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Platinum Priority – Prostate Cancer
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PRECISE Version 2: Updated Recommendations for Reporting Prostate Magnetic Resonance Imaging in Patients on Active Surveillance for Prostate Cancer

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Abstract

Background and objective: The Prostate Cancer Radiological Estimation of Change in Sequential Evaluation (PRECISE) recommendations standardise the reporting of prostate magnetic resonance imaging (MRI) in patients on active surveillance (AS) for prostate cancer. An international consensus group recently updated these recommendations and identified the areas of uncertainty.

Methods: A panel of 38 experts used the formal RAND/UCLA Appropriateness Method consensus methodology. Panellists scored 193 statements using a 1–9 agreement scale, where 9 means full agreement. A summary of agreement, uncertainty, or disagreement (derived from the group median score) and consensus (determined using the Interpercentile Range Adjusted for Symmetry method) was calculated for each statement and presented for discussion before individual rescoreing.

Key findings and limitations: Participants agreed that MRI scans must meet a minimum image quality standard (median 9) or be given a score of 'X' for insufficient quality. The current scan should be compared with both baseline and previous scans (median 9), with the PRECISE score being the maximum from any lesion (median 8). PRECISE 3 (stable MRI) was subdivided into 3-V (visible) and 3-NonV (nonvisible) disease (median 9). Prostate Imaging Reporting and Data System/Likert ≥ 3 lesions should be measured on T2-weighted imaging, using other sequences to aid in the identification (median 8), and whenever possible, reported pictorially (diagrams, screenshots, or contours; median 9). There was no consensus on how to measure tumour size. More research is needed to determine a significant size increase (median 9). PRECISE 5 was clarified as progression to stage $\geq T3a$ (median 9).

Conclusions and clinical implications: The updated PRECISE recommendations reflect expert consensus opinion on minimal standards and reporting criteria for prostate MRI in AS.

Patient summary: The Prostate Cancer Radiological Estimation of Change in Sequential Evaluation (PRECISE) recommendations are used in clinical practice and research to guide the interpretation and reporting of magnetic resonance imaging for patients on active surveillance for prostate cancer. An international panel has updated these recommendations, clarified the areas of uncertainty, and highlighted the areas for further research.

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1. Introduction

International guidelines recommend risk stratification with baseline magnetic resonance imaging (MRI) to confirm suitability for patients with prostate cancer considering active surveillance (AS) and suggest follow-up MRI during AS [1–3]. In 2016, the European School of Oncology convened the Prostate Cancer Radiological Estimation of Change in Sequential Evaluation (PRECISE) panel to provide a standardised approach to reporting serial MRI scans for patients on AS [4].

The PRECISE recommendations have been used in both clinical practice and research settings [5–21], which has prompted commentary on areas that would benefit from further discussion and clarification [22–24]. Despite prostate MRI interpretation being heavily influenced by image quality, the original recommendations offer no guidance on dealing with poor-quality scans [23]. The original recommendations did not suggest a preferable approach for lesion size measurement or the MRI sequence on which size should be measured [22,24]. They suggested no quantitative thresholds to define significant progression in tumour size

on sequential MRI [22–24]. It was unclear whether the PRECISE score should be derived by comparing patients' current scans with their baseline or most recent prior imaging [23]. Finally, the PRECISE v1 score does not differentiate between stable MRI-visible and MRI-invisible disease [23], despite evidence to suggest that these groups have significantly different prognostic trajectories [25].

An international panel was convened in September 2023 to update the recommendations. We report an updated PRECISE v2 scoring system, case report form, and checklist, as well as the areas for further research.

2. Patients and methods

2.1. Study design

We used a modified RAND/UCLA Appropriateness Method [26]. A core group (C.M.M., F.G., C.A., A.K., T.B., and C.E.) developed 38 survey questions and a draft set of 166 consensus statements, which were sent to all panel members. Each statement was scored on a 1–9 scale, in which 1 indi-

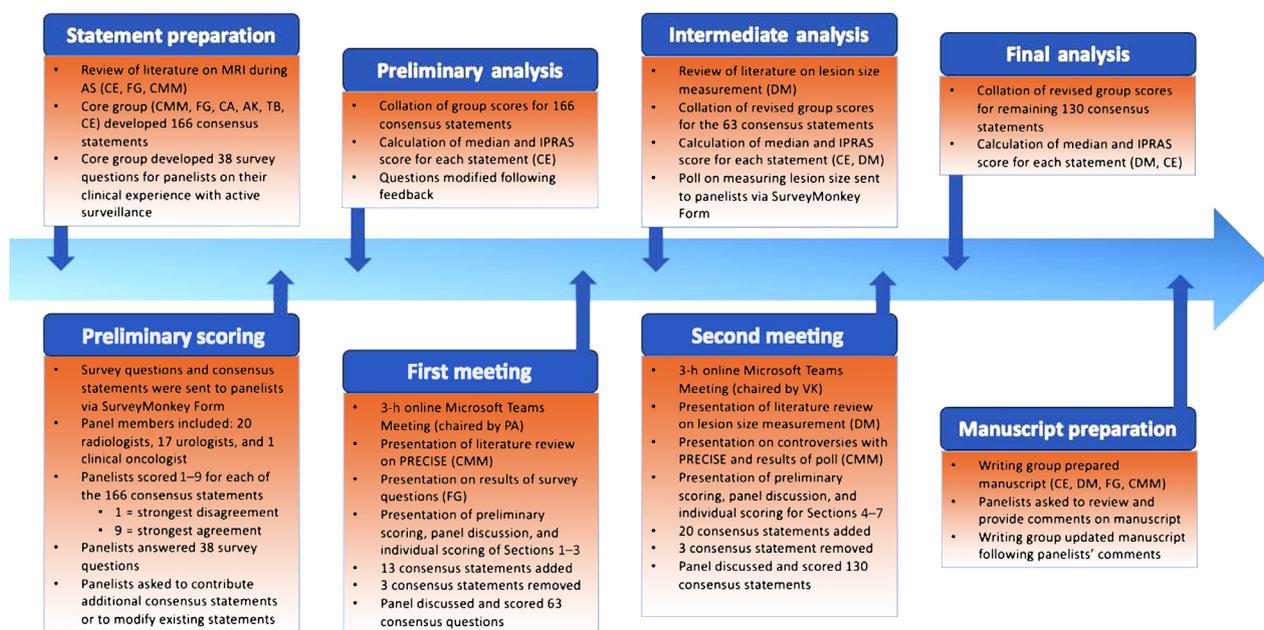


Fig. 1 – The PRECISE v2 consensus meeting process. AS = active surveillance; IPRAS = Interpercentile Range Adjusted for Symmetry; MRI = magnetic resonance imaging; PRECISE = Prostate Cancer Radiological Estimation of Change in Sequential Evaluation.

cated the strongest disagreement and 9 indicated the strongest agreement; a summary of agreement, uncertainty, or disagreement was derived from the group median score. Consensus or a lack thereof was determined for each statement using the Interpercentile Range Adjusted for Symmetry method that considers the proportion of panellists scoring within agreement (7–9), uncertainty (4–6), or disagreement (1–3) [26].

The panel met on two occasions a week apart in September 2023 (Fig. 1). Pre-meeting responses were presented for discussion, including a group median score and degree of consensus (Supplementary Fig. 1), and rescored anonymously by the panellists. Statements could be modified, removed, or added for clarity. A brief literature review of the most contentious topics was presented. A poll of radiologist panel members was conducted on how lesion size is measured in their current practice. Updated panellist scores informed the updated PRECISE score, case report form, and checklist of reporting criteria.

2.2. Setting and participants

The panel included 20 experts in radiology, 17 in urology, and one in radiation oncology from 13 countries across the UK, Europe, and North and South America (Fig. 2). Panellists were invited to participate based on their expertise in AS including publications on the clinical use of MRI in AS (Supplementary Table 1).

3. Results

The statements and scores of the 193 final statements are reported in Table 1. The panellist survey results on AS practice is detailed in Supplementary Table 2, and their

approaches to measuring MRI lesion size are presented in Figure 3 and Supplementary Table 3.

3.1. Scan quality

Participants agreed that image quality should be evaluated and reported using a dedicated scoring system such as the Prostate Imaging Quality (PI-QUAL) score (Q2: median score 8 with agreement and consensus) [27]. A minimum quality standard (ie, PI-QUAL ≥ 4 , which indicates adequate MRI diagnostic quality to rule in and rule out clinically significant prostate cancer) is required to facilitate MRI-based AS monitoring using the PRECISE recommendations (Q3: 9, agreement and consensus). If MRI quality is suboptimal at baseline or subsequently, a higher-quality repeat scan must be obtained (Q5: 9, agreement and consensus).

3.2. Contents of baseline MRI report in clinical practice

Prostate volume measured on T2-weighted imaging (T2-WI) and radiological T stage should be noted at baseline (Q10: 9, agreement and consensus). The likelihood of clinically significant prostate cancer on baseline imaging should be reported using a 1–5 scale (Prostate Imaging Reporting and Data System [PI-RADS] or Likert) for the whole prostate (Q7: 9, agreement and consensus) and for each lesion (Q8: 9, agreement and consensus). The size and radiological appearance (focal or diffuse change) of the four most suspicious lesions should be reported as per the PI-RADS recommendations (Q17: 8, agreement and consensus) [28].

A variety of methods for measuring lesion size were discussed, including (1) a single-axis or (2) two axes or (3) volume using either the ellipsoid formula ($d1 \times d2 \times d3 \times \pi/6$) or planimetry (either manually or software assisted). In clinical practice, participating radiologists reported prefer-

PRECISE Panellists from Centres Around the World

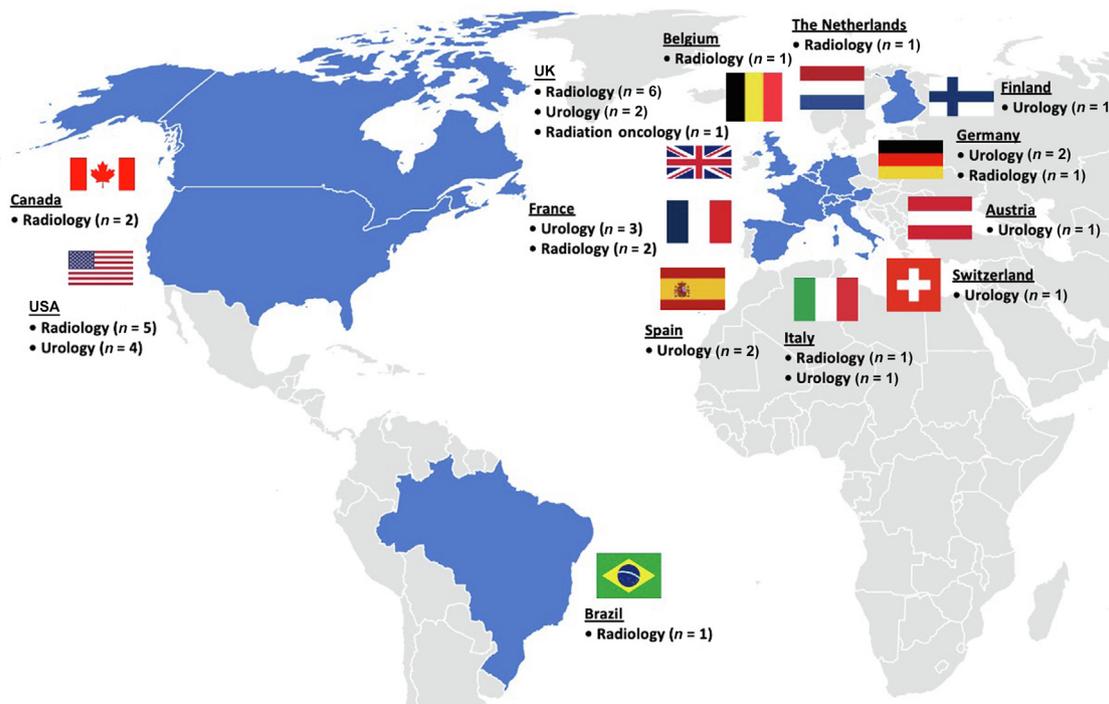


Fig. 2 – Map of panellists.

Table 1 – List of statements with final scoring

Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7-9)	Uncertain (median = 4-6)	Disagree (median = 1-3)			
<i>Section 1 – Scan quality</i>								
1.	When reporting prostate MRI scans:	Image quality should always be commented on in the report.	×			•		9
2.		A scoring system should be used to assess image quality (eg, PI-QUAL).	×			•		8
3.	When reporting a baseline prostate MRI scan for a patient starting active surveillance at your institution:	Unless the scan meets a minimum image quality standard, it should not be used to assess active surveillance eligibility.	×			•		9
4.		A baseline high-quality diagnostic scan is required before a patient can undergo MRI-based active surveillance using PRECISE.	×			•		9
5.		If a scan does not meet a minimum quality standard (ie, PI-QUAL ≥4), a higher-quality scan should be done.	×			•		8
6.		To compare cancer progress between scans, scan quality must meet the minimum standard criteria.	×			•		9
<i>Section 2 – Contents of baseline MRI report in clinical practice</i>								
7.	It is necessary to report the following assessment for each patient:	1-5 likelihood score for clinically significant disease (whole prostate).	×			•		9
8.		1-5 likelihood score for clinically significant disease (maximum for any lesion).	×			•		9
9.		Radiological T stage.	×			•		9
10.	For patients with a visible lesion on MRI, it is necessary to report the following:	Prostate size measured on T2-weighted sequences.	×			•		9
11.		Index lesion type (focal or diffuse change).	×			•		9
12.		Mean ADC value for the lesion.			×	•		2
13.		Minimum ADC value for the lesion.			×	•		2

Table 1 (continued)

Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7–9)	Uncertain (median = 4–6)	Disagree (median = 1–3)			
14.		The size of the index lesion should be reported.	×			•		9
15.		The size of the two most suspicious lesions should be reported.	×			•		9
16.		The size of the three most suspicious lesions should be reported.	×			•		9
17.		The size of the four most suspicious lesions (as per PI-RADS recommendation) should be reported.	×			•		8
18.		The size of all lesions should be reported.			×		•	3
19.		Lesion size should be determined using a single axis measurement.		×			•	4
20.		Lesion size should be determined using a biaxial measurement.	×				•	7
21.		Lesion size should be reported as a volume.		×			•	6
22.		Lesion size should be derived from three axes (ie, ellipsoid formula = 3 dimensions × 0.52).		×			•	5
23.		Lesion size should be determined using planimetry (contouring on each axial slice).			×		•	3
24.		The minimal standard for lesion size measurement is a single axis measurement.		×			•	5
25.		The minimal standard for lesion size measurement is two axes.	×				•	7
26.		The minimal standard for lesion size measurement is the ellipsoid formula (3 measurements × 0.52).			×		•	3
27.		Volume should be estimated by planimetry if possible, and the ellipsoid formula if not.		×			•	6
28.		Where possible (considering time constraints, lesion size and conspicuity, and software availability), the volume measured by the ellipsoid formula should also be reported.		×			•	6
29.		Where possible (considering time constraints, lesion size and conspicuity, and software availability), the volume measured by planimetry should also be reported.		×			•	5
30.		For research, the volume calculated by the ellipsoid formula must always be obtained and by planimetry where possible.		×			•	6
31.		The index tumour size should be measured on the T2-WI sequence.	×				•	7
32.		Whenever possible, the lesion should be measured on T2-WI, using other sequences to aid in the identification of the lesion if it is more conspicuous on these sequences.	×			•		8
33.		The lesion must be measured on T2-WI and also on the additional sequences to aid in the identification of the lesion if better delineated on these sequences.		×			•	6
34.		The minimum standard for lesion size required in clinical practice should be two axes measured on an axial slice, preferably on T2-WI using additional sequences to aid in the identification.	×			•		8
35.		The index tumour size should be measured on the DCE sequence.			×	•		2
36.		The index tumour size should be measured on the high b value sequence.			×	•		2
37.		The index tumour size should be measured on the ADC map.			×	•		3
38.	It is necessary to report the following index of suspicion:	Likelihood of extraprostatic extension per lesion with a Likert 1–5 scale.			×		•	3
39.		Likelihood of extraprostatic extension per lesion using yes/no/maybe.	×				•	8
40.		Likelihood of extraprostatic extension using a structured scoring system.	×				•	8
41.		The specific findings that indicate that extraprostatic extension should be described.	×			•		8
42.		Likelihood of seminal vesicle involvement with a Likert 1–5 scale.			×		•	3
43.		Likelihood of seminal vesicle involvement	×				•	8

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Table 1 (continued)

Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7–9)	Uncertain (median = 4–6)	Disagree (median = 1–3)			
		using yes/no/maybe.						
44.		Likelihood of seminal vesicle involvement using a structured scoring system.	×			•		8
45.		The specific findings that indicate that seminal vesicle involvement should be described.	×			•		8
46.		Overall likelihood of clinically significant cancer (per prostate, PI-RADS/Likert 1–5).	×			•		9
<i>Section 3—Contents of follow-up MRI report in clinical practice: reporting changes</i>								
47.	It is necessary to report the following assessment for each patient:	The same criteria used at baseline need to be assessed at follow-up also.	×					9
48.		Scans should be compared with and scored against the baseline scan alone when assessing for change.			×	•		3
49.		Scans should be compared with and scored against the previous scan alone when assessing for change.			×	•		3
50.		Scans should be compared with and scored against both the baseline and the previous scans when assessing for change.	×			•		9
51.		Unless the comparison is being made by the same reporter and using a standardised technique, the lesion should be remeasured on the previous and initial MRI scans at each new active surveillance scan (to minimise interscan measurement variability).	×			•		9
52.		The index tumour size should be measured on the sequence best showing the lesion.	×			•		9
53.		The index tumour size should be measured on the sequence on which it was last measured.	×			•		8
54.		The sequence used to measure the index tumour must be stated specifically.	×			•		8
55.		Whenever possible, the lesion should be measured on T2-WI, using additional sequences to help with interpretation as needed.	×			•		9
56.	For an individual patient it is necessary to report the following parameters on likelihood of significant change:	A score for likelihood of significant change (PRECISE score).	×			•		9
57.		A score for likelihood of significant change (PRECISE score), with an explanation of the reason for that likelihood given.	×			•		8
58.		Measurements should be done in distances of no smaller than 1 mm.	×			•		9
59.		% change in volume of each lesion from previous scan to latest scan.		×		•		5
60.		% change in volume of each lesion from baseline scan to latest scan.		×		•		5
61.		The MRI lesion volume doubling time should be calculated.			×	•		3
62.		Doubling time should be calculated if the lesion is >0.1 cc on both scans.		×		•		5
63.		Doubling time should be calculated if the lesion is >0.2 cc on both scans (6 mm diameter).		×		•		5
64.		Doubling time should be calculated if the lesion is >0.5 cc on both scans (10 mm diameter).		×		•		5
65.		Doubling time should be calculated using the most recent and baseline scans.		×		•		5
66.		Doubling time should be calculated using the most recent s and previous scans.		×		•		5
67.		Doubling time should be calculated using the most recent scan and the scan before the last biopsy.		×		•		5
68.		Doubling time should be calculated by the simple formula: 70/(percentage change per year).		×		•		5
69.		Doubling time should be calculated by the		×		•		5

Table 1 (continued)

Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7–9)	Uncertain (median = 4–6)	Disagree (median = 1–3)			
70.		more accurate formula: time interval \times (ln [2]/ln [new volume/old volume]). The simple formula for doubling time is acceptable, and the more accurate formula is optimal.		×		•		5
71.		Further research should be done to evaluate the doubling time of lesions to assess radiological progression for patients under active surveillance.	×		•			9
72.	For an individual patient, it is necessary to report the following parameters on the likelihood of a significant change:	Absolute value of lesion volume at baseline and latest scan.		×		•		6
73.		Absolute value of lesion volume on the current and previous scan.		×		•		5
74.		Absolute value of lesion volume at each scan.		×		•		5
75.	For an individual patient, it is necessary to report the following parameters on change of lesion diameter:	Absolute value of lesion diameter at baseline and the latest scan.		×		•		8
76.		Absolute value of lesion diameter on the current and previous scans.		×		•		8
77.		Absolute value of lesion diameter at each scan.		×		•		5
78.		The baseline MRI is the first MRI associated with a cancer diagnosis (ie, where a biopsy has shown cancer) irrespective of whether the MRI shows visible cancer or not.		×		•		8
79.	For an individual patient, it is necessary to report the following parameters of change:	Appearance of any new lesion of volume >0.1 cc.		×		•		6
80.		Appearance of any new lesion of volume >0.2 cc (6 mm diameter).		×		•		8
81.		Appearance of any new lesion of volume >0.5 cc (10 mm diameter).		×		•		9
82.		Appearance of any new lesion of volume >1 cc (12 mm diameter).		×		•		9
83.		Any change in likelihood score of significant cancer from baseline to current scan.		×		•		9
84.		Any change in likelihood score of significant cancer from previous to current scan.		×		•		9
85.		The visibility of a lesion on an additional sequence compared with the visibility of the lesion at baseline.		×		•		8
86.		An increase in conspicuity on any sequence.		×		•		8
<i>Section 4—Contents of follow-up MRI report in clinical practice: defining outcomes and radiological progression</i>								
87.	It is necessary to report the following assessment for each patient:	Change in characteristics of a lesion on MRI (eg, visibility on diffusion and T2-WI compared with visibility on T2-WI alone).		×		•		8
88.		An increase in conspicuity from baseline to repeat MRI on any sequence.		×		•		9
89.		The sequence on which an increase in conspicuity is seen should be specified.		×		•		9
90.		An increase from a PI-RADS/Likert 3 to a PI-RADS/Likert \geq 4 lesion.		×		•		9
91.		Appearance of a new lesion (PI-RADS/Likert 3) on MRI.		×		•		9
92.		Appearance of a new focal lesion (PI-RADS/Likert 3) on MRI		×		•		9
93.		Appearance of a new diffuse PI-RADS/Likert 3 lesion.		×			•	7
94.		Appearance of a new lesion (PI-RADS/Likert 4 or 5) on MRI.		×		•		9
95.		Change in radiological T stage to T3a or greater.		×		•		9
96.	Significant volume change is defined as:	>20% change in volume.		×		•		5
97.		>30% change in volume.		×		•		5
98.		>50% change in volume.		×		•		8
99.		>10% change in maximum diameter.		×		•		5
100.		>20% change in maximum diameter.		×		•		6
101.		>1 mm enlargement.		×		•		4

(continued on next page)

Table 1 (continued)

Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7–9)	Uncertain (median = 4–6)	Disagree (median = 1–3)			
102.		>0.1 cc enlargement.		×		•		5
103.		A combined score for volume such as >50% change in volume and >0.1 cc enlargement.		×		•		5
104.		A combined score for diameter such as >20% change in diameter and >1 mm.		×			•	5
105.		For a change in size to be considered significant, it should be a minimum of 20% increase in diameter (or >70% increase in volume) and ≥5 mm over baseline/nadir.		×			•	5
106.		For a change in size to be considered significant, it should be a minimum of 20% and ≥5 mm increase in diameter over baseline/nadir in two dimensions, or at least 70% increase in planimetric volume.		×		•		5
107.		More research needs to be done on what a significant size change on MRI is for men on active surveillance.	×			•		9
108.	The minimum interval between scans in active surveillance to assess clinically significant change should in general be:	1 yr.	×					8
109.		2 yr.		×			•	5
110.		3 yr.			×	•		3
111.		6 yr.			×	•		2
112.	The following actions should be recommended for a clinically significant change on MRI:	A decision on further monitoring using PSA, MRI, biopsy, or treatment should consider the MRI findings, along with previous biopsy information, and clinical data on comorbidities and patient preference.	×			•		9
<i>Section 5—Contents of follow-up MRI report in clinical practice: PRECISE scoring system</i>								
113.		The current PRECISE scoring system should be refined.	×			•		8
114.		Separate PRECISE scores should distinguish between radiological progression to stages T2 and T3a.	×			•		8
115.		There should be a separate PRECISE score to distinguish between stages T3a and T3b.		×			•	5
116.		There should be a subcategory within the PRECISE score that differentiates stable MRI-invisible disease from unchanged visible lesions.	×			•		8
117.		There should be a subcategory within the PRECISE score that accounts for lesions that show slight, but not significant, progression.		×			•	5
118.		A simplified 3-point PRECISE score (where 1 is reduction, 2 is stability, and 3 is progression) should replace the 5-point PRECISE score.		×			•	5
119.		The PRECISE v2 score should be a simplified 3-point scale where: 1 = radiological resolution or reduction in size or conspicuity; 2 = stable MRI (divided in 2-V and 2-NonV); and 3 = radiological progression.		×			•	5
120.		The PRECISE v2 score should be as follows: 1 = resolution; 2 = reduction in size or conspicuity; 3 = stable MRI (divided in 3-V and 3-NonV); and 4 = increase in size of a lesion or appearance of a new PI-RADS/Likert 4 lesion 5 stage progression.	×			•		8
121.		A refined PRECISE score should remain a 5-point scale.	×			•		8
122.		There should be an additional PRECISE score of × for a scan where it is not possible to give a PRECISE score (eg, a scan with artefacts).	×			•		8
123.		The lesion labelled as the index lesion should remain the same across successive scans.		×			•	5
124.		The lesion labelled as the index lesion can be changed across scans.	×				•	7
125.		The PRECISE score for a scan should be taken as the maximum PRECISE score from any of the reported lesions.	×			•		8
126.		The PRECISE score for a scan should be taken		×			•	5

Table 1 (continued)

Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7–9)	Uncertain (median = 4–6)	Disagree (median = 1–3)			
127.		as the PRECISE score of the index lesion. The PRECISE score should be taken by examining all lesions to determine an overall patient-level score (such as overall response in the RECIST guidelines).	×			•		7
128.		The overall PRECISE score for a patient should be determined by comparing a patient's most recent scan to baseline.	×			•		7
129.		The overall PRECISE score for a patient should be determined by comparing a patient's most recent scan to the immediate previous scan.		×		•		6
130.		The scan that the current scan is being compared with in order to derive a PRECISE score must be stated (eg, PRECISE 5 when compared with the previous scan).	×			•		9
131.		There should be a separate score for comparing follow-up scans with the previous and baseline scans.		×		•		5
132.		There should be a combined PRECISE score, eg, PRECISE 1–5, for comparison with the previous scan, with a "+" for enlargement compared with baseline.		×		•		5
133.		Progression can be defined as a significant change in size or significant increase in conspicuity.	×			•		8
134.		The baseline MRI to compare further MRI scans with should be the one taken after the most recent biopsy.		×		•		5
135.		The baseline MRI to compare further MRI scans with should be the one taken after stabilising on 5 α -reductase inhibitors.		×		•		5
136.		The baseline MRI to compare further MRI scans with should be the one taken after a TURP or surgery for BPH.		×		•		5
137.		There should be a minimum interval between scans in order to give a PRECISE score.	×			•		8
<i>Section 6—Format of the MRI report in clinical practice</i>								
138.		Scans should be reported using a standardised reporting template.	×			•		9
139.		A key image of the 2-axis measurement should be saved for reporters of later scans to refer to.	×			•		8
140.	If a standardised reporting template was implemented:	Prose is enough to describe the prostate and any lesions.			×	•		2
141.		All lesions should be labelled on a diagram.		×		•		6
142.		All PI-RADS/Likert ≥ 3 lesions should be labelled on a diagram.	×			•		8
143.		All concerning lesions (PI-RADS/Likert ≥ 4) should be labelled on a diagram.	×			•		8
144.		Any lesions labelled on a diagram should be followed up in subsequent MRI scans.	×			•		8
145.		It is important to show the lesions pictorially using either diagram, key images, or a contour	×			•		9
146.		All lesions should be saved as key images, and this should be noted in the report.	×			•		8
147.		All concerning lesions (PI-RADS/Likert ≥ 4) should be saved as key images, and this should be noted in the report.	×			•		9
148.		A computerised template (eg, integrated into existing reporting software) would be preferable.	×			•		9
<i>Section 7a—Additional information required in a clinical trial or study: reporting of the general conduct of the MRI</i>								
149.	It is necessary to report the following:	That the MRI conduct has met the minimum criteria for prostate MRI according to PI-RADS V2.1 guidelines.	×			•		9
150.		That the MRI conduct has met the minimum criteria for prostate MRI according to other stated guidelines.		×		•		5
151.		The manufacturer, make, and model of the MR machine.	×			•		7
152.		The field strength of the magnet.	×			•		9

(continued on next page)

Table 1 (continued)

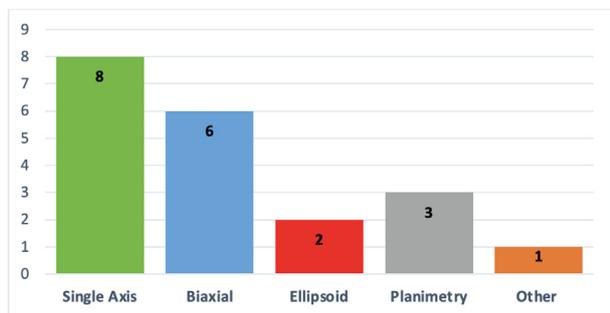
Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7–9)	Uncertain (median = 4–6)	Disagree (median = 1–3)			
153.		If the protocol diverged from international guidelines, then the protocol should always be included in the appendix	×			•		8
154.		The specific coils used (body, pelvic, phased array, endorectal, numbers of channels).	×			•		9
155.		The time between most recent biopsy and MRI.	×			•		8
156.		Whether the scan was biparametric or multiparametric.	×			•		9
157.		Image quality should always be assessed using dedicated scoring systems (eg, PI-QUAL).	×			•		8
<i>Section 7b—Additional information required in a clinical trial or study: MRI reading expertise</i>								
158.	It is necessary to report the following:	The number of radiologists reporting scans in the study.	×			•		8
159.		The experience of each radiologist in prostate MRI reporting (including the number of years reporting prostate MRI and the number of scans each radiologist reports).	×			•		8
160.		Whether the reporting radiologist meets the ESUR guidelines for the minimum number of prostate MRI scans reported (150 prostate MRI scans per year for a beginner radiologist, and an expert radiologist should have read 1000 cases).	×			•		8
161.		Whether each scan is reported by more than one radiologist.	×			•		8
162.		Where there is more than one radiologist reporting each scan, and whether their reports are done separately or in consensus.	×			•		8
163.		Where each radiologist reports separately, how a summary value of each reported parameter was calculated (eg, mean absolute values, mean change).	×			•		8
164.		How the variability between reporters was addressed formally.	×			•		8
<i>Section 7c—Additional information required in a clinical trial or study: information available to the radiologist</i>								
165.	It is necessary to report whether the following patient information was made available to the radiologist reporting the scan:	Current PSA.	×			•		9
166.		Baseline PSA.	×			•		9
167.		Previous PSAD.	×			•		9
168.		Previous biopsy results.	×			•		9
169.		Dates of any previous biopsies.	×			•		9
170.		Digital rectal exam.		×			•	5
171.		Age.	×			•		9
172.		Use of antiandrogen therapies.	×			•		9
173.		Use of 5-alpha reductase inhibitors.	×			•		9
174.		Prior MRI scan reports if performed externally.	×			•		9
175.		Prior MR images if performed externally.	×			•		9
176.		Availability of clinical information to reporting radiologist or not.	×			•		9
177.		Any knowledge of surgical procedures, eg, TURP.	×			•		9
178.		When reporting an MRI scan for a study planimetry should be used.		×			•	6
<i>Section 7d—Additional information required in a clinical trial or study: reporting individual scans for a study</i>								
179.	It is necessary to report the following:	Mean ADC value for a lesion.		×			•	5
180.		Mean ADC value for the lesion that has been normalised.		×			•	5
181.		Mean ADC value for the lesion that has been normalised to healthy prostate tissue.		×		•		5
182.		Mean ADC value for the lesion that has been normalised to urine in the bladder.		×		•		4
183.		Tumour size for each set of sequences where the lesion is seen.		×			•	5
184.		Tumour size for the set of sequences with the greatest tumour visibility.	×			•		8

Table 1 (continued)

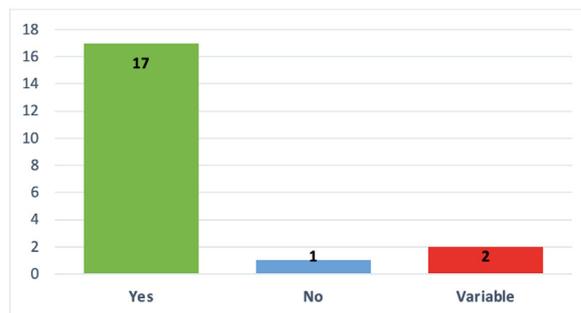
Q.	Stem	Statements	Level of agreement			Consensus reached	No consensus	Median
			Agree (median = 7–9)	Uncertain (median = 4–6)	Disagree (median = 1–3)			
185.		Tumour size for every set of sequences (where this will sometimes be “nonvisible” or 0 for a given set of sequence).		×		•		4
186.		The reporting method used (prose, scoring system, analogue scale, diagrammatic representation, MR images embedded in report).	×			•		8
187.		The individual results of each of the MRI sequences (T1, T2, DCE, diffusion).		×			•	5
188.		The use of a visual reporting scheme where needed.	×			•		8
189.		The method of visual reporting (eg, diagrams, MR snapshots within the report).	×			•		8
190.		The use of a previously published reporting system (eg, PI-RADS v1 or v2).	×			•		9
191.		The sequence that most easily identifies the lesion that should be identified.	×			•		8
192.		The criteria giving rise to each score for each sequence should be reported in detail.	×			•		8
193.		The criteria giving rise to each score for each sequence should be referenced where a previously published system is used (eg, PI-RADS).	×			•		8

ADC = apparent diffusion coefficient; BPH = benign prostatic hyperplasia; DCE = dynamic contrast enhanced; ESUR = European Society of Urogenital Radiology; MR = magnetic resonance; MRI = magnetic resonance imaging; 2-NonV = 2 nonvisible; 3-NonV = 3 nonvisible; PI-QUAL = Prostate Imaging Quality; PI-RADS = Prostate Imaging Reporting and Data System; PRECISE = Prostate Cancer Radiological Estimation of Change in Sequential Evaluation; PSA = prostate-specific antigen; PSAD = prostate-specific antigen density; T2-WI = T2-weighted imaging; TURP = transurethral resection of the prostate; 2-V = 2 visible; 3-V = 3 visible.

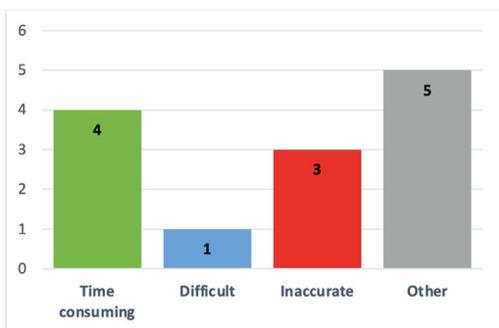
Q2. In clinical practice, what is your preferred method to report lesion size?



Q4. In clinical practice, when reporting lesion size, do you provide absolute measurements (i.e. in mm/cc)?



Q.6 In clinical practice, if you do not report lesion volume, what is the primary reason?



Q8. In trials, what methods do you use to report lesion size (select all that apply)?

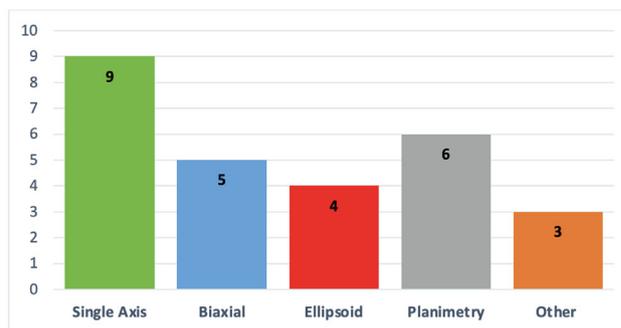


Fig. 3 – Polling results on lesion size measurement from the 20 radiologist panel members.

ring single-axis (eight of 20) and two-axis (six of 20) measurements compared with volume (two of 20 using the ellipsoid formula and three of 20 using planimetry),

whereas in research studies, volume was the commonest approach measured using planimetry (six of 20) and ellipsoid (four of 20), followed by single axis (seven of 20);

Fig. 3). No consensus was reached on a standard approach for lesion measurement and reporting of size. Some panelists stated that volume should be measured because diameter measurements are more prone to error due to slice registration and scanning parameter differences. Others stated that limitations on voxel size meant that calculations of lesion volume using the ellipsoid formula were inaccurate, while planimetry was too time consuming for clinical practice and prone to drawing errors. Panelists not reporting volume routinely claimed that it was too time consuming (four of 13), lacked accuracy or consistency (three of 13), or was too difficult (one of 13) for day-to-day reporting (Fig. 3).

The minimum standard for lesion size required in clinical practice should be two axes measured on an axial slice, preferably on T2-WI using additional sequences to aid in the identification (Q34: 8, agreement and consensus) if it is more conspicuous on these sequences (Q32: 8, agreement and consensus).

Findings indicating extraprostatic extension (Q41: 8, agreement and consensus) or those indicating seminal vesicle involvement (Q45: 9, agreement and consensus) should be described, although there was no consensus on the adoption of a formal structured scoring system for reporting these findings.

3.3. Contents of follow-up MRI report: reporting change

The panel defined the baseline MRI as the first MRI (either before or after biopsy) associated with a histological diagnosis of cancer, irrespective of whether the cancer was visible or not (Q78: 8, agreement and consensus). The PRECISE score for the likelihood of a significant change must be reported (Q56: 9, agreement and consensus), with an explanation for the score (Q57: 8, agreement and consensus). Both the baseline and the most recent prior scans should be used for comparison with the current scan to assess the PRECISE score (Q50: 9, agreement and consensus).

The panel discussed the measurement of lesion change over time. Unless a comparison is being made by the same reporter using a standardised technique, a lesion should be remeasured on the most recent prior and baseline MRI to compare with the current MRI (to minimise interscan observer measurement variability; Q51: 9, agreement and consensus). The index lesion should be measured on the sequence best showing the lesion (Q52: 9, agreement and consensus) as well as the sequence that it was last measured on (Q53: 8, agreement and consensus), specifying the sequence used for measurement (Q54: 8, agreement and consensus). Polling suggested that 15/20 of participating radiologists do this at each time point even if they reported the most recent prior scan. Additionally, the absolute values of lesion diameter on the current, most recent prior (Q76: 8, agreement and consensus), and baseline (Q75: 8, agreement and consensus) scans should be reported. The minimal unit of measurement for lesion size is 1 mm, in consideration of voxel size acquired on prostate MRI scans (Q58: 9, agreement and consensus) [29]. The panel determined that it is necessary to report the appearance of any new lesion >6 mm in diameter or 0.2 cc in vol-

ume (Q80: 8, agreement and consensus), any change in PI-RADS or Likert score (Q83: 9, agreement and consensus), or an increase in conspicuity of a lesion (Q86: 8, agreement and consensus). Further research is required on the use of lesion doubling time on MRI in the assessment of radiological progression during AS (Q71: 9, agreement and consensus).

3.4. Contents of follow-up MRI report: defining outcomes and radiological progression

The minimum interval between scans during AS to assess clinically significant change should be 1 yr (Q108: 8, agreement and consensus). Readers should report changes in lesion characteristics (Q87: 8, agreement and consensus), including appearance or disappearance and variation in conspicuity in one or more sequences (Q88: 9, agreement and consensus), and should specifically state the sequence on which they are identified (Q89: 9, agreement and consensus). An increase in the likelihood score for clinically significant disease of any PI-RADS/Likert ≥ 3 lesion should be reported (Q90: 9, agreement and consensus), as well as the appearance of any new focal lesion with a PI-RADS/Likert score of ≥ 3 (Q92: 9, agreement and consensus) or change in radiological T stage to $\geq T3a$ (Q95: 9, agreement and consensus).

After evaluation of a variety of cut-off values, including a combination of absolute and percentage changes in diameter and volume, the panel concluded that a >50% volume change was significant (Q98: 8, agreement and consensus), while recognising that further research is needed to determine absolute quantitative thresholds for clinically significant changes in lesion size on MRI for patients on AS (Q107: 9, agreement and consensus). Patient-clinician discussions regarding continued monitoring, including repeat biopsy, versus a move to active treatment should consider the imaging findings, along with previous biopsy information, and clinical data on comorbidities and patient preferences (Q112: 9, agreement and consensus).

3.5. PRECISE scoring system

The panel agreed that the PRECISE scoring system should be refined (Q113: 8, agreement and consensus). After discussion of the merits and limitations of a simplified 3-point score, the panel concluded that PRECISE should remain on a 1–5 scale (Q121: 8, agreement and consensus) and PRECISE 3 should further be divided into subcategories that differentiate between visible and nonvisible disease (Q120: 8, agreement and consensus) to account for different clinical trajectories of these patient populations (Table 2) [12,25]. In line with other scoring systems such as PI-RADS, a PRECISE score of 'X' should be provided when a 1–5 score is not possible due to issues such as poor image quality (Q122: 8, agreement and consensus) [28]. The panel agreed that the PRECISE score for radiological progression within stage T2, for example, T2a (half of one lobe) to T2b (more than half of one lobe) or T2c (both lobes), should be expressed as a progression of a visible lesion (PRECISE 4), and that PRECISE 5 should be used only for stage progression to T3a (extraprostatic extension), T3b (seminal vesicle inva-

Table 2 – The updated PRECISE v2 scoring system

PRECISE score	Likelihood of radiological change	Example
1	Complete resolution of previous suspicious features on MRI	Focal lesion previously visible on one or more sequences no longer visible on any sequence
2	Reduction in size and/or conspicuity of previous suspicious area	Focal lesion previously visible on two or more sequences now not visible on one of the sequences (eg, PI-RADS 4 downgraded to PI-RADS 3 when no longer visible on the high b value but still on the map for a peripheral zone lesion)
3	3 visible (3-V) 3 nonvisible (3-NonV)	Stable MRI appearance with a visible focal lesion Stable MRI appearance with no focal lesion
4	Stable MRI appearance with a visible focal lesion	Stable size and/or conspicuity
4	Significant increase in size and/or conspicuity of suspicious features; appearance of a new focal lesion	Lesion becomes visible on an additional sequence or significant increase in size (eg, >50% volume increase) of previously seen lesion
5	Definitive radiological stage progression	Evidence of extracapsular extension (T3a) and/or seminal vesicle invasion (T3b) and/or nodal or distant metastatic disease (N1 and/or M1)
X	Not possible to provide a PRECISE score	Image quality non-diagnostic

MRI = magnetic resonance imaging; 3-NonV = 3 nonvisible; PI-RADS = Prostate Imaging Reporting and Data System; PRECISE = Prostate Cancer Radiological Estimation of Change in Sequential Evaluation.

sion), or T4; appearance of nodal involvement; or distant metastatic disease (Q114: 8, agreement and consensus).

The overall PRECISE score for a scan should be taken as the maximum PRECISE score from any lesion (Q125: 8, agreement and consensus). The PRECISE score should normally consider a patient’s current scan in comparison with the baseline scan (Q128: 7, agreement and consensus). Where there are more than two scans available for a patient, the panel concluded that the scan being used for comparison to derive the PRECISE score should always be stated

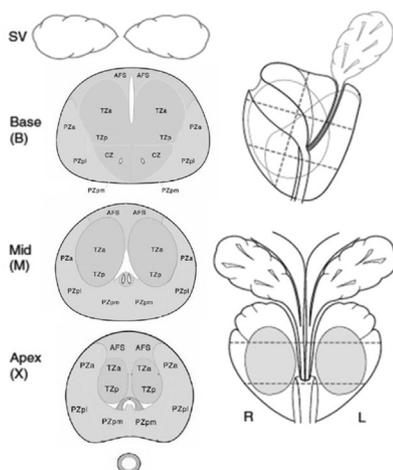
(Q130: 9, agreement and consensus), for example, a PRECISE 3 compared with the most recent prior scan or a PRECISE 5 compared with baseline.

Panellists debated whether the lesion labelled as the index lesion should remain the same across successive scans or whether it can be changed across scans. There was also uncertainty regarding whether the “baseline” MRI scan should be “reset” after a biopsy (Q134: 5, uncertain and no consensus) or any surgery for benign prostatic hyperplasia (Q136: 5, uncertain and no consensus).

PRECISE v2 Case Report Form

Date of scan:	PSA (ng/ml):	PI-RADS score (maximal)
Date of report:	Prostate volume (cc)	Likert score (maximal)
Reporting radiologist:	PSA density (ng/ml ²):	Capsular involvement (describe features):
PI-QUAL score:	TNM stage:	Seminal vesicle involvement (describe features):

Lesion	Focal	Diffuse	New since last scan	Sequence (best seen)	D1 (mm)	D2 (mm)	D3 (mm)	Volume (cc) by ellipsoid formula	Volume (cc) by planimetry (manual/software assisted)
1									
2									
3									
4									



Draw and number each lesion on the diagram, with the index lesion being number 1.

Lesion	Likert score	PI-RADS score	PRECISE score	Parameter which has changed
1				
2				
3				
4				
Overall PRECISE score for this scan ^a				

^aThe PRECISE score for a scan should be taken as the maximum PRECISE score from any of the reported lesions

Fig. 4 – The updated PRECISE v2 case report form. PI-QUAL = Prostate Imaging Quality; PI-RADS = Prostate Imaging Reporting and Data System; PRECISE = Prostate Cancer Radiological Estimation of Change in Sequential Evaluation; PSA = prostate-specific antigen; SV = seminal vesicle; TNM = tumour, node, metastasis.

3.6. Format of the MRI report in clinical practice

Scans should be reported using a standardised reporting template (Q138: 9, agreement and consensus), ideally with a computerised template using either a diagram, key images embedded on the Picture Archiving and Communication System, or contouring (Q145: 9, agreement and consensus).

There was discussion about how many lesions should be reported pictorially and if this should include PI-RADS/Likert 3 lesions. Some panellists felt that reporting PI-RADS/Likert 3 lesions was less important in AS where patients already had biopsy-confirmed cancer than in a detection setting. Ultimately, the panel stated that it was preferable to provide clinicians with information and labelling of all visible lesions (Q142: 8, agreement and consensus). All PI-RADS/Likert ≥ 4 lesions should be saved as key images. The PRECISE case report form has been updated to reflect the modified recommendations (Fig. 4).

3.7. Additional information required in a clinical trial or study

The PRECISE checklist for reporting MRI studies in a clinical trial or study has been updated to reflect consensus on additional information that should be included (Supplementary Table 4). There was no consensus about whether it is necessary to provide the radiologist with the results of digital rectal examinations (Q170: 5, uncertain and no consensus), although recent best practice in AS recommendations concluded that these are not necessary when MRI is used for on-going monitoring [30]. There was no consensus on the need to report the mean apparent diffusion coefficient values for lesions (Q179: 5, uncertain and no consensus). There

was also no consensus on whether planimetry (rather than the ellipsoid formula) should be used to calculate lesion volume in a research setting (Q178: 6, uncertain and no consensus). Polling of the 20 radiologists on the panel demonstrated that when conducting trials, six measure and report lesion size using planimetry, four with the ellipsoid formula, and 14 using diameters (nine single and five biaxial) with several panellists indicating that they use multiple approaches.

4. Discussion

4.1. Summary of results

The key recommendations from the PRECISE v2 consensus meeting are summarised in Table 3. The PRECISE v2 consensus also identified areas of uncertainty surrounding the use of serial MRI scans in patients on AS and the resulting topics requiring further research.

4.2. Clinical and research implications

The consensus meeting was structured to separately address recommendations for routine clinical practice and research.

In clinical practice, the use of MRI in patients on AS varies between countries, with the use of the PRECISE recommendations mostly limited to academic centres [5]. The updated scoring system and case report form have been designed to be acceptable for both dedicated genitourinary and general radiologists to promote dissemination and greater adoption in clinical practice.

Table 3 – Summary of key points from the PRECISE v2 consensus meeting

Section	Description
1 Scan quality	1. Assess image quality with a dedicated scoring system (eg, PI-QUAL)
2 Clinical practice baseline MRI report	1. The baseline MRI is the first scan associated with a biopsy-proven prostate cancer (visible or not) 2. Report: (a) Likelihood of clinically significant prostate cancer for whole prostate and each lesion (PI-RADS or Likert 1–5) (b) Radiological T stage (c) Prostate volume measured on T2-weighted imaging (d) Index lesion type (focal or diffuse change) (e) Size of 4 most suspicious lesions (f) Minimal standard for lesion size: 2 dimensions measured on an axial slice, preferably on T2-WI (additional sequences may be used and specified, if needed to help in identification)
3 Clinical practice follow-up MRI report	1. Compare current scan with baseline scan and most recent previous scan 2. Report: (a) Change in Likert/PI-RADS score (b) Appearance of any new lesions of >0.2 cc volume (6 mm diameter) or any new focal lesion of PI-RADS/Likert ≥ 3 (c) Change in lesion characteristics on any sequence (including increased conspicuity or visibility on new sequence) (d) Progression to radiological $\geq T3a$ (e) Lesion diameter at baseline, most recent previous, and current scans (f) PRECISE score for likelihood of significant change
4 Significant change	1. The minimum interval to assess significant change should be 1 yr 2. Significant change in size (eg, $>50\%$ volume increase), conspicuity, or stage (ie, $\geq T3a$)
5 Additions to PRECISE scoring system	1. PRECISE 3 stratified into visible (3V) and nonvisible (3Non-V) 2. PRECISE X score: when scan quality does not allow adequate PRECISE assessment (eg, artefacts)
6 Format of MRI report in clinical practice	1. Use standardised template with diagrams, key images, or contours 2. Save key image of the 2-axis measurement of each lesion
7 Additional information required for reporting in clinical trials	1. MR protocol (eg, bi- or multiparametric MRI) 2. Scoring system used (PI-RADS or Likert) 3. Report the sequence that identifies the lesions most easily 4. Report the lesion size for each sequence where lesion is seen

MRI = magnetic resonance imaging; 3-NonV = 3 nonvisible; PI-RADS = Prostate Imaging Reporting and Data System; PRECISE = Prostate Cancer Radiological

Further research is needed on the optimal way of measuring lesion size, the absolute or relative change in size that should prompt clinical action, and whether the concept of the time for a lesion to double in volume is helpful. The panel agreed after discussion that a 50% volume change indicated clinically significant progression. The use of the updated PRECISE v2 case report form and checklist will enable appropriate data to be collected to help address these issues.

4.3. Limitations

Despite significant efforts to include diverse international thinking, the virtual format, time differences, and finite number of participants can lead to a selection bias of panelists. The primary limitation of the consensus meeting remains the scarcity of available data addressing topics such as measuring lesion size. This consensus paper offers a framework for data collection in areas deemed most important by expert opinion. After a period of data collection, these areas should be revisited.

5. Conclusions

The PRECISE recommendations on assessing change in MRI findings in patients on AS for prostate cancer have been updated following a consensus meeting to address several contentious issues. Future research should focus on the best methods for measuring lesion size on MRI scans and identify criteria that reflect significant disease changes on serial MRI scans.

Author contributions: Francesco Giganti had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Englman, Maffei, Allen, Kirkham, Barrett, Giganti, Moore.

Acquisition of data: Englman, Maffei, Allen, Kirkham, Albertsen, Kasivisvanathan, Baroni, Briganti, De Visschere, Dickinson, Gómez Rivas, Haider, Kesch, Loeb, Macura, Margolis, Mitra, Padhani, Panebianco, Pinto, Ploussard, Puech, Purysko, Radtke, Rannikko, Rastinehad, Renard-Penna, Sanguedolce, Schimmöller, Schoots, Shariat, Schieda, Tempany, Turkbey, Valerio, Villers, Walz, Barrett, Giganti, Moore.

Analysis and interpretation of data: Englman, Maffei, Giganti, Moore.

Drafting of the manuscript: Englman, Maffei, Giganti, Moore.

Critical revision of the manuscript for important intellectual content: Englman, Maffei, Allen, Kirkham, Albertsen, Kasivisvanathan, Baroni, Briganti, De Visschere, Dickinson, Gómez Rivas, Haider, Kesch, Loeb, Macura, Margolis, Mitra, Padhani, Panebianco, Pinto, Ploussard, Puech, Purysko, Radtke, Rannikko, Rastinehad, Renard-Penna, Sanguedolce, Schimmöller, Schoots, Shariat, Schieda, Tempany, Turkbey, Valerio, Villers, Walz, Barrett, Giganti, Moore.

Statistical analysis: Englman, Maffei.

Obtaining funding: Giganti, Moore.

Administrative, technical, or material support: Englman, Maffei, Albertsen, Kasivisvanathan, Giganti, Moore.

Supervision: Giganti, Moore.

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Supplementary data

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