DELPHI PANEL FOR STANDARDIZING OUTCOME MEASURES IN RADICAL PROSTATECTOMY SURGICAL CARE PATHWAY

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INTRODUCTION

The transformation of surgical practices through minimally invasive surgery (MIS) is evident, with robot-assisted surgery (RAS) marking a significant advancement. However, integrating these technologies into healthcare systems and assessing their effectiveness pose substantial challenges. A key issue is the evaluation of medical devices, particularly surgical technologies, where establishing the importance of functional outcomes is complex. Unlike pharmaceuticals interventions, which are typically assessed through randomized controlled trials (RCTs) focusing on hard clinical endpoints such as survival or disease progression, medical devices require a greater emphasis on functional outcomes, patient recovery, and quality of life. This necessitates tailored methodologies to address the clinical and economic relevance of these endpoints, presenting methodological, ethical and regulatory hurdles that complicate their incorporation into decision-making frameworks like health technology assessments (HTA). **OBJECTIVE:** This study aimed to develop a core outcome set for clinical data collection in patients undergoing radical prostatectomy, using a modified Delphi method.

METHOD

A modified Delphi study was performed involving urologists, healthcare professionals, researchers, and patient society representatives. In total 46 participants were invited to the panel. Previously, initial outcomes were identified through a literature review, which included 27 items arranged in 3 domains. Two rounds of online Delphi surveys to refine these outcomes were conducted. Panel members were asked to rate each outcome using a nine-point Likert scale (where 1 meant “not at all important” and 9 meant “very important”). Consensus was considered to have been reached when options with scores between 7 and 9 reached ≥70%.

RESULTS

In the first round of the Delphi survey, 20 (43%) specialists responded out of the 46 who were invited. The 27 items evaluated reached consensus, and the experts suggested the inclusion of 4 new items, evaluated later in the second round. At this stage, 16 specialists (35%) answered the questionnaire. All the items reached consensus, resulting in a framework with 31 items (Table 1).

Domain I - Baseline data	
Item	**% obtained in consensus**
TNM classification (staging before treatment)	100.0%
Age	100.0%
Performance status (KPS or ECOG) - assesses how the disease affects the patient's functional capacity	100.0%
Patient has other underlying diseases in addition to prostate cancer	100.0%
Urinary function prior to treatment	95.0%
Multimodal treatment perspective - e.g., patient indicated for radiotherapy and surgery (and/or chemotherapy)	94.8%
Application of the EQ-5D-5L quality of life questionnaire, a generic scale for assessing health-related quality of life	93.7%
Classification of patients into risk groups using the “D'Amico Risk Classification” or according to the guidelines of the AUA/SUO - American Urological Association/Society of Urologic Oncology	92.8%
Sexual function prior to treatment	90.0%
Race/Ethnicity	79.0%
Patient socioeconomic status (SES)	75.0%
Assessment of prostate size	73.4%
Domain II - Service Efficiency	
Item	**% obtained in consensus**
Urologist explains the disease and makes a joint decision with the patient about the stages of treatment, types of treatment, risks involved, and possible adverse events	100.0%
Total length of patient stay until hospital discharge (reduction in total length of stay)	95.0%
Measure treatment costs in order to obtain accurate cost data, calculating the actual cost of resources consumed as the patient goes through each stage of care	90.0%
Time required to define the treatment modality after confirmed diagnosis of prostate cancer	70.0%
Patient undergoes a multidisciplinary assessment (nutrition, psychology, physical therapy) after diagnosis of prostate cancer	70.0%
Total time for the surgical procedure, from the patient's arrival in the operating room to the completion of surgery	70.0%
Domain III - Clinical outcomes	
Item	**% obtained in consensus**
Occurrence of reoperation within 30 days	100.0%
Time to complete recovery of urinary continence after surgery (urine control without the need for diapers)	100.0%
Occurrence of perioperative complications according to the Clavien-Dindo scale (during surgery and in the immediate postoperative period)	100.0%
Occurrence of hospital readmission within 30 days due to postoperative complications	100.0%
Time to recover sexual potency after surgery (ability to have sexual intercourse with an erection)	100.0%
Occurrence of unplanned ICU admission in the postoperative period	100.0%
Need for blood transfusion in patients undergoing prostatectomy during and/or after the procedure	95.0%
Need for opioid use for pain control	95.0%
Patient satisfaction survey at the end of the care cycle	95.0%
Complete resection of the tumor with negative surgical margins (Negative surgical margin: focal positive ≤3mm or non-focal positive >3mm)	94.1%
Application of the EQ-5D-5L quality of life scale after treatment for comparison purposes	93.7%
Time to post-anesthetic recovery (occur within the expected time frame)	85.0%
Total time of indwelling urinary catheter use (urinary catheter)	73.4%

Table 1. Final version of the standard set of outcomes (framework) for evaluating the care of prostate cancer patients eligible for radical prostatectomy, obtained through the Delphi consensus.

CONCLUSIONS

We developed Brazil's first core outcomes set framework for patients eligible for radical prostatectomy, based on a national Delphi study involving healthcare professionals, urologists, researchers and patient advocacy groups to support consistent and comparable data collection in clinical practice and research. Next steps include validating the framework in real-world settings and expanding the methodology to other surgical procedures, thereby improving decision-making in health technology assessment and contributing to value-based care.

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