

Monitoring Quality of Care in Men Diagnosed with Prostate Cancer: Developing Consensus Quality Indicators Using Modified-Delphi Methodology

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Abstract

Objective: To develop a core set of clinical indicators to measure the quality of care provided to men with prostate cancer.

Design: A modified Delphi study involving interviews of key informants and two rounds of survey to obtain consensus on the indicator set.

Setting: Melbourne, Australia

Participants: n=20, including specialists involved in prostate cancer management (urology, radiation oncology, medical oncology, nursing, psychology, palliative care) epidemiologists, scientists, consumers and a policy advisor.

Intervention(s): A literature review was undertaken to identify potential quality indicators. Interviews were undertaken to ensure completeness of the set and explore potential for inclusion of novel indicators. Survey of Delphi panel participants was conducted to refine the list.

Main Outcome Measure(s): Items with panel agreement $\geq 60\%$ for reliability and capacity to be objectively assessed and with a median validity score of ≥ 8 (scale ranged from 1 (not important) -9 (very important)).

Results: Of the total 104 proposed indicators, the panel retained 4/20 structural indicators, 15/46 process measures and 7/37 outcome indicators.

Conclusions: Indicators that scored highly in validity, reliability and objectivity included documentation of clinical stage, PSA level at diagnosis, surgical outcomes (rates of death, wound infection/bacteraemia and positive surgical margin), traditional measures of quality-of-care (10- and 15- year clinical and/or biochemical disease-free survival) and patient assessed post-treatment function using a validated survey instrument.

Keywords: Prostatic neoplasm; Quality indicator; Delphi; Consensus; Guidelines

suggest that in 2009 this rate was as high as 172 cases per 100,000 men [1]. Prostate cancer carries a huge economic burden to society. It is the most costly cancer, with a burden more than twice that of breast cancer, and three more than lung cancer [4].

Unlike many other cancers, many patients live with prostate cancer for decades and die from unrelated causes. Australian data indicates that 92% of men diagnosed with prostate cancer are alive five years later [5]. Recently published Victorian data demonstrate that the vast majority of men (93%) are diagnosed with localised disease and three quarters have low- or intermediate-risk disease [6]. Of those with low- or intermediate-risk disease, three-quarters will seek some form of active treatment in the initial 12 months post diagnosis. Treatment may consist of active surveillance, surgery (prostatectomy), radiotherapy, brachytherapy, hormone deprivation or a combination of these. To date, there is no conclusive evidence that any one treatment holds a survival advantage over another [7].

Given the high prevalence of prostate cancer in the community, its significant economic burden, the many treatment options available and the lack of evidence showing a survival advantage among treatment modalities, increasing attention is being paid to assessing whether quality-of-care and quality-of-life outcomes vary according to treatment and providers.

Best practice guidelines have been developed to guide prostate cancer management and clinical indicators have been devised to measure how well prostate cancer care aligns with these guidelines [8-11]. Researchers in the US have led quality indicator development using a multi-step process involving literature review, focus groups with patients and family members, interviews with clinical experts and panel discussion from the fields of urology, radiation oncology, medical oncology and health services research [12]. Proposed indicators were developed against criteria such as whether the indicator (1) had strong scientific basis; (2) had good face validity; (3) could be collected from a medical record, cancer registry, validated instrument or systematically recorded data source; and (4) was likely to be reliably reported. Failure to document information about the indicator would be a marker of poor quality [12]. As a result of this work, a consensus list of 49 quality indicators were developed from which a subset of 30 were tested in 770 private and public health care settings in the US providing external beam radiotherapy and surgery [13]. This identified considerable deficits in care, particularly for men undergoing surgery.

In Australia, this US-led work on quality indicator development provided valuable information to assist in the development of

Abbreviations: PCR: Prostate Cancer Registry; PSA: Prostate Specific Antigen; EBRT: External Beam Radiation Therapy; ADT: Androgen Deprivation Therapy

Background

Prostate cancer is the most commonly diagnosed non-skin cancer among Australian males and its incidence and prevalence is growing [1]. In 2012 an estimated 18,560 new cases were diagnosed in Australia [2]. According to a study investigating trends in prostate cancer incidence across 40 countries, Australia and New Zealand had the highest age-standardised incident rate of 104 new cases per 100,000 population in 2008 [3]. More recent statistics

quality indicators for a population-based Prostate Cancer Registry (PCR). The PCR was established as a clinical quality registry to assess the impact of patient, clinician- and health service-related factors on morbidity and mortality following a diagnosis of prostate cancer [14]. The registry was developed following recognition through the state-based cancer registry that there was variation in survival following a diagnosis of prostate cancer according to regional location of diagnosis, and that reasons for this were not apparent [15].

Following a literature review and with expert input by a panel of three epidemiologists, a radiation oncologist, medical oncologist, two surgeons and a clinical pharmacologist, a set of indicators was developed: one measuring structure of the health service, six measuring processes of care and five assessing health outcomes were reviewed, as well as those developed by specialty groups. In 2012, the PCR Steering Committee determined that the initial quality indicator set ought to be more formally evaluated by a wider panel of stakeholders including clinicians, patients and scientists.

The aim of this paper is to outline the process used to develop quality indicators to measure quality and safety of prostate cancer care and detail the quality indicators selected for collection by the PCR.

Methods

Literature Review

A list of proposed variables and covariates was collated by examining the available literature. Guidelines from the United Kingdom [16], United States [17], Australia [11] and Europe [8] were reviewed.

Interviews

Purposive sampling was used to identify experts in the field of urology, medical oncology, radiation oncology, pathology, psychology and nursing and a consumer to interview to discuss existing indicators, explore potential for novel indicators and provide insight into current and future directions for management of prostate cancer. Following the literature review, semi-structured interviews were conducted using a topic guide in person and by telephone. In these interviews informants were asked to review and provide comment on the proposed draft set of indicators the panel would vote on; advise whether the Delphi panel information accompanying the survey was adequate to enable panel members to know what was expected of them; and advise whether there were areas of practice or indicators which ought to be included but which were not adequately covered with an appropriate indicator. All interviewed participants were invited to contribute to the Delphi process.

Delphi Process

Following the interviews, a panel of people with knowledge of various aspects of prostate cancer disease were invited to participate as members of a Delphi panel to anonymously assess whether the proposed indicator had good face and validity and whether data to construct the indicator could be reliably and objectively be collected from the medical record. Panel members were provided with definitions to assist them in their determination. Validity was defined as the extent to which the indicator captures an aspect of quality that is widely regarded as important and subject to health system control; reliability referred to the extent to which there was confidence in data collectors being able to consistently reproduce the data; and objectivity was defined as the extent to which data could be collected without influence/opinion of others. The invited panel members all contributed as members of an expert working

group convened to develop a national prostate cancer registry. In addition, an international leader in prostate cancer research was invited and two additional urologists who participated in the interviews. Panel members were not informed of the identity of any other members of the panel. The Delphi method was originally developed at the RAND Corporation to systematically solicit the view of experts related to national defence [18]. The Delphi technique is well recognised as a tool for solving problems in health care settings [19]. It utilises a panel of experts to gain consensus of opinion through a series of questionnaires, interspersed with feedback [20].

Two rounds of online questionnaires were conducted. Members were asked to provide de-identified responses to multi-choice questions and free-text comments developed from the reviewed guidelines, literature search and semi-structured interviews. The responses were analysed by the research group and comments from the first round were incorporated in to the second round.

Each member was asked to rate each indicator on a scale of 1-9 to evaluate whether meeting the indicator would reflect high quality-of-care or, conversely, that not meeting the indicator would reflect poor quality-of-care. The indicators' reliability and objectivity were also assessed with a yes/no/I don't know designation. A proposed indicator was considered valid if consensus was achieved, defined as a median score of 8 or above—with no disagreement according to the IPRAS (Interpercentile Range Adjusted for Symmetry), calculated with the formula provided in the RAND Appropriateness Method User's Manual [9]. An indicator with a median score of 8 or above was considered reliable and objective if the proportion of panel members who responded "yes" was more than 60%. An indicator with a median score of 8 or above, but with fewer than 60% of panel members considering it reliable or objective, was rejected.

In the free-text comment boxes, the experts were asked to provide suggestions for additional indicators and to present short justifications for a 1 or 9 rating.

Only positive outcomes and suggestions for new indicators were included in the second round, which used the same criteria for inclusion as the first round. Everyone who was sent an invitation in round one was also invited again to contribute in round two. Results were analysed by Microsoft Excel 2007 (Redmond, WA, Microsoft Corporation 2007) to calculate the median scores and IPRAS. This project was approved by the Monash University Human research Ethics Committee (LR CF12/1848 – 2012001023).

Consent

Written informed consent was provided by all participants involved in the project. A copy of the written consent is available for review by the Editor of this journal.

Results

Participation

Twenty-three people were invited to participate in the Delphi panel; of whom 20 accepted the invitation. Table 1 provides details of the specialities involved and the years of relevant experience for each group. One participant did not provide details of their experience. All participated in round one but three did not contribute to round two (85% response rate).

Results from first round

The first round presented the panel with the initial list of 104 proposed quality indicators from the literature review and expert interviews. Using a framework for classifying quality of care created

by Donabedian [21], these comprised of 20 structure, 47 process and 37 outcome measures and 8 covariates (Table 2 presents a summary with detailed description in appendix A). Structural indicators measure attributes of the settings in which care occurs, process indicators measure what is done in giving and receiving care and outcomes denote the effects of the care on the health status of patients and populations.

Indicators with a median of seven or less were excluded for re-rating in the second round. At the end of round one, six new indicators were proposed and, in total 60 indicators (13 structure, 23 process and 24 outcome measures of quality) and five covariates qualified for re-rating in the second round. Table 3 provides a summary of indicators retained and suggested for entry into round two with details of indicators provided in appendix A.

Final endorsed indicators

Using the same criteria as in round one, at the end of round two, 26 indicators and five covariates were endorsed by the panel (4 structure, 15 process and 7 outcomes measures). The final lists of indicators are displayed in Table 4. The panel retained four of the 20 proposed structural indicators (20%), 15 out of the 46 proposed process measures (33%) and seven out of 37 proposed outcome indicators (19%).

Five out of eight covariates were agreed upon to be important to control for when assessing quality of care, namely patient age and stage of disease at diagnosis (including PSA and Gleason score), family history of prostate cancer in first degree relatives, co-morbidities and use of adjuvant or neoadjuvant hormone treatment. The three exclusions were family history of prostate

cancer in second degree relatives, personal history of other cancers and health insurance coverage.

Discussion

In this study, 31 indicators were endorsed as important measures of quality and safety when assessing prostate cancer management. In total there were four structural indicators, 19 process-of-care indicators and eight outcome indicators. Indicators that scored highly in validity, reliability and objectivity included documentation of clinical stage, PSA level at diagnosis, surgical outcomes (rates of death, wound infection/bacteraemia and positive surgical margin), traditional measures of quality-of-care (10- and 15- year clinical and/or biochemical disease-free survival) and patient assessed post-treatment function using a validated survey instrument. In general, our findings are very similar to those identified by a panel of experts in the United States and reported by Spencer et al [12] in 2003. However, we identified some indicators which are perhaps more pertinent in the Australian landscape, namely variation of access to services and consequently outcomes between regional and metropolitan patients, and also positive surgical margins, which the US panel did not endorse.

With regard to the structural indicators, the Delphi panel rejected patient-volume-of-prostatectomy, volume-of-external-beam-radiotherapy and of-seed-brachytherapy as quality indicators. This is at odds with a systematic review which suggested that provider volume (both hospital and surgeon) is an acceptable surrogate measure for quality-of-care in uro-oncological procedures [10]. In explaining why the panel did not enforce volume indicators, it may reflect the heterogeneity of the group or the contradicting evidence of a volume: quality relationship across all fields of medicine. Perhaps if a specialist urological panel were convened these indicators might have been endorsed. The structural indicator receiving greatest support was "Having access to MDM [multidisciplinary team meeting] decisions and outcomes". Notwithstanding this expert support, a national audit of implementation of multidisciplinary cancer care in Australia suggested that this feature is not being applied or documented consistently [22]. Two-thirds of the 155 hospitals surveyed did not have a multidisciplinary team, and of those with one, one-quarter did not document the recommendations in the patient record.

Many panel members commented that hospital accreditation should not be included as a structural quality indicator, as the association between accreditation and quality-of-care was tenuous at best, in their view. A systematic review conducted in 2011 found insufficient evidence that external inspection to review

Specialty	N	Number of years experience in specialty area Mean, (range)
Urologist	3	13 (7,20)
Radiation oncologist	3	18 (11, 22)
Medical oncologist	2	27 (25, 30)
Nursing	2	20 (20,20)
Epidemiologist	2	14 (12,17)
Scientist	3	21 (10, 28)
Health policy advisor	1	14
Consumer	2	Not relevant
Clinical psychologist	1	9
Palliative care	1	Not stated

Table 1: Specialists involved in the Delphi Panel and years' experience in the field.

	Safe	Effective	Patient-centred	Timely	Efficient	Equitable	Total
Structure	4	2	6	1	2	5	20
Process	7	7	13	6	2	12	47
Outcome	9	8	8	0	2	10	37
TOTAL	20	16	27	7	6	27	104

Table 2: Proposed indicators included in Round 1 of the Delphi process.

	Safe	Effective	Patient-Centred	Timely	Efficient	Equitable	Total
Structure	4*	2**	3	0	1	3	13
Process	4	3	9	1	2	4	23
Outcome	4	6	5	0	0	9	24
TOTAL	12	11	17	1	3	16	60

Table 3: Indicators agreed upon after Round 1 of the Delphi process.

*Four indicators were newly proposed in Round 1 and carried into Round 2

**Two indicators were newly proposed in Round 1 and carried into Round 2

Indicator	Validity (median)	Reliability (%)	Objectivity (%)
Structure			
1. Accessibility of uro-oncology nurse	8	76.5	76.5
2. Accessibility of interpreter for patients with non-English speaking background (NESB)	8	76.5	76.5
3. MDM decisions/outcomes easily accessible on hospital records system	8	72.2	88.9
4. Availability of pathologist with specialist skills in the interpretation of biopsy/radical prostatectomy results	8	76.5	82.4
Process			
5. Documentation of clinical stage in the medical record	8	88.2	94.1
6. PSA level recorded at diagnosis	8	94.1	100
7. Evidence of adherence to the Prostate Cancer Pathology Reporting Protocol of The Royal College of Pathologists of Australasia in radical prostatectomy specimens	8	82.4	76.5
8. Use of clinical/pathological TNM staging in determining treatment	8	76.5	76.5
9. Documented assessment of voiding	8	76.5	76.5
10. Documented assessment of potency	8	70.6	76.5
11. Documented assessment of comorbidity	8	82.4	88.2
12. Documentation that patient was offered the opportunity to consult with a urologist or medical oncologist (if provider is a radiation oncologist) or with a radiation oncologist or medical oncologist (if provider is a urologist)	8	70.6	64.7
13. Documentation that side effects and complications from treatment, based on the practitioner's or facility's experience, were presented to patient	8	76.5	64.7
Indicator			
14. Use of interpreter for patients with NESB	8	70.6	70.6
15. Documentation/evidence of communication with patient's primary care physician or provider of continuing care	8	76.5	88.2
16. At least two visits for follow-up by treating clinician during the first post treatment year	8	64.7	94.1
17. Variation of treatment between regional and metropolitan patients	8	70.6	64.7
18. Access to services between regional and metropolitan patients	8	82.4	64.7
19. Access to services between public and private patients	8	70.6	64.7
Outcome			
20. Rate of in-hospital death from surgical complications	8	88.2	100
21. Acute rate of wound infection/bacteraemia post-surgery or post-biopsy	8	94.1	94.1
22. Positive margin rate after radical prostatectomy	8	88.2	88.2
23. 10- and 15-year clinical and/or biochemical disease-free survival after primary treatment by radiation therapy or radical prostatectomy	8	100	94.1
24. 15-year disease-free survival	8	100	94.1
25. Patient assessment of urinary, sexual, and bowel functioning after primary treatment by radiation therapy or radical prostatectomy, using a reliable, validated survey instrument	8	100	94.1
26. Variation in mortality between regional and metropolitan patients	8	76.5	94.1
Covariates			
	Yes (%)		
1. Patient age	100%		
2. Stage of disease at diagnosis	100%		
3. Family history of prostate cancer in first degree relatives	70.6%		
4. Charlson† index of co-morbidity	94.1%		
5. Use of neo/adjuvant hormone treatment	94.1%		

Table 4: Quality indicators endorsed by the Delphi panel to monitor prostate cancer care.

† predicts the ten-year mortality for a patient who may have a range of conditions such as heart disease, AIDS, or cancer (a total of 22 conditions). Each condition is assigned with a score of 1,2,3 or 6.

compliance with Standards had any impact on improved patient outcomes and improved healthcare organisational and professional behaviour [23]. On the other hand, access to specialist pathologists for prostate specimens was prominently endorsed with panel members citing many occasions where initial pathology reports made by non-prostate-specialist pathologists disagreed with the reviewed opinion from specialist pathologists. The rationale for including it as an indicator was that treatment decisions were largely determined on the basis of histopathological reports. This is supported in the literature with a number of studies demonstrating discordant opinion on biopsy results, especially for extra prostatic extension and surgical margins, when specialist uro-pathologists'

findings were compared with those of general pathologists [24-26]. Differences in pathological findings have been shown to translate into different treatment provided with prognostic impact. While accessibility of uro-oncology nurses and interpreters have been endorsed as important indicators, the quality of such services has been highlighted as being much more difficult to assess objectively. Similarly, while the value of MDMs was recognised, some panel members question the thoroughness of MDM discussions, particularly if they are poorly attended, or if there are large numbers of patients to be discussed.

With regard to the process indicators, documentation of each

of TNM staging, PSA and Gleason score were strongly endorsed, as expected. Other measures which had strong support assessed the quality of patient-centred care, with a large proportion of the final list focused on communication and full disclosure with the patient as well as patient-assessed baseline and post-treatment function. Equity indicators also feature prominently, with access to expertise and variations in outcomes between metropolitan versus regional patients and public versus private patients considered important when assessing quality and consistency-of-care. Studies have shown that patient-centred care is important in decision preparation, satisfaction and regret, by using appropriate language and formats for communication, fully preparing patients for tests and treatments and meeting the patients' needs for involvement in decision-making [27-29]. A review of patient decision making for localised prostate cancer found that the physician's recommendation plays a significant role in influencing the patient's choice of management and that most men will select the first treatment recommended to them. It may be that that other modalities are not discussed fully [30].

Of the eight retained outcome indicators, three are confined to patients undergoing radical prostatectomy (indicators 24, 25 and 26). There was a high level of support for documentation/assessment of longer term survival and disease recurrence, in keeping with increasing survival and hence increasing likelihood of recurrence in light of new technologies and treatment regimens. Assessment of post-treatment urinary, bowel and sexual function with a validated survey instrument was strongly supported, but patient satisfaction with those functions and treatment choice were not. Patient satisfaction was cited as too variable depending on how and when they are asked and their variable interpretation on what constituted success in the view of our panel. Furthermore, panel members raised the concern that these measures are influenced by other competing health risks and could act as a confounder and would not be directly attributable to the treatment toxicities.

Well-documented limitations of a Delphi process apply to our study: Delphi panels are not random and may not be representative of the expert groups included; there is no evidence of reliability of the results; and the existence of consensus does not mean that the correct answer has been found. Limitations of our particular study include the very lengthy round one questionnaire and comments being conveyed by proxy through round two instead of in person. One panellist did not complete round one of the survey due to the questionnaire length. Round one was necessarily long, as to include as many potential indicators as possible. Three panel members who contributed in round one did not contribute in round two. Future researchers could consider focus groups to eliminate certain measures before the questionnaire process if a long list is collated after the literature review.

Participants were not exposed to all controversial issues or general comments after round one, although all were informed indirectly through the round two surveys by the addition of new indicators and modifications of existing indicators. Had focus groups been conducted to discuss clinical indicators which were the subject of contention in more depth, some indicators ruled out may have been retained. A literature review to identify all quality indicators was performed using only the MEDLINE database. Further exploration on other databases, and a more specified search strategy may have identified further novel indicators that were not included in the initial process. Finally, since the indicators were developed new guidelines have been released and contemporary recommendations were not included in the proposed indicator set. These included recommendations relating to pre-biopsy and T and N staging imaging, management of an initial negative biopsy, active

surveillance, the most effective radical prostatectomy method, combination of methods including EBRT and brachytherapy, and ADT and EBRT, ADT delivery and management of ADT side effects [31]. These updated recommendations highlight the need for quality indicators to be reviewed and updated on a regular basis to ensure they remain contemporary and relevant.

Conclusion

Through this project we have identified that the indicators originally selected for inclusion in the PCR remain relevant and important when assessed by a wider stakeholder group. The addition of 20 new indicators will provide a challenge to collect, and for this reason further work is required to quantify both the economic and data collection burden associated with these proposed indicators. However, if collection of the indicators translates to meaningful improvement in both quality of care and quality of life for men with prostate cancer, then this burden should be surmountable.

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