Purpose of review
We review recent literature surrounding the use of prebiopsy prostate MRI and MRI-targeted biopsy in men at risk for prostate cancer.

Recent findings
Large series have strengthened the case for the use of MRI prior to prostate biopsy to maximize the detection of clinically significant disease, reduce the detection of clinically insignificant disease, and allow for tumor localization during targeted biopsy. Prebiopsy MRI followed by targeted biopsy appears to have the ability to overcome the limitations of the standard 12-core template. Use of MRI and targeted biopsy in the setting of a prior negative biopsy is supported by the literature and a recent consensus statement by the American Urological Association and the Society of Abdominal Radiology Prostate Cancer Disease-Focused Panel but is contingent upon the availability and quality of multiparametric MRI acquisition and interpretation. In men with no previous biopsy, MRI and targeted biopsy appears to increase detection of clinically significant disease compared with systematic biopsy while reducing detection of indolent disease. The addition of prostate cancer biomarkers and predictive nomograms may further enhance prebiopsy risk assessment.

Summary
Prostate MRI prior to biopsy may guide counseling regarding prostate cancer risk, allow for accurate tumor localization during targeted biopsy, and increase detection of clinically significant prostate cancer while limiting detection of indolent disease. Its use prior to biopsy, in conjunction with biomarkers and predictive nomograms, may allow deferral of biopsy in select cases.

Keywords
MRI, prebiopsy, risk assessment, targeted biopsy

INTRODUCTION
Prostate MRI is becoming increasingly used in clinical practice in the diagnostic pathway for prostate cancer. MRI may add value as both a prebiopsy risk assessment tool that may influence the decision whether to perform biopsy as well as a minimally invasive method for tumor localization to direct targeted biopsy for detection of clinically significant prostate cancer. Prostate MRI has been endorsed more commonly in the setting of a negative biopsy [1], but there is evolving data on its use in men with no prior prostate biopsy, with the aim of maximizing the detection of clinically significant disease while reducing the detection of clinically insignificant disease.

Goals of biopsy

Goal of biopsy by indication
The goals of prostate biopsy in men with clinical suspicion of prostate cancer have changed in recent years. Although cancer detection remains of paramount importance, the aim of contemporary biopsy is to limit detection of indolent cancers while identifying clinically significant disease. In men without a prior biopsy, the goal is to detect clinically significant cancer, avoid over detection of insignificant cancer, and accurate risk stratification for proper selection of men who would benefit from treatment from those who may be managed with active surveillance.
Improving the evaluation and diagnosis of prostate cancer

KEY POINTS

- The MRI suspicion score correlates with the likelihood of clinically significant cancer, potentially allowing prebiopsy risk stratification for individualized decision-making.
- The current primary application of MRI is in men with an elevated serum PSA level for whom there is a suspicion for prostate cancer despite a previous negative prostate biopsy.
- Patients with previous history of negative biopsy receiving a Prostate Imaging Reporting and Data System version 2 score of 3–5 on MRI warrant repeat biopsy with image-guided targeting.
- MRI-targeted prostate biopsy in men at suspicion of prostate cancer, with no previous history of prostate cancer, detects more clinically significant prostate cancer, and less clinically insignificant prostate cancer, than systematic biopsy alone.

surveillance. Incorporation of prebiopsy MRI and targeted biopsy appears to be able to achieve these goals, as described below. Men with prior negative biopsies and persistent suspicion of prostate cancer represent a population with a relatively low prevalence of disease because of the prior sampling. As such, prebiopsy MRI may enhance detection of occult cancers by localization of disease in areas of the prostate undersampled by conventional systematic biopsy, allowing for targeted biopsy. In addition, prebiopsy MRI may not only predict the likelihood and severity of occult disease but also provide further discriminating information so as to identify candidates who are least likely to benefit from prostate biopsy.

Limitations of contemporary biopsy

Prostate cancer screening has traditionally been employed through the utilization of prostate specific antigen (PSA). The sensitivity of PSA is set by threshold, commonly 4 ng/ml, but the specificity is poor at nearly all thresholds used in clinical practice. Furthermore, PSA lacks the ability to distinguish aggressive cancer from indolent disease. As a consequence, more than 1 million prostate biopsies are performed annually among Medicare beneficiaries alone as a result of prostate cancer screening [2]. The contemporary random 12-core systematic biopsy strategy relies on sampling efficiency for cancer detection and, as a result, is subject to several sampling errors. First, as many as three quarters of men over age 50 years harbor clinically insignificant prostate cancer at autopsy [3]. These clinically insignificant cancers are often identified by chance during a systematic biopsy. Second, clinically significant cancers are frequently missed when employing the standard 12-core biopsy template as a consequence of cancers commonly being multifocal, small, intermingled with benign stroma, anterior, and not uniformly distributed within the gland [3]. Third, undersampling of the cancer during conventional transrectal ultrasound (TRUS)-guided biopsy may lead to incorrect risk stratification of clinically significant tumors as low volume or low grade. These limitations, taken together, contribute in part, to the problem of overdetection and overtreatment of indolent prostate cancer and underdetection of clinically significant cancer.

Biopsy optimization: American Urological Association white paper

The American Urological Association introduced a white paper on the optimal technique of prostate biopsy and specimen handling with a concurrent review article in 2013 [3,4]. Biopsy optimization includes detection of potentially lethal prostate cancer, avoidance of overtreatment of clinically insignificant cancer, generation of clinically useful data (accurate depiction of risk and cancer location), and maintenance of cost-effectiveness (avoidance of repetitive biopsy, cost-effective specimen handling). The panel determined that, when using a non-targeted approach, a 12-core systematic biopsy that incorporates apical and far-lateral cores in the template distribution optimizes cancer detection, minimizes risk of need for repeat biopsy, and, as compared with biopsies with fewer cores, offers more accurate identification of men who need therapy, while minimizing the detection of occult, indolent prostate cancer, as compared with biopsies utilizing more cores. Despite this, 20–30% of men undergoing 12-core systematic biopsy ultimately undergo repeat biopsy, and as many as 40–45% of men with low grade cancer diagnosed on 12-core biopsy harbor more aggressive or advanced disease [5].

MRI localization of tumor

Prostate MRI in detection and localization

The Prostate Imaging Reporting and Data System version 2 (PI-RADS v2) provides guidance for the performance of prostate MRI (cite PI-RADS v2). PI-RADS v2 indicates that examinations should include T2-weighted imaging, diffusion-weighted imaging (DWI), and dynamic contrast-enhanced (DCE) imaging. DWI should be performed using a high b value in the range of 1400–2000 s/mm² and with
reconstruction of apparent diffusion coefficient maps. DCE should be performed with a temporal resolution of at least 10 s. PI-RADS v2 also provides guidance in the interpretation and reporting of prostate MRI examinations. This approach entails characterizing each detected lesion's suspicion for clinically significant cancer using a 1–5 scale.

Prostate MRI provides high diagnostic performance for the detection of clinically significant cancer and assists disease localization and risk stratification. A recent pooled data meta-analysis assessing the performance of prostate MRI in prostate cancer detection showed a specificity of 88%, sensitivity of 74%, with a negative predictive value of 65–94% [6]. A separate study demonstrated the PI-RADS v2 score to be highly associated with tumor significance [7].

Role of MRI in men with previous negative biopsy

Outcomes

Men with prior negative biopsies often present for repeat biopsy as a consequence of the limited negative predictive value of a negative systematic biopsy [5]. Among this population of men, the advantage of MRI and targeted biopsy is in identifying areas of suspicion within the prostate that otherwise would be missed by repeat systematic sampling. The cancer detection rate for significant disease in men with a prior negative biopsy varies from 20 to 40% and is lower compared with detection rates in biopsy-naive patients [8,9]. The attenuation in cancer detection rate is likely due to the lower prevalence of high volume disease in patients with a prior biopsy [10]. Targeted biopsy in addition to systematic biopsy improves cancer detection rates of clinically significant disease in men with a previous negative biopsy compared with systematic biopsy only (Table 1) [7,10–23].

However, to date there have been no published randomized controlled trials comparing the performance of targeted and systematic biopsy with systematic biopsy only in men with at least one prior negative biopsy. Siddiqui et al. reported MRI/ultrasound fusion targeted biopsy data on 1003 men of 43% were men with prior negative biopsy. They found targeted biopsy diagnosed 30% more high risk and 17% less low risk cancer than systematic biopsy alone. In their cohort, there were significantly more anterior lesions seen in men with prior negative biopsy [19]. Filson et al. reported on 1042 patients who had undergone MRI-targeted biopsy, in which 324 men had a prior negative biopsy. The authors found the combination of targeted and systematic biopsy was superior to either modality alone, where 61% of the men had Gleason at least 7 cancer detected on targeted and systematic biopsy compared with 50% with systematic biopsy alone [26]. In a study of 172 men with a prior negative biopsy, Mendhiratta et al. [16] found that MRI-targeted biopsy detected more Gleason score at least 7 disease (14.9%) compared with systematic (9.3%, \( P = 0.02 \)). Using University of California, San Francisco - Cancer of the Prostate Risk Assessment (UCSF-CAPRA) criteria, only one man was reclassified from low risk to higher risk based on systematic results compared with MRI fusion targeted biopsy.

Table 1. Summary overall and clinically significant cancer detection of MRI targeted biopsy compared with systematic biopsy in men with a prior negative biopsy

<table>
<thead>
<tr>
<th>Reference</th>
<th>No. of patients</th>
<th>No. of patients (prior negative biopsy only)</th>
<th>Overall cancer detection</th>
<th>Clinically significant cancer detection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>TB+SB (%)</td>
<td>SB (%)</td>
</tr>
<tr>
<td>Abdi et al. [11]</td>
<td>172</td>
<td>172</td>
<td>42</td>
<td>22</td>
</tr>
<tr>
<td>Brock et al. [12]</td>
<td>121</td>
<td>121</td>
<td>52</td>
<td>46</td>
</tr>
<tr>
<td>Mariotti et al. [24]</td>
<td>389</td>
<td>143</td>
<td>51</td>
<td>41</td>
</tr>
<tr>
<td>Martorana et al. [7]</td>
<td>157</td>
<td>157</td>
<td>50</td>
<td>23</td>
</tr>
<tr>
<td>Maxeiner et al. [15]</td>
<td>169</td>
<td>169</td>
<td>42</td>
<td>NR</td>
</tr>
<tr>
<td>Mendhiratta et al. [16]</td>
<td>161</td>
<td>161</td>
<td>29</td>
<td>19</td>
</tr>
<tr>
<td>Salami et al. [18]</td>
<td>140</td>
<td>140</td>
<td>52</td>
<td>49</td>
</tr>
<tr>
<td>Siddiqui et al. [19]</td>
<td>1003</td>
<td>432</td>
<td>NR</td>
<td>49</td>
</tr>
<tr>
<td>Sonn et al. [25]</td>
<td>94</td>
<td>94</td>
<td>22</td>
<td>27</td>
</tr>
<tr>
<td>Truong et al. [21]</td>
<td>113</td>
<td>113</td>
<td>52</td>
<td>42</td>
</tr>
<tr>
<td>Valkin et al. [22]</td>
<td>162</td>
<td>92</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

SB, systematic biopsy; TB, targeted biopsy.
In light of evidence suggesting a clinical benefit of MRI for men with prior negative biopsies, the NCCN guidelines for prostate cancer detection have suggested obtaining an MRI in men who anterior and/or aggressive cancer is suspected when PSA increases and systematic prostate biopsies are negative [27]. A limitation of the literature regarding the performance of concurrent systematic biopsy along with MRI/ultrasound fusion targeted biopsy is that biopsy is often the reference standard given that whole mount prostatectomy is generally available for only a small fraction of such patients.

**Summary of the American Urological Association/Society of Abdominal Radiology prostate cancer disease-focused panel consensus statement**

In December 2016, the American Urological Association and the Society of Abdominal Radiology Prostate Cancer Disease-Focused Panel published a consensus statement on the role of prostate MRI and MRI targeted biopsy in patients with a negative biopsy [1]. Use of MRI and targeted biopsy in the setting of a prior negative biopsy is supported by the literature but is contingent upon the availability of high quality MRI acquisition and interpretation. The decision to use MRI and MRI targeted biopsy should also consider the results of other biomarkers along as well as the cost of the MRI. The consensus statement highlighted the need for MRI to be interpreted using PI-RADS v2 by radiologists experienced in prostate MRI interpretation and for biopsy to be performed by urologists experienced in performing MRI-targeted biopsies. Experienced radiologists achieved moderate reproducibility for PI-RADS v2 [28].

**Role of MRI in men with no previous biopsy**

**Outcomes**

In men presenting for first biopsy, the potential advantages of MRI-targeted biopsy are two-fold:

**Table 2.** Summary overall and clinically significant cancer detection of MRI targeted biopsy compared with systematic biopsy in men with no prior biopsy

<table>
<thead>
<tr>
<th>Reference</th>
<th>No. of patients (no prior biopsy only)</th>
<th>Overall cancer detection</th>
<th>Clinically significant cancer detection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TB (%)</td>
<td>SB (%)</td>
<td>TB (%)</td>
</tr>
<tr>
<td>Baco et al. [29]</td>
<td>175</td>
<td>175</td>
<td>59</td>
</tr>
<tr>
<td>Meng et al. [10]</td>
<td>601</td>
<td>81</td>
<td>39</td>
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<tr>
<td>Mendhiratta et al. [30]</td>
<td>382</td>
<td>382</td>
<td>24</td>
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<tr>
<td>Mozer et al. [31]</td>
<td>152</td>
<td>152</td>
<td>54</td>
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<tr>
<td>Pokorny et al. [32]</td>
<td>223</td>
<td>223</td>
<td>70</td>
</tr>
<tr>
<td>Porpiglia et al. [33]</td>
<td>212</td>
<td>212</td>
<td>51</td>
</tr>
<tr>
<td>Siddiqui et al. [19]</td>
<td>1003</td>
<td>199</td>
<td>46</td>
</tr>
<tr>
<td>Wysock et al. [34]</td>
<td>125</td>
<td>43</td>
<td>36</td>
</tr>
</tbody>
</table>

SB, systematic biopsy; TB, targeted biopsy.

**American Urological Association/Society of Abdominal Radiology prostate cancer DFP consensus statement clinical recommendations: systematic biopsy, Prostate Imaging Reporting and Data System indication for biopsy**

Patients receiving a PI-RADS assessment category of 3–5 warrant repeat biopsy with image-guided targeting [1]. At least two targeted cores should be obtained from each MRI-defined target. Each man must be individually assessed as to whether a concurrent systematic sampling is warranted. Performing solely targeted biopsy should only be considered once quality assurance efforts have validated the performance of prostate MRI interpretations with results consistent with the published literature [1]. In patients with negative or low suspicion MRI (PI-RADS assessment category of 1 or 2, respectively), other ancillary markers may be of value in identifying patients warranting repeat systematic biopsy. However, more data are needed regarding how MRI compares with biomarkers such as 4Kscore and Prostate Health Index (PHI), including whether they potentially should be used before MRI to help guide patient selection for MRI. If a repeat biopsy is deferred on the basis of MRI findings, then continued clinical and laboratory follow-up is advised, and consideration should be given to incorporating repeat MRI in this diagnostic surveillance regimen. Among men with very high suspicion (PI-RADS S) and a negative targeted biopsy, early consideration should be given to repeat biopsy.
improving detection of high-grade cancer by reducing the false-negative rate of biopsy, and avoiding detection of low-grade disease by selectively targeting tumor foci that are likely to be clinically significant (Table 2).

Mendhiratta et al. [30] observed a 15% increase in Gleason score at least 7 cancers by MRI/ultrasound fusion targeted biopsy compared with systematic biopsy among 382 consecutive biopsy naive men. In addition, the majority of cancers missed by targeted biopsy were clinically insignificant by Epstein (62%) and UCSF-CAPRA (82%) criteria, suggesting that systematic biopsy largely contributes to the detection of low-risk disease among biopsy naive men undergoing both targeted and systematic biopsies [30]. Of the 1003 men studied by Siddiqui et al., 20% of patients had no previous biopsy. The authors found no significant difference between the targeted biopsy risk distribution in the no-prior-biopsy patient cohorts and the cohort with prior biopsies (P = 0.52). The standard biopsy risk distribution was higher among patients without prior biopsy and not significantly different from the targeted biopsy distribution of that cohort [19]. Baco et al. preformed a randomized clinical trial of 175 biopsy-naive patients with suspicion for prostate cancer, randomized to an MRI group (n = 86) and a control group (n = 89) [29]. In the MRI group, two-core MRI targeted biopsy was followed by 12-core systematic. In the control group, two-core targeted for abnormal digital rectal examination and/or TRUS-suspicious lesions and 12-core systematic biopsy were performed. The cancer detection rate for any cancer (59 vs. 54%; P = 0.4) and clinically significant cancer (44 vs. 49%; P = 0.5) did not differ. In a randomized controlled trial of prebiopsy MRI and targeted biopsy vs. systematic biopsy in 212 biopsy-naive men, Porpiglia et al. [33] found the overall cancer detection rate (50.5 vs. 29.5%, respectively; P = 0.002) and clinically significant cancer (43.9 vs. 18.1%, respectively; P < 0.001) was higher in the MRI targeted arm.

Role of biomarkers

New biomarkers, such as kallikrein panels (4Kscore and PHI) and urine biomarkers [prostate cancer gene 3 (PCA3) and TMPRSS2–ERG], may improve further upon existing prostate cancer screening, detection, and risk assessment tools. The implementation of these biomarkers as secondary tools in conjunction with MRI could improve specificity markedly, sparing as many as half of men with an elevated PSA the need to undergo biopsy. In a study evaluating whether a combination of PCA3 and MRI suspicion score could further optimize detection of prostate cancer on MRI fusion-targeted biopsy among men with no history of biopsy, Fenstermaker et al. found that PCA3 less than 35 demonstrates a high negative predictive value among MRI suspicion score 2–3. However, in the case of high-suspicion MRI, PCA3 was not associated with cancer detection on MRI-targeted biopsy, adding little to cancer diagnosis. By biopsying men with a MRI suspicion score of 4–5 and obtaining PCA3 on men with a MRI suspicion score of 2–3, followed by biopsy only in men with PCA3 score more than 35, 36.1% of biopsies would be avoided, and 4.9% of Gleason score at least 3 + 4 cancers would have been missed [35]. Similar results were found using PCA3 in the rebiopsy setting in which the diagnostic uncertainty in the PI-RADS intermediate group can be ameliorated by the addition of PCA3 to avoid potential unnecessary biopsies [36,37]. Additional studies suggest that management of early stages prostate cancer may also benefit by performing MRI targeted biopsy coupled with molecular analysis [38].

MRI in prostate cancer screening

The role of MRI as a first-line screening test for prostate cancer, prior to obtaining a screening PSA, has been recently investigated. Nam et al. [39] recruited 47 men from the general population and performed an MRI as the primary screening test. Patients with an MRI lesion underwent targeted and systematic biopsy, whereas patients without a lesion underwent systematic sampling only. MRI had a 66.7% positive predictive value and an 85.7% negative predictive value for the prostate cancer on biopsy. In addition, the predictive value by MRI for prostate cancer was superior to that of PSA based early detection in their cohort. Although this preliminary trial demonstrates the feasibility of MRI in the screening setting, sufficient data does not yet exist to support or refute its effectiveness as a screening tool.

Application of the noninvasive risk stratification

Relationship of Prostate Imaging Reporting and Data System to cancer detection

The PI-RADS score serves not only as a predictive marker of the presence of prostate cancer, but as previously noted, also of its clinical significance [7,40,41]. In one study using MRI-targeted biopsy as reference standard, the yield of Gleason score 3 + 4 or greater prostate cancer in lesions with a PI-RADS v2 score of 2, 3, 4, and 5 was 5.6, 0, 21.3, and 75%, respectively [42]. PI-RADS v2 scores have also been shown to be predictive of cancer aggressiveness on radical prostatectomy [43].
Nomograms and risk calculators have been developed to help identify patients at risk for prostate cancer prior to biopsy, allowing counseling on both cancer risk and need for biopsy. Historically, nomogram variables have included PSA, percentage of free-PSA, digital rectal examination, and prostate volume. More recently, nomograms have been enhanced to incorporate MRI findings to predict both overall and clinically significant cancer risk. These nomograms have substantially improved predictive accuracy for both endpoints, even in diverse populations as well as in patients with no prior biopsy or with a prior negative biopsy [44–46]. These predictive nomograms may potentially reduce unnecessary prostate biopsy and overdiagnosis while improving risk stratification counseling.

Impact of avoiding biopsy in Prostate Imaging Reporting and Data System scores of 1 or 2

In patients with negative or low suspicion MRI (PI-RADS scores of 1 or 2, respectively), biopsy may be potentially avoided in select cases given the negative predictive value of MRI. The negative predictive value of low suspicion MRI has varied widely in the literature, in part due to study methodology. Many studies have combined PI-RADS score of 1 and 2, with no mention of how many normal MRI patients are included [26]. In addition, studies have varied in terms of whether using biopsy or radical prostatectomy as the reference standard [47]. In assessing the specific question of the role of a normal prostate MRI in clinical decision-making, studies using radical prostatectomy as reference standard have a selection bias in that men were presumably selected for radical prostatectomy on the basis of systematic biopsy findings suggesting significant disease, thereby potentially increasing the prevalence of significant disease in the cohort. The critical question remains the risk of clinically significant cancer on systematic biopsy in men with a normal MRI. In a study of 75 men with a normal MRI who underwent systematic 12-core biopsy, Wysock et al. [48] demonstrated that a normal prebiopsy MRI confers an overall negative predictive value of 82% on 12-core biopsy for all cancer and of 98% for Gleason score at least 7 cancer. In a study of transperineal biopsies, the negative predictive value of a PI-RADS score of or less 2 for clinically significant prostate cancer was 97.7% [49]. Although caution is warranted regarding assuring the quality of the MRI acquisition and interpretation, this reported high negative predictive value of prostate MRI may play a valuable role in deferring biopsy in select men.

The PROMIS trial

The recently published PROMIS trial was a prospective multicenter trial with the aims of establishing the proportion of men who could safely avoid biopsy altogether by undergoing a prostate MRI and the proportion of men correctly identified by MRI who actually had clinically significant prostate cancer [50]. In this study, 576 men with suspected prostate cancer underwent MRI followed by targeted trans-rectal ultrasound-guided biopsy and a standard systematic TRUS-guided biopsy. A transperineal template prostate mapping biopsy served as the reference standard. The template prostate mapping biopsy found that 71% of men in the study had prostate cancer, and 40% had clinically significant cancer. Of these, the MRI correctly diagnosed almost all of the clinically significant cancers (93%), whereas the TRUS biopsy correctly diagnosed only half (48%). Further, for men who had a negative MRI, nine out of 10 (89%) had either no cancer or insignificant cancer on mapping biopsy. The authors concluded that using MRI to triage men might allow 27% of patients to avoid a primary biopsy and a diagnosis of 5% fewer clinically insignificant cancers. If subsequent TRUS biopsies were directed by MRI findings, up to 18% more cases of clinically significant cancer might be detected compared with the standard pathway of TRUS biopsy for all men. Finally, MRI, used as a triage test before first prostate biopsy, could reduce unnecessary biopsies by about 25% [50]. In a European cost-effectiveness study using a health economic analysis de Rooij et al. [51] found similar total costs between MRI-targeted biopsy and TRUS-guided biopsy. These data taken together may suggest that incorporating MRI into the diagnostic and therapeutic pathway might reduce the number of unnecessary biopsies and generate better health outcomes, at a cost less than that of the standard TRUS-guided biopsy pathway.

CONCLUSION

Prostate MRI is now commonly employed in the detection of prostate cancer with the goals of reducing the detection of clinically insignificant disease, maximizing the detection of clinically significant cancer, along with better assessment of disease size, grade, and location. Although there is emerging consensus regarding the use of prebiopsy MRI in men with previous negative biopsy, its routine use among men with no previous biopsy remains controversial. Recent evidence from single institution studies, and the PROMIS trial, suggest that prebiopsy risk stratification among men presenting with elevated serum PSA may allow an opportunity to reduce prostate cancer overdiagnosis through
selective avoidance of biopsy in some men, and avoidance of systematic sampling in men undergoing biopsy. Use of prebiopsy MRI, in conjunction with traditional clinical parameters and secondary biomarkers, may allow more accurate risk stratification and assessment of need for prostate biopsy.

Acknowledgements

None.

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Conflicts of interest


REFERENCES AND RECOMMENDED READING

Papers of particular interest, published within the annual period of review, have been highlighted as:

n of special interest
■ of outstanding interest

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