



available at www.sciencedirect.com
journal homepage: www.europeanurology.com



European Association of Urology

Original Article – Editor's choice
Editorial by Erik Briers on pp. 275–276 of this issue

SPARC: The Standardised Prostate-specific Membrane Antigen Positron Emission Tomography/Computed Tomography Analysis and Reporting Consensus: A Delphi Analysis

Ken Herrmann^{a,b}, Jochen Walz^c, Steven MacLennan^d, Alberto Briganti^e, Philip Cornford^f, Johannes Czernin^g, Matthias Eiber^{h,i}, Stefano Fanti^j, Wolfgang P. Fendler^{a,b}, Karim Fizazi^k, Andrei Gafita^l, Silke Gillissen^{m,al}, Karolien Goffin^{n,ak}, Boris Hadaschik^{b,o}, Michael S. Hofman^{p,q}, Thomas A. Hope^r, Tobias Maurer^s, Alicia K. Morgans^t, Michael J. Morris^u, Declan G. Murphy^v, Daniela E. Oprea-Lager^w, Piet Ost^{x,y}, Joe M. O'Sullivan^z, Olivier Rouvière^{aa}, Shahneen Sandhu^q, Oliver Sartor^{ab}, Mike Machaba Sathekge^{ac,ad}, Clare Tempny^{ae}, Wim Witjes^{af}, Louise Emmett^{ag,ah}, Anders S. Bjartell^{ai,aj,*}

^a Department of Nuclear Medicine, University of Duisburg-Essen, Essen, Germany; ^b German Cancer Consortium (DKTK) University Hospital Essen, Essen, Germany; ^c Department of Urology, Institut Paoli-Calmettes Cancer Centre, Marseille, France; ^d Academic Urology Unit, Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK; ^e Division of Oncology, Unit of Urology, IRCCS Ospedale San Raffaele, Vita-Salute San Raffaele University, Milan, Italy; ^f Department of Urology, Bon Secours Hospital, Cork, Ireland; ^g Ahmanson Translational Theranostics Division, Department of Molecular and Medical Pharmacology, University of California Los Angeles UCLA, Los Angeles, CA, USA; ^h Department of Nuclear Medicine, Klinikum Rechts der Isar, Technical University of Munich, Munich, Germany; ⁱ Bavarian Cancer Research Center (BZKF), Erlangen, Germany; ^j Nuclear Medicine Division, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy; ^k Department of Cancer Medicine, Centre Oscar Lambret, Institut Gustave Roussy, University of Paris Saclay, Villejuif, France; ^l Johns Hopkins Theranostics Center, Department of Radiology and Radiological Sciences, Johns Hopkins University, Baltimore, MD, USA; ^m Oncology Institute of Southern Switzerland, Ente Ospedaliero Cantonale, Bellinzona, Switzerland; ⁿ Nuclear Medicine & Molecular Imaging, Department of Imaging and Pathology, KU Leuven, Leuven, Belgium; ^o Department of Urology, University of Duisburg-Essen, Essen, Germany; ^p Prostate Cancer Theranostics and Imaging Centre of Excellence (ProSTIC), Molecular Imaging and Therapeutic Nuclear Medicine, Cancer Imaging, Peter MacCallum Centre, Melbourne, Victoria, Australia; ^q Sir Peter MacCallum Department of Oncology, The University of Melbourne, Melbourne, Victoria, Australia; ^r Department of Radiology and Biomedical Imaging, University of California San Francisco, San Francisco, CA, USA; ^s Department of Urology and Martini-Klinik Prostate Cancer Center, University Hospital Hamburg-Eppendorf, Hamburg, Germany; ^t Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA, USA; ^u Genitourinary Oncology Service, Memorial Sloan Kettering Cancer Center, New York, NY, USA; ^v Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia; ^w Department of Medical Imaging, Radboud University Medical Center, Nijmegen, The Netherlands; ^x Department of Human Structure and Repair, Ghent University, Ghent, Belgium; ^y Iridium Network, Radiation Oncology, Wilrijk, Belgium; ^z Patrick G. Johnston Centre for Cancer Research, Queen's University, Belfast, UK; ^{aa} Department of Radiology, Hôpital Edouard Herriot, Hospices Civils de Lyon, Lyon, France; ^{ab} Department of Medical Oncology, Tulane University, New Orleans, LA, USA; ^{ac} Department of Nuclear Medicine, University of Pretoria & Steve Biko Academic Hospital, Pretoria, South Africa; ^{ad} Nuclear Medicine Research Infrastructure (NuMeRI), Pretoria, South Africa; ^{ae} Department of Radiology, Brigham and Women's Hospital, Boston, MA, USA; ^{af} European Association of Urology Research Foundation, Arnhem, The Netherlands; ^{ag} Theranostics and Nuclear Medicine Department, St Vincent's Hospital Sydney, Sydney, Australia; ^{ah} St Vincent's Clinical School, University of New South Wales, Sydney, Australia; ^{ai} Department of Urology, Skåne University Hospital, Malmö, Sweden; ^{aj} Department of Translational Medicine, Medical Faculty, Lund University, Lund, Sweden; ^{ak} Nuclear Medicine, University Hospital Leuven, Leuven, Belgium; ^{al} Faculty of Biomedical Sciences, Università della Svizzera, Italiana, Lugano, Switzerland

* Corresponding author. Department of Urology, Skåne University Hospital, Jan Waldenströmsgata 5, 205 02 Malmö, Sweden. Tel. +46 40 332685; Fax: +46 40 336911.
E-mail address: anders.bjartell@med.lu.se (A.S. Bjartell).

<https://doi.org/10.1016/j.eururo.2025.08.005>

0302-2838/© 2025 The Authors. Published by Elsevier B.V. on behalf of European Association of Urology. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).



Article info**Article history:**

Accepted August 26, 2025

Associate Editor:

Gianluca Giannarini, MD

Keywords:

Prostate cancer
 Prostate-specific membrane antigen
 Positron emission tomography/computed tomography



<https://mcq.eu-acme.org/login>

Please visit <https://mcq.eu-acme.org/login> to answer questions on-line. The EU-ACME credits will then be attributed automatically.

Abstract

Background and objective: Prostate-specific membrane antigen (PSMA) positron emission tomography/computed tomography (PET/CT) is an evolving diagnostic tool for prostate cancer. There is a need to harmonise existing guidelines and reporting recommendations for PSMA PET/CT. The Standardised PSMA PET/CT Analysis and Reporting Consensus (SPARC) project aims to consolidate classifications and recommendations by a multidisciplinary and international group of experts under one cohesive framework, establishing a dynamic and evolving structure for PSMA PET/CT reporting.

Methods: We employed a cross-sectional iterative process to define opinions and evaluate consensus. Thirty expert panel members, representing diverse specialities and geographic areas, were selected. A methods expert led the design, data collection, and analysis. Five groups of international multidisciplinary prostate cancer experts convened for literature review and formulation of statements on standardised reporting, detection, primary staging, biochemical recurrence, and treatment response. The groups compiled 91 statements for a two-round modified Delphi survey. The “RAND appropriateness method” was used for the analysis.

Key findings and limitations: Consensus increased to 93% between two rounds. The panel endorsed and adopted the following frameworks for reporting of PSMA PET/CT: molecular imaging PSMA for expression level and certainty, miTNM by PROMISE for reporting of PSMA PET/CT, the PRIMARY score for intraprostatic staging, PSMA volume, mean standardised uptake value, and maximum standardised uptake value (SUV_{max}). There were uncertainty about correlating PSMA PET/CT with conventional imaging risk groups in newly diagnosed metastatic prostate cancer and a lack of agreement that clinical management plans based upon PSMA PET/CT improved outcomes. There was consensus that SUV_{max} should be reported regionally, rather than reporting a single site. There were insufficient data to standardise a definition of response or progression by PSMA PET/CT. **Conclusions and clinical implications:** SPARC provides a standardised PSMA PET/CT analysis and reporting consensus to serve as a future reference for PSMA PET/CT reporting. Integration of common PSMA PET reporting criteria under one umbrella improves the explanation of imaging findings between imaging experts and treating clinicians for clinical implementation.

© 2025 The Authors. Published by Elsevier B.V. on behalf of European Association of Urology. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

ADVANCING PRACTICE**What does this study add?**

There is a need for harmonisation and integration of existing prostate-specific membrane antigen positron emission tomography/computed tomography reporting systems. New reporting standards enabling large-scale prospective data collection are required. This study establishes a foundation for a dynamic, living iterative reporting system.

Clinical Relevance

Molecular imaging is revolutionizing the management of prostate cancer. The SPARC project delivers the first international, multidisciplinary consensus on standardized PSMA PET/CT analysis and reporting in prostate cancer, integrating existing classification systems into a unified framework. For uro-oncologists, this harmonization facilitates clearer communication with imaging specialists, ensures greater consistency in staging and restaging, and strengthens clinical decision-making at a multi-stakeholder level. Importantly, SPARC also provides a dynamic platform for future prospective trials and evolving guidelines, with the ultimate goal of improving patient care through clearer and more reproducible imaging reports. Associate Editor: Gianluca Giannarini, MD.

Patient Summary

Prostate-specific membrane antigen (PSMA) positron emission tomography/computed tomography (PET/CT) scans are an integral part of patient management in prostate cancer. The Standardised PSMA PET/CT Analysis and Reporting Consensus project intends to improve intra- and interprofessional understanding of PSMA PET/CT reads. Standardised reporting of PSMA may improve patient care.

Table 1 – Standardised reporting recommendations for PSMA PET/CT

Reporting system	Purpose	Ref
PRIMARY SCORE	Using intra-prostatic PSMA uptake patterns to optimise prostate cancer diagnosis	Emmett et al [17]
PROMISE (including miTNM, PSMA expression score)	Standardised reporting of whole-body PSMA PET findings	Eiber et al [21] Seifert et al [20]
PSMA-RADS	Structured reporting system for PSMA PET imaging	Rowe et al [49] Werner et al [27]
ePSMA	Consensus guideline on PSMA PET reporting	Ceci et al [50]
PPP (PSMA PET progression criteria)	Proposal for PSMA PET-based systemic therapy response assessment criteria	Fanti et al [51]
PCWG3	Framework for the response assessment of patients with mCRPC enrolled in clinical trials	Scher et al [52]
RECIP	PSMA PET-based response criteria for mCRPC patients undergoing PSMA RLT	Gafita et al [32]

CT = computed tomography; mCRPC = metastatic castration-resistant prostate cancer; miTNM = molecular imaging tumour, node, and metastasis; PET = positron emission tomography; PSMA = prostate-specific membrane antigen; Ref = reference; RLT = radioligand therapy.

1. Introduction

The use of prostate-specific membrane antigen (PSMA) positron emission tomography (PET)/computed tomography (CT) has been well established for initial staging of high and unfavourable intermediate-risk newly diagnosed prostate cancer and for evaluating biochemical recurrence (BCR), due to its superior accuracy to conventional imaging (CI) [1,2]. Although not currently endorsed in guidelines, it is gaining traction for monitoring response to therapy including in patients undergoing PSMA-targeted radioligand therapy (RLT). PSMA PET/CT can be performed with comparable results using different radiolabelled tracers, with three tracers currently approved by the Food and Drug Administration (^{68}Ga]Ga-PSMA-11, ^{18}F]rhPSMA-7.3, and ^{18}F]DCFPyL) and three tracers approved in Europe (^{68}Ga]Ga-PSMA-11, ^{18}F]PSMA-1007, and ^{18}F]DCFPyL). Several reporting recommendations have been proposed for optimised diagnosis, improved disease localisation accuracy, description of lesion certainty, providing segmentation and classification tools, as well as enhancing response assessment classifications (overview in Table 1).

There is a clear need for standardised criteria and reporting of PSMA PET/CT to improve communication between nuclear medicine physicians and referring clinicians. Previous consensus meetings have examined the PSMA PET/CT response criteria [3] and the role of PSMA PET/CT in RLT [4,5]. However, because of the rapid advancements in this field, it is essential to bring key opinion leaders, academic societies, industry, and other stakeholders together to assess the existing guidelines and reporting recommendations.

In this report, we present the first results from the Standardised PSMA PET/CT Analysis and Reporting Consensus (SPARC) project, which aims to initiate a process for harmonising classifications and recommendations under one unifying framework and to establish an adaptive structure for PSMA PET/CT reporting.

2. Patients and methods

To meet the project's aim and objectives, we designed a cross-sectional iterative process to explore opinions and

assess consensus. An overview of the process is shown in Fig. 1.

The panel was purposively sampled [6] to reflect relevant clinical specialities, published expertise on PSMA PET/CT and reporting classifications, membership of relevant professional societies (American College of Radiology, Australian and New Zealand Urogenital and Prostate Cancer Trials Group, American Society of Clinical Oncology, European Association of Urology, European Association of Nuclear Medicine, and European Society For Medical Oncology), and global representation (Supplementary Table 1). A nonvoting consensus method expert (S.M.) was identified to lead the design, data collection, and analysis.

Five thematic areas (detection, primary staging, BCR, treatment response, and standardised reporting) were iden-

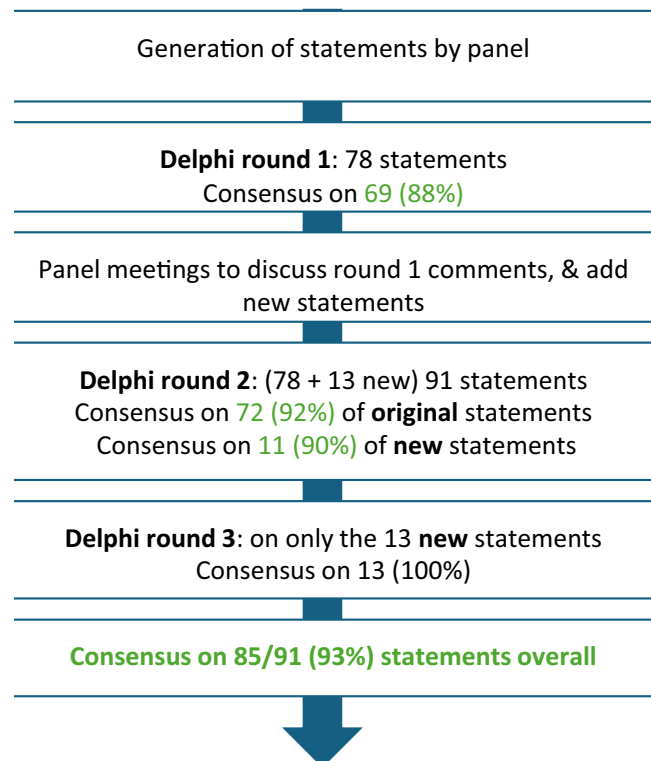


Fig. 1 – Overview of the consensus process.

tified. Five corresponding working groups, cochaired by two panel members, were tasked with formulating statements to be scored on a 9-point Likert scale ranging from 1 (strongly disagree) to 9 (strongly agree). The groups met online and communicated via e-mails to develop statements. Statements were reviewed by steering group members for ratification. A first set of 78 statements was generated, and another 13 questions were added during the process. All questions in the main Delphi results are shown in [Table 2](#).

The 78 statements were formatted as a two-round modified Delphi survey and administered using REDCap software [7]. The Delphi methodology was chosen because it allows time flexibility for panellists with anonymous between-round feedback while avoiding group processes such as groupthink coalescing with the opinion of dominant or authoritative voices [8–10].

In round 1, the panel was asked to state the strength of agreement on the 1–9 scale. Participants were directed to only choose a score of “5” if they neither agreed nor disagreed with the statement, and to choose “unable to score” if the statement was outside their expertise. A high proportion choosing unable to score may indicate difficulty in question wording or sampling errors, but is to be expected with variation of clinical expertise within the panel. Comment boxes allowed proposal of further statements.

Following round 1, a hybrid virtual and in-person meeting was convened in April 2024 to discuss the results, participants’ suggestions for further statements, and comments. Thirteen new statements were added to round 2, three in the BCR section and ten in the treatment response section.

In round 2, participants were shown a reminder of their round 1 scores and a bar chart showing the number of participants choosing each option on the 1–9 (unable to score) scale (refer to the [Supplementary material](#) for an example), and were asked to score each statement again, with 13 additional statements.

A third round was initiated but restricted to 13 new statements from round 2 to ensure that all statements had been considered twice with between-round feedback.

The “RAND appropriateness method” was used for an analysis [11]. This was chosen because it has been shown to be stable in relatively small panels [11]. It is based on the median and the 30–70th interpercentile range (IPR) and the IPR adjusted for symmetry (IPRAS) for each statement. IPRAS is calculated as $2.35 + (\text{asymmetry index} \times 1.5)$, with asymmetry being defined as the absolute difference between the central point of the IPR and 5 (the scale midpoint). If the IPR > IPRAS, then this is interpreted as a divergent opinion classified as “no consensus”, and vice versa for “consensus”. A calculator was created in Microsoft Excel [12] and used for all analyses. The median scores ranging from 1 to 3 were categorised as “disagree”, from 4 to 6 as “uncertain”, and from 7 to 9 as “agree”. A worked example is shown in the [Supplementary material](#). The number choosing unable to score was noted for each statement.

3. Results

The 30 panel members alongside their practice location, clinical role, and SPARC role are shown in [Supplementary Table 1](#), and the Delphi process is illustrated in [Fig. 1](#). Consensus improved between rounds and after each statement being scored twice by each panel member, with feedback provided between rounds. Across the rounds, consensus was achieved on 93% of the statements overall. For each question, the full results after two rounds are shown in [Table 2](#).

3.1. Detection

Prostate cancer diagnosis has improved significantly with the more widespread use of multiparametric magnetic resonance imaging (MRI) and Prostate Imaging Reporting and Data System (PI-RADS) to guide prostate biopsy [13–16]. How PSMA PET/CT adds to the diagnosis of prostate cancer is being explored in clinical trials; however, there is currently insufficient evidence for its integration into routine clinical practice. There was consensus that PSMA PET/CT is not a first-line imaging method for prostate cancer detection, but is a potential imaging modality in case of inconclusive MRI and/or inconclusive biopsy findings. There was consensus against forgoing biopsy based on either positive PSMA PET/CT (maximum standardised uptake value [SUV-max] >12 on ^{68}Ga -PSMA-11 PET), or negative PSMA PET/CT and negative MRI regardless of the prostate-specific antigen (PSA) level and PSA density. There was disagreement on the use of PSMA PET/CT with a normal (PI-RADS 1–2) or equivocal (PI-RADS 3) mpMRI scan as an early detection strategy. The panel agreed that any PSMA PET/CT tracer can be used for prostate cancer detection and that PSMA PET/CT tracers are preferred to choline, as PET tracer. There was consensus that the following information should be provided in the report reading a PSMA PET/CT result for prostate cancer detection: the suspicion level on a 5-point scale, with 5 meaning high suspicion and 1 meaning very low suspicion of finding significant prostate cancer. For generating the 5-point score, the SPARC panel endorsed the PRIMARY score, identifying lesions in the prostate based on zonal anatomy (peripheral and transition zones), pattern, and intensity [17].

3.2. Primary staging

The panel strongly agreed that PSMA PET/CT, regardless of the PSMA ligand chosen [18], is the optimal test for staging high-risk localised prostate cancer [1]. There was also consensus that PSMA PET/CT should not be performed routinely in patients with low or favourable intermediate-risk prostate cancer. There was no consensus, however, that clinical management plans based upon PSMA PET/CT scans are supported by evidence of improved outcomes, due to a lack of longitudinal prospective data [19]. However, experts agreed that in patients with retroperitoneal lymph nodes visible on PSMA PET/CT (miM1a) but not apparent on conventional CT,

Table 2 – Results of voting on 91 statements after two Delphi rounds (N = 30)

Section	Survey identifier	Median	30th percentile	70th percentile	Interpretation	Unable to score
A. Standardised reporting	1. PSMA PET should be applied to report only intraprostatic disease and not local disease outside the prostate	1	1	1	Consensus disagree	0
A. Standardised reporting	2. PSMA PET should be applied to report both prostatic disease and infiltration of the adjacent organs, with no separate mention of the seminal vesicles (T3)	2	1	2	Consensus disagree	1
A. Standardised reporting	3. PSMA PET should be applied to report minimal disease and infiltration of the adjacent organs, with separate mention of outside prostate (T3a) and seminal vesicle (T3b) involvement	9	8	9	Consensus agree	0
A. Standardised reporting	4. The PRIMARY score should be applied for initial evaluation of the prostate	8	8	8	Consensus agree	2
A. Standardised reporting	5. The PRIMARY score should be applied for other scenarios (eg, intraprostatic recurrence after therapy)	7	5	8	Consensus agree	2
A. Standardised reporting	6. PSMA PET diagnostic certainty should not be reported at all	1	1	1	Consensus disagree	0
A. Standardised reporting	7. PSMA PET diagnostic certainty should be reported as a 3-point scale (positive, negative, indeterminate)	6	5	8	Consensus uncertain	0
A. Standardised reporting	8. PSMA PET diagnostic certainty should be reported as a 5-point Likert scale	8	7	8	Consensus agree	0
A. Standardised reporting	9. PSMA PET diagnostic certainty should be reported in accordance with PSMA-RADS	8	8	8	Consensus agree	1
A. Standardised reporting	10. Subregions should be reported/coded (ie, ill, for internal iliac left, PS for presacral, RP for retroperitoneal)	9	8	9	Consensus agree	0
A. Standardised reporting	11. Conventional imaging (bone scan, CT scan, MRI) should be considered to define the certainty of diagnosis	8	7	9	Consensus agree	0
A. Standardised reporting	12. PSMA total tumour volume should not be reported	2	2	3	Consensus disagree	1
A. Standardised reporting	13. PSMA total tumour volume should be reported as exploratory data only	8	7	8	Consensus agree	1
A. Standardised reporting	14. PSMA total tumour volume should be reported as mandatory data for certain scenarios (mCRPC), otherwise exploratory	8	5	9	Consensus agree	0
A. Standardised reporting	15. SUV _{max} should not be reported	2	1	2	Consensus disagree	0
A. Standardised reporting	16. SUV _{max} should be reported as exploratory data only	7	5	8	Consensus agree	0
A. Standardised reporting	17. SUV _{max} should be reported as mandatory data for certain scenarios (mCRPC), otherwise exploratory	8	7	8	Consensus agree	0
A. Standardised reporting	18. SUV _{max} should not be reported	1	1	1.3	Consensus disagree	0
A. Standardised reporting	19. SUV _{max} should be reported as exploratory data only	2	1	3.6	Consensus disagree	0
A. Standardised reporting	20. SUV _{max} should be reported as mandatory data for certain scenarios (initial evaluation), otherwise exploratory	9	8	9	Consensus agree	1
A. Standardised reporting	21. Total number of lesions should not be reported	1	1	2	Consensus disagree	0
A. Standardised reporting	22. Total number of lesions should be reported as exploratory data only	2	1	3	Consensus disagree	0
A. Standardised reporting	23. Total number of lesions should be reported as mandatory data for certain scenarios (recurrence), otherwise exploratory	8.5	8	9	Consensus agree	0
A. Standardised reporting	24. PCWG4 and SPARC definitions should be synchronised	9	8.7	9	Consensus agree	0
A. Standardised reporting	25. PCWG4 and SPARC definitions should be different	1	1	2	Consensus disagree	0
B. Detection	1. PSMA PET/CT should not be the first-line imaging method in patients with suspected prostate cancer, with no prior MRI	9	9	9	Consensus agree	0
B. Detection	2. PSMA PET/CT should be obtained as a standard second-line imaging modality with a high clinical suspicion of prostate cancer and MRI (eg, PI-RADS ≥2)	2.5	1	7	No consensus	0
B. Detection	3. PSMA PET/CT is an option as a second-line imaging method, in patients with inconclusive MRI and biopsy findings (eg, negative MRI and biopsy and increasing PSA level)	1	1	1.7	Consensus disagree	0
B. Detection	4. Patients with positive PSMA PET/CT (SUV _{max} >12 on 68Ga-PSMA-11) can forego prostate biopsy (because the diagnosis of aggressive cancer is certain)	1	1	3	Consensus disagree	0
B. Detection	5. Patients with negative PSMA PET/CT and negative MRI can safely avoid biopsy, regardless of the PSA level and the PSA density	1	1	4	Consensus disagree	0
B. Detection	6. For tumour evaluation, PSMA PET/CT should be used to avoid biopsy due to false-positive changes as a consequence of biopsy	2	1	2.6	Consensus disagree	1
B. Detection	7. For intraprostatic cancer detection, the results of PSMA PET/CT should be reported using a 5-level score	8	8	9	Consensus agree	1
B. Detection	8. For cancer detection, the results of PSMA PET/CT should be reported using SUV _{max}	8	8	9	Consensus agree	0
B. Detection	9. PSMA reports should contain a qualitative description of the uptake compared with the surroundings	8	8	8.3	Consensus agree	0
B. Detection	10. For tumour detection, PSMA tracers are preferred to choline	9	9	9	Consensus agree	0
B. Detection	11. For tumour detection, any PSMA tracer can be used for PET/CT imaging	8	8	9	Consensus agree	1
B. Detection	12. All lesions should be reported	9	8	9	Consensus agree	0
B. Detection	13. The report should contain information about extracapsular extension or seminal vesical invasion	9	9	9	Consensus agree	0
B. Detection	14. There should be representative images with the report	9	9	9	Consensus agree	0
B. Detection	15. There should be a schema to pictorially identify the lesion (prostate and whole body)	9	8	9	Consensus agree	0
C. Primary staging	1. PSMA/PET is the most accurate test for staging high-risk apparently localised prostate cancer	9	9	9	Consensus agree	0
C. Primary staging	2. Clinical management plans based upon the results of PSMA PET scans are supported by evidence of improved outcomes	5	2	7.3	No consensus	0
C. Primary staging	3. Different PSMA/PET ligands are equally effective in staging high-risk localised prostate cancer	8	8	8	Consensus agree	2
C. Primary staging	4. PSMA PET should be used prior to TRUS biopsy to determine both where to biopsy and in whom a biopsy is necessary	3	2	3	Consensus disagree	1
C. Primary staging	5. PSMA PET should be used to stage prostate cancer	1	1	1	Consensus disagree	0
C. Primary staging	6. PSMA PET should be used to stage patients with favourable intermediate-risk prostate cancer	2	2	2	Consensus disagree	1
C. Primary staging	7. If disease outside of the pelvis is in bone, as noted on PSMA PET, a follow-up test (eg, MRI) and/or biopsy is required to confirm the presence of distant disease before determining the appropriate treatment pathway	2	1	3	Consensus disagree	1
C. Primary staging	8. If disease outside of the pelvis is in lymph node, as noted on PSMA PET, a biopsy is required to confirm the presence of distant disease before determining the appropriate treatment pathway	1	1	2	Consensus disagree	0
C. Primary staging	9. In a newly diagnosed patient with metastatic disease defined on initial staging PSMA PET/CT, baseline conventional imaging should also be performed for comparison in the majority of cases	3	2	3	Consensus disagree	0
C. Primary staging	10. In patients with retroperitoneal lymph nodes seen on PSMA PET/CT (m11a) but not apparent on conventional CT, management options should be considered based on conventional imaging alone (M0)	3	1	3	Consensus disagree	0
C. Primary staging	11. In patients with normal (PI-RADS 1–2) or equivocal (PI-RADS 3) mpMRI used as part of early detection, PSMA PET/CT of the prostate should be used to help guide a decision on whether to perform a prostate biopsy	3	3	3	No consensus	0
C. Primary staging	12. In a newly diagnosed patient with metastatic disease defined on baseline conventional imaging, PSMA PET/CT should also be performed for comparison in patients with low-volume disease	8	8	8.4	No consensus	1
C. Primary staging	13. In a newly diagnosed patient with metastatic disease defined on baseline conventional imaging, PSMA PET/CT should also be performed for comparison in patients with high-volume disease	3	1	8	No consensus	0
C. Primary staging	14. SUV _{max} should be reported routinely	9	8	9	Consensus agree	0
C. Primary staging	15. If SUV _{max} is reported, this should be broken down into regions (local, regional nodes, or metastatic) rather than just a single site	9	8	9	Consensus agree	0
C. Primary staging	16. When performing staging PSMA PET/CT, intravenous contrast should be administered for the CT component	8	8	9	Consensus agree	0
D. Biochemical recurrence	1. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between solitary and multiple positive locoregional lymph nodes	9	9	9	Consensus agree	1
D. Biochemical recurrence	2. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between solitary and multiple positive distant lymph nodes	9	9	9	Consensus agree	1
D. Biochemical recurrence	3. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between oligometastatic and polymetastatic lymph node disease	9	9	9	Consensus agree	1
D. Biochemical recurrence	4. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between unifocal, oligometastatic, and disseminated bone disease	9	9	9	Consensus agree	1
D. Biochemical recurrence	5. When reporting PSMA PET for (initial and biochemically recurrent) prostate cancer, the definition of oligometastatic disease implies up to five metastases, irrespective of their location and type	7	7	8	Consensus agree	1
D. Biochemical recurrence	6. The PSMA expression score (miPSMA) should be applied as a criterion to categorise the certainty of a lesion	9	8	9	Consensus agree	2
D. Biochemical recurrence	7. The disease extent in PSMA PET should be summarised using an adopted miTNM system	9	8	9	Consensus agree	1
D. Biochemical recurrence	8. The summary of the PSMA PET report should be structured in the following way: (1) local disease, (2) locoregional lymph node metastases, (3) distant lymph node metastases, (4) bone metastases, and (5) visceral metastases	9	9	9	Consensus agree	1
D. Biochemical recurrence	9. The certainty of findings in PSMA PET for BCR should be part of the summary	9	8	9	Consensus agree	0
D. Biochemical recurrence	10. Standardised reporting should be used for research purposes only	1	1	1	Consensus disagree	0
D. Biochemical recurrence	11. Standardised reporting should be used for both clinical and research purposes	9	9	9	Consensus agree	0
D. Biochemical recurrence	12. In the BCR setting, bone lesions with PSMA expression, but no anatomic correlate on CT, should be reported as equivocal findings	3	3	3	Consensus disagree	0
D. Biochemical recurrence	13. In the BCR setting after radical prostatectomy, PSMA expression in prostate bed, with no anatomic substrate on CT, should not be considered as local relapse	2	1	2	Consensus disagree	0
D. Biochemical recurrence	14. Providing relevant clinical information is mandatory for a correct interpretation of the findings, in the BCR setting	9	8.7	9	Consensus agree	0
E. Treatment response	1. There are no validated PSMA PET reporting criteria for treatment response to systemic therapy	8	8	8	Consensus agree	0
E. Treatment response	2. In any developed criteria, both PSMA and CT findings will need to be taken into account	9	8	9	Consensus agree	0
E. Treatment response	3. Any future treatment response criteria need to be widely accessible (no proprietary software)	9	9	9	Consensus agree	1
E. Treatment response	4. Standardised criteria for treatment response are required for systemic treatment across the spectrum of prostate cancer	9	9	8.4	Consensus agree	1
E. Treatment response	5. PSMA expression may be variable within 8 wk of commencing androgen signalling inhibition and needs to be interpreted with care	8.5	8	9	Consensus agree	0
E. Treatment response	6. New measures of reporting that include volume (visual or quantitative) will likely be important, but should not be implemented until sufficiently validated	8.5	8	9	Consensus agree	0
E. Treatment response	7. SPARC should identify important parameters that should be documented prospectively to develop optimal treatment response criteria	9	9	9	Consensus agree	1
E. Treatment response	8. SPARC should advocate implementation of PSMA PET in prospective therapy trials across the spectrum of prostate cancer to develop required evidence to replace conventional imaging	9	9	9	Consensus agree	1
New section: additional treatment response questions	1. Definitions of disease progression on PSMA PET need to correlate with overall survival	8	8	9	Consensus agree	0
New section: additional treatment response questions	2. Anatomic site of disease progression (lymph node, bone, and visceral) should be incorporated into a treatment response report as per PROMISE v2	8	8	9	Consensus agree	1
New section: additional treatment response questions	3. Site and number (grouped as 1–2, 35, 6–10, and >10) of new or resolved lesions should be included in a report for treatment response to a systemic therapy	9	9	9	Consensus agree	0
New section: additional treatment response questions	4. A new lesion should be defined based on the combination of anatomic site, intensity, and pattern of the lesion being consistent with metastatic prostate cancer	8	5	8	Consensus agree	1
New section: additional treatment response questions	5. Blood pool activity should be the activity below which a lesion can be described as new or resolved	9	8	9	Consensus agree	0
New section: additional treatment response questions	6. Sclerotic lesions on CT without PSMA PET/CT activity above blood pool should not be considered a new lesion	8	8	8	Consensus agree	0
New section: additional treatment response questions	7. Discordant findings between PSMA PET and low-dose CT should be included in a PSMA PET response report, or on diagnostic CT when the diagnostic CT is available for review (this includes separate acquisitions)	8	8	9	Consensus agree	0
New section: additional treatment response questions	8. Changes in SUV _{max} or SUV _{mean} should not be considered evidence of disease progression in a PSMA PET response criterion for systemic disease	8	8	8	Consensus agree	3
New section: additional treatment response questions	9. Treatment response imaging should be undertaken a minimum of 12 wk after commencing treatment to avoid PSMA expression changes unrelated to true progression	8	5	8	Consensus agree	1
New section: additional treatment response questions	10. Detection: clinical information available should be included in the report (disease stage, relevant medication, previous biopsy, latest PSA, if available PSA velocity, and previous imaging results)	8.5	8	9	Consensus agree	0
New section: additional biochemical recurrence statements	1. A negative PSMA PET report for BCR should indicate that the presence of low-volume prostate bed recurrence is not excluded by the scan result	8	8	8	Consensus agree	1
New section: additional biochemical recurrence statements	2. A site of PSMA-positive disease recurrence in BCR should demonstrate an intensity above blood pool	8	8	9	Consensus agree	0
New section: additional biochemical recurrence statements	3. A new lesion should be defined based on the combination of anatomic site, intensity, and pattern of the lesion being consistent with recurrent prostate cancer	9	8	9	Consensus agree	0

BCR = biochemical recurrence; CT = computed tomography; mCRPC = metastatic castration-resistant prostate cancer; miPSMA = molecular imaging PSMA; miTNM = molecular imaging tumour, node, and metastasis; mpMRI = multiparametric MRI; MRI = magnetic resonance imaging; PET = positron emission tomography; PI-RADS = Prostate Imaging Reporting and Data System; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen; SPARC = Standardised PSMA PET/CT Analysis and Reporting Consensus; SUV = standardised uptake value; SUV_{max} = maximum SUV; SUV_{mean} = mean SUV; TRUS = transrectal ultrasound.

Table 2 – continued

C. Primary staging	11. In patients with normal (PI-RADS 1–2) or equivocal (PI-RADS 3) mpMRI used as part of early detection, PSMA PET/CT of the prostate should be used to help guide a decision on whether to perform a prostate biopsy	3	3	7	No consensus	0
C. Primary staging	12. In a newly diagnosed patient with metastatic disease defined on baseline conventional imaging, PSMA PET/CT should also be performed for comparison in patients with low-volume disease	8	3.4	8	No consensus	1
C. Primary staging	13. In a newly diagnosed patient with metastatic disease defined on baseline conventional imaging, PSMA PET/CT should also be performed for comparison in patients with high-volume disease	3	1	8	No consensus	0
C. Primary staging	14. SUV _{max} should be reported routinely	9	8	9	Consensus agree	0
C. Primary staging	15. If SUV _{max} is reported, this should be broken down into regions (local, regional nodes, or metastatic) rather than just a single site	8	7	8	Consensus agree	0
C. Primary staging	16. When performing staging PSMA PET/CT, intravenous contrast should be administered for the CT component	8	8	9	Consensus agree	0
D. Biochemical recurrence	1. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between solitary and multiple positive locoregional lymph nodes	9	9	9	Consensus agree	1
D. Biochemical recurrence	2. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between solitary and multiple positive distant lymph nodes	9	9	9	Consensus agree	1
D. Biochemical recurrence	3. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between oligometastatic and polymetastatic lymph node disease	9	9	9	Consensus agree	1
D. Biochemical recurrence	4. Reporting of PSMA PET for biochemically recurrent prostate cancer should distinguish between unifocal, oligometastatic, and disseminated bone disease	9	9	9	Consensus agree	1
D. Biochemical recurrence	5. When reporting PSMA PET for (initial and biochemically recurrent) prostate cancer, the definition of oligometastatic disease implies up to five metastases, irrespective of their location and type	7	7	8	Consensus agree	0
D. Biochemical recurrence	6. The PSMA expression score (miPSMA) should be applied as a criterion to categorise the certainty of a lesion	8	7	8.9	Consensus agree	2
D. Biochemical recurrence	7. The disease extent in PSMA PET should be summarised using an adopted miTNM system	9	8	9	Consensus agree	1
D. Biochemical recurrence	8. The summary of the PSMA PET report should be structured in the following way: (1) local disease, (2) locoregional lymph node metastases, (3) distant lymph node metastases, (4) bone metastases, and (5) visceral metastases	9	9	9	Consensus agree	1
D. Biochemical recurrence	9. The certainty of findings in PSMA PET for BCR should be part of the summary	9	8	9	Consensus agree	0
D. Biochemical recurrence	10. Standardised reporting should be used for research purposes only	1	1	1	Consensus disagree	0
D. Biochemical recurrence	11. Standardised reporting should be used for both clinical and research purposes	9	9	9	Consensus agree	0
D. Biochemical recurrence	12. In the BCR setting, bone lesions with PSMA expression, but no anatomic correlate on CT, should be reported as equivocal findings	3	3	3	Consensus disagree	0
D. Biochemical recurrence	13. In the BCR setting after radical prostatectomy, PSMA expression in prostate bed, with no anatomic substrate on CT, should not be considered as local relapse	2	1	2	Consensus disagree	0
D. Biochemical recurrence	14. Providing relevant clinical information is mandatory for a correct interpretation of the findings, in the BCR setting	9	8.7	9	Consensus agree	0
E. Treatment response	1. There are no validated PSMA PET reporting criteria for treatment response to systemic therapy	8	8	9	Consensus agree	0
E. Treatment response	2. In any developed criteria, both PSMA and CT findings will need to be taken into account	9	8	9	Consensus agree	0
E. Treatment response	3. Any future treatment response criteria need to be widely accessible (no proprietary software)	9	9	9	Consensus agree	1
E. Treatment response	4. Standardised criteria for treatment response are required for systemic treatment across the spectrum of prostate cancer	9	8.4	9	Consensus agree	1
E. Treatment response	5. PSMA expression may be variable within 8 wk of commencing androgen signalling inhibition and needs to be interpreted with care	8.5	8	9	Consensus agree	0
E. Treatment response	6. New measures of reporting that include volume (visual or quantitative) will likely be important, but should not be implemented until sufficiently validated	8.5	8	9	Consensus agree	0
E. Treatment response	7. SPARC should identify important parameters that should be documented and evaluated prospectively to develop optimal treatment response criteria	9	9	9	Consensus agree	1
E. Treatment response	8. SPARC should advocate implementation of PSMA PET in prospective therapy trials across the spectrum of prostate cancer to develop required evidence to replace conventional imaging	9	9	9	Consensus agree	1
New section: additional treatment response questions	1. Definitions of disease progression on PSMA PET need to correlate with overall survival	8	8	9	Consensus agree	0
New section: additional treatment response questions	2. Anatomic site of disease progression (lymph node, bone, and visceral) should be incorporated into a treatment response report as per PROMISE v2	8	8	9	Consensus agree	1
New section: additional treatment response questions	3. Site and number (grouped as 1–2, 3, 5–10, and >10) of new or resolved lesions should be included in a report for treatment response to a systemic therapy	9	9	9	Consensus agree	0
New section: additional treatment response questions	4. A new lesion should be defined based on the combination of anatomic site, intensity, and pattern of the lesion being consistent with metastatic prostate cancer	8	5	8	Consensus agree	1
New section: additional treatment response questions	5. Blood pool activity should be the activity below which a lesion can be described as new or resolved	9	8	9	Consensus agree	0
New section: additional treatment response questions	6. Sclerotic lesions on CT without PSMA PET/CT activity above blood pool should not be considered a new lesion	8	8	8	Consensus agree	0
New section: additional treatment response questions	7. Discordant findings between PSMA PET and low-dose CT should be included in a PSMA PET response report, or on diagnostic CT when the diagnostic CT is available for review (this includes separate acquisitions)	8	8	9	Consensus agree	0
New section: additional treatment response questions	8. Changes in SUV _{max} or SUV _{mean} should not be considered evidence of disease progression in a PSMA PET response criterion for systemic disease	8	8	8	Consensus agree	3
New section: additional treatment response questions	9. Treatment response imaging should be undertaken a minimum of 12 wk after commencing treatment to avoid PSMA expression changes unrelated to true progression	8	5	8	Consensus agree	1
New section: additional treatment response questions	10. Detection: clinical information available should be included in the report (disease stage, relevant medication, previous biopsy, latest PSA, if available PSA velocity, and previous imaging results)	8.5	8	9	Consensus agree	0
New section: additional biochemical recurrence statements	1. A negative PSMA PET report for BCR should indicate that the presence of low-volume prostate bed recurrence is not excluded by the scan result	8	8	8	Consensus agree	1
New section: additional biochemical recurrence statements	2. A site of PSMA-positive disease recurrence in BCR should demonstrate an intensity above blood pool	8	8	9	Consensus agree	0
New section: additional biochemical recurrence statements	3. A new lesion should be defined based on the combination of anatomic site, intensity, and pattern of the lesion being consistent with recurrent prostate cancer	9	8	9	Consensus agree	0

BCR = biochemical recurrence; CT = computed tomography; mCRPC = metastatic castration-resistant prostate cancer; miPSMA = molecular imaging PSMA; miTNM = molecular imaging tumour, node, and metastasis; mpMRI = multiparametric MRI; MRI = magnetic resonance imaging; PET = positron emission tomography; PI-RADS = Prostate Imaging Reporting and Data System; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen; SPARC = Standardised PSMA PET/CT Analysis and Reporting Consensus; SUV = standardised uptake value; SUV_{max} = maximum SUV; SUV_{mean} = mean SUV; TRUS = transrectal ultrasound.

management options should take into consideration the PSMA PET/CT findings.

Experts had confidence in PSMA PET/CT findings, and recommended against performing baseline CI prior to PSMA PET/CT or follow-up tests such as MRI or biopsy to confirm unequivocally positive findings such as bone or nodal metastasis. Nevertheless, there was no consensus on whether PSMA PET/CT should be performed for further comparison in patients with low- or high-volume metastatic disease unequivocally diagnosed on CI.

When reporting scans, there was expert consensus that SUVmax should be reported routinely and divided into regions (local, regional, or metastatic nodes) rather than reporting only a single site. Importantly, there was consensus that intravenous contrast should be administered when performing a staging PSMA PET/CT scan.

There was consensus that for initial staging, PSMA expression score, the molecular imaging tumour-node-metastasis (miTNM) staging system from PROMISE V2 [20,21], a 5-point Likert scale for the certainty of extraprostatic lesions, PSMA volume (PSMA-VOL), and SUV should be used (please see below).

3.3. Biochemical recurrence

The panel strongly agreed that in PSMA PET/CT reporting for BCR, it is important to differentiate between solitary and multiple positive locoregional lymph node regions (miN1 vs miN2). A similar approach should be considered when reporting distant metastatic lymph node regions (miM1a). In addition, the discrimination between oligo- and poly-metastatic lymph node metastases should be included verbally in the report by reporting the number of lymph node metastases for oligometastatic disease.

For bone metastases (miM1b), there was consensus that the number of lesions should be reported to distinguish reliably between unifocal, oligometastatic (up to five lesions), and disseminated bone disease. Notably, there was less consensus on the proposal that a maximum of five lesions are regarded as oligometastatic disease. The final consensus of 80% for this statement was reached only after the second voting round.

Interpreting bone lesions on PSMA PET/CT is more challenging with [¹⁸F]F-PSMA-1007 and [¹⁸F]F-rhPSMA-7.3 than with [⁶⁸Ga]Ga-PSMA-11 due to a higher rate of nonmalignant uptake [22–25]. Benign conditions such as fractures, osteophytes, fibrous dysplasia, and haemangiomas can show PSMA uptake, leading to false positives. These findings are variably described as unspecific bone uptake [24] or nonspecific bone lesions [23], and are often clarified by clinical follow-up only, as histological confirmation is rare.

A comparison with prior imaging and characteristic CT/MRI features can aid interpretation. In matched-pair analyses, [¹⁸F]F-DCFPyL and [⁶⁸Ga]Ga-PSMA-11 showed fewer equivocal skeletal findings than [¹⁸F]F-PSMA-1007 [22,26]. PSMA-avid benign bone lesions are typically located in the ribs or pelvis and exhibit lower uptake than metastases, though uptake intensity alone does not allow reliable distinction. Solitary rib lesions without malignant CT morphology should be interpreted cautiously to avoid overstaging.

Application of the PROMISE criteria can help reduce false-positive assessments [20,21].

There was high consensus that disease extent should be summarised using an adopted miTNM system (see the section on structured reporting) and that the written report should cover (1) local disease, (2) locoregional lymph node metastases, (3) distant lymph node metastases, and (4) visceral lesions. The consensus was strong for the use of structured reporting for both clinical and research purposes. The panel strongly agreed that relevant clinical information should be provided by the referring physician and integrated into the report to allow correct interpretation of findings.

Finally, the experts agreed that local PSMA expression without an anatomical correlate is sufficient for the diagnosis of local recurrence and, after the second round, agreed that PSMA-positive bone lesions without an anatomical correlate should be interpreted as bone metastases if unspecific bone uptake is unlikely.

There was a consensus that for staging of BCR, the PSMA expression score, PSMA-VOL, and SUV should be used (please see below).

3.4. Treatment response

Among the various clinical applications of PSMA PET/CT for prostate cancer management, the evaluation of treatment response is least well established. Several PSMA PET/CT-based response criteria have been proposed, but these require prospective validation in large clinical datasets. There was no panel consensus that there is currently an evidence-based definition for what constitutes a response or progression event on the basis of PSMA PET/CT characteristics strictly, independent of the RECIST criteria represented by the CT component of the scan. However, there was strong consensus that these efforts to define response and progression criteria needed to be harmonised to reduce confusion and enable effective implementation.

There was consensus that the PSMA PET and CT (diagnostic or low dose) components should each be interpreted within the same report. Discordant lesions, whether at baseline or in follow-up studies, should be identified and described in the report. The exception is new sclerotic lesions with no PSMA activity, which should not be considered as new sites of disease, as these can be related to treatment response rather than active disease.

There was also consensus that the anatomic site of disease and number [20] of progressive sites should be incorporated into a treatment response report as per PROMISE V2 [20]. Lesions should be defined in relationship to blood pool activity, below which these could be described as resolved and above which these could be described as new, provided that the intensity, anatomic site, and pattern of the lesions are consistent with recurrent disease. There was also agreement that PSMA expression can be variable at first on-treatment imaging, and clinical decision-making should not be made on that basis alone.

It was recognised that response and progression criteria are required for both routine clinical care and regulatory requirements in clinical trials testing new diagnostics and

therapeutics. There was consensus that the definition of progression for regulatory purpose may be different from clinical care, and radiographic progression by any criteria may or may not indicate a clinical requirement for a treatment change. There was also consensus that PSMA PET/CT imaging should be incorporated into clinical trial design as at least a companion endpoint to CI in studies of prostate cancer therapeutics across the spectrum of the disease, to collect the required prospective imaging and clinical data in order to produce a common standard evidence-based definition of response and progression.

Finally, since the definitions for progression and response will be applied internationally, and the availability of software and other analytic tools varies geographically, there was consensus that any established PET features should widely be accessible across international borders and should not require proprietary or restrictive tools that might limit their widespread adoption.

3.5. Standardised reporting

PSMA PET/CT has become a key diagnostic tool for both routine clinical practice and clinical trials for the staging and restaging of prostate cancer. To ensure consistency and accuracy, several criteria for standardised PSMA PET/CT interpretation have been proposed. The panel has agreed to endorse and adopt the following frameworks for standardised reporting of PSMA PET/CT.

3.5.1. PSMA expression score (miPSMA)

The PSMA expression score as described originally in PROMISE V2 (Table 3) is a 4-point scale that uses normal organ uptake as reference, including blood pool, liver, and parotid gland [20,21]. A PSMA expression score of 0 indicates a lesion with no detectable uptake. A score of 1 is assigned to lesions with faint PSMA uptake, comparable with the blood pool. Scores of 2 and 3 represent lesions with uptake exceeding that of the liver or salivary glands, respectively. To minimise the impact of partial volume effects, the PSMA expression score is applied only to lesions with a CT correlate of >10 mm.

3.5.2. miTNM stage

The miTNM system enables standardised reporting of whole-body PSMA PET findings; miTNM organises staging by incorporating detailed information on the location and pattern of disease, similar to the World Health Organization classification (Table 4). The panel agrees to adopt miTNM

with subregions for standardised reporting of PSMA PET. By consensus, PSMA PET/CT should also report intraprostatic disease and infiltration of the adjacent organs with separate mention of extracapsular extension (miT3a) and seminal vesicle (miT3b) involvement.

3.5.3. PRIMARY score

The PRIMARY score was developed to assess intraprostatic lesions in patients who have not undergone local treatment or biopsy. It integrates PSMA PET/CT intraprostatic pattern, site, and intensity (Fig. 2). The PRIMARY score has been shown to correlate with the presence of clinically significant prostate cancer in biopsy-naïve men with suspected disease [17]. The panel agrees that the PRIMARY score should be applied for initial staging and other local evaluation of the prostate, including intraprostatic recurrence after therapy. For each patient with prostate gland, a single PRIMARY score is assigned based on the most clinically significant intraprostatic pattern (Table 5).

3.5.4. Five-point Likert scale for extraprostatic lesions

Equivocal findings should be minimised and restricted to specific situations, such as when additional diagnostic techniques may help clarify uncertain results. In accordance with PROMISE [20,21], the panel recommends incorporating a 5-point scale (Table 6) to report the level of diagnostic certainty. A standardised terminology for certainty of the final diagnosis will significantly enhance communication between imaging specialists, patients, and treating physicians. Furthermore, integrating this approach into study protocols can help identify ambiguous judgements and address potential diagnostic pitfalls [27].

3.5.5. PSMA-VOL and SUV

We propose reporting of additional tumour metrics, including total tumour lesion count, PSMA total tumour volume (PSMA-VOL; Fig. 3), and average as well as maximum SUV (mean SUV [SUV_{mean}] and SUV_{max}; Table 7). There is consensus that PSMA-VOL and respective SUV_{mean} and SUV_{max} should be reported as mandatory data for advanced prostate cancer where possible (metastatic castration-resistant prostate cancer). The panel agrees that the total tumour lesion count should be reported as mandatory data for recurrent disease. Otherwise, these findings are exploratory. PSMA-delineated total tumour volume (PSMA-VOL) is a quantifiable prognostic biomarker across various stages of prostate cancer. Integration of PSMA-VOL with other stan-

Table 3 – PSMA expression score (miPSMA score) in accordance with PROMISE V2 Seifert et al [20]

Score	Reported PSMA expression	Uptake
miPSMA 0	No	Equal to or lower than blood pool
miPSMA 1	Low	Equal to or lower than liver ^a and higher than blood pool
miPSMA 2	Intermediate	Equal to or lower than parotid gland and higher than liver ^a
miPSMA 3	High	Higher than parotid gland

miPSMA = molecular imaging PSMA; PSMA = prostate-specific membrane antigen.

^a The spleen is recommended as a reference organ instead of the liver for PSMA ligands with liver-dominant excretion (eg, [¹⁸F]F-PSMA-1007).

Table 4 – Whole-body stage (miTNM) reporting on a patient level in accordance with PROMISE V2 Seifert et al [20]

Local tumour (miT)			
miT0		No local tumour	
miT2		Organ-confined tumour	
miT3			
	miT3a	Limited tumour outside the prostate	
	miT3b	Involvement of seminal vesicles	
miT4		Tumour invades adjacent pelvic structures other than seminal vesicles	
miTr		Presence of local recurrence after radical prostatectomy	
Intrapelvic node metastasis (miN)			
miN0		No positive pelvic lymph nodes	
miN1		Single lymph node region with metastasis	Lymph node regions:
miN2		Multiple (≥ 2) lymph node regions with metastasis	II: internal iliac, laterality (L/R) EI: external iliac, laterality (L/R) OB: obturator, laterality (L/R) PS: presacral OP: other pelvic
Distant metastasis (miM)			
miM0		No distant metastasis	
miM1		Distant metastasis	
	a	Distant lymph node metastasis	miM1a regions: CI: common iliac, laterality (L/R) RP: retroperitoneal SD: supradiaphragmatic OE: inguinal and other extrapelvic
	b	Bone metastasis	Bone uptake patterns: uni: unifocal oligo: oligometastatic ($n \leq 3$) diss: disseminated dmi: diffuse marrow involvement
	c	Visceral metastasis	

L = left; miTNM = molecular imaging tumour, node, and metastasis; R = right.

standardised PSMA PET/CT findings allows for precise prediction of overall survival in early and late stages of prostate cancer [28–31]. Moreover, a reduction in PSMA-VOL is associated with prolonged survival, provided that the decrease is not due to the loss of PSMA expression [32,33].

3.5.6. Software tools

Standardised reporting is facilitated through several software applications that provide PSMA-VOL measurements along with corresponding SUV_{mean} and SUV_{max} . At present, there is no consensus on a standardised quantitative threshold for tumour segmentation. One used approach employs a liver uptake-specific threshold, which is useful with 177 -LuPSMA therapy (Fig. 3); methods using fixed thresholds such as a minimum SUV of 3 have also been evaluated prospectively [34,35].

4. Discussion

The use of PSMA PET-/CT has been established for primary staging of patients at a high risk of metastases and in the setting of BCR due to its superior accuracy to CI. This topic has been discussed by key opinion leaders at the Advanced Prostate Cancer Consensus Conference (APCCC) in 2023 and 2025 [28,36]. Several reporting recommendations have been published, addressing a variety of clinical concerns for PSMA PET/CT, including a staging structure, reporting certainty, intraprostatic reporting methods, and assessment of treatment response. There is a need to harmonise and consolidate existing guidelines and reporting recommendations for the use of PSMA PET/CT. Here, we report the first

results from the SPARC project, which aims to initiate a process to combine classifications and recommendations under one unifying umbrella and to establish a dynamic and evolving framework of PSMA PET/CT reporting.

Multi- or biparametric MRI is the standard diagnostic tool for prostate cancer detection together with biopsy [37]. In some cases, MRI is not available, or is contraindicated or inconclusive, and PSMA PET/CT might be a valid second-line imaging option to allow risk stratification and lesion identification [38]. The panel clearly stated that PSMA PET/CT is not a first-line option to replace MRI. The PRIMARY trial evaluated the additive value of pelvic-only PSMA PET/CT to prostate MRI in men with suspected prostate cancer, finding an improvement in negative predictive value from 72% with MRI up to 91% with the combination of PSMA PET/CT and MRI findings [38]. The PRIMARY score utilised a 5-point scoring system to identify clinically significant intraprostatic malignancy on PSMA PET/CT using a combination of location, pattern, and intensity [39]. However, further work is required to assess the value of PSMA PET/CT in prostate cancer diagnosis, particularly regarding its potential ability to reduce the need for a diagnostic biopsy. Additionally, the possible role of PSMA PET/CT in active surveillance and in patients being considered for focal therapy should also be explored [40].

There was consensus that PSMA PET/CT should not be performed routinely in patients with low or favourable intermediate-risk prostate cancer, consistent with recommendations such as the Society of Nuclear Medicine Appropriate Use Criteria [41]. No consensus was achieved regarding whether PSMA PET/CT should be performed for

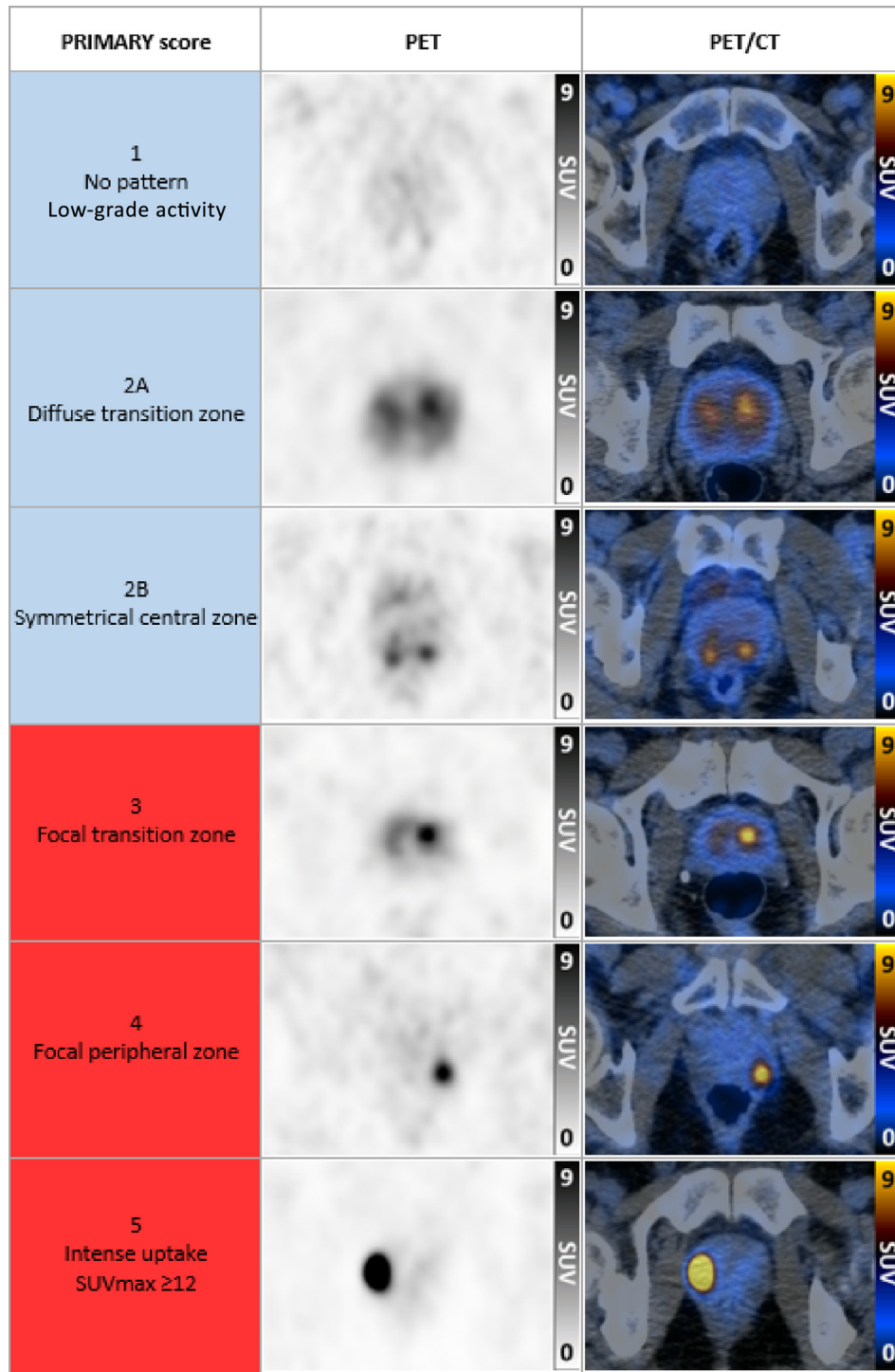


Fig. 2 – The PRIMARY scores range from 1 to 5 for intraprostatic characterisation, which is based on a combination of site (peripheral or transition zone), pattern (focal or diffuse), and intensity (SUV_{max} >12) to determine the chance of clinically significant malignancy. PRIMARY scores 1–2 are considered “benign” and 3–5 “malignant”. CT = computed tomography; PET = positron emission tomography; SUV = standardised uptake value; SUV_{max} = maximum SUV.

comparison in patients with low- or high-volume metastatic disease unequivocally diagnosed on CI. This highlights an area of controversy [42] and the importance of individualised clinical judgement until more robust evidence of clinical utility emerges. PSMA PET/CT leads to both downstaging and upstaging [43]. Thus, future volume-based definitions of tumour stages should be adjusted based

on patient outcome to inform future guidelines on the role of PSMA PET/CT in the metastatic setting.

Notably, consensus was low regarding the proposal that a maximum of five lesions are considered to define oligometastatic disease. Final consensus of 80% on this statement could be reached only after the second consensus round. This contributes to an on-going discussion on the definition

Table 5 – PRIMARY score to report certainty for intraprostatic lesions in accordance with the findings of Emmett et al [17]

Score	Pattern and intensity
1	No dominant intraprostatic pattern on PSMA. Low-grade activity
2	Diffuse transition zone activity or symmetrical central zone activity that does not extend to the prostate margin on CT
3	Focal transition zone activity visually twice above background
4	Focal peripheral zone activity (no minimum intensity)
5	Intense uptake (visual very high intensity or $SUV_{max} > 12^a$)

CT = computed tomography; PET = positron emission tomography; PSMA = prostate-specific membrane antigen; SUV_{max} = maximum standardised uptake value.

^a Quantitative parameters were established on ⁶⁸Ga-PSMA-11 PET.

Table 6 – Five-point Likert scale to report certainty for extraprostatic lesions in accordance with PROMISE (20,21)

Score	Reported certainty	Definition	Diagnosis
1	Benign	Lesion without abnormal PSMA uptake (miPSMA0)	Negative
2	Probably benign	Low uptake (miPSMA1) in a site atypical for prostate cancer	Negative
3	Equivocal	Low uptake (miPSMA1) in a site typical for prostate cancer or intermediate to high uptake (miPSMA2–3) in a site atypical for prostate cancer	Equivocal
4	Probably prostate cancer	Intermediate uptake (miPSMA2) in a site typical for prostate cancer	Positive
5	Definitive prostate cancer	High uptake (miPSMA3) in a site typical for prostate cancer	Positive

CT = computed tomography; miPSMA = molecular imaging PSMA; MRI = magnetic resonance imaging; PSMA = prostate-specific membrane antigen.

Role of conventional imaging (bone scan, CT, and MRI): (1) to determine typical/atypical sites, and (2) to adjust certainty. Certainty can be scaled up versus down depending on suspicion versus pitfalls.

of oligometastatic disease and its implication for care in BCR [44,45]. High consensus was obtained to use the PSMA expression score (miPSMA) as a criterion to provide the certainty of findings in BCR in the reporting. It is underpinned by investigations outlining that primary PSMA expression is an indicator for PSMA PET/CT in BCR [46]. The ProPSMA randomised trial, however, provided no evidence that separately acquired contrast-enhanced CT and bone scan were beneficial [1].

The expert panel agreed that local PSMA expression without an anatomical correlate is sufficient for the diagnosis of local recurrence and, after the second consensus round, also agreed that PSMA expression in the bone without an anatomical correlate should be interpreted as bone metastases. This is backed by previous retrospective data showing that anatomical correlates in CT are often lacking in cases where uptake in PSMA PET/CT clearly indicated malignancy [47].

Since PSMA expression can be modulated by therapy, including those that modulate androgen receptor signalling, PSMA PET/CT findings can be altered as a pharmaceutical effect that may confound the response to treatment assessment. As expected, there were insufficient data to establish a definition of response or progression by PSMA PET/CT imaging, and there is an urgent need for prospective trials to evaluate the robustness of PSMA PET/CT as a monitoring tool for treatment response.

While PSMA PET/CT is increasingly recognised as a powerful tool for staging and potentially for treatment response assessment, CI should currently be maintained as part of baseline and follow-up imaging protocols, especially in settings where standardised PET-based response frameworks are not yet adopted universally.

In clinical practice and clinical trials, CI remains the established standard for response evaluation (eg, as per RECIST 1.1 or PCWG3) and thus provides a reference framework for drug evaluation. Importantly, the use of baseline CI

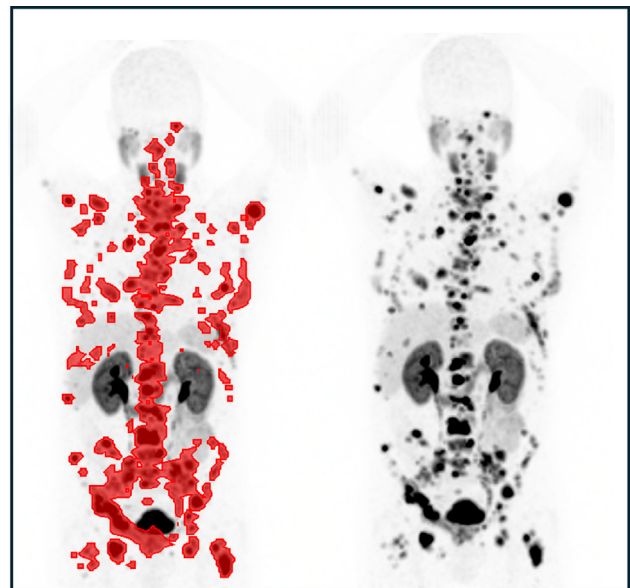


Fig. 3 – Quantitative parameters such as PSMA-VOL and SUV_{mean} are determined from the assessment of the total tumour volume coalescing each individual tumour deposit. In this case, a tumour deposit was derived using a minimum SUV_{max} of 3 and a volume of 0.2 ml for the algorithm to identify a tumour deposit. SUV_{mean} is the mean intensity of all the voxels in the identified whole-body tumour burden and is a marker of both tumour intensity and heterogeneity. PSMA = prostate-specific membrane antigen; PSMA-VOL = PSMA volume; SUV_{max} = maximum standardised uptake value; SUV_{mean} = mean standardised uptake value.

Table 7 – Exploratory metrics of prostate cancer extent and biology

Total tumour lesion count	N	Report N up to 20 or “>20”
Total tumour volume (PSMA-VOL) and respective average (SUV _{mean}) and maximum (SUV _{max}) SUV		Report PSMA-VOL in ml and SUV without a unit
PSMA-VOL = PSMA volume; PSMA = prostate-specific membrane antigen; SUV = standardised uptake value; SUV _{max} = maximum SUV; SUV _{mean} = mean SUV.		

enables longitudinal comparison if PSMA PET/CT is not available consistently.

Finally, the panel agreed that a standardised report template for PSMA PET/CT should be provided, facilitating the estimation of risk to find a case of significant prostate cancer or not, locate the lesion, and provide an estimation of possible locally advanced disease or metastatic disease. The standardised report template for PSMA PET/CT will include miPSMA and miTNM scores from PROMISE [20,21], 5-point scale for certainty of diagnosis, as well as key metrics PSMA-VOL, SUV_{mean}, and SUV_{max}.

SUV measurements may change significantly between different modes of normalisation and between different scanner types. SUV can be normalised to body mass, lean body mass, or body surface area. Therefore, the same mode of normalisation should be used for serial examinations, and devices should undergo accreditation ideally following the most recent EARL standard [48].

We provide a template for such a standardised prostate cancer detection report (Supplementary material) as well as example PSMA PET/CT images for each of the possible scores and scenarios (Fig. 2).

5. Conclusions

The SPARC consensus project revealed a high level of agreement within an expert multidisciplinary panel on the key requirements for optimal PSMA PET/CT reporting. SPARC has combined existing classifications and recommendations by PRIMARY and PROMISE under one unifying umbrella and aims to establish a living framework of PSMA PET/CT reporting as more data are added and with the likely automated technological advances.

Author contributions: Anders S. Bjartell and Steven MacLennan had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Bjartell, Herrmann, Walz, MacLennan, Witjes, Emmett, Morgans, Morris, Eiber, Hofman, Fendler, Fanti.

Acquisition of data: MacLennan, Herrmann, Walz, Witjes, Emmett, Bjartell.

Analysis and interpretation of data: MacLennan, Herrmann, Walz, Witjes, Emmett, Bjartell.

Drafting of the manuscript: Bjartell, MacLennan, Herrmann, Walz, Emmett.

Critical revision of the manuscript for important intellectual content: Herrmann, Walz, MacLennan, Briganti, Cornford, Czernin, Eiber, Fanti, Fendler, Fizazi, Gafita, Gillessen, Goffin, Hadaschik, Hofman, Hope, Maurer, Morgans, Morris, Murphy, Oprea-Lager, Ost, ÓSullivan, Rouvière, Sandhu, Sartor, Sathegke, Tempny, Witjes, Emmett, Bjartell.

Statistical analysis: MacLennan.

Obtaining funding: Bjartell, Herrmann, Walz, Witjes, Emmett.

Administrative, technical, or material support: Witjes.

Supervision: Bjartell, Herrmann, Walz, MacLennan, Emmett.

Other: None.

Financial disclosures: Anders S. Bjartell certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: Alberto Briganti reports association with Astellas Pharma, Janssen-Cilag, OPKO Health, MDx Health, Bayer, miR Scientific, LLC (“miR”), MSD/AstraZeneca, Ferring, Astellas Pharma, Janssen-Cilag, Sandoz-Novartis. Andrei Gafita reports consulting fees from Blue Earth Diagnostics Ltd. and Lilly, consulting fees from and being at speaker bureau for Novartis. Olivier Rouvière reports honoraria from Ipsen paid to Institution for a teaching course. Louise Emmett reports participation in advisory boards and talks for Astellas, AstraZeneca, Bayer, Clarity Pharma, Janssen, MSD, and Novartis/AAA; being a Scientific advisory board member for Clarity Pharma and Advancell; grant funding to institution from Movember, NHMRC, PCF challenge, St Vincent’s, Clinic and Curran Foundations. Alicia Morgans reports honoraria from AAA, Astellas, AstraZeneca, Bayer, Curium, Exelixis, Exact Sciences, BMS, Lantheus, Johnson and Johnson, MacroGenics, Merck, Sumitomo Pharma, Inc, Pfizer, Novartis, Telix, and Tolmar; consulting for AAA, Astellas, AstraZeneca, Bayer, Curium, Exelixis, BMS, Johnson and Johnson, MacroGenics, Merck, Sumitomo Pharma, Inc, Pfizer, Novartis, Telix, and Tolmar; research collaboration with or funding from Astellas, Bayer, Exelixis, Lantheus, Johnson and Johnson, Pfizer, Novartis, and Telix. Jochen Walz reports participation in advisory boards and speakers’ bureau of AAA/ Novartis, Astellas, AstraZeneca, Bayer, Blue Earth Diagnostics, Curium, Intuitive Surgical, Ipsen, Janssen, Lightpoint Medical, Takeda, Telix Pharmaceuticals, and Veracyte. Ken Herrmann reported receiving consultant fees from Advanced Accelerator Applications (a Novartis company), Amgen, AstraZeneca, Bain Capital, Bayer, Boston Scientific, Convergent, Curium, Debiopharm, EcoR1, Fusion, GE Healthcare, Immedica, Isotopen Technologien München, Janssen, Merck, MSD, Molecular Partners, NVision, POINT Biopharma, Pentixapharm, Pfizer, Radiopharm Theranostics, Rhine Pharma, Siemens Healthineers, Sofie Biosciences, Telix, Theragnostics, and ymabs; receiving research grants from Advanced Accelerator Applications (a Novartis company), Boston Scientific, and Janssen; having stock or other ownership interests in AdvanCell, Aktis Oncology, Convergent, NVision, and Sofie Biosciences. Karim Fizazi reports participation in advisory boards of and talks for Amgen, Astellas, AstraZeneca, Bayer, Clovis, Daiichi Sankyo, Janssen, MSD, Novartis/AAA, Pfizer, and Sanofi; honoraria to own institution Gustave Roussy; participation in advisory boards with personal honorarium for Arvinas, CureVac, MacroGenics, and Orion. Michael Morris is a consultant to Lantheus, Convergent Therapeutics, Z-Alpha, Ambrx, Flare Therapeutics, Fusion Pharmaceuticals, Arvinas, Exelixis, Amgen, Molecular Partners, Wren Labs, Isotopia, Actinium Pharmaceuticals, LinkinVax, and Advancell. Joe O-Sullivan reports being in advisory board/speakers’ bureau of AAA (a Novartis company), Astellas,

AstraZeneca, Bayer, GE Healthcare, Janssen, Merck, Novartis, Monrol, and Sanofi. Stefano Fanti reports advisory board participation and/or speakers fee and/or meeting sponsored attendance in AAA, Amgen, Astellas, Bayer, Debio, GE, Immedica, Janssen, Novartis, Telix, and United Imaging in the last 3 yr. Johannes Czernin is a founder of and serves as a scientific advisor for Aktis Oncology, Sofie Biosciences, and Infinity Topco; is also a founder of Sofie Biosciences and Trethera Therapeutics. Shahneen Sandhu reports grants to institution for clinical trials from Novartis/AAA, AstraZeneca, Merck Sharp & Dohme, Genentech, Pfizer, Amgen, Bristol Myers Squibb, Merck Healthcare, and Senhwa Biosciences Inc.; fees for attending an advisory board, which goes to a research fund at the institution, from Merck Sharp & Dohme, Bristol Myers Squibb, AstraZeneca, Abbvie, Janssen, Novartis, Skyline, and AdvanCell; receiving shares (equity) in company (personally) from AdvanCell. Oliver Sartor has served as a consultant to Abdera, Actithera, AdvanCell, Alpha9, Amgen, ARTBio, Astellas Pharma, AstraZeneca, Bayer, Clarity Pharmaceuticals, Convergent, Curium, Curdah, Isotopen Technologien, ITM Oncologics, JNJ, Lantheus, Merck, Modex, Norroy, North Star, Novartis, Nucleus Biopharma, Progenics, RATIO, Swiss Rockets, Telix Pharmaceuticals, and Wren Laboratories; has received institutional research funding from Amgen, AstraZeneca, Bayer, JNJ, and Novartis; has equity ownership with AbbVie, Cardinal Health, Clarity Pharmaceuticals, Curadh, Lilly, Pfizer, Ratio, Telix, and United Health Group, and options with AdvanCell, Abdera, Actithera, ArtBio, and Convergent. Michael Hofman acknowledges support from the Australian Cancer Research Foundation (ACRF), Prostate Cancer Foundation (PCF), a National Health and Medical Research Council (NHMRC) Investigator Grant, and Peter MacCallum Foundation; research support and/or advisory board consulting fees to Peter MacCallum Cancer Centre from AdvanCell, ANSTO, Bayer, Isotopia, Novartis, and MIM; consulting fees (personal) for lectures from or advisory board participation for Janssen, MSD, and Sanofi in the last 2 yr; potential equity (personal) from AdvanCell. Mike Sathekge reports grants to institution from Aktis Oncology, Lilly-POINT BIOPHARM, Molecular Partners, and Telix; honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Novartis, J&J, IBA and GE; support for attending meetings and/or travel from IAEA, ISMERAD, and BSNM; leadership or fiduciary role in other board, society, committee, or advocacy groups from AHRI and ADCOCK. Declan Murphy has received reimbursement for advisory board/speaker duty from Astellas, Bayer, Johnson & Johnson, Novartis, Ipsen, Mundipharma, and Device Technologies. Anders Bjartell reports consulting, advisory board, or speaker's fee from Accord, Astellas, AstraZeneca, Bayer, Ipsen, J&J, Pfizer, Sandoz, and Telix; research grants to institution from Astellas, AstraZeneca, Bayer, J&J, Movember, Roche, and Spectracure; being a cofounder/board member of Glactone Pharma AB; a shareholder of Glactone Pharma AB, and LIDDS AB, all of these outside of the submitted work. Boris Hadaschik reports consulting fees from Janssen, Bayer, ABX, Astellas, Merck, Amgen, MSD/Pfizer, Novartis, BMS, Monrol, Onkowissen, POINT Biopharma, Ipsen, AstraZeneca, Lightpoint Medical, Telix, and Accord Healthcare; travel support from AstraZeneca, BMS, Janssen, Bayer, and Ipsen; grants or contracts from Janssen, Deutsche Forschungsgesellschaft, Novartis, and BMS; participation in data safety monitoring boards for Janssen and ABX. Piet Ost reports research grant from Bayer; consultancy for AstraZeneca, Bayer, Janssen, and Novartis. Wolfgang P. Fendler reports fees from SOFIE Bioscience (research funding), Janssen (consultant and speaker), Perceptive (consultant and image review), Bayer (consultant, speaker, and research funding), Novartis (speaker and consultant), Telix (speaker), GE Healthcare (speaker and consultant), Eczacıbaşı Monrol (speaker), Abx (speaker), Amgen (speaker), Urotrials (speaker), Lilly (consultant), and AstraZeneca (research funding), outside of the submitted work. Thomas Hope has grant funding to the institution from Bayer, GE Healthcare, Lantheus, Janssen, Novartis, Telix Pharmaceuticals, the Prostate Cancer Foundation, and the National Cancer Institute (R01CA235741 and R01CA212148); received personal fees from

Bayer, Cardinal Health, BlueEarth Diagnostics, Lantheus, RayzeBio/BMS, and Sanofi; received fees from and has an equity interest in Curium, AdvanCell, and Utter Therapeutics. Karolien Goffin reports fees from Telix (consultant and speaker), Bayer (consultant and speaker), Novartis (consultant and speaker), Blue Earth Diagnostics (consultant), MSD (consultant), and FullLife Technologies (consultant), outside of the submitted work. Tobias Maurer reports speaker fees from ABX, Astellas, Bayer, Sanofi-Aventis, and Phillips; consultant fees from ABX, Advanced Accelerator Applications International S.A., Ascenian, Astellas, Axiom, Blue Earth Diagnostics, GEMoAb, Novartis, ROTOP Pharma, and Telix; and research funding from ABX, Brainlab, Intuitive Surgical, and Telix. Daniela Oprea-Lager reports speaker fees from Bayer, Curium, Ipsen, and Novartis; educational grants from Janssen. Phil Cornford reports speaker fees from Accord, Astellas, AZ, Bayer, Ferring, Aspen, Janssen, and Novartis; consultant fees from Accord, AstraZeneca, Bayer, Bristol Myers Squibb, Ferring Pharmaceuticals, and Janssen. Silke Gillessen reports personal honoraria for invited speaker from ESMO and Schweizerische Gesellschaft für Medizinische Onkologie (SGMO)/Meister ConCept GmbH; other honoraria from University of Applied Sciences and Arts of Southern Switzerland (SUPSI); travel grants from Bayer, Gilead, Intellisphere LLC, and Johnson & Johnson; institutional honoraria from, advisory board participation in, or participation in independent data monitoring-/steering committees of Amgen, Astellas, AstraZeneca, Avalere Health, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Innomedica, Ipsen, LinkinVax, Macrogenics, Merck, Novartis, and Pfizer; being an invited speaker for AdMeTech Foundation, EPG Health, ESMO, Intellisphere LLC, Medtoday Switzerland, Orikata, PeerVoice, Pfizer, Schweizerische Gesellschaft für Medizinische Onkologie (SGMO)/Meister ConCept GmbH, Silvio Grasso Consulting, Swiss group for Clinical Cancer Research (SAKK), and UroPratica Group; patent for a research method for biomarker WO2009138392. Matthias Eiber reports fees from Blue Earth Diagnostics Ltd. (consultant and research funding), Novartis/AAA (consultant and speaker), Telix (consultant), Bayer (consultant and research funding), RayzeBio (consultant), Point Biopharma (consultant), Eckert-Ziegler (speaker), Janssen Pharmaceuticals (consultant and speakers bureau), Parexel (image review), and Bioclinica (image review), outside the submitted work; a patent application for rhPSMA; being entitled to royalties on sales, with other inventors, from POSLUMA; serving on advisory boards and/or steering committees of Novartis, Blue Earth Diagnostics, and Telix. Clare Tempany reports funding from NIH (EB 028741 and EB 025823), MedScape (consultant and speaker), and UpToDate (contributor).

Funding/Support and role of the sponsor: Research grants for this study were given to the European Association of Urology by Curium, J&J, Novartis, and Telix. These organisations had no influence in the design of the study and had no role in drafting, reviewing, or approving the manuscript.

Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.eururo.2025.08.005>.

References

- [1] Hofman MS, Lawrentschuk N, Francis RJ, et al. Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. *Lancet* 2020;395:1208–16.
- [2] Pienta KJ, Gorin MA, Rowe SP, et al. A phase 2/3 prospective multicenter study of the diagnostic accuracy of prostate specific membrane antigen PET/CT with 18F-DCFPyL in prostate cancer patients (OSPREY). *J Urol* 2021;206:52–61.

- [3] Fanti S, Goffin K, Hadaschik BA, et al. Consensus statements on PSMA PET/CT response assessment criteria in prostate cancer. *Eur J Nucl Med Mol Imaging* 2021;48:469–76.
- [4] Fanti S, Briganti A, Emmett L, et al. EAU-EANM Consensus statements on the role of prostate-specific membrane antigen positron emission tomography/computed tomography in patients with prostate cancer and with respect to [177Lu]Lu-PSMA radioligand therapy. *Eur Urol Oncol* 2022;5:530–6.
- [5] Oprea-Lager DE, MacLennan S, Bjartell A, et al. European Association of Nuclear Medicine Focus 5: consensus on molecular imaging and theranostics in prostate cancer. *Eur Urol* 2024;85:49–60.
- [6] Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Adm Policy Ment Health* 2015;42:533.
- [7] Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform* 2019;95:103208.
- [8] Barrett D, Heale R. What are Delphi studies? *Evid Based Nurs* 2020;23:68–9.
- [9] Niederberger M, Spranger J. Delphi technique in health sciences: a map. *Front Public Health* 2020;8:457.
- [10] Nasa P, Jain R, Juneja D. Delphi methodology in healthcare research: how to decide its appropriateness. *World J Methodol* 2021;11:116.
- [11] Fitch K, Bernstein S, Aguilar M, et al. The Rand/UCLA appropriateness method user's manual. Santa Monica, CA: Rand; 2001.
- [12] Microsoft Corporation. Microsoft Excel. 2018. <https://office.microsoft.com/excel>.
- [13] Ahmed HU, El-Shater Bosaily A, Brown LC, et al. Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study. *Lancet* 2017;389:815–22.
- [14] Kasivisvanathan V, Wai-Shun Chan V, Clement KD, et al. VISION: an individual patient data meta-analysis of randomised trials comparing magnetic resonance imaging targeted biopsy with standard transrectal ultrasound guided biopsy in the detection of prostate cancer. *Eur Urol* 2025;87:512–23.
- [15] Kasivisvanathan V, Rannikko AS, Borghi M, et al. MRI-targeted or standard biopsy for prostate-cancer diagnosis. *N Engl J Med* 2018;378:1767–77.
- [16] Weinreb JC, Barentsz JO, Choyke PL, et al. PI-RADS prostate imaging – Reporting and data system: 2015, version 2. *Eur Urol* 2016;69:16–40.
- [17] Emmett L, Papa N, Buteau J, et al. The PRIMARY score: using intraprostatic 68Ga-PSMA PET/CT patterns to optimize prostate cancer diagnosis. *J Nucl Med* 2022;63:1644–50.
- [18] Evangelista L, Maurer T, van der Poel H, et al. [68Ga]Ga-PSMA versus [18F]PSMA positron emission tomography/computed tomography in the staging of primary and recurrent prostate cancer. A systematic review of the literature. *Eur Urol Oncol* 2022;5:273–82.
- [19] Vapiwala N, Hofman MS, Murphy DG, Williams S, Sweeney C. Strategies for evaluation of novel imaging in prostate cancer: putting the horse back before the cart. *J Clin Oncol* 2019;37:765–9.
- [20] Seifert R, Emmett L, Rowe SP, et al. Second version of the prostate cancer molecular imaging standardized evaluation framework including response evaluation for clinical trials (PROMISE V2). *Eur Urol* 2023;83:405–12.
- [21] Eiber M, Herrmann K, Calais J, et al. Prostate cancer molecular imaging standardized evaluation (PROMISE): proposed mITNM classification for the interpretation of PSMA-ligand PET/CT. *J Nucl Med* 2018;59:469–78.
- [22] Rauscher I, Krönke M, König M, et al. Matched-pair comparison of 68Ga-PSMA-11 PET/CT and 18F-PSMA-1007 PET/CT: frequency of pitfalls and detection efficacy in biochemical recurrence after radical prostatectomy. *J Nucl Med* 2020;61:51–7.
- [23] Arnfield EG, Thomas PA, Roberts MJ, et al. Clinical insignificance of [18F]PSMA-1007 avid non-specific bone lesions: a retrospective evaluation. *Eur J Nucl Med Mol Imaging* 2021;48:4495–507.
- [24] Grünig H, Maurer A, Thali Y, et al. Focal unspecific bone uptake on [18F]-PSMA-1007 PET: a multicenter retrospective evaluation of the distribution, frequency, and quantitative parameters of a potential pitfall in prostate cancer imaging. *Eur J Nucl Med Mol Imaging* 2021;48:4483–94.
- [25] Kroenke M, Mirzoyan L, Horn T, et al. Matched-pair comparison of 68Ga-PSMA-11 and 18F-rhPSMA-7 PET/CT in patients with primary and biochemical recurrence of prostate cancer: frequency of non-tumor-related uptake and tumor positivity. *J Nucl Med* 2021;62:1082–8.
- [26] Wondergem M, van der Zant FM, Broos WAM, Knol RJJ. Matched-pair comparison of 18F-DCFPyL PET/CT and 18F-PSMA-1007 PET/CT in 240 prostate cancer patients: inter-reader agreement and lesion detection rate of suspected lesions. *J Nucl Med* 2021;62:1422–9.
- [27] Werner RA, Hartrampf PE, Fendler WP, et al. Prostate-specific membrane antigen reporting and data system version 2.0. *Eur Urol* 2023;84:491–502.
- [28] Karpinski MJ, Claassen K, Möller L, et al. Incidence and survival of patients with prostate cancer in North-Rhine Westphalia, Germany. *Clin Genitourin Cancer* 2025;23:102289.
- [29] Seifert R, Kessel K, Schlack K, et al. PSMA PET total tumor volume predicts outcome of patients with advanced prostate cancer receiving [177Lu]Lu-PSMA-617 radioligand therapy in a bicentric analysis. *Eur J Nucl Med Mol Imaging* 2021;48:1200–10.
- [30] Karpinski MJ, Rahbar K, Bögemann M, et al. Updated prostate cancer risk groups by prostate-specific membrane antigen positron emission tomography prostate cancer molecular imaging standardized evaluation (PPP2): results from an international multicentre registry study. *Eur Urol*. In press. <https://doi.org/10.1016/j.eururo.2025.04.017>.
- [31] Emmet LN, Subramaniam S, Crumbaker M, et al. Predictive and prognostic value of baseline PSMA-PET total tumor volume and SUV mean within ENZA-p, a randomized phase II trial of enzalutamide versus enzalutamide plus [177Lu] Lu-PSMA-617 (ANZUP1901). *J Clin Oncol* 2025;43:5011.
- [32] Gafita A, Rauscher I, Weber M, et al. Novel framework for treatment response evaluation using PSMA PET/CT in patients with metastatic castration-resistant prostate cancer (RECIP 1.0): an international multicenter study. *J Nucl Med* 2022;63:1651–8.
- [33] Seifert R, Kessel K, Schlack K, et al. Total tumor volume reduction and low PSMA expression in patients receiving Lu-PSMA therapy. *Theranostics* 2021;11:8143–51.
- [34] Kuo PH, Morris MJ, Hesterman J, et al. Quantitative 68Ga-PSMA-11 PET and clinical outcomes in metastatic castration-resistant prostate cancer following 177Lu-PSMA-617 (VISION trial). *Radiology* 2024;312:e233460.
- [35] Buteau JP, Martin AJ, Emmett L, et al. PSMA and FDG-PET as predictive and prognostic biomarkers in patients given [177Lu]Lu-PSMA-617 versus cabazitaxel for metastatic castration-resistant prostate cancer (TheraP): a biomarker analysis from a randomised, open-label, phase 2 trial. *Lancet Oncol* 2022;23:1389–97.
- [36] Gillessen S, Turco F, Davis ID, et al. Management of patients with advanced prostate cancer. Report from the 2024 Advanced Prostate Cancer Consensus Conference (APCCC). *Eur Urol* 2025;87:157–216.
- [37] Cornford P, van den Bergh RCN, Briers E, et al. EAU-EANM-ESTRO-ESUR-ISUP-SIOG guidelines on prostate cancer—2024 update. Part I: screening, diagnosis, and local treatment with curative intent. *Eur Urol* 2024;86:148–63.
- [38] Emmett L, Buteau J, Papa N, et al. The additive diagnostic value of prostate-specific membrane antigen positron emission tomography computed tomography to multiparametric magnetic resonance imaging triage in the diagnosis of prostate cancer (PRIMARY): a prospective multicentre study. *Eur Urol* 2021;80:682–9.
- [39] Emmett L, Papa N, Counter W, et al. Reproducibility and accuracy of the PRIMARY score on PSMA PET and of PI-RADS on multiparametric MRI for prostate cancer diagnosis within a real-world database. *J Nucl Med* 2024;65:94–9.
- [40] Buteau JP, Moon D, Fahey MT, et al. Clinical trial protocol for PRIMARY2: a multicentre, phase 3, randomised controlled trial investigating the additive diagnostic value of [68Ga]Ga-PSMA-11 positron emission tomography/computed tomography in men with negative or equivocal multiparametric magnetic resonance imaging for the diagnosis of clinically significant prostate cancer. *Eur Urol Oncol* 2024;7:544–52.
- [41] Jadvar H, Calais J, Fanti S, et al. Appropriate use criteria for prostate-specific membrane antigen PET imaging. *J Nucl Med* 2022;63:59–68.
- [42] Ayati N, Herrmann K, Fanti S, Murphy DG, Hofman MS. More accurate imaging is not stage migration: time to move from “hubble” to “webb” in hormone-sensitive prostate cancer. *Eur Urol* 2023;83:6–9.

- [43] Unterrainer LM, De LN, Unterrainer M, et al. Evidence-based clinical protocols to monitor efficacy of [177Lu]Lu-PSMA radiopharmaceutical therapy in metastatic castration-resistant prostate cancer using real-world data. *J Nucl Med* 2025;66:1054–60.
- [44] Hayek OE, Rais-Bahrami S, McDonald A, Galgano SJ. Stereotactic body radiation therapy salvage for lymph node recurrent prostate cancer in the era of PSMA PET Imaging. *Curr Urol Rep* 2023;24:471–6.
- [45] Francolini G, Banini M, Di Cataldo V, et al. PSMA guided approach for biochemical relapse after prostatectomy- (PSICHE) trial (NCT05022914). Detection rate and treatment decision after 68Ga-PSMA PET/CT within a prospective study. *Prostate* 2023;83:1201–6.
- [46] Ferraro DA, Rüschoff JH, Muehlemaier UJ, et al. Immunohistochemical PSMA expression patterns of primary prostate cancer tissue are associated with the detection rate of biochemical recurrence with ⁶⁸Ga-PSMA-11-PET. *Theranostics* 2020;10:6082–94.
- [47] Eiber M, Maurer T, Souvatzoglou M, et al. Evaluation of hybrid ⁶⁸Ga-PSMA Ligand PET/CT in 248 patients with biochemical recurrence after radical prostatectomy. *J Nucl Med* 2015;56:668–74.
- [48] Research4Life. 68Ga PET/CT | PET/MR – EANM EARL. <https://earl.eanm.org/68ga-pet-ct-mr/>.
- [49] Rowe SP, Pienta KJ, Pomper MG, Gorin MA. Proposal for a structured reporting system for prostate-specific membrane antigen-targeted PET imaging: PSMA-RADS version 1.0. *J Nucl Med* 2018;59:479–85.
- [50] Ceci F, Oprea-Lager DE, Emmett L, et al. E-PSMA: the EANM standardized reporting guidelines v1.0 for PSMA-PET. *Eur J Nucl Med Mol Imaging* 2021;48:1626–38.
- [51] Fanti S, Hadaschik B, Herrmann K. Proposal for systemic-therapy response-assessment criteria at the time of PSMA PET/CT imaging: the PSMA PET progression criteria. *J Nucl Med* 2020;61:678–82.
- [52] Scher HI, Morris MJ, Stadler WM, et al. Trial design and objectives for castration-resistant prostate cancer: updated recommendations from the Prostate Cancer Clinical Trials Working Group 3. *J Clin Oncol* 2016;34:1402–18.