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Prostate Cancer

ProBIOPSY: A Multidisciplinary International Consensus on Standards for Prostate Biopsy

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Abstract

Background: Prostate biopsy is a complex, multi-step procedure lacking standardisation across patient selection, tools, technique, and biopsy strategy, potentially influencing local treatment planning. An international consensus project was initiated to harmonise these aspects.

Methods and analysis: A systematic review informed statement development. A modified Delphi process involving 34 international experts was conducted over three rounds. Panellists evaluated 96, 99, and 112 statements in Rounds 1–3, respectively, grouped into 36 stems. Statements were iteratively revised based on feedback and discussion. Consensus was assessed using a modified RAND appropriateness method.

Key findings and limitations: All experts completed the three rounds. Consensus was achieved for 29 of 36 stems (81%). Both biparametric and multiparametric magnetic resonance imaging were endorsed within the diagnostic pathway, provided imaging quality is adequate. Key elements of a targeted plus perilesional biopsy scheme were harmonised. For treatment planning, a targeted ± perilesional biopsy scheme was considered sufficient for most aspects of local treatment planning. However, additional contralateral sampling still seems necessary for specific indications, notably focal therapy candidate selection. Limitations include imbalances in specialty representation and heterogeneity in expertise across topics.

Conclusion and clinical implications: The ProBIOPSY consensus defines a contemporary, standardised framework for prostate biopsy. While targeted-based strategies are sufficient for most clinical scenarios, no single biopsy approach provides complete information for all treatment decisions, underscoring the need for indication-specific biopsy tailoring.

ADVANCING PRACTICE

What does this study add?
This consensus adds detail to the European Association of Urology guidelines' recommendations on prostate biopsy indications, standardises biopsy schemes, and provides expert views on the implications of prostate biopsy schemes for local treatment planning. It supports the noninferiority of biparametric magnetic resonance imaging (bpMRI) over multiparametric MRI, specifies the need for an imaging quality check, and provides practical approaches for indeterminate MRI findings. It standardises key procedural aspects, such as perilesional sampling, the transperineal approach, and the periprostatic block, while omitting antibiotics in most patients. Consensus was reached that the targeted and/or perilesional biopsy is sufficient for most local treatment planning, but not for all, indicating that there may not currently be a single biopsy strategy suitable for all interventional scenarios.

Clinical Relevance
This multidisciplinary consensus provides a practical framework for standardizing prostate biopsy in the MRI directed era. Targeted plus perilesional biopsy appears sufficient for many diagnostic and local treatment planning decisions, but no single biopsy strategy addresses all clinical scenarios. Additional sampling remains important in selected settings, particularly when contralateral disease would alter management. Associate Editor: Brian F. Chapin, MD.

Patient Summary
The ProBIOPSY consensus recommendations harmonise current clinical practice for prostate biopsy (PBx). An international panel of experts scored 112 statements clarifying areas of uncertainty in biopsy indications, PBx procedures, and interpretation of results. The practical recommendations will guide physicians performing prostate biopsies.

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1. Introduction

Between 2018 and 2020, four randomised controlled trials provided level 1 evidence that a prostate magnetic resonance imaging (MRI)-driven pathway can detect more clinically significant prostate cancer (csPCa) and reduce the detection of indolent prostate cancer compared with systematic prostate biopsy [1–5]. A further study showed that the combination of targeted biopsy (TBx) and systematic biopsy (SBx) yielded a 10% higher cancer detection rate than either scheme alone, despite a significant proportion of these patients receiving a diagnosis of clinically insignificant prostate cancer (ciPCa) [6]. Accordingly, in 2019, the European Association of Urology (EAU) guidelines on prostate cancer recommended the combination of TBx and SBx as the standard of care for the detection of csPCa. Subsequently, several studies showed that most SBx samples that detected csPCa were in proximity to the MRI target. The combination of TBx with perilesional biopsy (PLBx) or ipsilateral SBx had a similar detection rate for csPCa compared with TBx + SBx, with a lower risk of detecting ciPCa [7–9]. As a result, in 2024, the EAU guidelines were modified to recommend TBx + PLBx only in Prostate Imaging Reporting and Data System (PI-RADS) 4–5 lesions (level of recommendation: weak) [7,8,10–12]. Furthermore, uncertainty remains about which diagnostic pathway should be preferred in routine clinical practice. Finally, it is unclear whether a diagnostic approach that relies on a single biopsy strategy would be sufficiently informative for planning all types of local treatments.

To address these issues, the ProBIOPSY multidisciplinary consensus initiative aimed to identify procedural aspects of modern prostate biopsy where evidence is lacking or weak, and to propose harmonised and standardised protocols for diagnostic imaging and prostate biopsy procedures, including their indications, execution, and treatment implications.

2. Materials and methods

Thirty-four panellists were selected based on their expertise, including geographic location and health care system, gender, medical specialties involved in any prostate biopsy procedural step, relevant membership in international medical societies, and publication activity. Supplementary Materials 1 presents the list of experts.

2.1. Evidence summary

International guidelines, including the EAU, American Urological Association (AUA), and Pan-Asian guidelines, were reviewed to identify recommendations regarding procedural aspects for prostate biopsy with weak or lacking evidence [12–14], as well as those lacking standardisation.

A systematic review (PROSPERO: CRD420251006783) was performed, following the PRISMA 2020 checklist [15]. MEDLINE, Scopus, and LENS databases were screened. Inclusion criteria were limited to English-language articles published from April 2012 (date of publication of the first version of PI-RADS, which standardised imaging acquisition protocols, image interpretation, and scoring) to July 2025 [16]. The full search strategy, PRISMA checklist, and evidence summary are provided in Supplementary Material 2.

2.2. Modified Delphi consensus

Based on the results of the systematic review, the consensus methodology and the preliminary set of statements were generated and refined by an initial group of experts.

The statements were grouped into 36 stems: 20 stems included multiple statements defining a given topic, four stems included a single statement, and 12 stems were generated as single-option questions (SOQs). Panel members were asked to state their level of agreement with each statement on a 9-point Likert scale (where 1 = strongly disagree and 9 = strongly agree, with 5 indicating neither agree nor disagree), plus an "unable to answer" option for panellists not having sufficient expertise to score appropriately. For the SOQs, experts were asked to choose their most preferred option. Free-text boxes were also available for comments, including suggestions for changes, requests for clarifications, or deletions/additions.

Three modified Delphi rounds were then performed, with Round 1 (R1) conducted as an online survey in RedCAP [17,18], along with the results of the systematic review, which informed the generation of the statements.

Online meetings via Microsoft Teams were scheduled for R2 and R3 (2 and 3 wk apart, respectively), and chaired by B. M. and S.M., respectively, with scorings recorded and sent within 7 d from each e-meeting.

Overall, between R1 and R2, 27 statements were changed, dropped, or added, and between R2 and R3, 13 new statements were added.

2.3. Analysis methods

The modified RAND/UCLA appropriateness method was followed [19]. For each statement, the median score, the 30th and 70th interpercentile range (IPR), and the IPR adjusted for symmetry (IPRAS) were calculated; for this latter parameter, the formula: IPRAS = 2.35 + (asymmetry index $\times$ 1.5) was applied, where the asymmentry index is defined as the absolute difference between the central point of the IPR and 5 (ie, the central point on the 1–9 scale). A median score in the 1–3 range indicates panel disagreement with the statement, a score in the 4–6 range indicates neither agreement nor disagreement, and a score in the 7–9 range indicates panel agreement. When calculating the results, the number of "unable to score" responses was excluded from the denominator. For a statement to be considered to have agreement and consensus, two conditions had to be met: a median score in the 7–9 category, and an IPRAS < IPR [19].

For SOQ, we used the Advanced Prostate Cancer Consensus Conference definition of consensus: 75% or more of experts should choose the same option as their preference [20]. An overview of the consensus process is shown in Figure 1.

3. Results

The 112 final statements and their scores are summarised in Tables 1, 2, and 3: 109 statements were grouped in 22 stems with multiple statements, 12 SOQ were counted as

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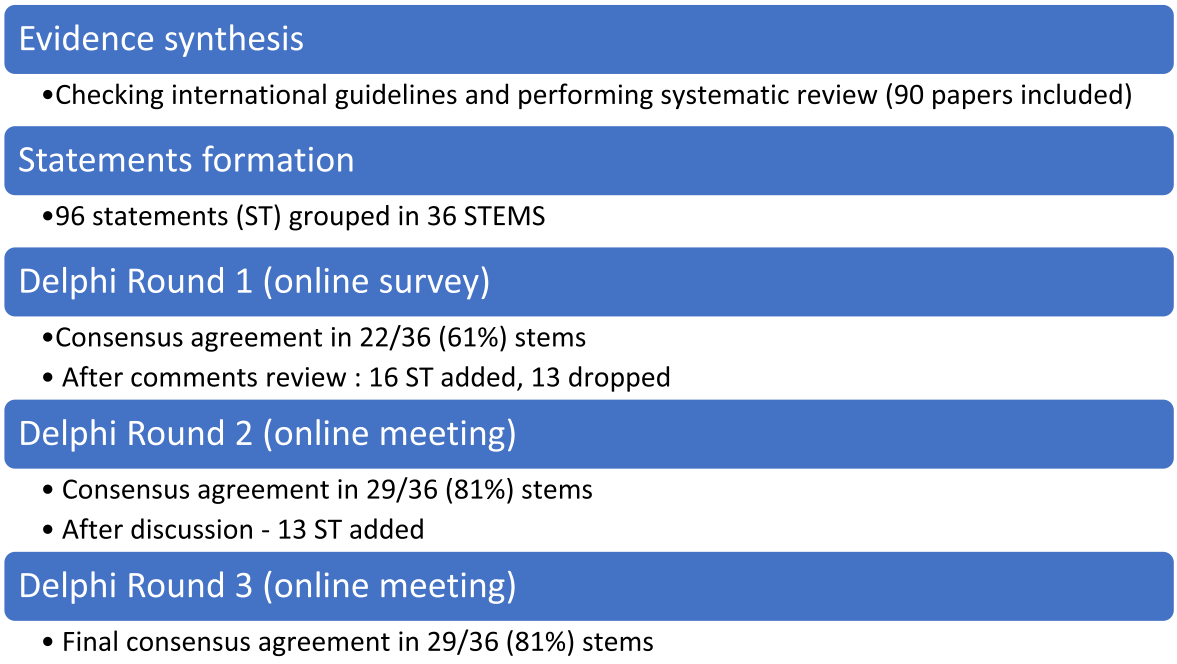

Fig. 1 – The ProBIOPSY consensus flowchart * ST = statements.

a separate stem each, and three stems consisted of only one statement each. Overall, consensus was achieved on 29/36 stems (81%). The distribution of experts' scores per statement is provided in Supplementary Material 3.

3.1. Domain 1: multiparametric versus biparametric MRI

Participants agreed that both multiparametric MRI (mpMRI) and biparametric MRI (bpMRI) may be equally recommended for MRI-driven prostate cancer (PCa) diagnosis, provided that image quality is adequate for clinical decision-making (Q5: median 8). A formal quality check of MRI sequences is highly recommended (Q4a: 9), and images should preferably be assessed according to Prostate Imaging Quality (PI-QUAL) version 2 criteria (Q4b: 8).

Panellists agreed that bpMRI alone may be sufficiently informative for PCa diagnosis, both in opportunistic screening (Q6: 8) and within organised screening pathways (Q7: 8). There is no minimum magnetic field strength requirement for either mpMRI or bpMRI, as both 1.5T and 3T scanners are considered equally suitable for PCa diagnosis (Q1: 8), provided that PI-RADS protocol recommendations for imaging acquisition are followed.

3.2. Domain 1: number of MRI lesions to be reported

No consensus was reached on the maximum number of lesions that should be reported when multiple MRI-visible lesions are present (Q8), with three being the option most frequently chosen.

3.3. Domain 1: role of ancillary tests for indeterminate lesions

For indeterminate lesions on bpMRI, panellists agreed that ancillary tests should be used to guide the decision to perform prostate biopsy. Specifically, an additional contrast-enhanced MRI sequence should be recommended when indeterminate lesions are located in the peripheral zone (Q10a: 7); prostate-specific antigen (PSA) density was the only biomarker achieving agreement consensus (Q11: 7). Indeterminate lesions on bpMRI could also be followed over time (Q10b: 8).

For indeterminate lesions on mpMRI, PSA density (Q14: 8) or a validated risk calculator (Q15: 7) should be used to support biopsy indication. No consensus was reached on the remaining statements regarding ancillary tests in this setting (Q12, Q13, Q16).

3.4. Domain 1: new imaging modalities

For primary PCa diagnosis, disagreement was expressed by the majority of panellists in considering diagnostic pathways led by either prostate-specific membrane antigen (PSMA) positron emission tomography (PET) (Q17) or micro-ultrasound (micro-US, Q20) as superior or alternative to MRI.

In patients with negative MRI but persistent high suspicion of csPCa, PSMA PET-CT was considered, if available, as an ancillary test to support the indication for biopsy (Q19: 8), whereas no consensus was found in the same scenario for the utility of micro-US. (Q22).

For indeterminate MRI lesions, no consensus was reached on the role of PSMA PET-CT (Q18) or micro-US (Q21) as complementary tests to guide biopsy decisions.

Panellists agreed that SBx should be performed in cases of negative MRI with high suspicion of csPCa (Q25: 7). This latter definition included patient and tumour characteristics (elevated PSA, with PSA density >0.15, and/or positive digital rectal examination, and/or family history, and/or Black ethnicity) or according to the EAU Rotterdam PCa risk calculator [12,21].

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Table 1 – List of Stems 1 (Indication) with final scoring

Stem number	Stem	Statement	Median	30th	70th	Interpretation	Unable to score
1	Magnetic field strength requirements for MRI	1. The 3T and 1.5T MRIs are equally recommended for prostate cancer diagnosis, irrespective of the type of MRI scheduled (multiparametric vs biparametric)	8	7	8	Consensus agree	1
2	PI-QUAL quality standards	4a. All the MRI sequences should be checked for quality standards	9	9	9	Consensus agree	0
		4b. All the MRI sequences should be checked for quality standards according to PI-QUAL V.2 scores	8	8	8	Consensus agree	1
3	mpMRI vs bpMRI	5. The bpMRI and mpMRI may be equally recommended for prostate cancer diagnosis, provided that image quality is adequate for decision-making	8	8	8	Consensus agree	1
		6. The bpMRI could be informative enough for prostate cancer diagnosis in patients under an early detection cancer pathway (opportunistic screening)	8	8	8	Consensus agree	1
		7. The bpMRI could be informative enough for prostate cancer diagnosis in patients under an organised cancer screening pathway	8	8	8	Consensus agree	1
4	Number of lesions at MRI°	8. In case of multiple visible lesions, the maximal number of lesions to be reported should be: (please, mark your best choice)	Most popular Option 1 – "3 lesions": 17 experts (53%)			No consensus	1
5	Indeterminate lesion on MRI - the role of additional tools	10a. In case of an indeterminate lesion at bpMRI, biopsy should be indicated by the result of an additional contrast-enhanced MRI sequence in case of a peripheral zone lesion	7	7	8	Consensus agree	2
		10b. In case of an indeterminate lesion at bpMRI, follow-up is needed	8	8	8	Consensus agree	1
		11. In case of an indeterminate lesion at bpMRI, biopsy should be indicated by the result of PSA density	7	7	7	Consensus agree	1
		12. In case of an indeterminate lesion at bpMRI, biopsy should be indicated by the result of the risk calculator	6	5	6	Consensus neither	1
		13. In case of an indeterminate lesion at bpMRI, biopsy should be indicated by the result of serum or urine biomarkers	4	3	4	Consensus to neither agree nor disagree	1
		14. In case of an indeterminate lesion at mpMRI, biopsy should be indicated by the result of PSA density	8	8	8	Consensus agree	1
		15. In case of an indeterminate lesion at mpMRI, biopsy should be indicated by the result of the risk calculator	7	5	7	Consensus agree	1
		16. In case of an indeterminate lesion at mpMRI, biopsy should be indicated by the result of serum or urine biomarkers	4	3	4	Consensus to neither agree nor disagree	1
6	New imaging modalities – PSMA PET	17. PSMA PET should be preferred to MRI if available/feasible for primary prostate cancer diagnosis	2	2	2	Consensus disagree	0
		18. In patients with an indeterminate MRI lesion, PSMA/PET-CT could be considered as an ancillary test, if available, to indicate a biopsy	6	5	7	Consensus to neither agree nor disagree	0
		19. In case of a negative MRI and persistence of high suspicion of csPCa, PSMA PET-CT could be considered as an ancillary test, if available, to indicate a biopsy	8	8	8	Consensus agree	0
7	New imaging modalities – Micro-ultrasound	20. Micro-ultrasound should be preferred to MRI if available/feasible for primary prostate cancer diagnosis	2	1	2	Consensus disagree	1
		21. In patients with an indeterminate MRI lesion, prostate micro-ultrasound should be performed, if available, to indicate a biopsy	3	2	3	Consensus to neither agree nor disagree	1
		22. In case of a negative MRI and persistence of high suspicion of csPCa, prostate micro-ultrasound should be performed	3	2	3	Consensus to neither agree nor disagree	1
		25. In case of a negative MRI and persistence of high suspicion of csPCa, systematic prostate biopsy should be performed	7	7	7	Consensus agree	1
8	Artificial Intelligence in MRI readings	26. If available, AI algorithms should be used upfront to identify suspicious lesions on MRI (before radiologists' assessment)	7	7	7	Consensus agree	1

3T = 3 tesla, 1.5T = 1.5 tesla, MRI = magnetic resonance imaging, PI-QUAL = Prostate Imaging Quality, V2 = version 2, mpMRI = multiparametric magnetic resonance imaging, bpMRI = biparametric magnetic resonance imaging, PSA = prostate-specific antigen, PSMA = prostate-specific membrane antigen, PET = positron emission tomography, PET-CT = positron emission tomography–computed tomography, csPCa = clinically significant prostate cancer, AI = artificial intelligence.

With respect to artificial intelligence (AI), a stem with multiple relevant statements was initially generated; however, after discussion at Round 1, panellists agreed that most of the statements should be dropped, as there is currently not enough evidence to support any meaningful opinion. Accordingly, only one statement was retained, reaching consensus agreement that AI algorithms may be used to identify suspicious MRI lesions as radiologic aids (Q26: 7).

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Table 2 – List of statements of Stem 2 (Procedure) with final scoring

Stem number	Stem	Statements	Median	30th	70th	Interpretation	Unable to score
9	Targeted Bx – Number of targeted cores	34. The optimal number of targeted cores per lesion should be adjusted based on PIRADS/Likert score	6	6	6	Consensus to neither agree nor disagree	2
10	Targeted Bx – Number of targeted cores	35. For a visible MRI lesion, the targeting should include not less than:	Most popular: Option 2 – "3 cores" 21 experts (66%)			No consensus	1
11	Targeted Bx – Number of targeted cores	36. For PIRADS/Likert 4-5 lesions, the targeting should include not less than:	Most popular: Option 2 – "3 cores" 21 experts (68%)			No consensus	1
12	Bx around the ROI – Number of ores taken around the ROI	37a. If doing it, which term best describes extra cores taken around the region of interest:	Option 1: "Perilesional" 28 experts (97%)			Consensus	3
13	Bx around the ROI – Number of ores taken around the ROI	38. If doing it, extra cores taken around the region of interest (ROI) should be taken in a range of:	Option 2 - "10mm around ROI" 23 experts (82%)			Consensus	2
14	Bx around the ROI – Number of ores taken around the ROI	39. If doing it, the number of extra cores taken around the region of interest (ROI) should depend on the size of the MRI lesion.	7	7	7	Consensus agree	1
15	Bx around the ROI – Number of ores taken around the ROI	40. If doing it, for smaller visible MRI lesions (<10 mm), the minimum number of extra cores taken around the region of interest (ROI) is:	Most popular: Option 1 – "2 cores"18 experts (67%)			No consensus	2
16	Bx around the ROI – Number of ores taken around the ROI	41. For larger visible MRI lesions (>10 mm), the maximum number of extra cores taken around the region of interest (ROI) is:	Option 1: "2 cores" 20 experts (76%)			Consensus	2
17	Bx scheme according to MRI results -Unifocal MRI visible lesion	42. In case of a visible MRI lesion, ONLY a targeted biopsy should be performed	4	3	4	Consensus to neither agree nor disagree	1
		43. In case of a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI should be performed	7	7	8	Consensus agree	1
		44a. In case of unifocal visible MRI lesions, targeted biopsy (Bx) + contralateral Bx should be performed	5	4	6	Consensus to neither agree nor disagree	0
		44 In case of a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral Bx should be performed	6	5	6	Consensus to neither agree nor disagree	1
		45 In case of a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + systematic Bx should be performed	3	3	3	Consensus disagree	1
18	Multifocal MRI visible lesion	46a. In case of a multifocal ipsilateral visible MRI lesion, ONLY a targeted biopsy should be performed	6	6	6	Consensus to neither agree nor disagree	0
		46b. In case of multifocal ipsilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI should be performed	6	6	7	Consensus to neither agree nor disagree	0
		47a. In case of multifocal ipsilateral visible MRI lesions, targeted biopsy (Bx) +contralateral Bx should be performed	4	2	6	Consensus to neither agree nor disagree	1
		47. In case of multifocal ipsilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral Bx should be performed	5	3	5	Consensus to neither agree nor disagree	1
		48. In case of multifocal ipsilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI + systematic Bx should be performed	4	2	4	Consensus to neither agree nor disagree	1
		49a. In case of multifocal bilateral visible MRI lesions, ONLY targeted biopsy (Bx) should be performed	6	6	7	Consensus to neither agree nor disagree	1
		49. In case of multifocal bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI should be performed	7	6	8	Consensus agree	1
		50. In case of multifocal bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI + systematic Bx should be performed	4	2	4	Consensus to neither agree nor disagree	1
19	Systematic Bx – Which Scheme	51. In the case systematic biopsy is indicated, the sextant (3 cores per lobe) biopsy template should be used	3	2	3	Consensus disagree	1
		52. In the case systematic biopsy is indicated, the 12-core (6 cores per lobe) biopsy template should be used	8	8	8	Consensus agree	1
		53. In the case systematic biopsy is indicated, the Ginsburg biopsy template (at least 12 cores per lobe) should be used	3	3	3	Consensus disagree	1
		54. In the case that systematic biopsy is indicated, the 0.5 mm saturation biopsy should be used	2	1	2	Consensus disagree	1

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Table 2 – continued

Stem number	Stem	Statements	Median	30th	70th	Interpretation	Unable to score
20	Negative MRI but high suspicion of csPCa – Which scheme	55a. In the case of a negative MRI but high suspicion of csPCa, 12 cores (6 cores per lobe) biopsy systematic biopsy should be performed.	7	7	7	Consensus agree	1
		55b. In the case of a negative MRI but high suspicion of csPCa, systematic biopsy according to the Ginsburg scheme should be performed	6	4	6	Consensus to neither agree nor disagree	1
		56. In the case of a negative MRI but high suspicion of csPCa, saturation biopsy should be performed (24 cores)	2	1	2	Consensus disagree	1
		57. Systematic biopsy should be reduced to a maximum of 6 cores in total in men with suspicion of locally advanced disease on digital rectal examination and/ or PSA> 50 ng/mL, or those who are not fit for curative treatments	8	8	8	Consensus agree	1
21	Approach and Anaesthesia	58. The standard approach for prostate biopsy should be:	Option 2: "Transperineal approach" 26 experts (97%)			Consensus	2
22	Approach and Anaesthesia	59. Anaesthesia standard for transrectal biopsy should be:	Option 2: "Periprostatic nerve block" 17 experts (83%)			Consensus	2
23	Approach and Anaesthesia	60. Anaesthesia standard for transperineal biopsy should be:	Option 2: "Periprostatic nerve block" 16 experts (90%)			Consensus	2
24	Prophylaxis	62. In case of transperineal biopsy, antibiotic prophylaxis regimen: (please, mark your best choice) *Risk factors are: Antibiotic use in the previous 6 mo, international travelling in the previous 6 mo, Hospitalisation in the previous 6 mo, non-sterile urine culture, UTI in the previous 6 mo, sub(de)compensated DM	Option 2: "should be omitted for every patient except those with risk factors" 23 experts (88%)			Consensus	2
25	Prophylaxis	63. In case of transrectal biopsy, the preferred antibiotic prophylaxis regimen is:	Most popular: Option 3: "augmented antibiotic prophylaxis" 22 experts (67%)			No consensus	2

Bx = biopsy, MRI = magnetic resonance imaging, PI-RADS = Prostate Imaging Reporting and Data System, ROI = region of interest, mm = millimetres, csPCa = clinically significant prostate cancer, PSA = prostate-specific antigen, ng/mL = nanograms per millilitre, mo. = months, UTI = urinary tract infection, DM = diabetes mellitus.

3.5. Domain 2: number of targeted cores

Experts did not reach agreement on whether the optimal number of TBx cores should be adjusted based on the PI-RADS/Likert score (Q34: median 6). Similarly, no consensus was reached on the minimum number of TBx cores for any MRI-visible lesion, or specifically for PI-RADS/Likert 4–5 lesions (Q35–36), with three cores being the most popular choice.

3.6. Domain 2: definitions and location of cores taken around the region of interest

Consensus was reached to adopt "perilesional biopsy" (PLBx) as the term best describing the additional cores taken around the region of interest (ROI) (Q37a: 97% of experts) (Fig. 2A). Panellists agreed that PLBx cores should be obtained within a 10-mm margin around the ROI (Q38a: 82% of experts) (Fig. 2B).

A consensus was reached that the number of PLBx cores should be adjusted based on MRI lesion size (Q39: 7). Experts agreed that a maximum of two PLBx cores should be taken for lesions ≥10 mm (Q41: 76% of experts). Conversely, no agreement was reached for lesions <10 mm, with "2 cores" being the most popular option (Q40: 67% of experts).

3.7. Domain 2: biopsy schemes

In cases of unifocal and multifocal bilateral MRI-visible lesion(s), the TBx + PLBx scheme reached consensus as the optimal approach (Q43: median 7; Q49: median 7). However, no consensus was achieved on the optimal scheme for multifocal ipsilateral lesions (Q46a–48).

When SBx is indicated, including cases with negative MRI but high clinical suspicion of PCa (Q55a: 7), it should include six cores for each of the right and left lobes (Q52: 8). Conversely, SBx should be reduced to a maximum of six cores in total in patients with suspected locally advanced disease (cT3) on digital rectal examination and PSA of >50 ng/mL, or in those unfit for curative treatment (Q57: 8).

3.8. Domain 2: approach, anaesthesia and antibiotic prophylaxis

Consensus was reached regarding the transperineal approach as the standard route for prostate biopsy (Q58: 97% agreement). Periprostatic nerve block was considered the standard anaesthetic technique for both transrectal (Q59: 83% agreement) and transperineal (Q60: 90% agreement) approaches.

No consensus was reached regarding optimal antibiotic prophylaxis for transrectal biopsy (Q63). For transperineal biopsy, however, experts agreed that antibiotic prophylaxis should be omitted in patients without risk factors for infection (Q62: 88% of experts).

3.9. Domain 3: planning focal treatment

When planning focal treatment in patients with a unifocal MRI-visible lesion, experts reached consensus that con-

Table 3 – List of statements of Stem 3 (Results) with final scoring

Stem number	Stem	Statement	Median	30th	70th	Interpretation	Unable to score
26	Planning focal therapy – Unifocal lesion	64. In patients with unifocal visible MRI, targeted biopsy (Bx) ONLY is informative enough for focal treatment planning.	5	4	6	Consensus to neither agree nor disagree	1
		64a. In patients with unifocal visible MRI, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for focal treatment planning.	5	5	6	Consensus to neither agree nor disagree	1
		65a. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + contralateral Bx should be performed for focal treatment planning.	5	4	7	Consensus to neither agree nor disagree	1
		65. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral systematic Bx should be performed for focal treatment planning.	7	5	7	Consensus agree	1
		66. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx)+ bilateral systematic Bx should be performed for focal treatment planning.	5	4	5	Consensus to neither agree nor disagree	1
27	Planning nerve sparing – Unifocal lesion	67a. In patients with unifocal visible MRI, targeted biopsy (Bx) ONLY is informative enough for nerve-sparing surgical planning.	6	5	7	Consensus to neither agree nor disagree	2
		67. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for nerve-sparing surgical planning.	7	7	7	Consensus agree	3
		68a. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + contralateral Bx should be performed for nerve-sparing surgical planning.	5	3	6	Consensus to neither agree nor disagree	3
		68. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral systematic Bx should be performed for nerve-sparing surgical planning.	4	2	4	Consensus to neither agree nor disagree	2
		69. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + bilateral systematic Bx should be performed for NS surgical planning.	4	2	4	Consensus to neither agree nor disagree	2
28	Planning nerve sparing – Bilateral lesions	70a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) ONLY is informative enough for nerve-sparing surgical planning.	7	7	7	Consensus agree	2
		70. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for nerve-sparing surgical planning.	7	7	8	Consensus agree	2
		71a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + contralateral Bx should be performed for nerve-sparing surgical planning.	4	2	5	Consensus to neither agree nor disagree	2
		71. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI + systematic Bx should be performed for nerve-sparing surgical planning.	3	3	3	Consensus disagree	2
		72. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + bilateral systematic Bx should be performed for nerve-sparing surgical planning.	4	3	4	Consensus to neither agree nor disagree	2
29	Planning lymph nodes dissection – Unifocal lesion	73a. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) ONLY is informative enough for selecting patients as candidates for lymphadenectomy.	6	5	6	Consensus to neither agree nor disagree	2
		73. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for selecting patients as candidates for lymphadenectomy.	6	6	7	Consensus to neither agree nor disagree	2
		74a. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + contralateral Bx should be performed to select patients as candidates for lymphadenectomy.	4	2	6	Consensus to neither agree nor disagree	2
		74. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral systematic Bx should be performed to select patients as candidates for lymphadenectomy.	3	2	3	Consensus disagree	2
		75. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + bilateral systematic Bx should be performed to select patients as candidates for lymphadenectomy.	3	2	3	Consensus disagree	2
30	Planning lymph nodes dissection – Bilateral lesions	76a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) ONLY is informative enough for selecting patients as candidates for lymphadenectomy.	7	6	7	Consensus agree	2
		76. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for selecting patients as candidates for lymphadenectomy.	7	7	7	Consensus agree	2
		77a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + contralateral Bx should be performed for selecting patients candidate to lymphadenectomy.	4	2	5	Consensus to neither agree nor disagree	3
		77. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI + systematic Bx should be performed for selecting patients as candidates for lymphadenectomy.	3	2	3	Consensus disagree	2
		78. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + bilateral systematic Bx should be performed for selecting patients candidate to lymphadenectomy.	2	2	2	Consensus disagree	2

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Table 3 – continued

31	Planning whole gland radiotherapy – Unifocal lesion	79a. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) ONLY is informative enough for whole gland radiotherapy planning.	7	7	8	Consensus agree	2
		79. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for whole gland radiotherapy planning.	8	7	8	Consensus agree	2
		80a. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + contralateral Bx should be performed for whole gland radiotherapy planning.	4	2	6	Consensus to neither agree nor disagree	3
		80. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral systematic Bx should be performed for whole gland radiotherapy planning.	4	2	4	Consensus to neither agree nor disagree	2
		81. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + bilateral systematic Bx should be performed for whole gland radiotherapy planning.	3	2	3	Consensus disagree	2
32	Planning whole gland radiotherapy – Bilateral lesions	82a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) ONLY is informative enough for whole gland radiotherapy planning.	7	7	8	Consensus agree	2
		82. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for whole gland radiotherapy planning.	7	7	8	Consensus agree	2
		83a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + contralateral Bx should be performed for whole-gland radiotherapy planning.	3	2	4	Consensus disagree	3
		83. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI + systematic Bx should be performed for whole gland radiotherapy planning.	3	2	3	Consensus disagree	2
		84. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + systematic Bx should be performed for whole gland radiotherapy planning.	3	2	3	Consensus disagree	2
33	Planning focal radiotherapy boost planning – Unifocal lesion	85a. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) ONLY is informative enough for focal radiotherapy boost planning.	8	7	8	Consensus agree	2
		85. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for focal radiotherapy boost planning.	7	7	7	Consensus agree	2
		86a. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + contralateral Bx should be performed for focal radiotherapy boost planning.	4	2	5	Consensus to neither agree nor disagree	3
		86. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral systematic Bx should be performed for focal radiotherapy boost planning.	4	3	4	Consensus to neither agree nor disagree	2
		87. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + bilateral systematic Bx should be performed for focal radiotherapy boost planning.	3	2	3	Consensus disagree	2
34	Planning focal radiotherapy boost planning – Bilateral lesions	88a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) ONLY is informative enough for focal radiotherapy boost planning.	7	7	7	Consensus agree	2
		88. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for focal radiotherapy boost planning.	8	8	8	Consensus agree	2
		89a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + contralateral Bx should be performed for focal radiotherapy boost planning.	3	2	3	Consensus disagree	3
		89. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI + systematic Bx should be performed for focal radiotherapy boost planning.	3	2	3	Consensus disagree	2
		90. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + systematic Bx should be performed for focal radiotherapy boost planning.	3	2	3	Consensus disagree	2
35	Planning ADT length – Unifocal lesion	91a. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) ONLY is informative enough for ADT length planning.	7	7	7	Consensus agree	1
		91. In patients with a unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for ADT length planning.	8	8	8	Consensus agree	2
		92a. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + contralateral Bx should be performed for ADT length planning.	4	2	5	Consensus to neither agree nor disagree	2
		92. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + Bx of the area around the ROI + contralateral systematic Bx should be performed for ADT length planning.	3	3	3	Consensus disagree	1
		93. In patients with unifocal visible MRI lesion, targeted biopsy (Bx) + bilateral systematic Bx should be performed for ADT length planning.	3	2	3	Consensus disagree	1
36	Planning ADT length – Bilateral lesions	94a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) ONLY is informative enough for ADT length planning.	7	7	7	Consensus agree	1
		94. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + Bx of the area around the ROI only is informative enough for ADT length planning.	8	7	8	Consensus agree	1
		95a. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + contralateral Bx should be performed for ADT length planning.	3	2	4	Consensus disagree	2
		95. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + perilesional Bx + systematic Bx should be performed for ADT length planning.	2	2	2	Consensus disagree	1
		96. In patients with bilateral visible MRI lesions, targeted biopsy (Bx) + systematic Bx should be performed for ADT length planning.	2	2	2	Consensus disagree	1

MRI = magnetic resonance imaging, Bx = biopsy, ROI = region of interest, NS = nerve sparing, ADT = androgen deprivation therapy.

tralateral SBx, in addition to TBx and PLBx, is necessary to adequately support the indication for focal therapy (Q65: 7).

3.10. Domain 3: planning nerve-sparing surgery during radical prostatectomy

For nerve-sparing surgery (NSS), experts agreed that, in patients with a unifocal MRI-visible lesion, TBx and PLBx alone provide sufficient information, without the need for additional systematic or contralateral cores (Q67: 7).

In the context of bilateral MRI-visible lesions, consensus similarly supported omitting contralateral SBx; TBx were considered adequate for surgical decision-making (Q70a–70: 7).

3.11. Domain 3: planning lymph node dissection

No consensus was reached regarding the informative value of different PBx schemes for PLND planning in patients with a unifocal MRI-visible lesion (Q73a–73: 6).

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In contrast, for bilateral MRI-visible lesions, consensus was achieved that TBx ± PLBx are adequate to guide lymphadenectomy planning (Q76a–76: 7).

3.12. Domain 3: planning whole-gland radiotherapy and/or boost radiotherapy

Experts agreed that, in patients with unifocal or bilateral MRI-visible disease, TBx ± PLBx provides sufficient information to plan whole-gland radiotherapy (RT) (Q79a–79: 7–8; Q82a–82: 7) and/or a focal boost radiotherapy (Q85a–85: 7–8; Q88a–88: 7–8).

3.13. Domain 3: planning ADT duration in patients undergoing radiotherapy

Panellists agreed that, for patients with unifocal or bilateral MRI-visible disease, information derived from TBx ± PLBx is sufficient to determine the appropriate duration of androgen deprivation therapy (Q91a–91: 7–8; Q94a–94: 7–8).

4. Discussion

Multiple aspects of prostate biopsy lack substantial evidence and have weak recommendations in international guidelines, which the ProBIOPSY consensus addressed; the panel remained challenged about which biopsy scheme would have been most informative for local treatment interventions.

With respect to the diagnostic pathway, high-quality MRI standards are mandatory, despite significant heterogeneity observed in real-world practice. In the pre-trial MRI scanner check of the PRIME study (Prostate Imaging using MRI ± Contrast Enhancement), 68% of scanners from the centres recruited provided MRI images of suboptimal quality (PI-QUAL v1 $\leq$ 4) [22]. The PRIME trial showed that bpMRI was noninferior to mpMRI in diagnostic accuracy for csPCa in a selected cohort of men with suspicious PCa on an early diagnostic pathway; however, MRI quality remained an issue, with 29.3% of MRI scans scoring PI-QUAL v1 $\leq$ 4 at central review. The high image quality imperative was highlighted by the panel, which endorsed bpMRI scans as equivalent to mpMRI in diagnostic and screening settings, irrespective of MRI magnetic field strength (with 3T preferred to 1.5T, if available), provided that a quality check is systematically undertaken, preferably using the latest version of the PI-QUAL score [23]. These aspects are not specifically addressed in current EAU guidelines, so that the consensus may help inform practice by supporting bpMRI as a reasonable alternative when image quality is adequate.

Different considerations emerged for novel imaging modalities in the diagnostic pathway. PSMA PET-CT has shown high diagnostic accuracy for csPCa detection, even higher if performed in combination with MRI [24,25]. However, the experts disagreed on the upfront use of PSMA PET-CT to guide prostate biopsy, mirroring a similar recommendation from the SPARC (Standardized PSMA PET Analysis and Reporting Consensus) consensus findings [26]. On the other hand, the panel agreed that PSMA PET-CT could be employed, if available, in high-suspicion cases when MRI is negative.

Two level 1 trials showed that micro-ultrasound and multiparametric-ultrasound have noninferior diagnostic yields to mpMRI [27,28]. Nevertheless, the panel did not endorse the adoption of these novel ultrasound techniques in any of the evaluated scenarios (upfront, as an alternative or a complement to MRI after indeterminate/negative imaging), potentially reflecting the lack of widespread uptake of the technique among urological centres and potential reproducibility concerns [27–29].

The panel endorsed the transperineal (TP) route as the standard biopsy approach, performed with periprostatic nerve block without antibiotic prophylaxis for patients with no risk factors (listed in Q62). These recommendations are consistent with EAU but not with AUA guidelines [12,13], with the latter not advocating any particular route. Indeed, despite the growing scientific body as well as real-world data favouring the adoption of the TP approach for better access to anterior lesions [30], much lower need for antibiotic prophylaxis [31–34], shorter hospital stay, as well as lower complications [35–37], the transrectal option remains popular due to technical aspects, lower costs, and difficulties in changing local workflow [38–40].

The lack of standardisation regarding the definition and scheme of extra sampling around the MRI-defined ROI was one of the most disputed issues, with diverse templates described in the literature, including ipsilateral systematic biopsy, sample in adjacent quadrants, or perilesional biopsy, in addition to significant heterogeneity regarding the number of cores as well as the extent of cores for the relevant area to be targeted. Brisbane et al showed that a 25% of csPCa was detected by SBx cores taken within a 1 cm area around the ROI [7,41]. The rationale for the utility of PLBx seems to be as a corrective measure to address errors generated during the fusion biopsy process, such as registration errors and mis-sampling, which may be more likely with smaller lesion size. Our panel achieved consensus agreement by endorsing perilesional biopsy as the best definition describing extra sampling around the ROI, with cores to be taken within a range of 10 mm, and with a variable number of cores adapted according to the size of the targeted lesion (fewer for larger lesions, more for smaller lesions). These characteristics should be used as a new standard template when performing PLBx.

Furthermore, panellists agreed that, for both unilateral and bilateral MRI-visible lesions, the preferred sampling scheme on a diagnostic pathway should be TBx+PLBx for lesion characterisation and risk stratification.

Nevertheless, discordance emerged when experts were asked to assess which biopsy scheme would best fit treatment planning. TBx alone or in association with PLBx was endorsed as an informative biopsy scheme to plan whole-gland RT focal boost, as well as androgen deprivation therapy duration for either unifocal or bilateral MRI-visible lesions. For focal treatment planning, there was considerable disagreement regarding the need for systematic biopsy cores. Multiple consensus statements on prostate focal therapy have attempted to standardise patient selection and the definition of treatment failures. The consensus led by Focal Therapy Group underlined the need for a 12-core systematic biopsy besides TBx for focal therapy planning [42]. Sim-

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ilarly, our expert panellists endorsed the TBx + PLBx, plus contralateral systematic biopsy, as the best biopsy scheme for patient selection to reduce the risk of undertreatment of invisible MRI lesions in the other lobe. Nevertheless, concerns were highlighted about the clinical impact and natural history of invisible lesions, and that, if a patient were diagnosed on a TBx ± PLBx scheme, a further set of contralateral biopsies would be, paradoxically, necessary.

As imaging modalities alone (MRI and PSMA PET-CT) have low sensitivity for the prediction of extracapsular extension and lymph node invasion, several nomograms have been developed, including the histology data from systematic biopsy, to better stratify patients for an NSS approach or PLND risk for either of the two conditions [43–48]; these tools are commonly used. A recent study found that ipsilateral biopsy of unilateral MRI lesions did not substantially alter urologists' surgical planning regarding NSS and PLND indications [49,50]. While our consensus panel endorsed TBx + PLBx as the best biopsy scheme to plan NSS, both for unilateral and bilateral MRI-visible lesions, a different view emerged regarding the biopsy scheme for PLND. The consensus acknowledged that, in some centres, PLND is no longer performed, or that PSMA outcomes are not informative enough to select patients for this intervention. The lack of consensus may also reflect uncertainty about how to use or interpret the nomograms without information from contralateral systematic biopsy. Taken together, the treatment-planning domain showed that an optimal "one size fits all" biopsy scheme is not yet endorsed, due to the heterogeneity of treatment scenarios and the use of ancillary tools for PCa detection across different centres and health care systems. The implications of biopsy strategy for treatment planning are only partially addressed in current EAU guidelines, and this consensus may provide a useful multidisciplinary framework for matching biopsy schemes to specific treatment planning.

This report has several strengths and limitations. Strengths include the use of a rigorous modified RAND/UCLA methodology, the involvement of a multidisciplinary panel (urologists, radiologists, radiation oncologists, pathologists, nuclear medicine physicians), and diversity of regional distribution. Nevertheless, the recommendations or endorsements could be influenced by the panel's composition, limited size, and experience, as well as by gaps in the underlying literature. Experts' responses were analysed as a single homogeneous cohort without specialty-stratified voting, which may obscure discipline-specific differences in diagnostic and treatment pathways [51,52]. The feasibility of real-world implementation may differ among health systems due to variations in access to software-fusion platforms, anaesthesia support, MRI quality assurance, antibiotic stewardship policies, and reimbursement [53–55]. The consensus recommendations cannot be considered equivalent to guideline recommendations because of the nature of the consensus itself, which is not based exclusively on evidence but also on experts' views and experience. Lastly, active surveillance was not considered a treatment option, as the consensus focused on active treatment modalities.

5. Conclusion

This consensus offers recommendations on when and how to perform a prostate biopsy, as well as how to use the biopsy results for local treatment planning based on the adopted biopsy scheme. It emphasises that while TBx + PLBx should be the standard biopsy approach for diagnosis, it may not be sufficiently informative for some local treatment indications. Despite the inherent limitations of a consensus process, several recommendations can serve as a reference standard in the absence of strong literature evidence and can also guide the formulation of clinical questions for future practice and research.

Consensus reporting: Follows ACCORD and DELPHISTAR guidelines.

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Critical revision of the manuscript for important intellectual content: Moore, Giganti, Padhani, Kasivisvanathan, Barret, Giganti, Klotz, Malavaud, Murphy, Ploussard, Schoots, Briganti.
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Supplementary data

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