Prostate cancer overdiagnosis in the MRI era: an evidence review

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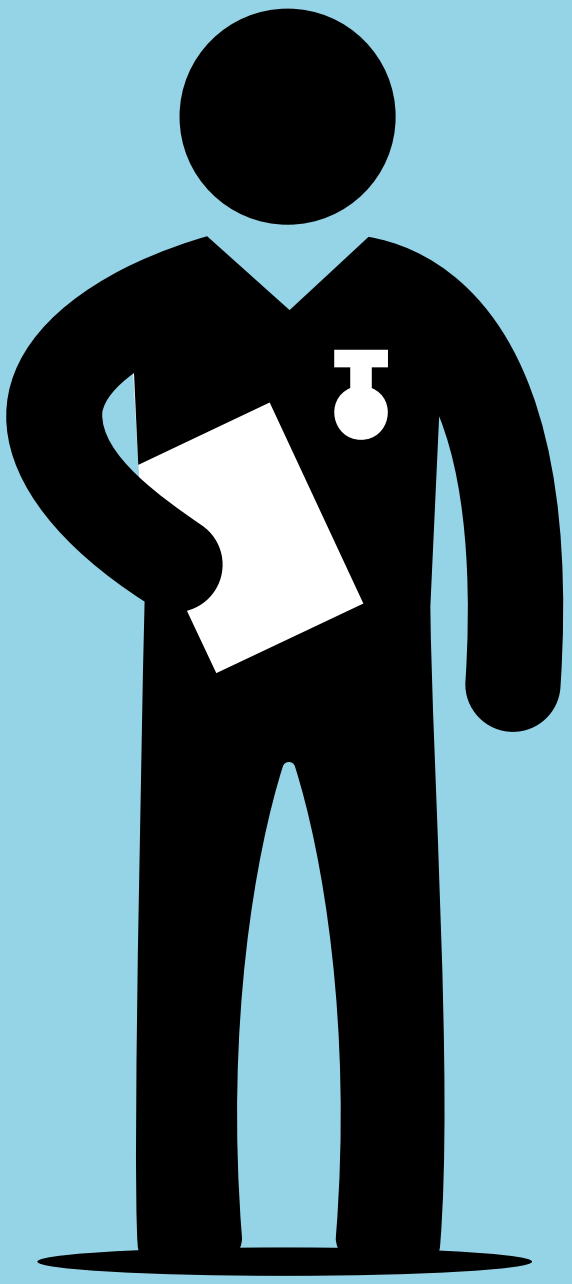

PROSTATE CANCER UK

Contents

About this document

This evidence review was conceptualised and authored by Prostate Cancer UK. It provides a comprehensive analysis of recent evidence on overdiagnosis within the MRI era and explores potential strategies to reduce its impact on patients and clinical practice.

Reference

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Author

Natalia Norori, on behalf of the Data & Evidence team at Prostate Cancer UK

Please contact **dataandevidence@prostatecanceruk.org** for any questions, comments or feedback on the report

1. Introduction

On average, more than 56,000 men are diagnosed with prostate cancer every year in the UK. Prostate cancer is the second leading cause of cancer death in men, accounting for 12,000 deaths each year.[1] Despite its high incidence and mortality, as of July 2025, Prostate cancer is the only major cancer without a screening programme in the UK.

The aim of cancer screening programmes is to diagnose cancers or pre-cancerous lesions at an early stage and improve the likelihood of successful treatment and survival.[2] Past prostate cancer screening trials have highlighted that screening with the PSA test reduces prostate-cancer specific mortality by up to 21%, and metastatic prostate cancer diagnoses by 30% .[3,4] However, screening with the PSA test causes several harms, including side effects as a result from the diagnostic process, psychological distress, and overdiagnosis.[3,5]

Overdiagnosis is defined as the diagnosis of prostate cancer that would not have caused any harm during a man's lifetime.[2] In the ERSPC trial, after 16 years of follow-up, 570 men needed to be invited for screening and 18 needed to be diagnosed to prevent one prostate cancer death. This reflects the increased incidence of prostate cancer among screened men. At 16 years, the excess incidence of prostate cancer cases in the screening arm, when compared to the control arm was 41%, indicating a substantial rate of potential overdiagnosis.[3] An intention-to-treat analysis of the Rotterdam arm of the ERSPC trial showed a reduction in these figures, with 246 men needed to be invited and 18 needed to be diagnosed to prevent one prostate cancer death.[6] In light of this evidence, the UK National Screening Committee (NSC) recommended against population-wide screening for prostate cancer, concluding that the potential harms outweigh the overall benefits.[7]

The prostate cancer screening trials that highlighted the harms of overdiagnosis tested prostate cancer screening using the PSA test followed by a prostate biopsy, an approach that no longer represents UK clinical practice. The prostate cancer diagnostic pathway has evolved substantially since the completion of these trials. Advances such as the introduction of pre-biopsy MRI, the rise of trans perineal biopsy, the development of risk stratified diagnostic and prognostic strategies, and the wider adoption of active surveillance have contributed to making the prostate cancer pathway safer and more accurate.[8,9] The UK National Screening Committee is currently conducting a new evidence review that evaluates the latest evidence on prostate cancer screening, including the cost-effectiveness of screening for prostate cancer using the PSA test followed by a pre-biopsy MRI.

Overdiagnosis remains a key concern in this context and continues to be central to the debate surrounding PSA-based prostate cancer screening in the UK. With the widespread adoption of pre-biopsy MRI and novel risk-stratified approaches, the landscape of prostate cancer detection is continuously evolving. This paper aims to provide an overview of recent evidence on overdiagnosis within the MRI era and explore potential strategies to mitigate its consequences.

2. Key concepts

Overdiagnosis

Overdiagnosis occurs when asymptomatic individuals are diagnosed with a disease that was never going to cause symptoms or harm during a person's remaining lifetime.[10] The concept can be difficult to grasp at an individual level, as patients rarely view diagnoses of potentially lethal diseases as harmful.[11]

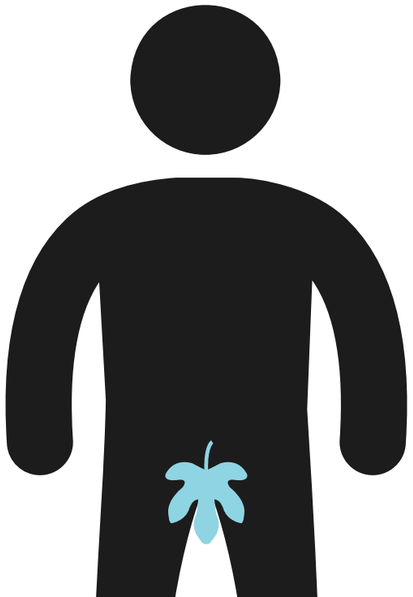
Overdiagnosis is a common challenge to implementing prostate cancer screening, as many prostate cancer tumours grow slowly or may never progress at all. Past prostate cancer screening trials have demonstrated that overdiagnosis manifests as excess prostate cancer incidence in the screened arm, that persists after several years of follow up.[12] Overdiagnosis is linked to several physical and psychological harms and poses a large economic burden to healthcare systems.[13]

These issues highlight the urgent need for improved prognostic tools and risk stratification methods that can more accurately predict which prostate cancers are likely to cause harm. The Cambridge Prognostic Groups (CPGs), a five-tiered risk stratification system for non-metastatic prostate cancer, has shown greater predictive accuracy for prostate cancer-specific mortality than traditional three-tiered classifications. This system enables clinicians to better assess individual risk and guide treatment decisions. Although it is not possible to fully determine at the time of diagnosis whether a tumour will progress if left untreated, the system offers a reliable tool to estimate risk of progression and death and delay radical treatment until it is required.[14]

Clinically insignificant prostate cancer

Prostate cancers that are unlikely to cause harm if left untreated are also referred to as 'clinically insignificant' or 'indolent' prostate cancers. A literature review found the characteristics used to define clinically insignificant prostate cancer varies widely.[15] The criteria most frequently used to define clinically insignificant prostate cancer includes T stage, tumour volume, and Grade group pattern.[15] The majority of studies consider prostate cancers diagnosed in grade group 1 (previously known as Gleason 6), T stage 1, and tumour volume of less than 0.5cm as clinically insignificant. However, some groups go beyond this and consider Grade Group 2 (previously Gleason grade 3+4) and T stage 1 or 2 as clinically insignificant.[16]

Sometimes clinically insignificant prostate cancer is used as a proxy for overdiagnosis; however, this is misleading as not all clinically insignificant prostate cancers will remain low risk. While evidence suggests that most low-risk prostate cancers are unlikely to cause harm, a small percentage could still progress over time and may eventually require radical treatment.[17,18]



3. Harms of overdiagnosis

Overdiagnosis has been associated with detrimental physical and psychological effects. Common physical consequences include complications from the diagnostic process, such as infection and sepsis following biopsy, as well as side effects from overtreatment like erectile dysfunction, urinary incontinence, and bowel dysfunction. Overdiagnosis has also been linked to psychological harms, such as anxiety and worry.[10]

Psychological harms

The psychological harms associated with the prostate cancer diagnostic process can vary from mild to severe and include anxiety, depression, and severe distress.[10,19] These harms can have a profound impact on men's quality of life and can appear at different points in the diagnostic process. Distress and worry can arise before patients have a test, while they are waiting for test results, at the point of diagnosis, and during treatment. Studies assessing the harms vary in size and design, from small qualitative assessments to large, randomised trials.[19]

A literature review of 8 studies that examined the psychological impact of active surveillance among men diagnosed with prostate cancer uncovered key themes such as anxiety, clinical depression, and uncertainty. Men on active surveillance reported higher levels of prostate-related anxiety when compared to men receiving radical treatment. While active surveillance was shown to provoke uncertainty and fear, anxiety levels may decrease over time.[20]

Complications from the diagnostic process

Complications after biopsy

A prostate biopsy is the final step in the prostate cancer diagnostic pathway. While generally safe, prostate biopsies can result in various complications that differ depending on the biopsy technique used. Common complications include bleeding in urine, pain, urinary dysfunction and sexual dysfunction.[21] Other complications include bowel dysfunction and infection.[22] The most severe complication from biopsy is sepsis, which can be life-threatening, although biopsy related mortality is rare.[21] The incidence of sepsis has decreased over time. In the CAP trial, 0.1% of men developed sepsis following prostate biopsy. More recent real-world data from hospitals in London, examining men undergoing the current MRI-based prostate cancer diagnostic pathway, reported even lower sepsis rates of 0.02%.[8]

Until recently, prostate biopsies were primarily performed using transrectal ultrasound (TRUS) guidance with 10-12 core samples taken. This approach involved inserting several needles into the prostate and was associated with a wide range of side effects.[8] The PRECISION trial compared the standard TRUS biopsy with MRI-guided biopsy and found that MRI-guided biopsies were more effective at detecting clinically significant prostate cancers, and reducing clinically insignificant diagnoses when compared to TRUS biopsies. This trial also found that participant-reported complications at 30 days were less frequent in the MRI-guided biopsy group than in the TRUS biopsy group, including events of blood in the urine (30% vs. 63%), blood in the semen (32% vs. 60%), pain at the site of the procedure (13% vs. 23%), rectal bleeding (14% vs. 22%), and erectile dysfunction (11% vs. 16%).[23]

Trans perineal (LATP) biopsies have gained popularity in recent years due to its avoidance of rectal flora.[24] Evidence suggests LATP biopsies are superior at targeting MRI visible anterior and apical lesions when compared to TRUS biopsies.[24] LATP biopsies are also associated with fewer side effects including lower rates of sepsis when compared to transrectal biopsies.[25] The TRANSLATE trial compared LATP and TRUS biopsy in a controlled setting and found no statistically significant differences in biopsy complications. However, serious biopsy complications were more frequent in the TRUS group (4%) when compared to the LATP group (2%).[24] In addition, a UK cohort study that compared complications for patients who had a trans perineal biopsy vs a transrectal biopsy found that those who had a trans perineal biopsy were less likely to be readmitted due to sepsis, but slightly more likely to be readmitted due to urinary retention. Use of the LATP biopsy instead of TRUS would prevent one readmission for sepsis in 278 patients at the cost of three additional patients readmitted for urinary retention.[26] The National Prostate Cancer Audit reported that in 2021, 40% of men diagnosed with prostate cancer in England undergo a LATP biopsy.[27]

Unnecessary biopsies

Going through the prostate cancer diagnostic pathway can be an anxiety inducing process. The PSA test is the first in the prostate cancer diagnostic pathway, but it is not a diagnostic test on its own. A scenario analysis of real-world data estimates that among 10,000 men who undergo a PSA test, approximately 6% will be diagnosed with prostate cancer, but only about 2.3% will have clinically significant prostate cancer.[8] Although the use of pre-biopsy MRI has reduced the number of men who have a biopsy that shows no cancer, several men that don't have cancer still go through this invasive procedure. 8 Five studies have demonstrated that using MRI triage before biopsy can rule out between 21% and 49% of men from undergoing biopsy.[9] Our analysis of Real-world data shows that this is being delivered in clinical practice.[8]

Overtreatment

Overtreatment occurs when over-diagnosed cancers are treated. When men have treatment that they don't need, they don't get any benefits from treatment but experience the harms that come with it.[13] This can significantly impact their quality of life. According to the latest data from the National Prostate Cancer Audit, 8% of men with lowest risk cancers are potentially over-treated within a year of diagnosis, although rates vary by trust and range between 2% to 24%.[28]

The side effects from radical prostatectomy and prostate radiotherapy can cause a severe decline on quality of life. These include urinary incontinence, erectile disfunction, and bowel incontinence.[29] An analysis of quality of life outcomes of men involved in the ProtecT trial showed that prostatectomy had a greater negative effect on urinary function and sexual function when compared to radiotherapy and active monitoring. In contrast, radiotherapy is associated with higher rates or bowel incontinence when compared to radical prostatectomy.[22] Novel techniques like robotic assisted radical prostatectomy have been shown to reduce some urinary complications, making it a safer option for selected patients.[30,31]

In addition to radical treatment, hormone therapy, like Androgen Deprivation Therapy (ADT) can cause various side effects. For instance, erectile dysfunction affects 94% of men on ADT.[32] Other common adverse effects include loss of libido, hot flashes, fatigue, changes in body image, anaemia, depression, and an increased risk of bone fractures and cardiovascular disease.[32]

4. Strategies to mitigate the harms of overdiagnosis

While the harms of overdiagnosis have been reduced after the introduction of new technologies into the prostate cancer diagnostic pathway, they have not been completely eliminated. Overdiagnosis is still a valid concern, and some men will still experience harm. Active surveillance and risk-based early detection approaches can help further reduce these harms.

Active surveillance

Active surveillance involves regular monitoring for signs of cancer progression in patients with low- to intermediate-risk, localised prostate cancer, in order to avoid or delay radical treatment.[33] The ProtecT trial showed no difference in prostate cancer specific mortality among men assigned to active surveillance and radical treatment after 15 years of follow up, although the way in which AS was monitored deferred from current practice.17 Estimates suggest that of all men diagnosed with non-metastatic prostate cancer in England, 17.7% are CPG 1 and 21.9% are CPG 2 and potential candidates for active surveillance.[34] The CPGs can be used to classify men's risk of progression and prostate cancer mortality. It uses a wide range of tumour characteristics to determine those who would benefit from active surveillance.[35]

Men diagnosed with CPG 1 and 2 have a very favourable prognosis.[14,18] NICE Guidelines for the diagnosis and management of prostate cancer recommend active surveillance as the first treatment choice for men diagnosed with CPG1. For men diagnosed with CPG2, the recommendation is to offer a choice between active surveillance and radical treatment options.[36] If administered well, active surveillance can effectively delay treatment until it is necessary, preserving quality of life.

A study published in 2019 reported significant variation in active surveillance practice across UK hospitals.[33] A recent FOI analysis confirms this variation persists, revealing important differences between current hospital protocols and NICE guidelines. Key areas of variation include the criteria used to recommend active surveillance to men, risk-stratified follow up approaches, and clinical end points to determine when active surveillance is recommended.[37] Standardising active surveillance practices across the UK is critical to improving the quality and safety of active surveillance and reducing inequalities in prostate cancer care.

Risk-based approaches

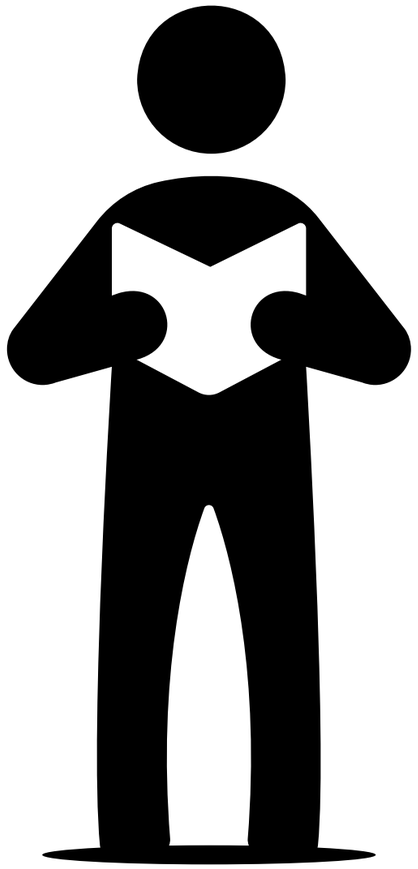
Routine prostate cancer screening is not recommended in the UK, but the NHS follows an informed choice policy set by the Prostate Cancer Risk Management Programme (PCRMP). PCRMP states that the PSA test is available for free to any men who request it and has been informed of the potential benefits and harms of the test. The policy prevents GPs from raising the issue with asymptomatic men.[38] This informed choice approach has contributed to high rates of PSA testing in the UK.[39] In addition, approaches that rely on informed choice are likely to widen health inequalities and increase overdiagnosis,[39] as those who have higher levels of health literacy are better equipped to request the test, but they are not necessarily the most likely to benefit from it. In the UK, PSA testing rates are unevenly distributed. Men living in the south, older men, and men from affluent areas are more likely to get access to PSA testing.[40] A recent study reported large variation in asymptomatic PSA detected prostate cancer diagnoses between practice, which speaks to the ongoing lack of clarity regarding prostate cancer screening practice in the UK.[41]

Research suggests a comprehensive, risk based prostate cancer detection programme that considers approaches for men at highest risks and based on best evidence on how to use PSA testing and manage subsequent diagnostic follow-up and treatment could reduce overdiagnosis and overtreatment.[39] In addition, targeted awareness raising approaches can help reach and activate higher risk men to check their prostate cancer risk. Focusing interventions on men at the highest risk, including Black men and men with a family history aged 45 and over, can help ensure that those most likely to benefit from the PSA test are the ones who access it.[42]

5. Conclusion

The prostate cancer pathway is safer and more accurate than ever before, but some men continue to experience harm. The majority of the evidence of the harms of the diagnostic process builds on the experiences of men that went through the pre-MRI prostate cancer pathway. Understanding the physical side effects that men experience while going through the current prostate cancer diagnostic pathway and monitoring the psychological impact of the diagnostic process and active surveillance remains important. Improving the quality of support men receive throughout their journey can play a crucial role in reducing the psychological impacts experienced by men diagnosed with low-risk prostate cancer.[43]

Targeting early detection interventions towards men at higher risk of prostate cancer can minimise the harms of overdiagnosis while maximising overall benefit.[44] A risk-based prostate cancer early detection programme could also help reduce variation in PSA testing rates, overdiagnosis and overtreatment.[39] In addition, standardising active surveillance practices, updating guidelines to reflect the latest evidence, and ensuring men have access to appropriate support while on active surveillance are essential so that men with low-risk prostate cancer can safely delay treatment until it is truly needed. Ongoing efforts to improve the safety and accuracy of the prostate cancer diagnostic pathway must be sustained to guarantee all men have access to a safe and accurate diagnosis.



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