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Platinum Priority – Prostate Cancer

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# Magnetic Resonance Imaging for the Detection, Localisation, and Characterisation of Prostate Cancer: Recommendations from a European Consensus Meeting

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**Abstract**

***Background:*** Multiparametric magnetic resonance imaging (mpMRI) may have a role in detecting clinically significant prostate cancer in men with raised serum prostate-specific antigen levels. Variations in technique and the interpretation of images have contributed to inconsistency in its reported performance characteristics.

***Objective:*** Our aim was to make recommendations on a standardised method for the conduct, interpretation, and reporting of prostate mpMRI for prostate cancer detection and localisation.

***Design, setting, and participants:*** A consensus meeting of 16 European prostate cancer experts was held that followed the UCLA-RAND Appropriateness Method and facilitated by an independent chair.

***Measurement:*** Before the meeting, 520 items were scored for "appropriateness" by panel members, discussed face to face, and rescored.

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***Results and limitations:*** Agreement was reached in 67% of 260 items related to imaging sequence parameters. T2-weighted, dynamic contrast-enhanced, and diffusion-weighted MRI were the key sequences incorporated into the minimum requirements. Consensus was also reached on 54% of 260 items related to image interpretation and reporting, including features of malignancy on individual sequences. A 5-point scale was agreed on for communicating the probability of malignancy, with a minimum of 16 prostatic regions of interest, to include a pictorial representation of suspicious foci. Limitations relate to consensus methodology. Dominant personalities are known to affect the opinions of the group and were countered by a neutral chairperson.

***Conclusions:*** Consensus was reached on a number of areas related to the conduct, interpretation, and reporting of mpMRI for the detection, localisation, and characterisation of prostate cancer. Before optimal dissemination of this technology, these outcomes will require formal validation in prospective trials.



## 1. Introduction

Magnetic resonance imaging (MRI) has considerable potential to improve the prostate cancer diagnostic pathway. Until fairly recently, the accuracy of morphologic MRI to detect, localise, and characterise prostate cancers was limited, and as a result, MRI has not been routinely incorporated into clinical care. However, evidence is accumulating that suggests an improved performance of MRI, provided that modern sequences are used and their outputs combined in so-called multiparametric MRI (mpMRI). Currently these include T1- and T2-weighted images, dynamic contrast, diffusion weighting, and proton spectroscopy [1,2].

Although experts in the field generally regard the performance characteristics of mpMRI of the prostate as promising [3], there exists professional disagreement on its accuracy and usefulness in clinical practice [4], limiting wider adoption. These concerns relate in part to the variable quality and methodology of studies that have resulted in marked variation in indication, conduct, interpretation, and reporting [5–11]. These issues have made it difficult to summarise the literature in any meaningful way [1].

This problem is not a new one. Over the last 2 decades, breast cancer experts have had to manage similar issues in relation to x-ray mammography and, more recently, breast MRI [12,13]. The solution to this problem was formal attempts to establish agreement among experts on areas of uncertainty. As a result, a series of recommendations emerged on the minimum standards acceptable for mammography [14–17] and breast MRI [18,19]. The principal innovation proved to be the incorporation of scoring systems to communicate the likelihood of malignancy in women with suspected breast cancer. These recommendations conferred at least two benefits: reduced interobserver variability [20,21] and improved positive predictive value for obtaining pathology from breast biopsy [21].

Based on the breast cancer experience, it seemed timely and necessary to see if experts in the field of prostate cancer and prostate MRI could achieve similar consensus. This paper reports the recommendations of a panel of uroradiology experts who participated in a formal consensus process aimed at defining when prostate MRI should be applied and how it should be conducted and reported.

## 2. Materials and methods

### 2.1. The consensus method

A number of formal consensus methods have been used in health care settings [22,23]. The RAND-UCLA Appropriateness Method (RAM) was chosen as the most appropriate for our objectives [24]. RAM includes a combination of postal and face-to-face consensus rounds. It is most suited to topic areas where there is little or poor quality evidence to enable a gold standard recommendation. Appropriateness levels are used to communicate the perceived balance between risks and benefits of each item under discussion. The RAM User's Manual was followed throughout the process [24].

### 2.2. Panel selection

Leading clinicians from the United Kingdom, France, Belgium, and the Netherlands with known subspecialty expertise in prostate cancer diagnostic imaging were approached, all prominent European members published in the field. The chair, Jan van der Meulen, is a clinical epidemiologist with experience using formal consensus methods to develop clinical guidelines. Commercial bias was excluded through the use of institutional funds.

### 2.3. Construct of the questionnaire

A questionnaire containing 537 items was constructed between August and November 2009. The first draft was produced by panel members Louise Dickinson, Mark Emberton, Hashim U. Ahmed, Clare Allen, Shonit Punwani, Alex Kirkham, and Anwar R. Padhani. Refinements were made through consultation with the other panel members.

The questionnaire was designed to address the minimum and optimum imaging requirements for performance, interpretation, and delivery of results for prostate MRI, including T1-weighted, T2-weighted, diffusion-weighted, dynamic contrast-enhanced, and proton spectroscopy. These aspects related to the localisation and detection of prostate cancer in men with suspected or known cancer in the absence of biopsy artefact (ie, before biopsy or at an appropriate time frame after diagnostic prostate biopsies). It focused on early T staging only (without breach of the capsule) and did not address lymph node or metastatic assessments.

**Table 1 – Proportion of items scored inappropriate, uncertain, or appropriate**

| | Inappropriate with consensus | Uncertain with consensus | Uncertain no consensus | Appropriate with consensus |
|---|---|---|---|---|
| Premeeting | 10% (54) | 2% (10) | 73% (392) | 15% (81) |
| Postmeeting | 31% (161) | 3% (15) | 39% (205) | 27% (139) |

**Table 2 – Areas of consensus for general magnetic resonance imaging components**

| Minimal requirements | Optimal requirements |
|---|---|
| The data set should include T1-weighted, T2-weighted, diffusion-weighted, and contrast-enhanced MRI but *not* MR spectroscopy<br>Imaging could be adequately performed at 1.5 T<br>A pelvic phased-array coil is required | The data set should include T1-weighted, T2-weighted, diffusion-weighted, contrast-enhanced MRI<br>Imaging should be performed at 3 T<br>A pelvic phased-array coil, endorectal coil, power injector, and bowel relaxant are required |

MR = magnetic resonance; MRI = magnetic resonance imaging.

**Table 3 – Areas of positive consensus for disease detection and characterisation for individual magnetic resonance sequences**

| It is possible to gain the following information from each MR sequence in isolation: | MR sequence | | | | |
|---|---|---|---|---|---|
| | T1W | T2W | DW | CE | MRSI |
| Detection of any cancer in the peripheral zone | | √ | √ | √ | |
| The Gleason grade of lesions in the peripheral zone | | | √ | | |
| Exclusion of clinically significant disease as defined by a lesion size ≥0.2 $cm^3$ (approximately 7 mm) in the peripheral zone | | | √ | | |
| Exclusion of clinically significant disease as defined by a lesion size ≥0.5 $cm^3$ (approximately 10 mm) in the peripheral zone | | | √ | √ | |
| Exclusion of clinically significant cancer according to the definition of a lesion ≥0.5 $cm^3$ and/or Gleason ≥4 + 3 in the peripheral zone | | | √ | | |

CE = contrast enhanced; DW = diffusion weighted; MR = magnetic resonance; MRSI = magnetic resonance spectroscopy; T1W = T1 weighted; T2W = T2 weighted; √ = areas considered appropriate (positive consensus).

### 2.4. First-round questionnaire completion before the meeting

Each item was scored on a scale between 1 (inappropriate/strongly disagree) and 9 (appropriate/strongly agree). A midpoint score of 5 indicated uncertainty. Panel members were asked to provide a score on all items they considered themselves sufficiently knowledgeable to answer.

### 2.5. Meeting format

The meeting was convened at the Royal College of Surgeons of England for a single day in December 2009. The panellists comprised 16 uroradiology, urology, and oncology experts. Two neutral observers were in attendance (Paul Cathcart and Michael Baum) together with the meeting organiser (Louise Dickinson) to document key points of discussion.

All panel members were sent questionnaires to complete before the meeting with relevant literature on previous scoring systems used for breast imaging (a list of articles is available on request). For each individual item, the scores were presented and discussed during the consensus meeting, after which the panellists rescored that item.

At given time points during the consensus meeting, panel members presented on the following topics: current scoring systems in use, diffusion-weighted MRI, dynamic contrast-enhanced MRI, spectroscopy, definition of clinically significant cancers, and validation of the scoring system. Speakers were asked to summarise the evidence in the given area and to highlight areas of controversy.

Some items were found to be either inadequate or ambiguous. If that was the case, the item was reworded to improve clarity. Some items were added after full agreement by panel members and scored during the meeting.

### 2.6. Interpretation of the results

The results were interpreted according to the RAM User's Manual. If <16 panellists scored an item, consensus was defined using the manual's recommendations based on that particular panel size. Only those items scored by at least eight panel members were included in the results.

## 3. Results

The premeeting questionnaire included 537 items, reduced to 520 items during the meeting. Nineteen items were added and 36 items omitted. Wording changes were made to 20 items.

### 3.1. Areas of consensus

Consensus was reached in 27% of items in the premeeting questionnaire, which increased to 61% during the meeting (Table 1). Postmeeting consensus was reached on 67% of 260 items related to imaging parameters for tumour detection and localisation, and on 54% of 260 items related to imaging interpretation and reporting, including features on individual MRI sequences indicating malignancy. Tables 2–4 summarise the key items of consensus. Table 7 lists the full postmeeting results for the individual items. Further discussion took place electronically among all panel members following the consensus meeting, once the outcomes of the questionnaires were known.

**Table 4 – Areas of consensus on imaging interpretation, scoring, and reporting**

| Areas of positive consensus |
|---|
| When scoring the prostate for the presence or absence of cancer for T2-weighted, diffusion-weighted, contrast-enhanced, and MR spectroscopy sequences, the range of scores should be 1–5, for each imaging type |
| Both individual lesions and areas of the prostate should be separately scored for probability of malignancy |
| The maximum diameter of the largest abnormal lesion should be recorded |
| The following should be scored for involvement with an individual scoring range of 1–5:<br>- Extracapsular extension<br>- Seminal vesicles (extra- and intraprostatic)<br>- Distal sphincter<br>- Rectal wall<br>- Neurovascular bundles<br>- Bladder neck |
| As a minimum requirement, the prostate should be divided into 16 regions of interest (apical, mid, and base quadrants) and, as an optimum requirement, into 27 regions of interest |
| The ADC value should be stated for any suspicious lesion detected |
| Dynamic contrast-enhanced MRI should be scored according to the morphological enhancement pattern |
| The following clinical information is important for reporting the imaging and should be included:<br>- PSA level<br>- Digital rectal examination<br>- Time scale since prostate biopsies and results of previous biopsies<br>- Results of previous MRI scans<br>- History of previous prostate treatment or intervention (eg, TURP, prostate radiotherapy)<br>- History of medical treatment (eg, 5α-reductase inhibitors, hormones) |
| As a minimum requirement, each MRI should be assessed and scored by one radiologist and, as an optimal requirement, scored by two radiologists independently and discrepancies referred for consensus |
| If one of the modalities within the minimum data set is noninterpretable due to artefact, the denominator of the scoring system should be changed to allow for a lack of score for the affected sequence |
| Dedicated software for imaging interpretation should be developed for this purpose with the ability to display, co-register, segment, fuse, and analyse every tool in an integrated single work space |
| The final report should be presented electronically, in both number and picture form, and should include relevant images |

ADC = apparent diffusion coefficient; MR = magnetic resonance; MRI = magnetic resonance imaging; PSA = prostate-specific antigen; TURP = transrectal resection of the prostate.

Members of the panel were able to agree on the following 5-point scale for the scoring of all MRI sequences: score 1, clinically significant disease is highly unlikely to be present; score 2, clinically significant cancer is unlikely to be present; score 3, the presence of clinically significant cancer is equivocal; score 4, clinically significant cancer is likely to be present; score 5, clinically significant disease is highly likely to be present. Clinically significant disease was defined as Gleason $\geq 4+3$ and/or lesions $\geq 0.5\ cm^3$ in volume.

Fig. 1 shows the minimal and optimal number of regions of interest and their divisions as agreed by consensus. As per the meeting results, it is intended that a 1–5 score be assigned for each region of interest and for each individual lesion identified.

The panel agreed that diffusion-weighted imaging is capable of providing information on Gleason grade and of excluding lesions of both $0.2\ cm^3$ and $0.5\ cm^3$ in the peripheral zone.

### 3.2. *Areas lacking consensus*

Several important areas of continued uncertainty or lack of consensus were identified, some of which are detailed in Table 5. The value of including MR spectroscopy for optimal imaging remains uncertain. The use of certain hardware such as endorectal coils, power injectors, and bowel relaxants as a minimum standard failed to reach consensus, although their use was recommended as part of optimum imaging.

There was no consensus on whether different MR sequences are able to detect lesions fulfilling other definitions of clinical significance that are more conservative than a volume of $0.5\ cm^3$ and dominant Gleason pattern 4 (Table 6).

## 4. Discussion

### 4.1. *Summary of results*

The use of the RAM method produced consensus in 61% of the items (315 of 520). Consensus was achieved in several key areas where inconsistency between studies had previously been a problem. In particular, the panel recommended that all sequences (T2-weighted, diffusion-weighted, and dynamic contrast enhanced sequences) except proton spectroscopy should comprise the minimum standard. Recent evidence from a large prospective multicentre study showing no benefit of spectroscopy for prostate cancer localisation compared with T2-weighted imaging alone

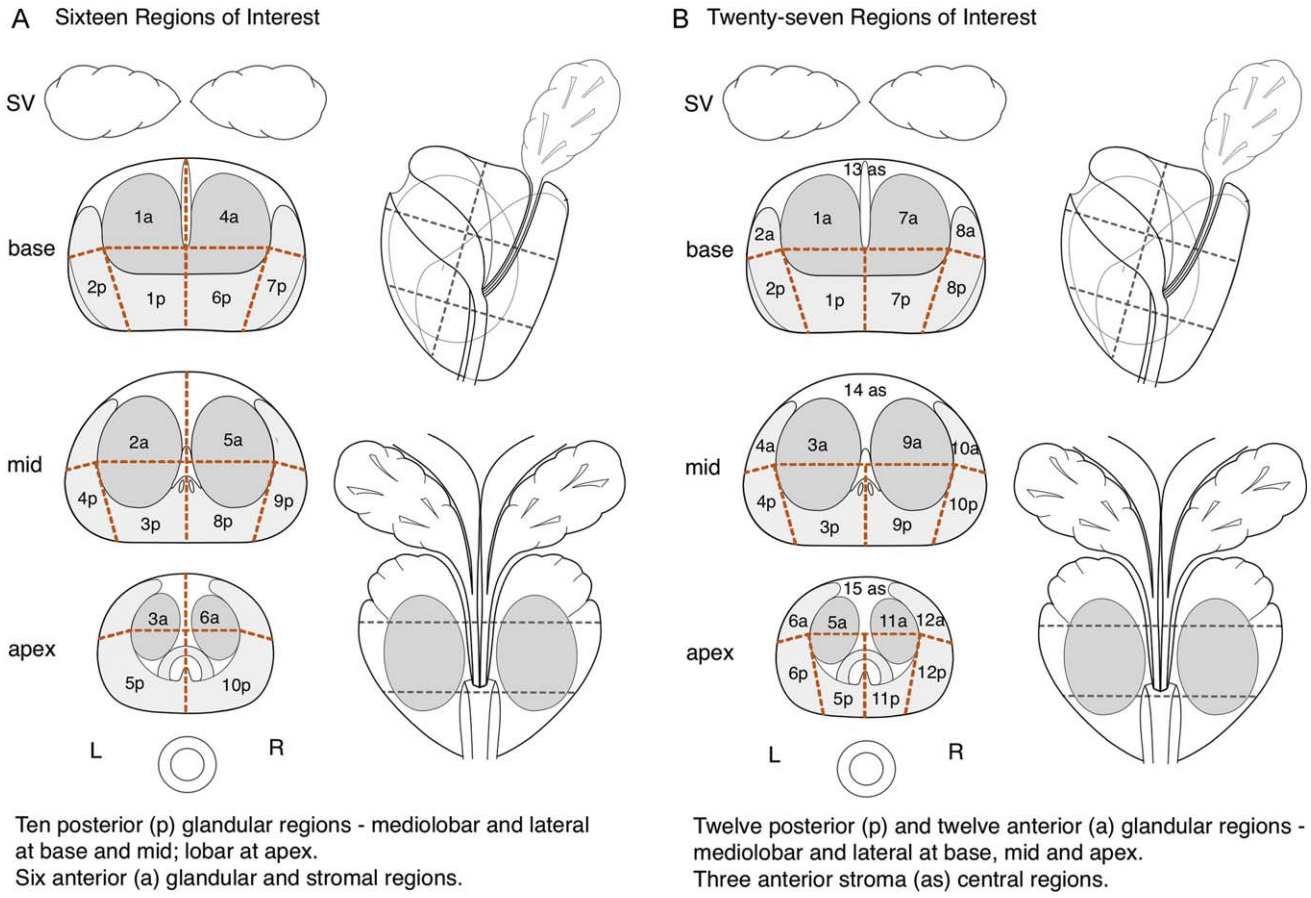


**Fig. 1 – (A) Sixteen regions/sectors standardised magnetic resonance imaging (MRI) prostate reporting scheme. Posteriorly (p), average axial sections at prostate base and midgland are subdivided into four regions (midlobar and lateral) and at the prostate apex into two regions. Anteriorly (a), prostate base, midgland, and apex are divided into two regions. The anterior region starts 17 mm from the prostatic posterior surface (biopsy core length). A 10-core extended biopsy scheme would be expected to sample the 10 posterior sectors. (B) Twenty-seven regions/sectors standardised MRI prostate reporting scheme. Posteriorly (p), average axial sections at prostate base, midgland, and apex are subdivided into four regions (midlobar and lateral). Anteriorly, the prostate is divided into four anterior regions (a) (midlobar and lateral) and three anterior stroma regions (as). The anterior region starts 17 mm from the prostatic posterior surface (biopsy core length). A 12-core extended biopsy scheme would be expected to sample the 12 posterior sectors.**

supports this recommendation [25]. Consensus was also reached in the area of reporting. A 5-point scoring scale should be used in all reports to communicate the probability of prostate cancer. However, several areas were identified where no consensus could be derived, either due to lack of evidence to inform opinion or the panel deciding that current evidence was sufficiently controversial to permit professional disagreement. For example, endorectal coil use, an area of current clinical inconsistency, was recommended for optimal practice, but no consensus was reached on its use in standard (minimal) practice.

### *4.2. Methodologic limitations*

Despite achieving high levels of concordance in key areas, some caution is called for. Face-to-face consensus methods or expert group discussions are prone to biases. Dominant personalities are known to be capable of influencing scoring to a significant extent [26]. During our meeting a neutral chairperson, who had experience running formal consensus meetings, moderated the discussions.

One of the benefits of the group approach that does not arise in postal processes is that the group can agree on poor

**Table 5 – Areas lacking consensus on imaging interpretation, scoring, and reporting**

| |
|---|
| Areas of the prostate should be scored separately rather than by individual lesions |
| The overall score for probability of tumour given by the radiologist should be influenced by other clinical results (eg, PSA level) |
| The overall score should be based purely on imaging appearances |
| A separate radiologist's "hunch" score should be given that represents the radiologist's personal overall hunch view on the likelihood of malignancy regardless of the objective radiologic score |
| The final score should be given as individual scores, a sum of the individual scores, or as a radiologist's overall opinion score |
| T staging should be a formal part of the final report |

PSA = prostate-specific antigen.

**Table 6 – Areas lacking consensus or with negative consensus on disease detection and characterisation by individual sequences**

| It is possible to be gain the following information from each MR sequence in isolation: | MR sequence | | | | |
|---|---|---|---|---|---|
| | T1W | T2W | DW | CE | MRSI |
| Detection of any cancer in the peripheral zones | X | ? | √ | √ | √ |
| Detection of any cancer or exclusion of clinically significant disease as defined by both lesion sizes (≥0.2 $cm^3$ and ≥0.5 $cm^3$) in the transition zone | X | ? | ? | ? | ? |
| The Gleason grade of lesions or the exclusion of clinically significant disease as defined by a lesion size ≥0.2 $cm^3$ (approximately 7 mm) in the peripheral zone | X | ? | √ | ? | ? |
| The Gleason grade of lesions in the transition zone | X | X | ? | ? | ? |
| Exclusion of clinically significant disease as defined by a lesion size ≥0.5 $cm^3$ (approximately 10 mm) in the peripheral zone | X | ? | √ | √ | ? |
| Differentiation between low-grade and intermediate/high-grade tumours (defined as a tumour with a Gleason 4 grading component) in the peripheral or transition zones | X | X | ? | ? | ? |
| Exclusion of clinically significant cancer according to the definition of a lesion ≥0.2 $cm^3$ and/or Gleason ≥3 + 4 in the peripheral and transition zones | X | ? | ? | ? | ? |
| Exclusion of clinically significant cancer according to the definition of a lesion ≥0.5 $cm^3$ and/or Gleason ≥4 + 3 in the peripheral zone | X | ? | √ | ? | ? |
| Exclusion of clinically significant cancer according to the definition of a lesion ≥0.5 $cm^3$ and/or Gleason ≥4 + 3 in the transition zone | X | ? | ? | ? | ? |

CE = contrast enhanced; DW = diffusion weighted; MR = magnetic resonance; MRSI = magnetic resonance spectroscopy; T1W = T1 weighted; T2W = T2 weighted;? = areas lacking consensus; X = areas considered inappropriate (negative consensus); √ = areas with consensus.

or imprecise questions and agree on amendments. The group structure also meant that all panellists were exposed to the latest evidence, and as a result the consensus approach had high face validity.

The other problem worth identifying relates to the European versus US perspective. There are clear differences in the conduct of MRI between the two. The main one is that endorectal coils and spectroscopy are used more frequently in the United States. Our consensus is largely European, although we did make great efforts to include the worldwide literature. Of relevance to spectroscopy, only a few panellists chose to score several questions due to lack of clinical experience and interpretation software. As a result, these could not be analysed.

Finally, our recommendations were based on published studies of limited clinical evidence (four or fewer on the Oxford Centre for Evidence-Based Medicine levels of evidence), a problem previously shared by the breast imaging community and demanding the use of formal methodology to derive consensus opinion.

### 4.3. *Clinical implications*

The ability to detect, locate, and characterise prostate cancers radiologically has significant implications for the patient diagnostic pathway. It is hoped that widespread incorporation of the recommendations of this meeting will allow a more consistent and standardised approach to MRI. The consequence of this will be that reports from different centres might be amenable to pooled analyses.

If the accuracy of mpMRI demonstrates levels that warrant widespread adoption, we may have the beginnings of a triage test that, by ruling out the presence of clinically significant disease, could result in fewer men needing to undergo biopsy. The incorporation of mpMRI before biopsy in men with suspected prostate cancer is currently being performed in a few centres. The benefits of this approach have been discussed elsewhere [27]. In addition, the detection and localisation components of such a test could assist in targeting biopsies, a strategy that has well served other cancer detection pathways.

Imaging in the form of mpMRI is likely to have important roles in the tissue-preserving strategies of active surveillance [28] and focal therapy [29]. These two therapies differ slightly in their requirements from the pure diagnostic challenge because mpMRI would need to be repeated over time to detect interval change. This process will demand high levels of reliability, which can only be achieved once standardised conduct and reporting have been agreed on and implemented.

### 4.4. *Research implications*

We do not regard our consensus statements as an end product. We hope and expect that they will stimulate and provoke other groups to adapt and improve on our outputs. It is key that research be prioritised to areas with little or no consensus. To both integrate and validate the recommendations from this meeting in future imaging protocols and research, they must be embedded in prospective trials. The ideal population would be men with a raised serum prostate-specific antigen (PSA) who undergo prostate mpMRI before histologic verification with biopsies. Thus verification or work-up bias would be limited and the at-risk population evaluated. This will require an accurate reference standard that can be applied to this population. The random and systematic errors inherent in transrectal ultrasound (TRUS) guided biopsy rule this out as a reference standard. Most studies currently use whole-mount prostatectomy specimens as the reference standard. This introduces work-up bias. Furthermore, correlation of MRI regions of interest with equivalent regions on prostatectomy specimens is inconsistent. Transperineal template mapping biopsies are probably the optimal reference standard because they overcome random and systematic errors by sampling the gland every 5 mm, provide three-dimensional coordinates for correlation to imaging, and can be applied to all men. A multicentre trial in

**Table 7 – Full table of results**

| | Inappropriate | Uncertain | Appropriate |
|---|---|---|---|
| 1. Overview | | | |
| Minimum and optimum MR data sets for the detection and localisation of prostate cancer should be established | | | X |
| A scoring system is necessary for the interpretation of diagnostic MRI of the prostate | | | X |
| A standard method dividing the prostate into sectors needs to be agreed on | | | X |
| A standard method for reporting the results needs to be agreed on | | | X |
| 2. General MRI components | | | |
| Minimum imaging requirements | | | |
| The data set should include T1-weighted, T2-weighted, diffusion-weighted, and contrast-enhanced MRI | | | X |
| The dataset should include MR spectroscopy | X | | |
| Imaging could be adequately performed at 0.5 T | X | | |
| Imaging could be adequately performed at 1.5 T | | | X |
| Imaging should be performed at 3 T | | X* | |
| A pelvic phased-array coil is required | | | X |
| An endorectal coil and bowel preparation are required | X | | |
| A power injector is required | | X* | |
| Bowel relaxant is required | | X* | |
| Optimum imaging requirements | | | |
| The data set should include T1-weighted, T2-weighted, diffusion-weighted, and contrast-enhanced MR images | | | X |
| The data set should include MR spectroscopy | | X* | |
| Imaging should be performed at 0.5 T | X | | |
| Imaging should be performed at 1.5 T | | X* | |
| Imaging should be performed at 3 T | | | X |
| A pelvic phased-array coil, power injector, and bowel relaxant are required | | | X |
| An endorectal coil is required | | X* | |
| Bowel preparation is required | | X | |
| All imaging | | | |
| If bowel relaxant is used, both Buscopan and glucagon are suitable agents | | | X |
| An endorectal coil must be used for 1.5-T and 3-T imaging | X | | |
| | | | |

**Table 7 (*Continued*)**

| | Inappropriate | Uncertain | Appropriate |
|---|---|---|---|
| 3. MRI sequence parameters | | | |
| a. T2-weighted MRI | | | |
| Minimum requirements | | | |
| Maximum slice thickness for diagnostic imaging at 1.5 T should be 4 mm | | | X |
| Maximum slice thickness for diagnostic imaging at 3 T should be 3 mm | | | X |
| The planes of imaging should include the axial plane and one other plane | | | X |
| The in-plane image resolution should be 0.5 × 0.5 mm to 0.7 × 0.7 mm at both 1.5 T and 3 T | | | X |
| Quantification of T2 relaxation time should be performed as standard (minimal) practice | X | | |
| Optimum requirements | | | |
| Maximum slice thickness for diagnostic imaging at 1.5 T should be 3 mm | | | X |
| Maximum slice thickness for diagnostic imaging at 3 T should be 3 mm | | | X |
| The planes of imaging should include the axial, sagittal, and coronal planes | | | X |
| The in-plane image resolution should be 0.5 × 0.5 mm to 0.7 × 0.7 mm at 1.5 T | | | X |
| The in-plane image resolution should be 0.3 × 0.3 mm to 0.5 × 0.5 mm at 3 T | | | X |
| Quantification of T2 relaxation time should be performed as optimal practice | | X* | |
| b. Diffusion-weighted imaging | | | |
| Minimum requirements | | | |
| Maximum slice thickness should be 5 mm for diagnostic imaging at both 1.5 T and 3 T | | | X |
| The planes of imaging should include the axial plane only | | | X |
| The in-plane image resolution should be 1.5 × 1.5 mm to 2 × 2 mm at both 1.5 T and 3 T | | | X |
| ADC quantification should be performed as standard (minimal) practice | | X* | |
| An ADC map should be used for diagnostic interpretation as standard (minimal) practice | | | X |
| Minimum requirements for diffusion-weighted imaging: | | | |
| - A single "high b-value" diffusion-weighted image | | X* | |
| - A b0 image and a single diffusion-weighted image allowing quantification of ADC via monoexponential fitting | | X* | |
| - A b0 image and multiple (≥2) b values allowing quantification of ADC via monoexponential fitting | | X* | |
| - Multiple b values allowing biexponential ADC derivation | X | | |
| For calculation of ADC, the highest b-value that should be used is 800 (with adequate signal-to-noise ratio) | | | X |

| | | | |
|---|---|---|---|
| If a high single b-value image is used for lesion detection, the minimal required is any of 800, 1000, or 1400 | | X* | |
| If a high single b-value image is used for lesion detection, the minimal required is either 2000 or 3000 | X | | |
| Diffusion tensor imaging should be part of the minimum requirement for prostate diffusion imaging | X | | |
| Optimum requirements | | | |
| Maximum slice thickness for diagnostic imaging should be 5 mm for 1.5-T imaging and 4 mm for 3-T imaging | | | X |
| The planes of imaging should include the axial plane only | | | X |
| The in-plane image resolution should be 0.3 × 0.3 mm to 0.5 × 0.5 mm or 0.5 × 0.5 mm to 0.7 × 0.7 mm or 0.7 mm × 0.7 mm to 1 × 1 mm at 1.5 T | X | | |
| The in-plane image resolution should be 1 × 1 mm to 1.5 × 1.5 mm or 1.5 × 1.5 mm to 2 × 2 mm at 1.5 T | | X* | |
| The in-plane image resolution should be 1 × 1 mm to 1.5 × 1.5 mm at 3 T | | | X |
| ADC quantification should be performed as part of optimal practice | | | X |
| An ADC map should be used for diagnostic interpretation as part of optimal practice | | | X |
| Optimum requirements for diffusion-weighted imaging: | | | |
| - A single "high b-value" diffusion-weighted image | X | | |
| - A b0 image and a single diffusion-weighted image allowing quantification of ADC via monoexponential fitting | | X* | |
| - A b0 image and multiple (≥2) b values allowing quantification of ADC via monoexponential fitting | | | X |
| Multiple b-values allowing biexponential ADC derivation | | X* | |
| For calculation of ADC, the highest b-value that should be used is 1000 (with adequate signal-to-noise ratio) | | | X |
| If a high single b-value is used for lesion detection, this should be at a value of 1400 for optimal imaging | | | X |
| Diffusion tensor imaging should be part of the optimum requirement for prostate diffusion imaging | | X | |
| All diffusion-weighted imaging | | | |
| A standard set of b-values should be used at all institutions for prostate imaging | | | X |
| ADC values should be quoted with the b-values used for calculation | | | X |
| Perfusion-insensitive ADC values should be quoted separately from the total ADC value | | X | |
| Diffusion tensor imaging | | | |
| - Aids in the characterisation of nodules in the transition zone when combined with trace diffusion images | | X | |
| - Aids in the characterisation of nodules in the peripheral zone when combined with trace diffusion images | | X* | |
| c. Contrast-enhanced imaging | | | |
| Minimum requirements | | | |
| Maximum slice thickness should be 4 mm for both 1.5-T and 3-T imaging | | | X |
| Imaging should be performed in the axial plane | | | X |

**Table 7 (*Continued*)**

| | Inappropriate | Uncertain | Appropriate |
|---|---|---|---|
| Quantitative or semiquantitative dynamic contrast-enhanced MRI should be performed as standard (minimal) practice | X | | |
| The minimum contrast-enhanced MRI data set should be sufficient for: | | | |
| - Detecting early arterial enhancement and early washout only (ie, baseline, early arterial image, and venous phase image) | | X* | |
| - Plotting a signal intensity-time curve allowing extraction of curve parameters (slope of enhancement, maximum enhancement, time to enhancement, and curve shape) | | X* | |
| - Physiologic modelling via contrast agent quantification | X | | |
| For signal intensity time curves, the in-plane image resolution should be 0.7 × 0.7 mm to 1 × 1 mm at 1.5 T and 0.5 × 0.5 mm to 0.7 × 0.7 mm at 3 T | | | X |
| For analysis of signal intensity time curve parameters, the maximum temporal resolution should be 10–15 s | | | X |
| For dynamic contrast-enhanced imaging, a power injector should be used as part of minimal practice | | | X |
| The rate of injection should be 3 ml/s | | | X |
| Optimum requirements | | | |
| Maximum slice thickness for diagnostic imaging should be 3 mm for both 1.5- and 3-T imaging. | | | X |
| Contrast enhanced imaging should be performed in the axial plane | | X* | |
| Contrast enhanced imaging should be performed in the coronal or sagittal planes | X | | |
| Contrast enhanced imaging should be performed as an isometric acquisition | | X | |
| Quantitative or semiquantitative dynamic contrast enhanced MRI should be performed as optimal practice | | | X |
| The optimum contrast-enhanced MRI data set should be sufficient for: | | | |
| - Detecting early arterial enhancement and early washout only (ie, baseline, early arterial image, and venous phase image) | | X* | |
| - Plotting a signal intensity time curve allowing extraction of curve parameters (slope of enhancement, maximum enhancement, time to enhancement, and curve shape) | | X* | |
| - Physiologic modelling via contrast agent quantification | | X* | |
| For dynamic contrast-enhanced imaging, a power injector should be used as part of optimal practice | | | X |
| The rate of injection should be 3 ml/s | | | X |
| All contrast-enhanced imaging | | | |
| A single dose of contrast agent should be used | | | X |
| For the three time-point technique, apart from the baseline and 90-s time points, a third time point should be specified | | X* | |
| For DCE imaging. acquisition should be continued for 5 min to detect washout | | | X |
| d. MR spectroscopy | | | |
| Single-voxel spectroscopy should be performed in areas of concern following review of the imaging by a radiologist as part of standard (minimal) practice | X | | |

| | | | |
|---|---|---|---|
| Chemical shift imaging through the whole prostate should be performed as part of standard (minimal) practice | X | | |
| The maximum voxel size should be 0.5 $cm^3$ | | | X |
| For voxels that are considered usable on signal-to-noise ratio grounds, as a minimum requirement for benign versus malignant assignment, two adjacent voxels only can be considered | | | X |
| MR spectroscopy analysis should be qualitative using visual classification of the patterns observed | | | X |
| Optimum requirements | | | |
| Single-voxel spectroscopy should be performed in areas of concern following review of the imaging by a radiologist as part of optimal practice | X | | |
| Chemical shift imaging through the whole prostate should be performed as part of optimal practice | | X* | |
| The maximum voxel size should be 0.5 $cm^3$ | | | X |
| For voxels that are considered usable on signal-to-noise ratio grounds, as a minimum requirement for benign versus malignant assignment, three or more adjacent voxels only can be considered | | | X |
| MR spectroscopy analysis should be qualitative using visual classification of the patterns observed or quantitative using ratios of heights of spectroscopy curves | | X* | |
| MR spectroscopy analysis should involve quantitative and qualitative ratios together | | X* | |
| MR spectroscopy analysis should involve full quantification with metabolite concentrations | X | | |
| NB: Insufficient numbers of panellists were able to answer further questions about MR spectroscopy and conduct; therefore a report of these statements is not included | | | |
| 4. Image interpretation | | | |
| a. Detection of any cancer | | | |
| It is possible to be highly suspicious for the presence of *any* cancer in the *peripheral zone* only on the following sequences in isolation: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | | X |
| - Diffusion weighted | | | X |
| - Contrast enhanced | | | X |
| - MR spectroscopy | | X* | |
| It is possible to be highly suspicious for the presence of *any* cancer in the *transition zone* only on the following sequences in isolation: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |

**Table 7 (*Continued*)**

| | Inappropriate | Uncertain | Appropriate |
|---|---|---|---|
| b. Information about Gleason grade alone | | | |
| The following sequences in isolation provide information about the Gleason grade of lesions in the *peripheral zone*: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | | X |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| The following sequences in isolation provide information about the Gleason grade of lesions in the *transition zone*: | | | |
| - T1 weighted | X | | |
| - T2 weighted | X | | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| c. Information about lesion size alone | | | |
| The following sequences in isolation are useful to exclude "clinically significant" disease as defined by a lesion size of $\geq$0.2 $cm^3$ (approximately 7 mm) in the *peripheral zone*: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | | X |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| The following sequences are useful in isolation to exclude "clinically significant" disease as defined by a lesion size of $\geq$0.2 $cm^3$ (approximately 7 mm) in the *transition zone*: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| The following sequences are useful to exclude "clinically significant" disease as defined by a lesion size of $\geq$0.5 $cm^3$ (approximately 10 mm) in the *peripheral zone* in isolation: | | | |

| | | | |
|---|---|---|---|
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | | X |
| - Contrast enhanced | | | X |
| - MR spectroscopy | | X* | |
| The following sequences are useful to exclude "clinically significant" disease as defined by a lesion size of $\geq$0.5 $cm^3$ (approximately 10 mm) in the *transition zone* in isolation: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| d. Differentiation between low-and intermediate/high-grade tumours | | | |
| The following sequences can be used to differentiate between low-grade and intermediate/high-grade tumours (defined as a tumour with a Gleason 4 grading component) in the *peripheral zone* in isolation: | | | |
| - T1 weighted | X | | |
| - T2 weighted | X | | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| The following sequences can be used to differentiate between low-grade and intermediate/high-grade tumours (defined as a tumour with a Gleason 4 grading component) in the *transition zone* in isolation: | | | |
| - T1 weighted | X | | |
| - T2 weighted | X | | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| e. Exclusion of "clinically significant" disease | | | |
| It is possible to exclude "clinically significant" cancer on the following sequences in isolation according to definition 1: lesion $\geq$0.2 $cm^3$ and/or Gleason $\geq$3 + 4 in the *peripheral zone*: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |

**Table 7 (*Continued*)**

| | Inappropriate | Uncertain | Appropriate |
|---|---|---|---|
| It is possible to exclude "clinically significant" cancer on the following sequences in isolation according to definition 1: lesion $\geq$0.2 $cm^3$ and/or Gleason $\geq$ 3 + 4 in the *transition zone:* | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| It is possible to exclude "clinically significant' cancer on the following sequences in isolation according to definition 1: lesion $\geq$0.5 $cm^3$ and/or Gleason $\geq$ 4 + 3 in the *peripheral zone*: | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | | X |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| It is possible to exclude "clinically significant" cancer on the following sequences in isolation according to definition 1: lesion $\geq$0.5 $cm^3$ and/or Gleason $\geq$ 4 + 3 in the *transition zone:* | | | |
| - T1 weighted | X | | |
| - T2 weighted | | X* | |
| - Diffusion weighted | | X* | |
| - Contrast enhanced | | X* | |
| - MR spectroscopy | | X* | |
| f. Scoring system | | | |
| When scoring the prostate for the presence or absence of cancer for T1-weighted imaging, the range of scores should be 1–4, 1–6, 1–10, or 1–20 | X | | |
| When scoring the prostate for the presence or absence of cancer for T1-weighted imaging, the range of scores should be 1–3 or 1–5 | | X* | |
| When scoring the prostate for the presence or absence of cancer for T2-weighted, diffusion-weighted, contrast enhanced, and MR spectroscopy sequences, the range of scores should be 1–5 | | | X |
| Each individual lesion should be separately scored for probability of malignancy | | | X |
| Only areas of the prostate should be scored rather than by individual lesions | | X* | |
| Both individual lesions and areas of the prostate should be given a score | | | X |
| The maximum diameter of the largest abnormal lesion should be recorded | | | X |
| The following should be scored for involvement: | | | |
| - Extracapsular extension | | | X |
| - Seminal vesicles (extra- and intraprostatic) | | | X |

| | | | |
|---|---|---|---|
| - Distal sphincter | | | X |
| - Rectal wall | | | X |
| - Neurovascular bundles | | | X |
| - Bladder neck | | | X |
| All extracapsular involvement features should have an individual scoring range of 1–5 | | | X |
| g. Regions of interest | | | |
| As a minimum requirement, the prostate should be divided into 16 regions of interest (apical, mid, and base quadrants) | | | X |
| As an optimum requirement, the prostate should be divided into 27 regions of interest | | | X |
| h. Sequence reporting methodology | | | |
| The ADC value should be stated for any suspicious region detected | | | X |
| Dynamic contrast-enhanced MRI should be scored according to the morphological enhancement pattern | | | X |
| Physiologic modelling is a method that can be appropriately used in the present time | | X | |
| Full quantification is a method of scoring that should be reconsidered in the next 2–5 yr | | X* | |
| i. Other recommendations | | | |
| The following clinical information is important for reporting the imaging and should be included: | | | |
| - PSA level | | | X |
| - Digital rectal examination | | | X |
| - Other markers (eg, PCA3 level) | | X* | |
| - Times scale since prostate biopsies and results of previous biopsies | | | X |
| - Results of previous MRI scans | | | X |
| - History of previous prostate treatment or intervention (eg, TURP, prostate radiotherapy) | | | X |
| - History of medical treatment (eg, 5α-reductase inhibitors, hormones) | | | X |
| The overall score should be based purely on imaging appearances | | X* | |
| The overall score for probability of tumour given by the radiologist should be influenced by other clinical results (eg, PSA level) | | X* | |
| The radiologist should be blinded to the patient's clinical details | X | | |
| As a minimum requirement, each MRI should be assessed and scored by one radiologist | | | X |
| As an optimal requirement, each MRI should be assessed and scored by two radiologists independently and discrepancies referred for consensus | | | X |
| When used for the detection or localisation of disease, 10 or 20 prostate MRI studies should be the minimum annual reporting requirement for reporting radiologists | X | | |
| When used for the detection or localisation of disease, 50, 80, or 100 prostate MRI studies should be the minimum annual reporting requirement for reporting radiologists | | X* | |
| A separate radiologist's "hunch" score should be given that represents the radiologist's personal overall hunch view on the likelihood of malignancy regardless of the objective radiologic score | | X* | |

**Table 7 (*Continued*)**

| | Inappropriate | Uncertain | Appropriate |
|---|---|---|---|
| The final score should be given as individual scores, a sum of the individual scores, or as a radiologist's overall opinion score | | X* | |
| If one of the modalities within the minimum dataset is noninterpretable due to artefact, the denominator of the scoring system should be changed to allow for a lack of score for the affected sequence | | | X |
| Dedicated software for imaging interpretation should be developed for this purpose with the ability to display, co-register, segment, fuse, and analyse every tool in an integrated single workspace | | | X |
| The scoring system results should be presented electronically | | | X |
| It should be presented in both number and picture form | | | X |
| The final report should include relevant images | | | X |
| T staging should be a formal part of the final report | | X* | |

ADC = apparent diffusion coefficient; DCE = dynamic contrast-enhanced; MR = magnetic resonance; MRI = magnetic resonance imaging; PCA3 = prostate cancer antigen 3 gene; PSA = prostate-specific antigen; TURP = transurethral resection of the prostate.
X* = responses with disagreement.

the United Kingdom offering mpMRI to men with a raised PSA followed by both TRUS guided biopsy and template mapping biopsies is due to start recruitment next year. This will offer an ideal platform to validate our proposed imaging methods.

## 5. Conclusions

MpMRI is undergoing a period of development with a number of reports demonstrating its potential as a tool in the diagnostic pathway for prostate cancer. Consistency in conduct and reporting is required before more widespread dissemination of this imaging modality. Through formal consensus methods, we have agreed on a number of standards required for imaging and reporting mpMRI of the prostate. Before these recommendations can be developed into protocols, they must be validated in prospective trials.

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*Study concept and design:* Emberton, van der Meulen.
*Acquisition of data:* Dickinson, Ahmed, Allen, Barentsz, Carey, Futterer, Heijmink, Hoskin, Kirkham, Padhani, Persad, Puech, Punwani, Sohaib, Tombal, Villers, van der Meulen, Emberton.
*Analysis and interpretation of data:* Dickinson.
*Drafting of the manuscript:* Dickinson, Ahmed, Emberton, van der Meulen.
*Critical revision of the manuscript for important intellectual content:* Dickinson, Ahmed, Allen, Barentsz, Carey, Futterer, Heijmink, Hoskin, Kirkham, Padhani, Persad, Puech, Punwani, Sohaib, Tombal, Villers, van der Meulen, Emberton.
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*Obtaining funding:* Emberton, van der Meulen, Ahmed.
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*Supervision:* Emberton, van der Meulen, Ahmed.
*Other* (specify): None.

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analysis, interpretation of the data, preparation, review, and approval of the manuscript.

## Appendix A. PREDICT Consensus Panel Members

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