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Reporting MRI in men on active surveillance for prostate cancer – the PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation) Recommendations: a report of a European School of Oncology Task Force

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Abstract (293/300 words)

Background

Published data on prostate MRI during follow up of men on active surveillance are lacking. Current guidelines for prostate MRI reporting concentrate on prostate cancer detection and staging. A standardised approach to prostate MRI reporting for active surveillance will facilitate the robust collection of evidence in this newly developing area.

Objective

To develop preliminary recommendations for reporting of individual MRI studies in men on active surveillance, and for researchers reporting the outcomes of cohorts of men having MRI on active surveillance.

Design, setting and participants

The RAND/UCLA appropriateness method was used. Experts in urology, radiology and radiation oncology developed a set of 394 statements relevant to prostate MRI reporting in men on active surveillance for prostate cancer. Each statement was scored for agreement on a 9-point scale by each panellist, prior to a panel meeting. Each statement was discussed and rescored at the meeting.

Outcome measurements and statistical analysis

Measures of agreement and consensus were calculated for each statement. The most important statements, derived from both group discussion and scores of agreement and consensus, were used to create the PRECISE checklist and case report form.

Results and limitations

Key recommendations include reporting the index lesion size using absolute values at baseline and at each subsequent MRI. Radiologists should assess the likelihood of true change over time (ie change in size, or change in lesion characteristics on 1 or more sequences) on a 1-5 scale. A checklist of items for reporting a cohort of men on active surveillance was developed. These items were developed based on expert consensus in many areas where data are lacking, and are expected to develop and change as evidence is accrued.

Conclusions

The PRECISE recommendations are designed to facilitate the development of a robust evidence database, for documenting changes in prostate MRI findings over time of men on active surveillance. If used, they will facilitate data collection to distinguish measurement error and natural variability in MR appearances from true radiological progression.

Patient summary

There are few published reports on how to use and interpret MRI for men on active surveillance for prostate cancer. The PRECISE panel recommends that data should be collected in a standardised manner, so that natural variation in the appearance and measurement of cancer over time can be distinguished from changes indicating significant tumour progression.

Introduction

The use of multiparametric magnetic resonance imaging (MRI) to inform the detection of prostate cancer has grown rapidly in the last few years. There have been numerous publications looking to standardise the conduct and reporting of prostate MRI (1-3). Most recently the European Society of Uroradiology and the American College of Radiology (4) published the second version of the Prostate Imaging - Reporting and Data System (PI-RADS v2) outlining the conduct, interpretation and reporting of prostate MRI. These guidelines focused on prostate cancer detection, where the questions asked are 'How likely is it that this man has prostate cancer?' and 'How can this best be biopsied?'

The 2014 United Kingdom National Institute for Clinical Excellence (NICE) prostate cancer guidelines (5) suggest a role for MRI in initial and repeat assessment of men on active surveillance, although no guidance is offered on imaging criteria for selection or continuation of surveillance. NICE recommends MRI and /or biopsy for re-evaluation where there is 'concern over prostate specific antigen (PSA) kinetics or clinical assessment'. The question asked of MRI is then: 'Has there been any significant change?' To distinguish between significant change, measurement error and natural fluctuations in tumour appearance, we need to understand the natural history of MRI changes over time, in men on active surveillance, in terms of change to MRI lesions and 'normal' MRI findings. Once these data are established, radiological thresholds can be set that indicate significant actionable, clinical change in disease.

Schoots et al. reviewed the evidence for MRI in men on active surveillance (6). They found a lack of published data in the use of MRI in active surveillance follow up. The European School of Oncology then convened the PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation) panel to develop recommendations for MRI in men on active surveillance for prostate cancer. Formal consensus methodology, including the use of a face to face meeting, was chosen. This technique is helpful to determine the level of agreement amongst experts and to identify areas which require further data before agreement can be reached. The panels' objective was to develop recommendations for reporting of individual MRI studies in men on active surveillance (the PRECISE report form), and for researchers reporting the outcomes of cohorts of men having MRI on active surveillance (the PRECISE checklist).

Materials and methods

Study design

We used the RAND/UCLA appropriateness method (7). A core group (CMM, IGS, AK, CA, FG) developed a draft set of 350 statements and sent them to all panel members for modification. Statements could be revised, removed or added at this stage. A revised set of 394 statements was scored by each panel member on a scale of agreement from 1-9, where 1 indicated strongest disagreement and 9 indicated strongest agreement. These scores were collated and a summary of agreement, uncertainty or disagreement (derived from the group median score) was calculated for each statement. Calculations to determine consensus or lack of consensus for each statement were performed using RAND/UCLA classical criteria, which takes into account the proportion of panellists scoring within a given category of agreement (7-9), uncertainty (4-6) or disagreement (1-3). For a statement to have consensus a clear majority scoring in that category is needed.

A chair (PA) who did not participate in scoring convened a panel meeting. A graphical representation of the group response was presented for each statement which included the group median score and the degree of consensus (figure 1). Each statement was discussed. Some statements were modified or removed, while others were added as a result of the discussions. Following discussion, each statement was rescored anonymously by each panel member. Following the meeting, the individual panellist scores were collated, and the degree of agreement and consensus calculated for each statement. The collated scores, and the content of the discussion were used to develop the PRECISE checklist of reporting criteria for studies of MRI in men on active surveillance and the PRECISE case report template form to report MRI at baseline or follow up in these men.

The checklist provides a guide for authors in preparation of a manuscript for publication, and for reviewers and editors when assessing manuscripts. The case report template form is suitable for clinical use allowing communication of imaging findings and their likely relevance to referring clinicians, and will also allow data collection to inform on reporting of cohorts of men.

Setting and participants

The panel included experts in urology (10), radiology (8) and radiation oncology (1) (see supplementary table 1 for panellist experience). Faculty attending the two day European School of Oncology Active Surveillance February 2016 workshop in Milan were initially approached to join the panel. Additional members not attending the workshop were invited to ensure a balance of expertise. Two panel members were unable to travel to the meeting and

participated by webconference (BT, PP) with audioparticipation and desktop viewing so that they could see all of the presentations.

Results

To avoid ambiguous statements, and to identify consensus where it existed, 38 statements were deleted, 56 statements modified and 11 statements added during the panel meeting, giving a final set of 367 statements which were scored.

During the first round 201/394 statements were scored with consensus and agreement. Table 1 shows the scoring during the meeting.

The PRECISE case report form for reporting an MR study in an individual man on active surveillance (figure 2)

The PRECISE case report form includes each item that should be reported for an individual man having an MRI at baseline or follow up during active surveillance.

The PRECISE checklist for reporting cohorts of men having MRI in active surveillance (table 2)

The PRECISE checklist shows the panel recommendations for reporting on a cohort of men who have a prostate MRI during active surveillance. All statements in the checklist were scored with consensus and agreement. Items were not included in the checklist if they were scored with disagreement or lack of consensus at the meeting. Items were grouped together, and all definitively agreed statements were included. The full list of items and their scores is given as Supplementary table 2. The intention was to develop a comprehensive but not restrictive set of statements, balancing the need for clarity and brevity and recognising that there is variation in current reporting practice, both in histological and radiological data.

Reporting of the conduct of the MRI

The PRECISE guidelines are not intended to replace or compete with the comprehensive guidelines on the conduct of prostate MRI developed by the PI-RADS group (4). The panel agreed that publications should state whether study MRI scans were conducted in accordance with contemporary guidelines and should cite the guidelines used. We recognize that the conduct of MRI may change over the reporting period of a study because of the longitudinal nature of active surveillance cohorts.

Reporting of the MRI

The number of radiologists reporting scans in the study cohort should be stated. Where an

individual scan was reported by more than one radiologist, then the use of separate or consensus reporting should be clarified. When scans were reported separately, the method used to combine results should be used (eg mean of absolute size values at each time point, mean change in size between scans per reporter). The format of the radiology report should be stated (e.g., prose, template, and/or diagrammatic reporting, with/without embedded or annotated MRI images). The PRECISE case report form has been designed to facilitate the routine collection of clinical and imaging data in a manner that will allow cohort comparison of men on active surveillance in a standardised manner. It should be stated whether the MRI readings were done retrospectively, with one reading of a set of MRI's from previous time points, or whether scans were reported contemporaneously, with or without reference to previous images or reports.

Reporting of the biopsy at entry to active surveillance

There was agreement and consensus on the use of Gleason score, but uncertainty and no consensus on the use of maximum cancer core length, maximum number and proportion of cores. Panel members felt that many cohorts of men on active surveillance will not have had an MRI-targeted biopsy at study entry, and that the number or proportion of positive cores would be strongly influenced by the strategy used to perform the biopsies (standard or targeted to MRI lesions). Reporting the maximum number of positive cores is a helpful indicator in a standard random biopsy, but is less helpful when oversampling is intended during a targeted biopsy of a lesion seen on MRI. It was acknowledged that it is helpful for the radiologist in the clinical setting to know the location of positive biopsies, although this information would not be known in a blinded study.

Reporting of the MRI at baseline and follow up

Prostate volume on T2-weighted sequences and PSA density should be reported. Determination of an assessment of likelihood of clinically significant disease on a 1-5 scale is required for each MRI. The use of the term 'assessment' was chosen to include both those groups who use PI-RADS (version 1 or version 2) and those who use a 1-5 scale based on overall clinical impression without predefined characteristics per sequence (commonly called a Likert scale). The scale used should be identified.

The highest likelihood of clinically significant cancer of all separate lesions should give the likelihood of clinically significant cancer on the whole prostate. For men with a visible lesion, the key metric is the size of the index lesion on the baseline MRI and at each time point thereafter. The term index lesion can be used to denote the largest lesion, or the one with the highest Gleason grade, or of highest suspicion on MRI criteria (6). It was noted that not all men with prostate cancer suitable for active surveillance will have a visible lesion on MRI. It

was agreed that size can be measured using volume (by planimetry or calculated from 3 diameters), by bi-axial measurement of maximum diameters on an axial slice, or by a single measurement of maximum diameter. The panel felt that there was insufficient evidence as yet to determine which of the methods for measuring size was optimal for distinguishing between natural fluctuation in tumour volume, measurement errors over time, or true disease progression. Some felt that planimetry volume would be most accurate whilst others were concerned that this was too time consuming. For lesions best seen on functional image sequences (eg high b-value images), a single diameter may be more reproducible than a volume because of the need to use larger voxel sizes in sequence acquisitions. Comparative data from the same cohort on the reproducibility of different size measurements (eg planimetry volume and biaxial diameter) would be of great value in exploring this further.

All parameters reported on the baseline MRI should be re-reported on follow up MRI. In addition, any MRI report after the baseline MRI report should include an assessment of the likelihood of significant radiological progression from the baseline MRI scan, on a 1-5 scale, along with a description of the change that has given rise to that assessment (eg change in size or change in conspicuity on one or more sequences). Further details are shown in table 3. It should be noted that there are no robust data on which to base the threshold for a significant change in size or conspicuity. The intention is that data collection using the suggested format will allow such data collection, and that, in time, thresholds can be set.

Clinically significant disease in men on active surveillance

It was agreed that Gleason grading and maximum cancer core lengths (MCCL) were important determinants of clinically significant disease in men on active surveillance, but no cut off could be agreed. It was agreed that Gleason $\geq$ 4 + 3 or $\geq$T3a disease or any involvement of lymph nodes or bone metastases is clinically significant. Some panellists deemed any Gleason pattern 4 as significant whilst others felt that small volume secondary pattern 4 disease alone was not necessarily of clinical significance in all men. PSA and PSA derivatives such as PSA density and PSA doubling time were deemed of interest in determining clinically significant disease, although again no threshold was identified.

It was acknowledged that clinical significance of MRI lesions is also influenced by patient factors such as age and co-morbidities, where a lesion may be deemed significant in a younger man of age 50, but not in an older man with several co-morbidities.

Noteworthy areas of uncertainty

There was no agreement on the best way to present change in lesion size or appearance over time across a cohort of men. It was acknowledged that some lesions become non-visible

during follow up, and there was uncertainty over how best to deal with this when aggregating results across a cohort. There was concern that use of percentage change of lesion volume across a cohort could yield a large percentage change in small lesions (eg a 0.1cc lesion increasing to a 0.3 cc lesion) and thereby skew results across the cohort. In addition it was noted that the measurement errors of small lesions could be larger than any change, even if significant in percentage terms.

The panel did not reach consensus on whether repeat standard biopsy and/or targeted biopsy should be performed on men with MRI changes. Some felt that a man eligible for treatment at the start of the surveillance period (eg small volume Gleason 3 + 4 disease) would not require additional biopsy confirmation for minor radiological change. Whilst some expressed a wish for biopsy verification of suspected MRI depicted disease progression, it was recognised that patients and clinicians may reasonably opt for treatment without further biopsy.

Discussion

Summary of results

The PRECISE checklist outlines key information that should be reported by researchers in a study of a cohort of men having MRI on active surveillance for prostate cancer. The PRECISE case report form is designed for clinical radiologists to report an individual MRI at baseline or follow up. Use of the case report form will ensure that appropriate data is collected to inform cohort reporting

The number of statements scored with agreement and consensus reduced from pre-meeting scoring to scoring at the meeting. The purpose of the face to face element of a formal consensus meeting is to allow detailed discussion and interaction of the panellists, to fully explore a topic. This can reduce or increase consensus. The reduction in agreed consensus showed that many challenging topics were discussed, in an area where data are emerging.

Clinical and research implications

MRI is being used more frequently in men on active surveillance to assess for clinically significant disease missed at initial biopsy, or to reduce the need for repeat biopsy (8). There are data to suggest that stability on MRI can predict Gleason score stability (9).

The use of MRI in men on active surveillance varies between countries and health systems, with lower use of MRI outside of academic centres (10). Some centres exclude men with visible lesions on MRI from an active surveillance programme, in order to reduce the likelihood of unfavourable pathology (11,12). It is known that some small lesions on prostate MRI can be pathologically benign, or of low grade tumour only (13). However, others recognise that it is likely that long established active surveillance series would no doubt have included men who would have had visible lesions on MRI, had it been available at that time, and treatment of all men with MRI-visible disease is likely to lead to significant overtreatment. Data have shown that men with a visible lesion (positive MRI) are more likely to receive treatment than men with a negative MRI. The extent to which clinical decisions may have been influenced by this factor is not easy to determine, as there are few studies where clinicians were blinded to MRI results.

We hope that use of the PRECISE checklist will allow the natural history of MRI changes in men on active surveillance to become clearer, allowing appropriate significance thresholds for radiological disease to be set both at baseline, and during surveillance. The correlation of radiological findings with PSA and histological data, and treatment free survival will also be of great value. The use of the PRECISE recommendations to analyse large data sets such as those from the Movember Global Action Project on Active Surveillance (14) would allow rapid

assessment and refinement of the recommendations based on data from multiple centres worldwide.

Limitations

The greatest limitation of these recommendations is the lack of published data on which to base recommendations. The intention of these recommendations is that they will allow robust data collection in those areas deemed most important by expert opinion, so that further iterations of the recommendations will be based on those data. In particular the areas most in need of research are the optimal way of measuring lesions size to allow repeatability over time, and both the change in size and absolute size which should prompt clinical action. Whilst there is a possibility of bias in the groups selected for the consensus meeting, however, only a small number of centres declined the invitation to participate.

Conclusions

These PRECISE recommendations have been developed to facilitate robust data collection to assess the natural history of MRI findings in men on active surveillance. If widely used then the data derived will facilitate the determination of thresholds that identify radiologically significant disease, and significant radiological change on MRI. It is likely that initial validation work will lead to refinement of the recommendations in due course.

Acknowledgements

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List of figures (see separate tif files)

List of tables

Table 1: Summary of the group responses before and during the meeting

	Agreement & consensus	Disagreement & consensus	Uncertainty or no consensus
Pre-meeting (n = 394)	**201 (51%)**	**12 (3%)**	**181 (46%)**
During meeting (n = 367)	**144 (39%)**	**34 (9%)**	**189 (52%)**

Table 2: The PRECISE checklist

Item	Section of paper	Description
1	Title	The study should be identified as reporting results from MRI in men on active surveillance, either to identify men as suitable for AS or as a tool for repeat assessment on AS
2	Introduction	The introduction should include a clear statement of the research question or study aim (eg correlation of pathological outcomes with radiological change, assessment of radiological change on repeat MRI) and background information such as the take up of AS in men deemed suitable
3	Study design and population	The setting, location, and recruitment period and study design (prospective/retrospective) should be reported. It should be made clear (and citation given) if the report is an update of a previously published cohort.
		The inclusion and exclusion criteria with the maximum Gleason score, maximum PSA and the name, version and citation of an established AS protocol or risk classification system (where relevant) should be reported.
		The requirement for confirmatory biopsy, frequency of PSA testing and the indication and frequency for biopsy, MRI and any additional test eg genomic classifiers.
		Indications for a switch to active treatment should be specified.
4	Conduct of the MRI	Whether or not the MRI conduct met the minimum criteria set by the European Society of Uro-radiology (ESUR) and the American College of Radiologists (ACR). (Weinreb, Eur Urol 2015*)* or other stated guidelines.
		The field strength and the specific coils used should be stated, & a brief description of the sequences.
		The inplane resolution and slice thickness of the T2-weighted (T2W) images should be stated; the image sets

		analysed for diffusion weighted imaging (DWI) including the highest b value acquired and whether the highest b value was extrapolated or not; the temporal resolution for dynamic contrast enhanced (DCE) images
5	Reporting of the MRI	The number of radiologists reporting scans in the study should be stated.
		The availability (or not) of clinical information and previous MRI images to the reporting radiologist should be stated.
		When more than one radiologist reports a scan it should be stated whether this is done in separately, or in consensus. When done separately it should be stated how a summary value was derived eg mean absolute values ; mean change between scans per reporter.
		The reporting method used (eg prose, vs diagrammatic report, name and version of scoring system) should be given.
6	Conduct of the biopsy	The anatomical approach (transrectal/transperineal) and method of targeting MRI lesions; the use of separate pots for targeted and systematic cores (if applicable)
		The time interval between MRI and biopsy (median and range)
		Whether systematic cores are taken in all, and the intended number of systematic cores per prostate and targeted cores per lesion; whether systematic biopsy was performed blind to MRI findings. The criteria for choosing a lesion to be targeted, whether the biopsy operator had direct access to the MR images. Where software assisted was used for registration of MRI and ultrasound images the manufacturer and model should be stated.
7	Patient characteristics	The age range, baseline PSA and MRI derived prostate volume, distribution of Gleason score and risk categories across the group and the maximum cancer core length *(MCCL*). The number of men taking drugs which would affect the hormonal environment of the prostate, (eg 5 alpha reductase inhibitors, testosterone)

		should be recorded.
		A flow chart of participants showing numbers of men eligible, offered and enrolled to the study, with those who continue on AS and the treatment status of those who are not on AS.
8	Individual patient Baseline MRI report	The baseline MRI report should contain the prostate volume measured on T2-weighted imaging and a likelihood of clinically significant cancer on a scale of 1-5 for the whole prostate and for each lesion. The likelihood of extra prostatic extension and seminal vesicle involvement should be reported on a 1-5 scale. The index lesion size should be reported using volume (by planimetry or derived from 3 diameters) or measurement of 1 or 2 diameters.
9	Follow up MRI	In addition to features reported at baseline, any subsequent MRI report should include: • a score on a 1-5 scale for the likelihood of significant change, along with a description of the change that has given rise to the score eg change in size, change in conspicuity on one or more sequences • any change in likelihood of significant cancer (1-5 scale) • an increase in suspicion due to extension into seminal vesicles or a suspicious lymph node or bone lesion. • absolute values of lesion size at baseline and each subsequent scan • the appearance of any new lesion • any lesion becoming non-visible
10	Reporting of follow up biopsy findings	Separate reporting of systematic and targeted cores with a maximum cancer core length and Gleason grouping per patient irrespective of whether this was derived from targeted or systematic cores; mean/median number of cores per prostate and per lesion; mean/median number of lesions per patient where targeted cores were taken;

11	Statistical analysis	The effect of inter-reader variability; whether any effect is dependent on the size of the baseline lesion; whether outliers (very large or very small lesions) were excluded; how the disappearance of a lesion is handled in the statistical analysis. Where there is adequate power to do so, univariate and multivariate analysis should be used to assess the added value of a reporting statement to baseline clinical data; the odds ratio for a single and a combination of unfavourable factors should be given
12	Discussion	The clinical applicability of the findings should be discussed, along with the correlation of the observed MRI changes with traditional tools to measure disease progression (DRE, PSA kinetics, biopsy findings)

Table 3 Assessment of likelihood of radiological progression on MRI in men on active surveillance

Likert	**Assessment of likelihood of radiological progression**	Example
1	Resolution of previous features suspicious on MRI	Previously enhancing area no longer enhances
2	Reduction in volume and/or conspicuity of previous features suspicious on MRI	Reduction in size of previously seen lesion that remains suspicious for clinically significant disease
3	Stable MRI appearance: no new focal/diffuse lesions	Either no suspicious features or all lesions stable in size and appearance
4	Significant increase in size and/or conspicuity of features suspicious for prostate cancer	Lesion becomes visible on diffusion – weighted imaging; significant increase in size of previously seen lesion
5	Definitive radiological stage progression	Appearance of extracapsular extension, seminal vesicle involvement, lymph node involvement or bone metastasis

Supplementary table 1: Panellist experience

Centre	Panellists	Risk-assessment-method	Any published follow up protocol for AS	Most recent relevant publications (max 2)
University College London, UK	Caroline M Moore (Urologist), Alex Kirkham (Radiologist)	UCL traffic light (biopsy) Likert scale (MRI)	None	1. Moore CM, Parker C. The Evolution of Active Surveillance for Prostate Cancer. Eur Urol 2015; 68(5):822-3. 2. Schoots IG, Petrides N, Giganti F, et al. Magnetic resonance imaging in active surveillance of prostate cancer: a systematic review. Eur Urol 2015; 67(4):627-36.
Erasmus Medical Center, Rotterdam, *The Netherlands*	Ivo Schoots (Radiologist), Chris Bangma (Urologist)	D'Amico MSKCC nomogram ERSPC nomogram Rotterdam risk calculator	PRIAS PRIAS-MRI	1. Bangma CH, Valdagni R, Carroll PR, et al. Active surveillance for low-risk prostate cancer: developments to date. Eur Urol 2015; 67(4): 646-8. 2. Schoots IG, Petrides N, Giganti F, et al. Magnetic resonance imaging in active surveillance of prostate cancer: a systematic review. Eur Urol 2015; 67(4):627-36.
San Raffaele Scientific Institute, *Milan,*	Alberto Briganti (Urologist)	D'Amico UCSF-CAPRA NCCN	PRIAS	1. Schoots IG, Petrides N, Giganti F, et al. Magnetic resonance imaging in active surveillance of prostate cancer: a systematic review. Eur Urol 2015; 67(4):627-36.

Italy		Briganti nomogram		
Sunnybrook Health Sciences Center, Toronto, Canada	Massoom Haider (Radiologist), Laurence Klotz (Urologist)	D'Amico NCCN	Toronto	1. Scheenen TW, Rosenkratz AB, Haider MA, Fütterer JJ. Multiparametric Magnetic Resonance Imaging in prostate cancer management: current status and future perspectives. Invest Radiol 2015; 50(9):594-600. 2. Bangma CH, Valdagni R, Carroll PR, et al. Active surveillance for low-risk prostate cancer: developments to date. Eur Urol 2015; 67(4): 646-8.
Helsinki University Central Hospital, Helsinki, Finland	Antti Ranniko (Urologist)	D'Amico MSKCC nomogram.	PRIAS PRIAS-MRI	1. Schoots IG, Petrides N, Giganti F, et al. Magnetic resonance imaging in active surveillance of prostate cancer: a systematic review. Eur Urol 2015; 67(4):627-36.
Hôpital Universitaire Pitié-Salpêtrière, Paris, France	Raphaele Renard-Penna (Radiologist)	No	No	1. Rozet F, Bastide C, Beuzeboc P, et al. Management of low-risk prostate cancer. Prog Urol 2015; 25(1):1-10. 1. Ouzzane A, Renard-Penna R, Marliere F, et al. Magnetic resonance imaging targeted biopsy improves selection of patients considered for active surveillance for clinically low risk prostate cancer based on systematic biopsies. J Urol 2015; 194(2):350-6.

Fondazione IRCCS Istituto Nazionale	Riccardo Valdagni	D'Amico & NCCN	PRIAS	1. Bangma CH, Valdagni R, Carroll PR, et al. Active surveillance for low-risk prostate cancer:

Tumori, *Milan,* *Italy*	(Radiation Oncologist)		SAINT protocol	developments to date. Eur Urol 2015; 67(4): 646-8 2. *Bul M, Zhu X, Valdagni R, Pickles T, Kakehi Y, Rannikko A, Bjartell A, van der Schoot DK, Cornel EB, Conti GN, Boevé ER, Staerman F, Vis-Maters JJ, Vergunst H, Jaspars JJ, Strölin P, van Muilekom E, Schröder FH, Bangma CH, Roobol MJ. Active surveillance for low-risk prostate cancer worldwide: the PRIAS study. Eur Urol. 2013 Apr;63(4):597-603.*
National Cancer Institute, *NIH,* *Bethesda,* *USA*	Peter Pinto (Urologist), Baris Turkbey (Radiologist)	NCCN	None	1. Turkbey B, Mani H, Aras O, et al. Prostate cancer: can multiparametric MR imaging help identify patients who are candidates for active surveillance? Radiology 2013; 268(1):144-52. 2. Fascelli M, George AK, Frye T, Turkbey B, Choyke PL, Pinto PA. The role of MRI in active surveillance for prostate cancer. Curr Urol Rep 2015; 16(6):42.
University of California, *San Francisco, USA*	Peter Carroll (Urologist) Antonio Westphalen (Radiologist)	UCSF CAPRA score	None	1. Welty CJ, Carroll PR. The ongoing need for improved risk stratification and monitoring for those on active surveillance for early stage prostate cancer. Eur Urol 2014; 65(6): 1032-3. 2. Fradet V, Kurhanewicz J, Cowan JE, et al. Prostate cancer managed with active surveillance: role of anatomic MR imaging and MR spectroscopic imaging. Radiology 2010; 256(1):176-83.

Università La Sapienza, *Rome,* *Italy*	Valeria Panebianco (Radiologist)	No	PRIAS PRIAS-MRI Other	1. Panebianco V, Barchetti F, Sciarra A, et al. Multiparametric magnetic resonance imaging vs standard care in men being evaluated for prostate cancer: a randomized study. Urol Oncol 2015; 33(1):17.e1-7.
Mount Vernon Cancer Centre, Northwood, *UK*	Anwar Padhani (Radiologist)	NICE 2014	NICE 2014	1. Kirkham AP, Haslam P, Keanie JY. Prostate MRI: who, when, and how? Report from a UK consensus meeting. Clin Radiol 2013; 68(10): 1016-23. 2. Barentsz JO, Weinreb JC, Verma S, Thoeny HC, Tempany CM, Shtern F, Padhani AR, Margolis D, Macura KJ, Haider MA, Cornud F, Choyke PL. Synopsis of the PI-RADS v2 Guidelines for Multiparametric Prostate Magnetic Resonance Imaging and Recommendations for Use. Eur Urol. 2016 Jan;69(1):41-9.
Centre Hospitalier Régional Universitaire, Lille, *France*	Adil Ouzzane (Urologist), Philippe Puech (Radiologist)	D'Amico	None	1. Ouzzane A, Renard-Penna R, Marliere F, et al. Magnetic resonance imaging targeted biopsy improves selection of patients considered for active surveillance for clinically low risk prostate cancer based on systematic biopsies. J Urol 2015; 194(2):350-6. 2. Marliere F, Puech P, Benkirane A, et al. The role of MRI-targeted and confirmatory biopsies for cancer upstaging at selection in patients considered for active surveillance for clinically low-risk prostate cancer. World J Urol 2014; 32(4):951-8.

Memorial Sloan-Kettering *Cancer Center,* *New York,* *USA*	Karim Touijer (Urologist)	MSKCC nomogram NCCN	Other	1. Recabal P, Assel M, Sjoberg DD, et al. The efficacy of multiparametric magnetic resonance imaging and MRI-targeted biopsy in risk classification for patients with prostate cancer on active surveillance. J Urol 2016; doi: 10.1016/j.juro.2016.02.084. 2. Vargas HA, Akin O, Afaq A, et al. Magnetic resonance imaging for predicting prostate biopsy findings in patients considered for active surveillance of clinically low risk prostate cancer. J Urol 2012; 188(5):1732-8.
Institut Paoli-Calmettes, Marseille, *France*	Jochen Walz (Urologist)	D'Amico MSKCC nomogram	Toronto	None

Supplementary table 2: Comprehensive list of items and responses

Item	Disagreement with consensus	Uncertain	Agreement with consensus
TITLE and INTRODUCTION			
Section 1. Title It is necessary for the title of the study report to include the following information:			
1. Identification as a study reporting results from MRI in men on Active surveillance (AS)			**X**
2. The use of MRI to identify men suitable for AS			**X**
3. The use of MRI as a surveillance tool for repeat assessment in AS			**X**
4. The parameters used to recommend active treatment (PSA, MRI, biopsy, patient preference)		**X**	
5. The "target condition" (e.g. change on MRI in men on AS; use of active treatment in men on active surveillance; radiological progression; upgrading or upstaging)		**X**	
6. The population studied e.g. biopsy entry criteria, risk classification criteria		**X**	
7. The use of MRI targeted biopsy to identify men not suitable for AS		**X**	
8. The study design (prospective, retrospective, randomised, cohort)			**X**
Section 2: Introduction It is necessary for the introduction to report the following:			
9. A clear statement of the research question or study aim e.g. to identify parameters on baseline MRI which predict for upgrading at repeat biopsy in men initially suitable for active surveillance			**X**
10. Background information (eg. Take up of AS amongst men diagnosed with prostate cancer deemed eligible for AS)			**X**

11. Any national guidelines for clinical practice (and publication date) in the country where the study was held, which need to be acknowledged (eg. UK NICE guidelines - January 2014)		**X**	

METHODS			
Section 3: Adherence to published AS protocol (or not) It is necessary to report the following details of the AS protocol used:			
12. Name of established protocol			**X**
13. Name and version of established protocol			**X**
14. Inclusion and exclusion criteria of protocol			**X**
15. Requirement for confirmatory biopsy prior to enrolment on AS			**X**
16. Frequency of PSA testing during protocol			**X**
17. Frequency of DRE during protocol		**X**	
18. Indication for additional biomarker tests during protocol where used (e.g. MRI for adverse PSA kinetics)			**X**
19. Frequency of additional biomarkers tests during protocol (e.g. PCA3)			**X**
20. Frequency of repeat biopsy			**X**
21. Trigger for repeat biopsy on protocol			**X**
22. Use of MRI at baseline (prior to enrolment on AS)			**X**
23. Use of MRI after decision to follow AS			**X**
24. Frequency of MRI during AS on protocol, where used			**X**
25. Trigger for MRI during AS (e.g. scheduled annually, above PSA threshold, prior to planned repeat biopsy)			**X**
26. Trigger for switch to active treatment (e.g. pathological progression, patient choice, PSA kinetics)			**X**
Section 4: Patient Population			

It is necessary to report:			
Design duration setting			
27. The setting (public hospital, academic centre, multi-centre studies)			**X**
28. The location of the study (city/country)			**X**
29. The dates between which the study recruited and followed up patients			**X**
30. Whether data collection was prospective or retrospective			**X**
31. The study design (cohort, randomised)			**X**
32. Whether this is an update of a previously reported cohort			**X**
33. When doing a multi-centre meta-analysis, the inclusion and exclusion criteria for chosen study centres and clinicians (e.g. minimum number of years of experience)		**X**	
34. Where relevant, details of the method of randomisation			**X**
35. Whether ethical permission was sought and gained			**X**
36. Whether recruitment was based on PSA values alone, or results from other tests such as MRI, TRUS or biopsy			**X**
37. If a risk classification system was used to determine eligibility			**X**
38. Which risk classification system was used (eg. D'Amico, Partin tables, MSKCC nomogram, ERSPC nomogram, UCSF-CAPRA score, Sunnybrook, Milan, NCCN)			**X**
39. A citation of the original paper stating the risk classification criteria			**X**
40. The parameters for risk classification should be cited individually (eg. PSA boundaries, biopsy criteria, age, MRI findings)			**X**
41. Whether genomic classifiers have been used in patient selection for AS		**X**	
42. Which genomic classifiers have been used in patient selection for AS		**X**	
43. Use of ultrasound findings to select men for AS		**X**	
Individual patient inclusion criteria			
44. Biopsy based inclusion criteria		**X**	
45. Maximum Gleason score			**X**

46. Maximum cancer core length, when available			**X**
47. Maximum % core involvement of cancer		**X**	
48. Maximum number of positive cores		**X**	
49. Maximum proportion of positive cores		**X**	
50. Maximum Gleason grouping		**X**	
51. Maximum PSA			**X**
52. Maximum PSA density		**X**	
53. TNM classification		**X**	
54. Other parameters used in inclusion criteria (eg. genomic classifiers)		**X**	
Section 5a: Reporting of the general conduct of the MRI It is necessary to report the following:			
55. That the MRI conduct has met the minimum criteria for prostate MRI, according to the PIRADS v 2 (ESUR & ACR) guidelines (Weinreb, European Urology, 2015)			**X**
56. That the MRI conduct has met the minimum criteria for prostate MRI according to other stated guidelines			**X**
57. Scanning angulation (axial/perpendicular to rectum)		**X**	
58. Total scan time		**X**	
59. The manufacturer, make and model of the MR machine		**X**	
60. The field strength of the magnet			**X**
61. The specific coils used (body, pelvic, phased array, endorectal, number of channels)			**X**
62. A brief description of the sequences used			**X**
63. Any adverse events from performing the diagnostic tests		**X**	
64. The time between most recent biopsy and MRI			**X**
Section 5b: Reporting of the conduct of the T2-weighted sequences It is necessary to report the following:			
65. Scanning direction (phase-encoding; anterior-posterior; right-left)	**X**		

66. Field of view (isotropic/non-isotropic)	**X**		
67. Original matrix size (128/256/512)		**X**	
68. Reconstruction matrix size (256/512)	**X**		
69. In plane resolution			**X**
70. Slice thickness/gaps			**X**
71. TE times	**X**		
72. TR times	**X**		
73. Bandwith	**X**		
74. NEX/averages	**X**		
75. Scan time per sequence	**X**		
Section 5c: Reporting of the conduct of the Diffusion-weighted sequences It is necessary to report the following:			
76. Special filling k-space (parallel imaging) DWI – b values used		**X**	
77. DWI – which image sets analysed (high b value image, ADC map, both)			**X**
78. The highest b value acquired			**X**
79. Whether the highest b value was extrapolated or not			**X**
80. ADC – specify whether qualitative or quantitative analysis was used		**X**	
81. Scan time per sequence		**X**	
Section 5d: Reporting of the conduct of the Dynamic contrast enhanced sequences It is necessary to report the following:			
82. DCE – temporal resolution			**X**
83. DCE – pharmacokinetic model used for post processing, if used		**X**	
84. DCE – qualitative analysis (curve types or yes/no), if used		**X**	
85. DCE – quantitative analysis parameters		**X**	
86. Scan time per sequence		**X**	
Section 5e: MRI reading expertise			

It is necessary to report the following:			
87. The number of radiologists reporting scans in the study			**X**
88. The experience of each radiologist in prostate MRI reporting		**X**	
89. The number of scans experience of each radiologist in prostate MRI		**X**	
90. Whether each scan is reported by more than one radiologist		**X**	
91. Where there is more than one radiologist reporting each scan, whether their reports are done separately, or in consensus			**X**
92. Where each radiologist reports separately how a summary value of each reported parameter Is calculated (eg. Mean absolute values; mean change)			**X**
93. How the variability between reporters was formally addressed		**X**	
Section 5f: Information available to the radiologist It is necessary to report the following patient information was made available to the radiologist reporting the scans:			
94. PSA		**X**	
95. Previous biopsy results		**X**	
96. Dates of any previous biopsies		**X**	
97. Digital rectal examination		**X**	
98. Age		**X**	
99. Use of anti-androgen therapies		**X**	
100. Use of 5-alpha reductase inhibitors		**X**	
101. Prior MRI scan reports		**X**	
102. Prior MR images			**X**
103. Availability of clinical information to reporting radiologist or not			**X**
Section 5g: Format of the radiology report It is necessary to report the following:			
104. The reporting method used (prose, scoring system, analogue scale, diagrammatic representation, MR images embedded in report)			**X**

105. Whether any computer aided diagnosis (CAD) software was used for MR interpretation		**X**	
106. The individual results of each of the MRI sequences (T1, T2, DCE, diffusion, MRS)		**X**	
107. The use of a visual reporting scheme, where used		**X**	
108. The method of visual reporting (e.g. diagrams, MR snapshots within the report)		**X**	
109. The use of a previously published reporting system (e.g. PI-RADS v.1 or v. 2) [1]		**X**	
110. The sequence that most easily identifies the lesion should be identified		**X**	
111. The criteria giving rise to each score for each sequence should be reported in detail	**X**		
112. The criteria giving rise to each score for each sequence should be referenced where a previously published system is used (e.g. PI-RADS)		**X**	
Section 6a: Conduct of the biopsy It is necessary to report the following:			
113. The approach used for access (transrectal/transperineal/transgluteal)			**X**
114. The method of the target during the biopsy process (cognitive registration, image registration, in bore targeting) [2]			**X**
115. Whether cores are potted separately for targeted and systematic techniques			**X**
116. The time interval between MRI and biopsy (median/median and range)			**X**
117. Any adverse events from performing the diagnostic tests		**X**	
118. The person(s) performing the biopsies (e.g. radiologist, urologist, technologist)		**X**	
119. The number of years experience of the operator(s) in taking prostate biopsies		**X**	
120. The experience of the operator(s) in taking targeted biopsies		**X**	
121. The system used to take transperineal cores (20 zone Barzell, 12 zone Barzell, Ginsburg anterior sparing approach)		**X**	
122. Whether the anterior gland is routinely sampled		**X**	
123. Whether systematic cores are taken in all participants			**X**
124. The intended number of systematic cores per prostate			**X**
125. When targeted or systematic biopsy was done at the same biopsy session		**X**	

126. Whether systematic biopsy was performed blinded to MRI findings			**X**
127. Whether MRI targeted biopsies was performed by a different operator to the systematic biopsy		**X**	
For targeted biopsies, it is necessary to report the following			
128. The intended number of biopsy cores per targeted lesion			**X**
129. The intended sampling density per targeted lesion (cores/ml)		**X**	
130. The criteria for choosing a lesion to be targeted			**X**
131. Whether additional targeted biopsies from suspicious areas on TRUS, but not noted as suspicious on MRI, were taken		**X**	
Section 6b: Targeted biopsies using cognitive registration For studies involving cognitive registration, it is necessary to report the following:			
132. Whether the biopsy operator had direct access to the MR images			**X**
133. Which MR sequences were reviewed		**X**	
134. Whether the biopsy operator views a diagrammatic report		**X**	
135. Whether the biopsy operator views a prose report only		**X**	
136. Whether the biopsy operator is told distances of the target from critical structures		**X**	
Section 6c: Targeted biopsies using software based image registration For studies involving software based image registration, it is necessary to report the following:			
137. The use of rigid or dynamic registration [3]			**X**
138. Which MRI sequence is used for the image registration		**X**	
139. Which software for image-registration system was used (manufacturer, make and model)			**X**
Section 6d: Targeted biopsies using in bore guiding equipment For studies using in bore biopsies, it is necessary to report the following:			
140. The software used (manufacturer, make and model)			**X**
141. The needles used (manufacturer, make and model)		**X**	
142. The MRI sequence used for needle placement		**X**	
143. The number of cores taken from each lesion			**X**

144. The patient position during the biopsy procedure (prone or supine)		**X**	
145. Whether the procedure was robot-assisted or hand assisted		**X**	

RESULTS			
Section 7: Baseline characteristics *Baseline patient characteristics* It is necessary to report the following:			
146. The age range of study participants			**X**
147. The race of the study participants, if available		**X**	
148. A flow chart of the numbers of men suitable to be considered for the study, those who were offered and accepted the study, those who were then excluded and those who completed the study			**X**
149. Number of men excluded from study population due to inability to have MRI (e.g. pacemaker, claustrophobia, renal impairment)		**X**	
150. Co-morbidity of the study participants		**X**	
151. Urinary symptoms of the study participants		**X**	
152. Sexual (dys)function of the study participants	**X**		
153. Number of men excluded from study population due to inability to have TRUS biopsy (e.g. not willing, too painful, infection risk, etc.)		**X**	
154. Number of men taking drugs, which would affect the hormonal environment in the prostate (e.g. 5 alpha reductase inhibitors or testosterone)			**X**
155. Number of men who have had previous surgical or minimally invasive treatment for symptomatic prostate enlargement (e.g. transurethral resection of the prostate - TURP, laser treatment)		**X**	
Baseline prostate characteristics			

It is necessary to report the following:			
156. The PSA prior to biopsy (mean/median and range)			**X**
157. Time between PSA and biopsy (mean/median and range)		**X**	
158. Digital rectal examination – DRE (positive/negative)		**X**	
159. Clinical T stage (T1/2/3/4)		**X**	
160. Radiological (MRI derived) T stage		**X**	
161. Prostate volume derived by ultrasound (mean/median and range)		**X**	
162. Prostate volume derived by MRI (mean/median and range)			**X**
Biopsy results at entry to active surveillance It is necessary to report the following:			
163. Mean number of previous negative sets of biopsies		**X**	
164. Mean number of previous positive sets of biopsies		**X**	
165. The number of men with each Gleason sum (e.g. 3+3, 3+4, 4+3, 4+4, etc)			**X**
166. The mean or median maximum cancer core length per man (including the intervening areas of benign glands)		**X**	
167. The mean or median maximum cancer core length per man not counting the intervening areas of benign glands (according to International Society of Urological Pathology – ISUP)		**X**	
168. The mean or median total percentage of biopsy material with cancer involvement		**X**	
169. The mean or median maximum cancer core length in mm		**X**	
170. Maximum Gleason score			**X**
171. Maximum number of positive cores		**X**	
172. Maximum proportion of cores, to include numerator and denominator		**X**	
173. Maximum mm cancer core involvement			**X**
174. Distribution of Gleason score			**X**
175. Distribution of risk category (for a named risk category)			**X**
Section 8: Reporting of the baseline MRI per patient			

It is necessary to report the following assessments for each patient:			
176. PI-RADS version 1 score (whole prostate) – if used, state which version used		**X**	
177. PI-RADS version 1 score (maximum for any lesion)	**X**		
178. PI-RADS version 2 score (whole prostate)		**X**	
179. PI-RADS version 2 score (maximum for any lesion)		**X**	
180. 1-5 scale for likelihood of clinically significant disease (whole prostate)			**X**
181. 1-5 scale for likelihood of clinically significant disease (maximum for any lesion)			**X**
182. Radiological T stage		**X**	
183. The appearance of the "normal" prostate (i.e. away from the area of a lesion)	**X**		
Using whichever scoring system has been previously identified – it is necessary to report the following:			
184. T2WI score		**X**	
185. DWI score		**X**	
186. DCE score		**X**	
187. MRSI score		**X**	
For men with a visibile lesion on MRI – it is necessary to report the following:			
188. DCE type (according to PI-RADS version 1 classification as reported in Barentsz et al. [1])	**X**		
189. Index lesion type (mass or diffuse change)		**X**	
190. Mean ADC value for the lesion		**X**	
191. Minimum ADC value for the lesion		**X**	
For each man – it is necessary to report the following volumetric assessment:			
192. Prostate size measured on T2-weighted sequences			**X**
193. An estimation of tumour size (e.g. by planimetry volume, derived from 3 axes, biaxial or single axis measurement)			**X**
194. It is not possible, based on current data, to determine the single best way to assess tumour size			**X**
195. The index lesion should be reported			**X**
196. The size of all lesions should be reported		**X**	

197. Index tumour size measured on T2-weighted sequences			**X**
198. Index tumour size measured on DCE sequences		**X**	
199. Index tumour size measured on high *b*-value sequences	**X**		
200. Index tumour size measured on ADC map	**X**		
201. Total tumour size measured on T2-weighted sequences		**X**	
202. Total tumour size measured on DCE sequences	**X**		
203. Total tumour size measured on high *b*-value sequences	**X**		
204. Total tumour size		**X**	
205. Volumes measured by formula (3 dimensions * 0.52)		**X**	
206. Lesion size for each lesion per patient (mean/median and range)		**X**	
207. Lesion size for the largest lesion only per patient (mean/median and range)		**X**	
208. Total lesion size per patient (mean/median and range) [i.e. if a patient has two lesions, the total volume for that patient would be the sum of the volume for both lesions)	**X**		
209. Volumes measured by planimetry (contouring on each axial slice)		**X**	
210. Tumour size for each set of sequences where the lesion is seen	**X**		
211. Tumour size for the set of sequences with greatest tumour visibility		**X**	
212. Tumour size for every set of sequences (where this will sometimes be “non visible” or 0 for given set of sequences	**X**		
It is necessary to report the following dimensions:			
213. Longest dimension of each lesion per patient (mean/median and range)		**X**	
214. Longest dimension for largest lesion only per patient (mean/median and range)		**X**	
215. Longest dimension of lesion(s) per patient (mean/median and range) [e.g. if a patient has two lesions, the longest dimension for that patient would be the sum of longest dimension of both lesions)	**X**		
216. Maximal diameter of lesion in axial plane		**X**	
217. Two dimensions (right-angled) including the longest dimension for each lesion (mean/median and range)		**X**	

218. Two dimensions (right-angled) including the longest dimension for the largest lesion		**X**	
219. Longest dimension for the index lesion (mean/median and range)			**X**
220. Two dimensions (right-angled) including the longest dimension for the index lesion (mean/median and range)		**X**	
It is necessary to report the following index of suspicion:			
221. Likelihood of clinically significant cancer (Likert 1-5, PI-RADS 1-5) per lesion			**X**
222. Likelihood of extraprostatic extension per lesion (Likert 1-5 or yes/no/maybe)			**X**
223. Likelihood of seminal vesicle involvement (Likert 1-5 or yes/no/maybe)			**X**
224. Likert value (1-5) for suspicion of T3 disease per lesion		**X**	
225. Overall likelihood of clinically significant cancer (per prostate, Likert 1-5)			**X**
226. Overall PI-RADS v. 1 score for the whole prostate		**X**	
Section 9: Reporting of the follow-up MRI per patient It is necessary to report the following assessments for each patient:			
227. The same criteria used at baseline need to be assessed also at follow up			**X**
The reporting of a change on prostate MRI at follow up compared to baseline For an individual patient it is necessary to report the following parameters of likelihood of significant change:			
228. A Likert score (1-5) for likelihood of significant change			**X**
229. A Likert score (1-5) of likelihood of change, with an explanation of the reason for that likelihood given			**X**
230. A Likert score (1-5) of likelihood of significant change based on: - disease abnormality disappeared/normal appearance - improving disease: morphology and/or function - stable cancer abnormality (morphology/function) and/or no new focal/diffuse lesion consistent with cancer - worsening disease state: morphology and/or function - new abnormality consistent with disease worsening		**X**	
For an individual patient it is necessary to report the following parameters of change of lesion volume:			
231. % change in size of each lesion from previous scan to latest scan		**X**	

232. % change in size of each lesion from baseline scan to latest scan		**X**	
233. > 20% change in size	**X**		
234. > 30% change in size	**X**		
235. > 50% change in size		**X**	
236. 100% (doubling) of lesion size		**X**	
237. Lesion becoming non-visible on follow up			**X**
238. Absolute values of lesion size at baseline and latest scan			**X**
239. Absolute values of lesion size at current and previous scan			**X**
240. Absolute values of lesion size at each scan			**X**
For an individual patient it is necessary to report the following parameters of change of lesion diameter:			
241. Absolute values for lesion diameter at baseline and latest scan		**X**	
242. Absolute values for lesion diameter at current and previous scan		**X**	
243. Absolute values of lesion volume at each scan		**X**	
244. > 20% change in diameter	**X**		
245. > 30% change in diameter		**X**	
246. > 50% change in diameter		**X**	
247. 100 % (doubling) of lesion diameter		**X**	
For an individual patient it is necessary to report the following parameters of change:			
248. Change in the “normal” gland (i.e. away from a given lesion)		**X**	
249. Appearance of any new lesion			**X**
250. Appearance of any new lesion of volume > 0.2 cc (6 mm diameter)		**X**	
251. Appearance of any new lesion of volume > 0.5 cc (10 mm diameter)		**X**	
252. Appearance of any new lesion of volume > 1 cc (12 mm diameter)		**X**	
253. Any change in PI-RADS score on most recent scan			**X**
254. Any change in Likert score of clinical suspicion of significant cancer on most recent scan			**X**
255. The visibility of a lesion on an additional sequence compared to the visibility of the lesion at baseline		**X**	

256. Either quantitative or qualitative analysis of ADC values		**X**	
257. A change in the quantitative DCE analysis (e.g. from type 2 to type 3)	**X**		
258. A change in the qualitative DCE analysis		**X**	
259. An increase in conspicuity on any sequence		**X**	
260. An increase in suspicion of disease requiring treatment based on abutment/bulging/extension to/through the capsule (radiologic T stage progression)		**X**	
261. An increase in suspicion based on the extension into seminal vesicles (radiological T-stage progression)			**X**
262. An increase in suspicion based on the appearance of a suspicious lymph node (radiological N-stage progression)			**X**
263. An increase in suspicion based on the appearance of a bone lesion (radiological M-stage progression)			**X**
For a cohort of men with baseline and follow up MR imaging, it is necessary to report:			
264. Mean change in index lesion size over time		**X**	
265. Mean change in total tumour size over time		**X**	
266. The proportion of men exceeding a given threshold of change (i.e. < 20% increase)		**X**	
267. The proportion of men who have lesions that exceed a given size thresholds (e.g. > 0.5 mls - > 8 mm diameter)		**X**	
268. Different outcomes depending on baseline lesion size (e.g. > 2 mm change in absolute diameter for lesions < 8 mm, > 20 % increase in size for lesions > 8 mm diameter)		**X**	
269. A waterfall plot showing lesion change over time across the cohort		**X**	
Section 10: Reporting of the follow-up biopsy results per patient It is necessary to report the following:			
270. The mean/median number of cores per prostate			**X**
271. Separate reporting of systematic and targeted cores			**X**
272. Reporting according to location or zone of origin using a diagram		**X**	
273. Location or zone of origin using a standardised reporting scheme (e.g. peripheral cores, anterior cores, etc.)		**X**	

For targeted biopsies, it is necessary to report the following:			
274. The mean/median number of lesions per patient from which at least 1 targeted core was taken			**X**
275. The total number of lesions in the population from which at least 1 targeted core was taken			**X**
276. The mean/median number of cores per lesion			**X**
277. The mean/median number of cores per prostate			**X**
278. The number of men in each Gleason group (1= 3+3; 2=3+4; 3= 4+3; 4=4+4; etc.)			**X**
279. The mean/median maximum cancer core length per patient using targeted cores alone			**X**
280. The mean/median total cancer core length per patient using targeted cores alone		**X**	
281. The mean/median percentage cancer core length per patient using targeted cores alone		**X**	
282. The number of men in each Gleason grouping using systematic cores alone			**X**
283. The mean/median maximum cancer core length per patient using systematic cores alone			**X**
284. The mean/median total cancer core length per patient using systematic cores		**X**	
285. The mean/median percentage cancer core length per patient using systematic cores alone		**X**	
286. The maximum cancer core length and Gleason grouping per patient, irrespective of whether this was derived from systematic or targeted cores			**X**
Section 11: Reporting of additional measures per patient It is necessary to report the following:			
287. Use of genomic classifiers (serum based)		**X**	
288. Use of genomic classifiers (tissue based)		**X**	
289. Use of genomic classifiers (urine based)		**X**	
290. Use of nomogram scores for likelihood of significant disease		**X**	
291. Use of nomogram scores for likelihood of disease progression		**X**	
Defining active surveillance outcomes **Section 12a: Reporting non-radiological paremeters to allow assessment of disease progression** Change in the following parameters should be reported and included in the definition of significant change in men on active surveillance for prostate cancer:			
292. Gleason grading			**X**

293. Gleason grouping			**X**
294. Maximum cancer core length in mm (counting the intervening areas of benign tissue)			**X**
295. Maximum cancer core length in mm (not counting the intervening areas of benign gland, according to the method recommended by ISUP)		**X**	
296. Total cancer core length in mm		**X**	
297. DRE findings		**X**	
298. PSA			**X**
299. PSA density			**X**
300. PSA velocity		**X**	
301. PSA doubling time			**X**
Section 12b: Thresholds for recommending active treatment based on systematic biopsy alone On a per patient level the following finding in at least one biopsy core of at least the following histological grade or core length confers clinically significant prostate cancer:			
302. Gleason 3+4		**X**	
303. Gleason 4+3			**X**
304. Gleason 7		**X**	
305. Gleason ≥ 8			**X**
306. MCCL > 2 mm and/or Gleason ≥ 3+4 (Goto criteria)	**X**		
307. MCCL ≥ 3 mm and/or Gleason ≥ 3+4 (Harnden criteria)	**X**		
308. MCCL ≥ 4 mm and/or Gleason ≥ 3+4 (UCL definition 2)		**X**	
309. MCCL ≥ 5 mm and/or Gleason ≥ 3+4 (Haffner criteria)		**X**	
310. MCCL ≥ 6 mm and/or Gleason ≥ 4+3 (UCL definition 1)			**X**
311. MCCL ≥ 6 mm and/or Gleason 3+4		**X**	
Section 12c: Defining outcome – recommending active treatment according to a composite risk assessment On a per patient level the following criteria confer a threshold, which should trigger active treatment in men on active surveillance:			
312. D'Amico intermediate risk (T2b, Gleason 7, PSA > 10 ng/ml or PSA density < 0.2 ng/ml		**X**	

313. D'Amico high risk (T2c, Gleason score ≥ 8, PSA > 20 ng/ml or PSA density > 0.2 ng/ml			**X**
314. Stage T1b/N0/M0	**X**		
315. Stage T2a/N0/M0	**X**		
316. Stage T2b/N0/M0		**X**	
317. Stage T3b/N0/M0			**X**
318. Any N1			**X**
319. Any M1			**X**
Section 12d: Defining outcome – MRI based definitions of radiological progression			
320. Any increase in tumour volume on any MRI parameter, which has been repeated after baseline		**X**	
321. There are insufficient data at present to define radiological progression in men on active surveillance for prostate cancer			**X**
322. A 20% increase in tumour volume on any MRI parameter, which has been repeated after baseline		**X**	
323. A 50% increase in tumour volume on any MRI parameter, which has been repeated after baseline		**X**	
324. A 100% increase (i.e. doubling) in tumour volume on any MRI parameter, which has been repeated after baseline		**X**	
325. Any increase in largest tumour diameter on any MRI parameter, which has been repeated after baseline		**X**	
326. A 20% increase in largest tumour diameter on any MRI parameter, which has been repeated after baseline		**X**	
327. A 50% increase in largest tumour diameter on any MRI parameter, which has been repeated after baseline		**X**	
328. A 100% increase (i.e. doubling) in largest tumour diameter on any MRI parameter, which has been repeated after baseline		**X**	
329. An increase in conspicuity from baseline to repeat MRI on T2-weighted MRI		**X**	
330. An increase in conspicuity from baseline to repeat MRI on dynamic contrast enhanced (DCE) images		**X**	
331. An increase in conspicuity from baseline to repeat MRI on diffusion weighted images (highest *b*-value)		**X**	
332. An increase in conspicuity from baseline to repeat MRI on diffusion weighted images (ADC values)		**X**	

333. Appearance of a new lesion on MRI		**X**	
334. Change in characteristics of a lesion on MRI (e.g. visibility on diffusion and T2-WI compared to visibility on T2-WI alone)		**X**	
335. Change in radiological T-stage to > T3a			**X**
The following actions should be recommended for clinically significant change on MRI:			
336. Repeat MRI after a given interval		**X**	
337. Additional imaging (e.g. PET-CT)	**X**		
338. Repeat standard biopsy		**X**	
339. Repeat standard and targeted biopsy		**X**	
340. Targeted biopsy to suspicious area		**X**	
341. Discussion of active treatment		**X**	
342. Recommendation for active treatment	**X**		
343. There is too little publically available data to make recommendations for action based on change on MRI			**X**
Section 13: Statistical analysis Power and sample size analysis – where possible, it is necessary to report the following:			
344. All numerators and denominators should be apparent in either the text or table for all percentages			**X**
345. Where a scan has been reported by more than one radiologist, the effect of inter-reader variability on the responses			**X**
346. Whether any effect is dependent on the size of the baseline lesion			**X**
347. Whether outliers (e.g. very large or very small lesions) were excluded			**X**
348. How the disappearance of lesions is handled in the statistical analysis			**X**
In order to be able to assess the added value of a single reporting item - in addition to baseline clinical data - it is important to assess and report the following:			
349. Univariate analysis			**X**
350. Multivariate analysis			**X**
351. Odds ratio for a single unfavourable factor			**X**

352. Odds ratio for a combination of unfavourable factors			**X**
When choosing a single reporting parameters to add value to the baseline clinical assessment, it is important to assess:			
353. PI-RADS v. 1 score		**X**	
354. PI-RADS v. 2 score			**X**
355. A 1-5 score of likelihood of clinically significant disease		**X**	
356. Minimum ADC value of lesion	**X**		
357. Mean ADC value of lesion		**X**	
358. Index lesion type (mass/no mass)		**X**	
359. Index lesion volume		**X**	
360. Index lesion maximal diameter		**X**	
When choosing a single imaging feature to add value to baseline clinical assessment, the most important imaging sequence is:			
361. T2-WI		**X**	
362. DCE	**X**		
363. ADC		**X**	
364. DWI (high *b*-value)		**X**	
365. MRSI	**X**		

DISCUSSION			
Section 14: Discussion It is necessary for the following to be reported:			
366. The clinical applicability of the study findings			**X**
367. The correlation of observed MRI changes to traditional tools to monitor disease significance during active surveillance (DRE, PSA kinetics, biopsy findings)			**X**

(1) Barentsz JO, Richenberg J, Clements R, Choyke P, Verma S, Villeirs G, et al. ESUR prostate MR guidelines 2012. Eur Radiol. 2012;22(4):746-57.

(2) Cognitive registration refers to the use of operator judgement to guide targeted biopsy based on viewing the MRI images or report prior to the biopsy procedure, in the absence of image-registration software during the procedure; image registration refers to the use of software to allow the MRI image (lesion alone or whole prostate) to be seen on an ultrasound platform for the biopsy procedure); in-bore targeting – samples taken within the MR scanner.

(3) Rigid registration registers the MRI image with an initial ultrasound image; dynamic registration registers the MR image with a real time ultrasound image, which may alter as the biopsy procedure is performed e.g. swelling following needle placement

Reporting MRI in men on active surveillance for prostate cancer – the PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation) Recommendations

Take home message

The PRECISE panel recommends that prostate MRI reports in men on active surveillance include index lesion size in absolute values at each timepoint, and an estimation of the likelihood of significant change between baseline and current images.

37 words

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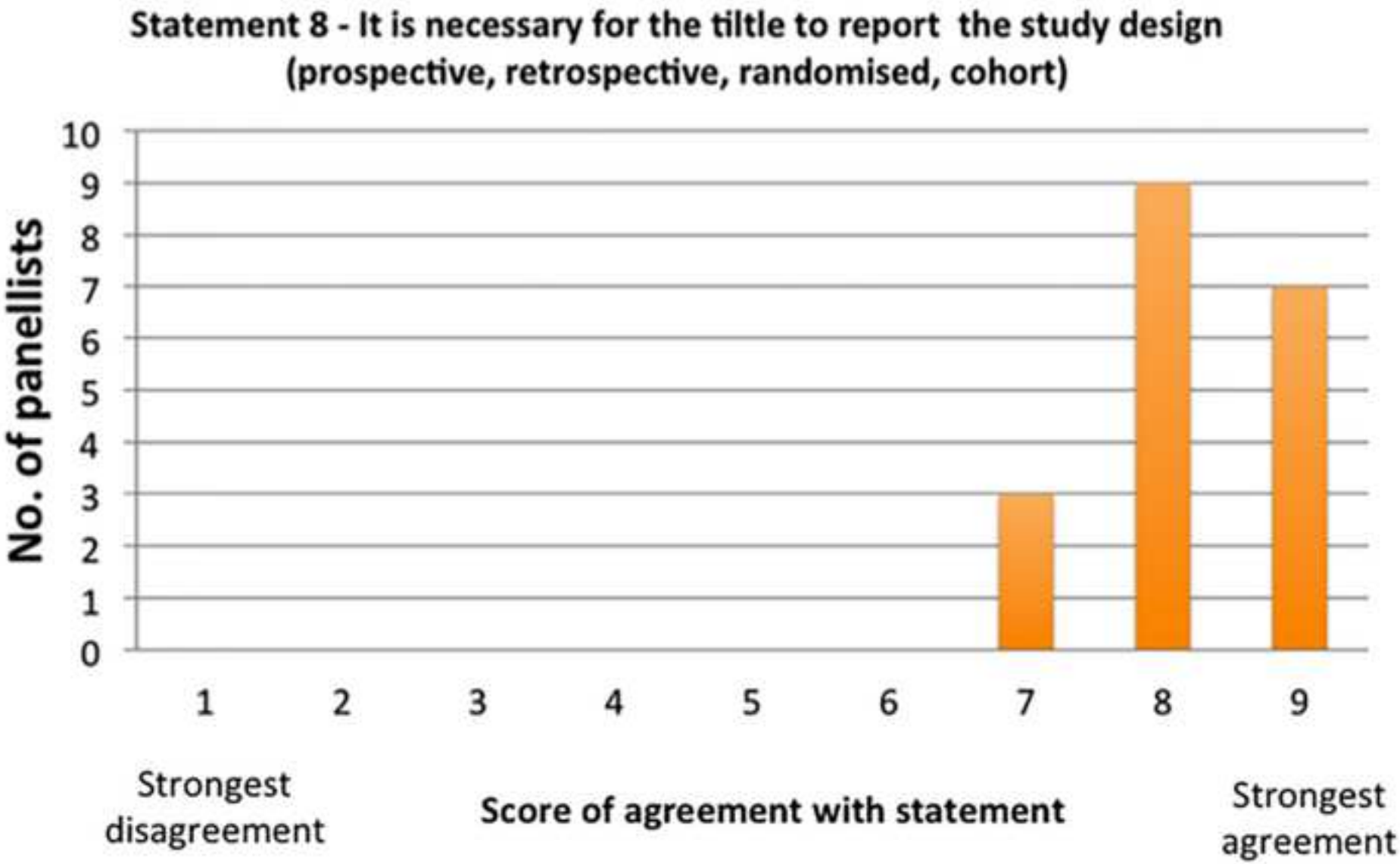

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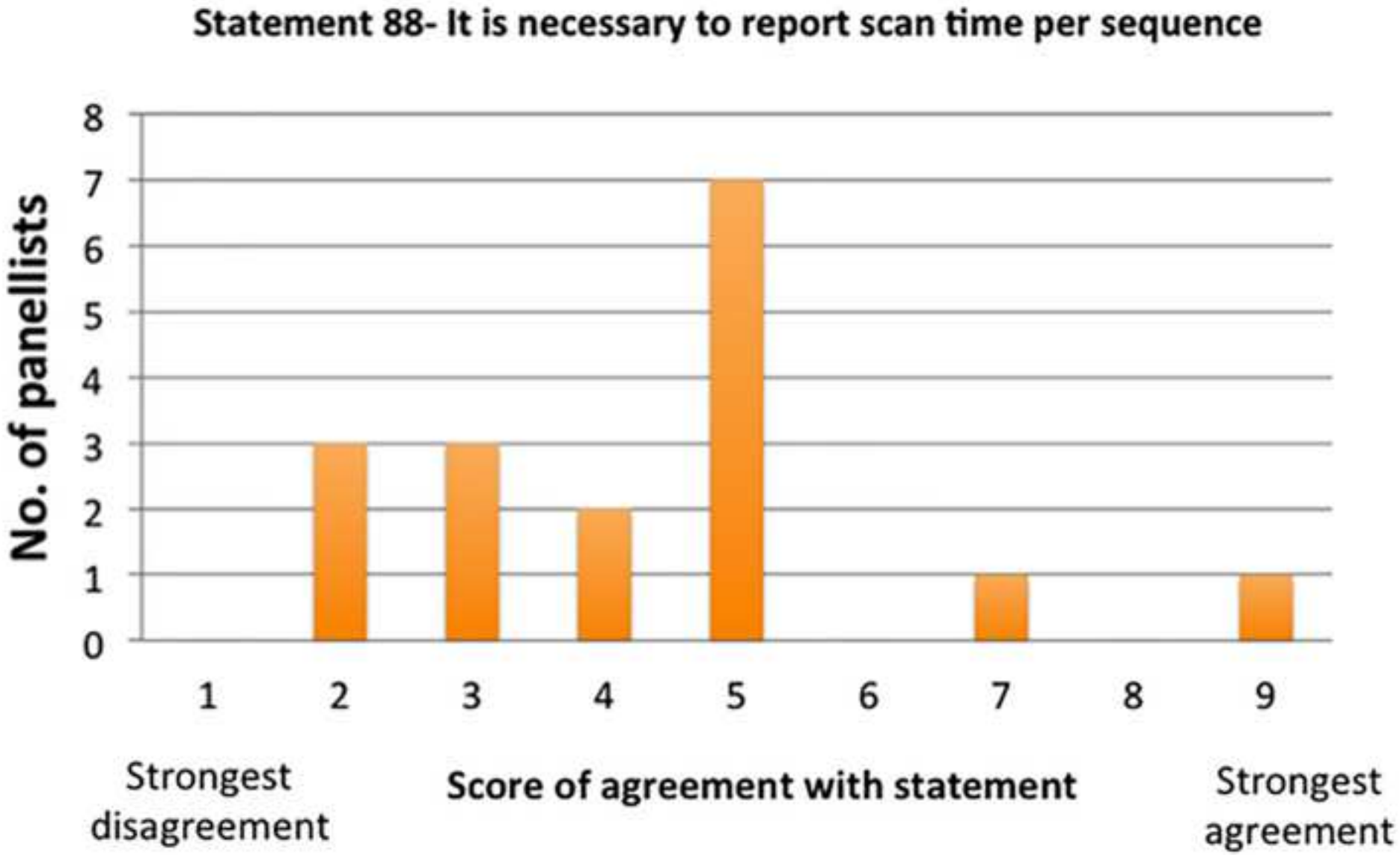

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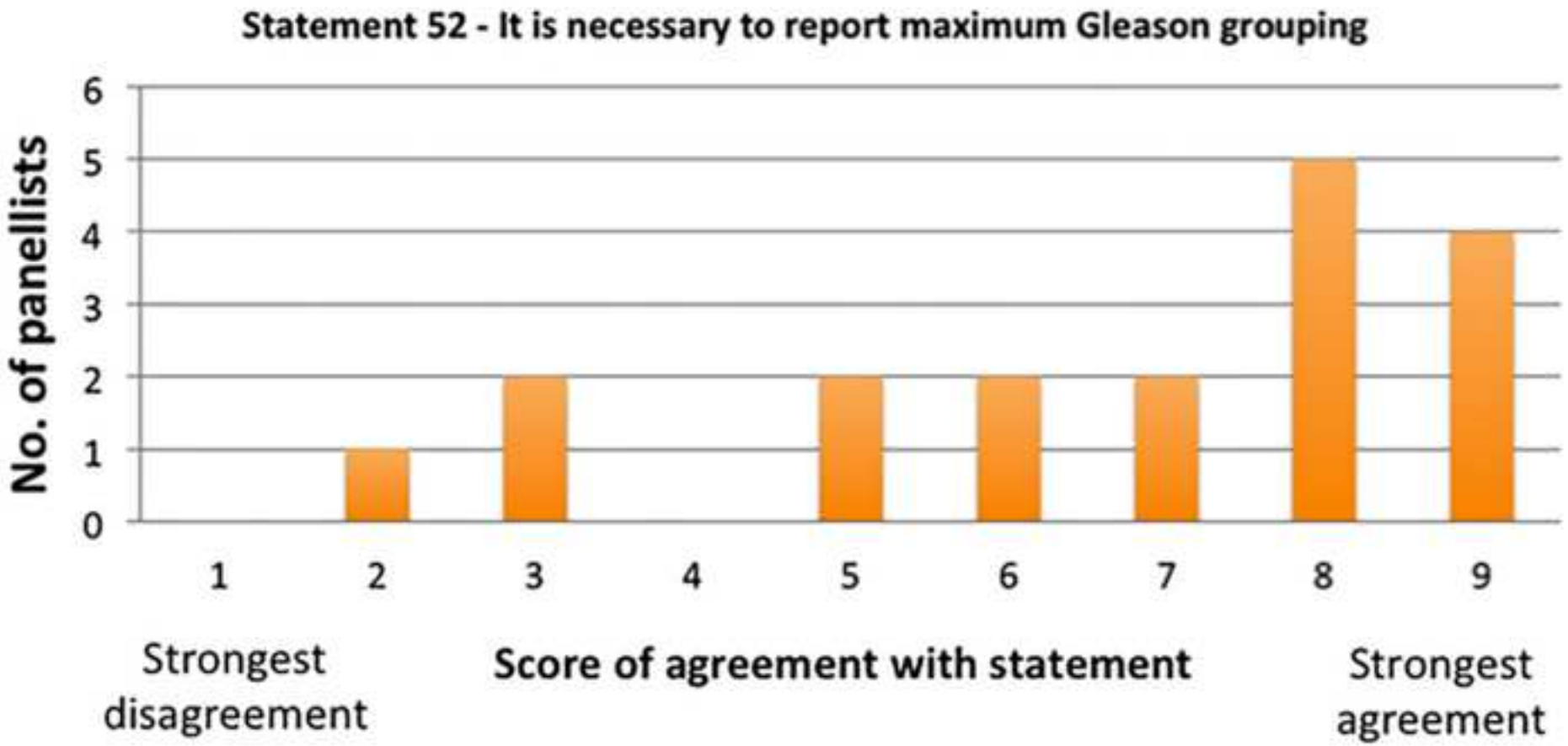

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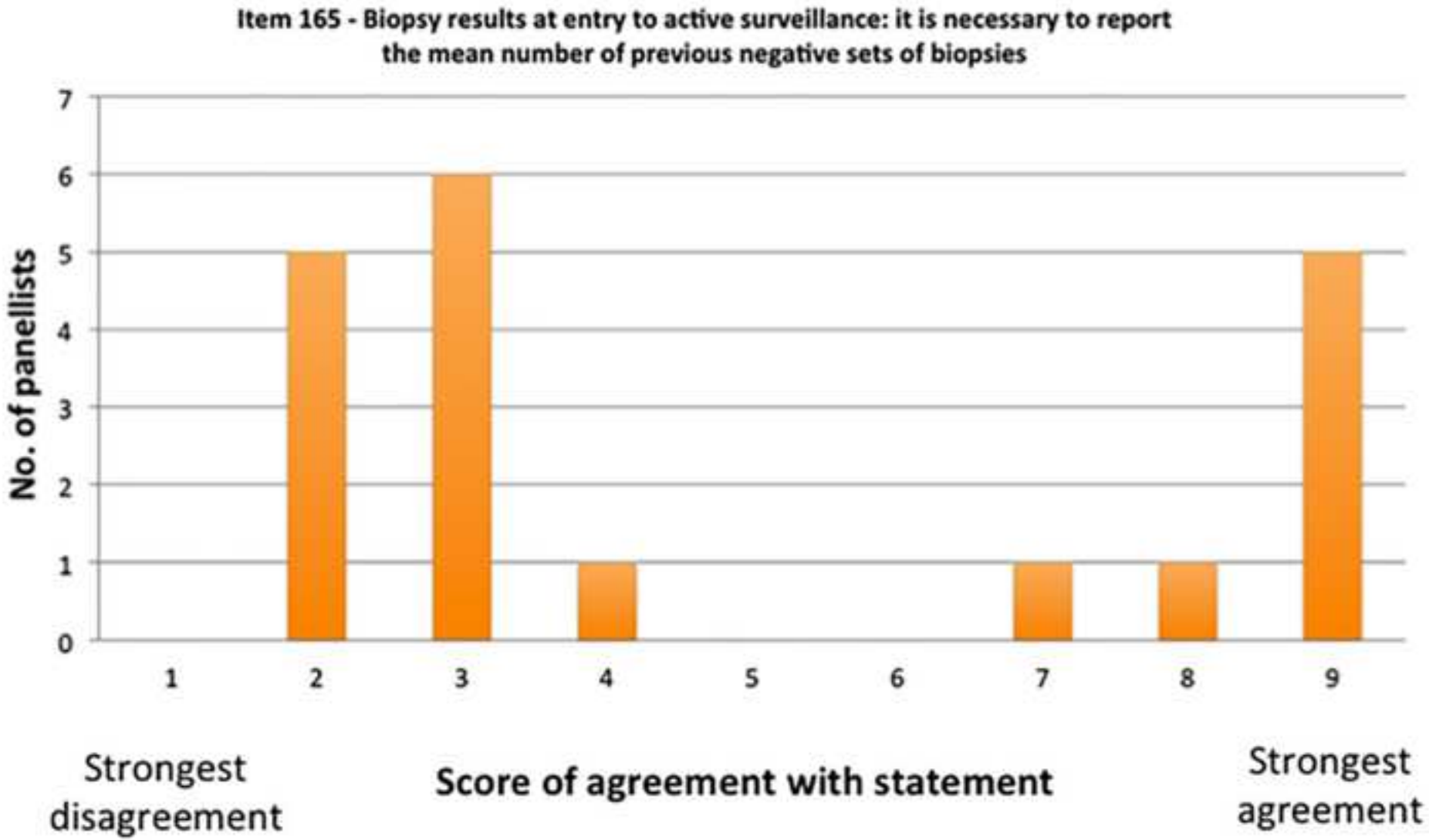
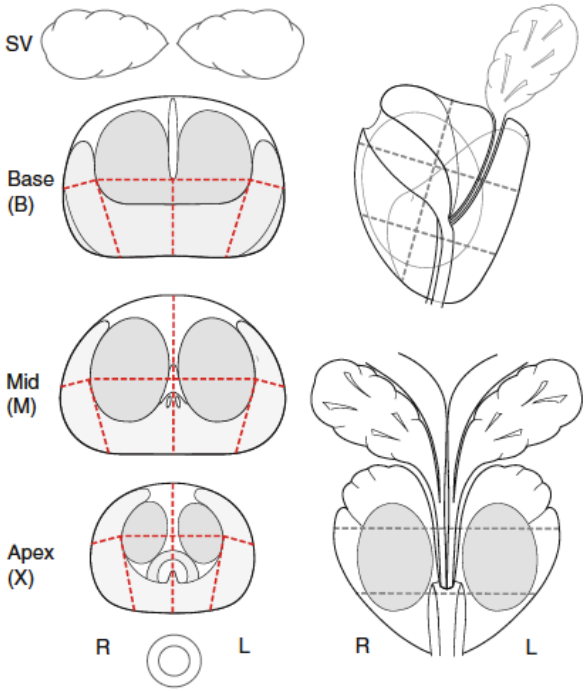


Illustration

PRECISE Case report form for men having baseline MRI on active surveillance

Reporting radiologist		Date of scan		Date of report	
PSA		PSA date		PSA density	
Prostate volume on T2-weighted imaging		Magnet strength		Coil used	
Likelihood of clinically significant disease (1-5)*		PIRADS 2 score (maximal)		TNM stage	
Likelihood of extraprostatic extension (T3a) (1-5)*		Likelihood of seminal vesicle invasion (T3b) (1-5)*			



Lesion	Appeared since last scan?	Not visible	D1	D2	D3	Volume (D1 x D2 x D3 x 0.52)	Volume by planimetry	Likelihood of clinically significant disease (1-5)*	PIRADS- 2 score
1									
2									
3									

	Sequence where lesion best seen	Volume where lesion best seen	Volume on T2-weighted imaging
Lesion 1			
Lesion 2			
Lesion 3			

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

*Likert score of 1-5 for likelihood where 1= Very low likelihood; 2= Low likelihood 3 = Intermediate/equivocal; 4 = High likelihood ; 5 = Very high likelihood

	Date of previous MRI	Likelihood of change from previous MRI (1-5 score)	Parameter which has changed eg volume on T2W-I, visibility on DWI, Likert score or PIRADS score, T3a or T3b disease
Lesion 1			
Lesion2			
Lesion 3			

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☐ Approval of the manuscript

OR

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