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Review Article

Prostate Cancer Screening: Toward a Risk-Stratified Public Health Model to Reduce Overdiagnosis and Optimize Resource Allocation

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Abbreviations: 4Kscore: Four-Kallikrein Panel; AUA/SUO: American Urological Association / Society of Urologic Oncology; BRCA2: BReast CAncer gene 2; CAP: Cluster Randomized Trial of PSA Testing for Prostate Cancer; EAU: European Association of Urology; ERSPC: European Randomized Study of Screening for Prostate Cancer; mpMRI: Multiparametric Magnetic Resonance Imaging; NCCN: National Comprehensive Cancer Network; PHI: Prostate Health Index; PI-RADS: Prostate Imaging-Reporting and Data System; PRS: Polygenic Risk Score; PSA: Prostate-Specific Antigen; QALY: Quality-Adjusted Life-Year; SDM: Shared Decision-Making; USPSTF: US Preventive Services Task Force

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Abstract

Introduction: PSA-based screening reduces prostate cancer mortality but is associated with significant overdiagnosis and overtreatment. This review evaluates the transition from age-based screening to risk-stratified models to optimize resource allocation.

Methods: We synthesized data from landmark randomized trials (ERSPC, Göteborg-1, CAP), recent clinical guidelines (AUA/SUO, NCCN, EAU), and emerging results from risk-stratified trials such as ProScreen and BARCODE1.

Results: Evidence suggests that integrating baseline PSA, multiparametric MRI (mpMRI), and blood-based biomarkers (e.g., Stockholm3) significantly reduces unnecessary biopsies and overdiagnosis. While Polygenic Risk Scores (PRS) show potential in identifying high-risk individuals, their clinical integration is currently limited to trial settings. Sequential screening algorithms demonstrate the feasibility of maintaining mortality benefits while reducing healthcare expenditure.

Conclusion: A shift toward risk-stratified public health models is essential to balance the benefits and harms of screening. Future efforts must focus on validating these models across diverse populations and ensuring scalability in resource-limited settings.

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Introduction

Prostate cancer is the most commonly diagnosed non-cutaneous malignancy and the second leading cause of cancer death among men in the United States [1,2]. Approximately 75% of newly diagnosed cases present with localized disease, and 10-year prostate cancer–specific survival for localized disease exceeds 95% [1,3]. The central tension in prostate cancer screening lies between the modest mortality reduction conferred by PSA-based early detection and the considerable harms of overdiagnosis—the identification of cancers that would never have caused symptoms or death during a patient's lifetime [4,5].

The 2018 US Preventive Services Task Force (USPSTF) recommendation endorsed Shared Decision-Making (SDM) for men aged 55-69 years and recommended against screening in men 70 years and older [5]. However, this age-based framework does not account for the heterogeneity of prostate cancer risk across individuals. A growing body of evidence now supports risk-stratified screening as a means to concentrate resources on men most likely to benefit while sparing low-risk individuals from unnecessary testing and its downstream consequences [4,6].

The evidence base for PSA screening: Benefits and harms

Mortality Reduction

The European Randomized Study of Screening for Prostate Cancer (ERSPC), the largest and longest-running screening trial, reported a 13% relative reduction in prostate cancer mortality at 23 years of follow-up, with an absolute risk reduction of 0.22% [4]. The number needed to invite to prevent one prostate cancer death decreased from 628 at 16 years to 456 at 23 years, and the number needed to diagnose fell from 18 to 12 [4]. The Göteborg-1 trial, with the most favorable screening protocol (biennial screening from age 50), demonstrated a number needed to screen of 23 and number needed to diagnose of 6 to prevent one death at 15 years [6]. The Cluster Randomized Trial of PSA Testing for Prostate Cancer (CAP) found a small absolute reduction in prostate cancer mortality (0.09%) after a single PSA screening invitation with 15 years of follow-up, but no effect on overall survival [7].

While the ERSPC demonstrates a significant mortality benefit, it is subject to limitations, including high rates of opportunistic screening in control arms and protocol heterogeneity across European centers, which may dilute the observed effect size.

Overdiagnosis and overtreatment

Overdiagnosis remains the most consequential harm of PSA-based screening. Trial data suggest that 20-50% of screen-detected prostate cancers are overdiagnosed [5]. The ERSPC reported a doubling in the detection of low-risk cancers in the screening group and an excess incidence of 27 cases per 1,000 men [4]. Among men who are screened regularly, approximately 15% will receive a false-positive result over 10 years, and cancer is not detected in 75% of biopsies performed [2]. Treatment-related harms include long-term urinary incontinence in approximately 20% of men undergoing radical prostatectomy and erectile dysfunction in up to two-thirds [5]. These figures underscore the ethical necessity of risk-stratified models that prioritize the detection of Grade Group ≥2 disease while minimizing the identification of indolent tumors.

The case for risk stratification

The final ERSPC report explicitly called for "a more targeted strategy for prostate cancer screening that focuses on identifying population subgroups that are most likely to benefit from early detection while reducing unnecessary interventions for those with the highest risk of overdiagnosis" [4]. Risk stratification can be applied at multiple levels: determining who should be screened, how often, and what diagnostic pathway should follow an elevated PSA.

Baseline PSA as a risk stratifier

Midlife PSA levels are powerful predictors of long-term prostate cancer outcomes. In the Malmö Preventive Project, men aged 45-49 years with PSA in the highest decile (≥1.6 ng/mL) contributed to nearly half of prostate cancer deaths over the next 25-30 years, whereas those with PSA below the median (0.68 ng/mL) had a 25-year metastasis risk of only 0.85% [6]. Men aged 60 years with PSA 1 ng/mL had a 25-year risk of prostate cancer death of only 0.2% in a largely unscreened population [6]. These data support lengthening screening intervals or discontinuing screening in men with very low baseline PSA, while intensifying surveillance in those with higher values. The 2023 AUA/SUO guideline recommends re-screening intervals of 1-4 years for PSA 1-3 ng/mL and prolonged intervals for PSA 1 ng/mL [6]. The NCCN (v2.2026) similarly recommends 2-4 year intervals for PSA 1 ng/mL and 1-2 year intervals for PSA 1-3 ng/mL [8].

Clinical and demographic risk factors

Black/African American men have significantly higher prostate cancer incidence, earlier age at diagnosis, and increased mortality compared with White men [8]. The NCCN recommends that Black individuals consider beginning SDM about PSA screening at age 40 years and consider annual screening intervals [8]. Carriers of germline pathogenic variants in DNA damage repair genes, particularly BRCA2, face 2- to 8.6-fold higher risk of prostate cancer and a higher risk of aggressive disease [9]. The European Association of Urology now recommends screening in BRCA2 carriers beginning at age 40 [10]. Family history, Agent Orange exposure, and other environmental factors further modulate individual risk [8].

Polygenic risk scores

Genome-wide association studies have identified over 170 common germline variants associated with prostate cancer risk. Polygenic Risk Scores (PRS) aggregate these variants to estimate individual genetic susceptibility. The BARCODE1 trial, published in the New England Journal of Medicine in 2025, screened 6,393 men aged 55–69 years using a 130-variant PRS

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[10]. Among the 745 men (11.7%) with PRS in the 90th percentile or higher, 40% were found to have prostate cancer on MRI and biopsy, and 55.1% of detected cancers were classified as intermediate risk or higher by NCCN criteria [10]. Critically, 71.8% of these clinically significant cancers would not have been detected by the standard UK diagnostic pathway (elevated PSA plus positive MRI) [10]. The estimated overdiagnosis rate was 15.6-20.8%, comparable to PSA-based screening studies [10]. A modeling study from the United Kingdom found that risk-based screening using a 10-year absolute risk threshold of approximately 4% (incorporating PRS and age) generated the greatest number of Quality-Adjusted Life-Years (QALYs), with one-third fewer overdiagnoseds cancers compared with age-based screening [11]. However, the NCCN currently states that PRS "should not be used for clinical management at this time and use is recommended in the context of a clinical trial" [12].

Similarly, the BARCODE1 trial, while transformative, relied on a cohort of predominantly European ancestry. The generalizability of its PRS to diverse global populations remains a critical gap in the evidence base.

Refining the diagnostic pathway: MRI and blood-based biomarkers

Multiparametric MRI

The integration of mpMRI before biopsy represents a major advance in reducing overdiagnosis. The NCCN now designates mpMRI as a Category 1 recommendation for men with elevated PSA prior to biopsy. In contrast, blood-based biomarkers such as PHI and 4Kscore are classified as Category 2B, emphasizing they should supplement rather than replace image-guided pathways [8]. MRI-targeted biopsy significantly increases detection of clinically significant (Grade Group ≥3) disease while lowering detection of low-risk (Grade Group 1) disease [8]. Microsimulation modeling calibrated to ERSPC data demonstrated that incorporating MRI prior to biopsy decreased overdiagnosis by 6%, and adding a risk calculator further reduced overdiagnosis to 10%, while maintaining equivalent prostate cancer mortality [13].

Blood-based risk prediction models

The Stockholm3 test, which combines clinical variables, plasma protein biomarkers, and a polygenic risk score, has been validated in the STHLM3-MRI randomized trial [14]. Compared with traditional PSA-based screening with systematic biopsies, the combination of Stockholm3 and MRI-targeted biopsy was associated with a 69% reduction in overdetection while maintaining sensitivity for clinically significant cancer [14]. Nine-year follow-up data confirmed that Stockholm3 identifies aggressive cancers at PSA levels below 3 ng/mL that would be missed by PSA-only strategies, while few clinically important cancers are missed when biopsy is deferred in men with elevated PSA but low Stockholm3 scores [15,16]. Other validated biomarkers include the Prostate Health Index (PHI), 4Kscore, ExoDx Prostate Test, and MyProstateScore, though the NCCN classifies these as category 2B recommendations and emphasizes they should not replace mpMRI [8].

The ProScreen trial

The Finnish ProScreen trial randomized 60,745 men aged 50–63 years to a three-phase screening algorithm (PSA → 4-kallikrein panel → MRI with targeted biopsy) versus no screening invitation [17]. The kallikrein panel reduced the proportion of men referred to MRI to 6.8%, and after MRI, only 2.7% underwent biopsy [17]. Among screened participants, 80% of detected cancers were high-grade (Grade Group ≥2), compared with a substantially higher proportion of low-grade cancers in traditional PSA-only screening [17]. These preliminary results demonstrate the feasibility of a sequential, risk-adapted algorithm that preserves detection of clinically significant disease while dramatically reducing unnecessary procedures.

Cost-effectiveness and resource allocation

Cost-effectiveness analyses consistently favor risk-stratified over age-based screening. A UK modeling study found that age-based screening was the least cost-effective strategy studied, whereas risk-based screening at a 10-year absolute risk threshold of 4% was cost-effective in 57.4% of simulations at a willingness-to-pay threshold of £30,000 per QALY [11]. A Swedish microsimulation study found that screening with Stockholm3 at a PSA reflex threshold of ≥2 ng/mL combined with MRI reduced MRI utilization by 60% compared with PSA-only screening and was cost-effective with a probability of 70% at a threshold of €47,218 per QALY [18]. A German microsimulation study found that PSA-based Risk-Adaptive Screening (PSA-RAS) reduced overdiagnosis and biopsy rates, with PSA-RAS (ages 50-60) without MRI emerging as the most cost-efficient strategy, saving approximately €1.2 million per 100,000 men compared with no screening [19]. The EAU risk-adapted protocol (PSA-based intervals, risk calculator, and MRI) was shown by microsimulation to optimize long-term screening efficiency, significantly reducing biopsies and overdiagnosis while maintaining equivalent prostate cancer mortality [13].

Toward an integrated risk-stratified screening framework

Unlike traditional age-based frameworks, the proposed integrated model prioritizes a sequential 'gatekeeper' approach. By positioning secondary biomarkers and mpMRI as mandatory filters before biopsy, this framework specifically targets the reduction of overdiagnosis by an estimated 6-10%, offering a precision-medicine approach that moves beyond the broader, less-defined screening intervals found in current international guidelines.

Synthesizing the available evidence, a risk-stratified public health model for prostate cancer screening would incorporate the following elements:

Tier 1 - Population-level risk assessment: Baseline PSA measurement at age 45 (or 40 for high-risk groups, including Black men and BRCA2 carriers) to stratify men into risk categories [6,8]. Men with PSA below the age-specific median

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can safely extend screening intervals to 2-4 years or longer [6,8].

Tier 2 - Enhanced risk prediction for men with elevated PSA: Rather than proceeding directly to biopsy, men with PSA above threshold values undergo secondary risk assessment using validated tools such as risk calculators, blood-based biomarkers (Stockholm3, PHI, 4Kscore), or PRS to refine the probability of clinically significant cancer [8,14].

Tier 3 - Image-guided diagnostic pathway: Men with confirmed elevated risk undergo mpMRI, with biopsy reserved for those with suspicious lesions (PI-RADS ≥3) or high PSA density. MRI-targeted biopsy, preferably via a transperineal approach, is preferred over systematic biopsy alone [8].

Tier 4 - Risk-adapted management: Men diagnosed with low-risk prostate cancer are managed with active surveillance as the preferred approach, reducing overtreatment [20]. Screening intervals and cessation are individualized based on PSA trajectory, life expectancy, and comorbidity burden [6] (Table 1 and Figure 1).

This flowchart integrates NCCN Category 1 recommendations for mpMRI with a sequential multi-tier approach. Tier 1 focuses on baseline PSA stratification, while Tiers 2 and 3 utilize biomarkers and advanced imaging to refine biopsy selection.

Challenges and future directions

Several barriers impede the implementation of risk-stratified screening at scale. PRS validation across diverse ancestral populations remains incomplete, and the NCCN currently recommends PRS use only within clinical trials [12].

Table 1: Integrated risk-stratified screening framework.

Tier	Focus	Key Interventions
Tier 1	Population Assessment	Baseline PSA at age 45 (40 for Black men or *BRCA2* carriers).
Tier 2	Risk Refinement	Secondary assessment using Stockholm3, PHI, 4Kscore, or Risk Calculators.
Tier 3	Advanced Imaging	mpMRI for PI-RADS assessment; biopsy reserved for suspicious lesions.
Tier 4	Personalized Care	Active Surveillance for low-risk disease; individualized screening cessation.

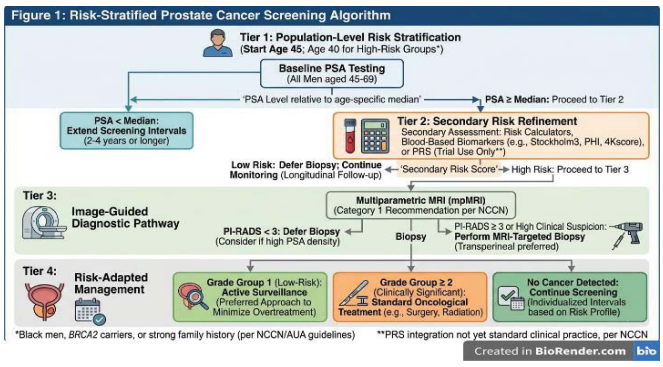

Figure 1: Risk-stratified prostate cancer screening algorithm. This flowchart integrates NCCN Category 1 recommendations for mpMRI with a sequential multi-tier approach. Tier 1 focuses on baseline PSA stratification, while Tiers 2 and 3 utilize biomarkers and advanced imaging to refine biopsy selection.

The optimal combination and sequencing of biomarkers, MRI, and risk calculators has not been established in head-to-head randomized trials with long-term mortality endpoints. Access to high-quality mpMRI and radiologic expertise varies widely, particularly in resource-limited settings [8]. Shared decision-making, while universally recommended, is inconsistently implemented in clinical practice [6,21]. Finally, the long-term mortality outcomes of risk-stratified screening trials (ProScreen, STHLM3-MRI, Göteborg-2) are still maturing and will be essential to confirm that the observed reductions in overdiagnosis translate into equivalent or superior mortality outcomes compared with traditional screening.

In resource-limited settings, such as parts of North Africa, the scarcity of high-field MRI units and specialized radiologic training for PI-RADS scoring creates a 'diagnostic divide'. Furthermore, the high upfront costs of biomarkers like Stockholm3 or 4Kscore may be prohibitive without clear evidence of long-term cost-offsets in local healthcare economies. Future public health strategies must therefore focus on cost-effective alternatives, such as the use of clinical risk calculators or biparametric MRI, to bridge the gap between evidence-based guidelines and local infrastructure constraints.

Conclusion

The evidence increasingly supports a transition from uniform, age-based PSA screening to a risk-stratified model that tailors screening initiation, frequency, and diagnostic workup to individual risk profiles. This approach has the potential to preserve the mortality benefits of early detection while substantially reducing overdiagnosis, unnecessary biopsies, treatment-related morbidity, and healthcare costs.

While the BARCODE1 trial highlights the transformative potential of Polygenic Risk Scores (PRS) in identifying high-risk individuals missed by PSA alone, their integration into routine care remains contingent upon validation across diverse ancestral populations and clearer guideline endorsements. As the NCCN currently limits PRS use to clinical trial settings, the immediate focus should remain on optimizing the sequential use of PSA kinetics, clinical biomarkers, and mpMRI to refine the screening pathway.

Declaration

Conflict of interest: The authors declare that they have no competing interests.

Guarantor of submission: The corresponding author is the guarantor of the submission.

Availability of data and materials: Supporting material is available if further analysis is needed.

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