to suggest that the presence of an RDP improved access to secondary PCa diagnostic services [26, 27]. In a questionnaire with a small sample (n=10), GPs rated the RDP a 7/10 for accessibility and in free-text comments expressed a need for more “one-stop” slots each week [27]. While we note the above-mentioned GPs’ preference 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 RDPs. We hypothesize that the implementation of an RDP 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 [27]; however it may also lead to over-referral. HCPs working on a PCa RDP in Ireland described reviewing the same patients multiple times, which was not the original intention of the service, implying how contextual pressures may impinge upon or stretch the RDP’s original scope [31].

Organizational 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 (C) may be perceived as a decreased, more streamlined or satisfying workload (M), leading to increased staff satisfaction and engagement with the required service changes (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 initially feeling more stressed or a loss of enthusiasm for the new pathway (O).

The main aim of RDPs 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 [22, 23, 25]. Our first theory is that this may produce greater satisfaction in staff who, in 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 [27].

However, our second theory highlights potential challenges. While potentially more prominent in the piloting or implementation, these early stages can be determining for the success

or acceptance of 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 [22, 32]. 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 [31]. 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”.

Organizational 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 [26]. 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 timeframe for producing and sharing results [27].

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 [26] (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. 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, leading to staff challenging resource use [24]. 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 [33].

Organizational Factors 3: Costs, Efficiency and Value

If health care services are politicized and viewed as overburdened / cost inefficient with near-constant pressure to improve services and reduce expenditure (C), then reduced pathway steps and reduced time to diagnosis may be perceived as better value (M), leading to a greater likelihood of sustained investment and broader organizational (e.g. managerial) buy-in (O).

One of the normative programme theories underpinning many RDCs 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 [22]. In the articles identified in this review, most of the RDPs for suspected PCa patients produced their intended outcomes, namely increased cost-effectiveness and reduced time to discharge or diagnosis [25, 27, 34]. While challenges to implementation are expected, organizational buy-in can help smooth the path from piloting to embedding a service change. In this programme theory, we posit that if an RDP demonstrates the intended effects, 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 RDPs producing these intended outcomes.

Patient Experience 1: Communication and Differing Experiences

If “Cancer” constitutes a frightening word that potentially engenders an existential confrontation with mortality (C), then waiting for results may be experienced as a particularly anxious time (M) and using virtual consultations may be perceived as reducing the waiting period (M), leading to a greater acceptance of phone consultations (O).

Conversely, patients who receive a PCa diagnosis will have undergone diagnostic tests and received a worrisome result in a shorter period (C). The nature of phone consultations

potentially engenders a less interactive experience for patients (M), impacting information absorption, opportunities to ask questions and generating a greater degree of confusion or disquiet (O).

Telephone and virtual consultations are viewed as convenient and cost-efficient ways to deliver results [27, 34, 35]. A UK-based clinic provided biopsy results by phone to cancer-free patients and in-person to those with a PCa diagnosis; this was perceived as convenient by staff and patients [27]. In one PCa RDC, a nurse provided biopsy results by telephone, which most patients (71% of 132) accepted, identifying no disadvantages [35]. Patients for whom this approach did not work well were those with inconclusive or complicated results. This group of patients felt that the nurse delivering the results had limited information. They reported feeling overwhelmed, describing an anxious period of waiting for a consultation with the urology consultant after receiving the results by phone [35]. Patients receiving a PCa diagnosis generally value direct communication, but also require time to formulate and ask questions. Where such opportunities for clarification are absent, some patients felt dissatisfied or dismissed [36]. Some of those who received a PCa diagnosis described not feeling prepared by the literature they were given. Efforts to minimize distress for the majority of RDP patients who will not have PCa may create challenges to comprehension for patients receiving a PCa diagnosis, resulting in a greater degree of shock [29, 30]. These points inform our programme theories which emphasize the differing experience of RDPs 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 RDP, 96% rated their experience as ‘good’ or ‘very good’, with 57% reporting that they received their results faster than expected [25]. 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 [37]. 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 [38].

However, there’s some evidence that patients referred to a PCa RDP may experience its rapidity as concerning as they misinterpret the speed as a sign that they have been expedited due to potential seriousness [29, 34, 37]. Further, 8% of patients who were recommended for a biopsy at a one-stop PCa RDC refused this procedure [25, 39]. While the reasons for this were not known, we posit that speed of results may put additional pressure on patients to process information and make important decisions quickly –such as consenting to biopsy or whether they want results by phone or in-person. In cases where further investigations are required, the process of booking, scheduling and making arrangements within a rapid timeframe may prove challenging for patients under stressful circumstances.

It seems intuitive that patients receiving a cancer diagnosis will have a different experience of RDPs and the mechanisms for receiving bad news when 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 RDP were more likely to experience depression for longer periods post-diagnosis when compared with patients who received a PCa diagnosis on a traditional diagnostic pathway [37]. While in Brocken *et al*’s [37] systematic review this finding was unexplained, Groarke *et al*. [40] 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. The same paper suggests offering counselling services to patients with suspected PCa [40].

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 [21, 35]. 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 [27, 34, 35]. 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 [25, 37]. Nonetheless, overall speed and convenience were treated as positive indications in the articles identified in this synthesis.

Discussion

Summary of findings

There are a number of approaches to, and growing interest in, RDPs / RDCs for various cancers and, broadly, they deliver their objective of speeding up time to diagnosis [10]. The PCa RDPs explored in this review were located within secondary care services, requiring referral from GPs or other primary care HCPs and, while there may be key differences, RDPs face similar challenges upon implementation. This review generates three broad areas impacted by RDPs, namely: primary care; organizational factors; patient experience. The theories we produced align with research that recognizes the complicated nature of change in an interconnected health system. The

‘primary care’ and ‘organizational factors’ themes underline the myriad ways in which pathway change is in part dependent on referral processes and adjoining specialisms.

Comparison with existing literature

A systematic review considering the effectiveness of RDPs (broadly conceived) also reports their association with reduced time to diagnosis and their acceptability to patients and HCPs [41]. The same review also reports that the adverse effects of one-stop clinics are statistically insignificant or of low significance [41]. Erridge *et al* [42] describe the questions raised by RDPs, such as what they might mean for the health care profession in terms of training and education. As above, there are also concerns regarding the potential “overuse” of one-stop clinics [43].

Primary Care

The theories presented under ‘Primary Care’ chime with research that explores the constraints within primary care and the challenges patients experience when trying to obtain a referral to diagnostic pathways [44]; GP perceptions of secondary service constraints negatively impact patient experience and outcomes [45]. Research corroborates patient perceptions of gatekeeping behaviours, finding that delays to diagnosis occur predominantly in primary (49%) or secondary (38%) care, as opposed to the pre-consultation (13%) stage [4]. PSA testing was a prominent theme, with its inaccuracies causing more confusion than clarity. The PPI group working on this project also views PSA testing as a point of contention that should be noted in relation to PCa RDPs. NICE guidance holds a cautious attitude towards PSA testing due to its inaccuracies and acknowledges that DRE also has an imperfect predictive value [14]. A recent systematic review states that DRE constitutes a poor referral mechanism and that symptomatic patients with a normal DRE still have a PCa risk of above 15% and therefore make a case for referral from primary care based on symptoms alone [46]. Here we point out that patients do not necessarily experience

services as discrete and experience prior to referral will likely colour patient experience of diagnostic services.

Organizational Factors

Diagnostic pathway reform is the art of making what is considered to be a straightforward and well-defined change within a complex environment with multiple factors and actors influencing the outcome – or, put differently, they are interventions or ‘events within complex social systems’ [47]. Similar to research exploring pathway change in other areas [48], we identified at least three levels across which organizational factors operate: the individuals whose work directly supports the desired changes (urology staff for PCa RDPs), adjoined or connected specialism-level services (radiology, primary care referring services), and the broader hospital and health board context. This tripart approach to service change aligns with behaviour change models, like the ‘Behaviour Change Wheel’ [49], which emphasizes the multi-directional dependencies when working towards service change: issuing guidelines without individual buy-in is unlikely to work, yet individual enthusiasm is unlikely to drive change without organizational support. For example, a urology department aiming to trial a PCa RDP may be supported by an organizational context that uses its influence and resources to encourage adjoining departments to participate, adapt and evaluate as required for the trial period. The organization may use behavioural change techniques such as incentivization, persuasion or coercion to influence, with the approach chosen also impacting the motivation (or other mechanisms for behavioural change) of individual actors [49]. While this review has produced three levels, we acknowledge that these exist within a broader context and this review has not identified research pertaining to the impact of individual personalities or broader contextual factors, which nonetheless exert influence [50]. The theories produced here in relation to organizational factors illustrate the interdependent nature of change and the support required at these three levels.

Patient Experience

Communication and distress are significant subthemes under ‘Patient Experience’. The convenience of RDPs constitutes a significant benefit for those living in rural areas, particularly in cases where MRI results are provided on the same day or virtually. However, given that anxiety and other distressing mental health symptoms occur as subthemes, we also hypothesize that a one-size-fits-all approach to the delivery of results may have adverse effects on some patients. Distress is unsurprising and to a certain extent unavoidable as people with unexplained symptoms undergoing tests often experience symptoms like anxiety or depression [51]. As such, some RDPs take steps to try to reduce anxiety – for example, emphasizing to patients that, for the majority of those referred to an RDP, the results will find them cancer-free. Yet, some research suggests that by adopting this utilitarian approach, those who receive a cancer diagnosis may be under-prepared, which (coupled with the speed of RDPs) may contribute to and exacerbate distress.

Strengths / Limitations / Future Research

To our knowledge, this is the first realist review of PCa diagnostic processes; PPI constitutes one of its strengths. This review may be used to inform interpretation and implementation of public health policy and targets for earlier cancer diagnosis. We focus on PCa diagnostic pathway, and while points may be transferrable to other cancer pathways, this may be limited. So far, much of the research in this area is outcome-centric; this realist review adds to the literature by identifying and exploring contextual and mechanistic factors influencing the way RDPs work.

Conclusions / Recommendations

Above, we have produced theories regarding PCa RDPs. From this review, we have extrapolated three recommendations:

1. If the presence of PCa RDPs make GPs more likely to refer, then inclusion of GP voices in the referral criteria in addition to communication strategy to ensure patients are aware of the purpose of the pathway and to avoid undue anxiety related to rapidity.
2. When planning to trial or implement an PCa RDP, consider the multiple levels of engagement required for behaviour change and include adjoining services, particularly radiology, and managerial/ decision-making levels accordingly.
3. When trialing or implementing a PCa RDP, consider identifying patients who may be less resilient during the process and signposting patients to appropriate support. As a caveat, ensure that support is readily available and easy to access to avoid creating additional labour, waiting-related anxiety and stress for the patient.

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References

- [1] Neal, R. D., Tharmanathan, P., France, B., Din, N. U., Cotton, S., Fallon-Ferguson, J., Hamilton, W., Hendry, A., Hendry, M., Lewis, R., Macleod, U., Mitchell, E. D., Pickett, M., Rai, T., Shaw, K., Stuart, N., Tørring, M. L., Wilkinson, C., Williams, B., Williams, N., Emery, J. (2015). Is increased time to diagnosis and treatment in symptomatic cancer associated with poorer outcomes? Systematic review. *British journal of cancer*, 112 Suppl 1(Suppl 1), S92–S107. <https://doi.org/10.1038/bjc.2015.48>
- [2] 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>
- [3] CRUK (2018). Cancer in the UK 2018. *CRUK*
Website: www.cancerresearchuk.org/sites/default/files/state_of_the_nation_apr_2018_v2_0.pdf.
- [4] Swann, R., Lyratzopoulos, G., Rubin, G., Pickworth, E., & McPhail, S. (2020). The frequency, nature and impact of GP-assessed avoidable delays in a population-based cohort of cancer patients. *Cancer epidemiology*, 64, 101617. <https://doi.org/10.1016/j.canep.2019.101617>
- [5] NHS English (2018). The long term plan for the NHS. NHS England. Accessed: <https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/>
- [6] CRUK (2020). Key Messages: Accelerate, Co-ordinate, Evaluate. CRUK. <https://www.cancerresearchuk.org/health-professional/diagnosis/accelerate-coordinate-evaluate-ace-programme>

- [7] Vedsted, P., & Olesen, F. (2015). A differentiated approach to referrals from general practice to support early cancer diagnosis - the Danish three-legged strategy. *British journal of cancer*, 112 Suppl 1(Suppl 1), S65–S69. <https://doi.org/10.1038/bjc.2015.44>
- [8] NHS England (2018). New ‘one stop shops’ for cancer to speed up diagnosis and save lives. NHS England. Accessed: [NHS England » New ‘one stop shops’ for cancer to speed up diagnosis and save lives](#)
- [9] 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>
- [10] Dolly, S. O., Jones, G., Allchorne, P., Wheeler, D., Ali, S., Mukadam, Y., Zheng, S., Rahman, L., Sindhar, J., Moss, C. L., Harari, D., Van Hemelrijck, M., Cunliffe, A., & De Michele, L. V. (2021). The effectiveness of the Guy's Rapid Diagnostic Clinic (RDC) in detecting cancer and serious conditions in vague symptom patients. *British journal of cancer*, 124(6), 1079–1087. <https://doi.org/10.1038/s41416-020-01207-7>
- [11] 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>
- [12] MFT (2016). Manchester Lung Health Check Pilot. Accessed: [Manchester's Lung Health Check Pilot report \(mft.nhs.uk\)](#)
- [13] Prostate Cancer UK (2023). About Prostate Cancer. Accessed: [About prostate cancer | Prostate Cancer UK](#)
- [14] NICE (2019). Prostate cancer: diagnosis and management. NICE Guidance. Accessed: <https://www.nice.org.uk/guidance/ng131/chapter/recommendations>
- [15] Noh, T. I., Tae, J. H., Kim, H. K., Shim, J. S., Kang, S. G., Sung, D. J., Cheon, J., Lee, J. G., & Kang, S. H. (2020). Diagnostic Accuracy and Value of Magnetic Resonance Imaging-Ultrasound Fusion Transperineal Targeted and Template Systematic Prostate Biopsy Based on Bi-parametric Magnetic Resonance Imaging. *Cancer research and treatment*, 52(3), 714–721. <https://doi.org/10.4143/crt.2019.716>
- [16] Hsi, R. A., Dinh, T. K., Greer, M., Bensen, C., Mitchell, M. A., Li, A. Y., Stamm, A., & Henne, M. (2022). Performance of multiparametric prostate magnetic resonance imaging validated by targeted and systematic transperineal biopsies. *BJUI compass*, 4(1), 96–103. <https://doi.org/10.1002/bco2.184>

- [17] Pawson, R., & Tilley, N. (1997). An introduction to scientific realist evaluation. In E. Chelmsky & W. R. Shadish (Eds.), *Evaluation for the 21st century: A handbook* (pp. 405–418). Sage Publications, Inc. <https://doi.org/10.4135/9781483348896.n29>
- [18] Wong, G., Greenhalgh, T., Westhorp, G. *et al.* Realist methods in medical education research: What are they and what can they contribute? *Medical Education*, 2012; 46(1): 89-96. doi:10.1111/j.1365-2923.2011.04045.x p. 92
- [19] 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>
- [20] 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>
- [21] 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>
- [22] 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>
- [23] 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>
- [24] Withington, J., Kaur, K., Sobczak, J., McNally, C., Moghul, M., Cahill, D., & Kinsella, N. (2021). Putting clinical assessment and patient experience at the centre of prostate cancer diagnostics: The superior prostate experience and efficient diagnostics (SPEED) pathway. *European Urology*, 79, S1318-S1319.
- [25] 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>
- [26] 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>

[27] 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

[28] Emery, J. D., Walter, F. M., Gray, V., Sinclair, C., Howting, D., Bulsara, M., Bulsara, C., Webster, A., Auret, K., Saunders, C., Nowak, A., & Holman, D. (2013). Diagnosing cancer in the bush: a mixed methods study of GP and specialist diagnostic intervals in rural Western Australia. *Family practice*, 30(5), 541–550. <https://doi.org/10.1093/fampra/cmt016>

[29] 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>

[30] 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>

[31] 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

[32] Allgood, E., Abreu, A. L., & Palmer, S. L. (2021). Expedited Workflow for "One-Stop" Magnetic Resonance Imaging and Image Fusion Prostate Biopsy: Implementation and Lessons Learned. *Seminars in roentgenology*, 56(4), 406–409. <https://doi.org/10.1053/j.ro.2021.08.004>

[33] Brice, S. N., Harper, P., Crosby, T., Gartner, D., Arruda, E., England, T., Aspland, E., & Foley, K. (2021). Factors influencing the delivery of cancer pathways: a summary of the literature. *Journal of health organization and management*, 35(9), 121–139. <https://doi.org/10.1108/JHOM-05-2020-0192>

[34] 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>

[35] 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>

[36] 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>

[37] Brocken, P., Prins, J. B., Dekhuijzen, P. N., & van der Heijden, H. F. (2012). The faster the better?—A systematic review on distress in the diagnostic phase of suspected cancer, and the influence of rapid diagnostic pathways. *Psycho-oncology*, 21(1), 1–10.

<https://doi.org/10.1002/pon.1929>

[38] 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>

[39] Lopez, J. F., & Bryant, R. J. (2023). The 'Rapid Access Prostate Imaging and Diagnosis' (RAPID) diagnostic pathway: what is the rush?. *BJU international*, 131(4), 377–379.

<https://doi.org/10.1111/bju.15971>

[40] 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>

[41] Friedemann Smith, C., Tompson, A., Holtman, G. A., Bankhead, C., Gleeson, F., Lasserson, D., & Nicholson, B. D. (2019). General practitioner referrals to one-stop clinics for symptoms that could be indicative of cancer: a systematic review of use and clinical outcomes. *Family practice*, 36(3), 255–261. <https://doi.org/10.1093/fampra/cmy069>

[42] Erridge, S., Lyratzopoulos, G., Renzi, C., Millar, A., & Lee, R. (2021). Rapid Diagnostic Centres and early cancer diagnosis. *The British journal of general practice : the journal of the Royal College of General Practitioners*, 71(712), 487–488.

<https://doi.org/10.3399/bjgp21X717413>

[43] Patel, R. S., Smith, D. C., & Reid, I. (2000). One stop breast clinics--victims of their own success? A prospective audit of referrals to a specialist breast clinic. *European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology*, 26(5), 452–454. <https://doi.org/10.1053/ejso.1999.0920>

[44] Sripa, P., Hayhoe, B., Garg, P., Majeed, A., & Greenfield, G. (2019). Impact of GP gatekeeping on quality of care, and health outcomes, use, and expenditure: a systematic review. *The British journal of general practice : the journal of the Royal College of General Practitioners*, 69(682), e294–e303. <https://doi.org/10.3399/bjgp19X702209>

[45] Cavers, D., Duff, R., Bikker, A. *et al.* (2021). Patient and GP experiences of pathways to diagnosis of a second primary cancer: a qualitative study. *BMC Cancer* 21, 496.

<https://doi.org/10.1186/s12885-021-08238-0>

- [46] Jones, D., Friend, C., Dreher, A., Allgar, V., & Macleod, U. (2018). The diagnostic test accuracy of rectal examination for prostate cancer diagnosis in symptomatic patients: a systematic review. *BMC family practice*, 19(1), 79. <https://doi.org/10.1186/s12875-018-0765-y>
- [47] Moore, G. F., Evans, R. E., Hawkins, J., Littlecott, H., Melendez-Torres, G. J., Bonell, C., & Murphy, S. (2019). From complex social interventions to interventions in complex social systems: Future directions and unresolved questions for intervention development and evaluation. *Evaluation*, 25(1), 23-45. <https://doi.org/10.1177/1356389018803219>
- [48] Jabbour, M., Newton, A.S., Johnson, D. *et al.* Defining barriers and enablers for clinical pathway implementation in complex clinical settings. *Implementation Sci* 13, 139 (2018). <https://doi.org/10.1186/s13012-018-0832-8>
- [49] Michie, S., van Stralen, M.M. & West, R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Sci* 6, 42 (2011). <https://doi.org/10.1186/1748-5908-6-42>
- [50] Bronfenbrenner, U. (1977). Toward an experimental ecology of human development. *American Psychologist*, 32(7), 513–531. <https://doi.org/10.1037/0003-066X.32.7.513>
- [51] Romanazzo, S., Mansueto, G., & Cosci, F. (2022). Anxiety in the Medically Ill: A Systematic Review of the Literature. *Frontiers in psychiatry*, 13, 873126. <https://doi.org/10.3389/fpsy.2022.873126>

