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Prostate cancer

Development of quality indicators to monitor radiotherapy care for men with prostate cancer: A modified Delphi method

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ABSTRACT

Background and purpose: Quality indicators (QIs) have been developed for many aspects of prostate cancer care, but are under-developed with regard to radiotherapy treatment. We aimed to develop a valid, relevant and feasible set of core QIs to measure quality of radiotherapy care in men with prostate cancer.
Materials and methods: We used a RAND-modified Delphi process to select QIs that were regarded as both important and feasible measures of quality radiotherapy care. This involved two phases: (1) a literature review to identify a list of proposed QIs; and (2) a QI selection process by an expert panel (n = 12) conducted in a series of three rounds: two online questionnaires' and one face-to-face meeting. The RAND criterion identified variation in ratings and determined the level of agreement after each round of voting.
Results: A total of 144 candidate QIs, which included measures from pre-treatment to post-treatment and survivorship care were identified. After three rounds of voting, the panel approved a comprehensive set of 17 QIs, with most assessing a process of care (n = 16, 94.1%) and the remaining assessing a health outcome.
Conclusion: This study developed a core set of 17 QIs which will be used to report from the Prostate Cancer Outcomes Registry-Australia & New Zealand, to monitor the quality of radiotherapy care prostate cancer patients receive.
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The delivery of quality care has been recognised as an indispensable aspect of the healthcare system and important in achieving optimal health outcomes [1,2]. Best-practice guidelines distil evidence and provide recommendations to support clinicians on how quality care ought to be delivered. However, publishing guidelines do not ensure adherence, and suboptimal practice has been observed [3,4].

Quality indicators (QIs) derived from best-practice guidelines allow for standards of healthcare to be assessed, benchmarked and ultimately improved within and between providers [5].

Donabedian proposed a conceptual model which proposes that information about quality of care can be categorised according to a framework assessing healthcare structures, processes and outcomes [6]. Further to this, the Institute of Medicine proposed that quality of care is best assessed according to whether it is effective, efficient, accessible, patient-centred, equitable, and safe [7].

The Prostate Cancer Outcome Registry-Australia and New Zealand (PCOR-ANZ) was developed in 2012 as a clinical quality registry. In 2015 a set of QIs were agreed upon for reporting from the registry, based on the dataset for the national registry and following a review of existing published prostate cancer (CaP) QIs and evidence-based guidelines [8]. Despite 22% of men with localised disease receiving radiotherapy as monotherapy [9], the initial set failed to capture radiotherapy-specific QIs, limited by the sparse radiotherapy data fields in the dataset [8].

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In 2017, PCOR-ANZ developed capacity to import data fields from two large commercial radiotherapy information technology platforms, expanding the options available for the registry to develop radiotherapy-specific CaP QIs. This study was undertaken to develop consensus on a set of radiotherapy QIs which PCOR-ANZ could use to monitor quality of care.

Methods

A RAND-modified Delphi process was selected to identify and define radiotherapy focused QIs, combining evidence from guidelines with expert opinion [10]. This method has been widely used in the development of QIs across the field of healthcare [8,11,12]. The development process involved two phases: (1) Identifying a list of proposed QIs through a literature review and (2) the indicator selection process, conducted in a series of three rounds.

The principles guiding indicator selection were to select: (1) valid and important measures of radiotherapy care which are reflective of quality; (2) indicators spanning the continuum of CaP care (from pre-treatment to post-treatment and survivorship care); and (3) indicators with linkage to supporting high quality evidence or, in the case of novel indicators, to strong overarching consensus.

Delphi panel members

A panel of content experts contributed to the indicator selection process. The panel comprised of radiation oncologists who were either the nominated clinical leaders of the PCOR-ANZ Steering Committee within their jurisdiction and endorsed by the Royal Australian and New Zealand College of Radiologists (RANZCR), or were nominated by the urologist clinical leader on the PCOR-ANZ Steering Committee. One urologist clinical leader from the PCOR-ANZ Steering Committee was invited to participate on the panel to provide an overall perspective and to provide expert advice on proposed QIs that had a surgical component. To be eligible, all clinicians were required to be currently practicing and treating patients with CaP, registered with the Australian Health Professionals Regulation Authority, and actively involved in CaP research.

Phase 1: Literature review

Step 1. Developing a list of proposed indicators

International guidelines relevant to CaP or radiotherapy were reviewed to identify evidence-based recommendations. The guidelines included seven European [13–19], five Australasian [20–24], two Asian [25,26] and five American publications [27–31]. The OVID Medline database was searched to identify literature containing existing QIs relevant to CaP and radiotherapy care developed by research groups. Guideline recommendations were converted to quantitative QIs with proposed numerators and denominators developed by three authors (ET, JM, SE). Pre-assessment of the proposed QIs was conducted, and any indicators determined not measureable or quantifiable were removed.

Step 2. Development of supplementary material to assist panellists

A supplementary document was created to assist panellists in making an informed decision when selecting QIs. Indicators were stratified into structure, process and outcome quality domains [6] and then further categorised into the Institute of Medicine's dimensions of healthcare [7]. The grade of evidence was recorded for each proposed QI. To accommodate for the different grading systems between guidelines, the grade of evidence was standardised and categorised by the reviewer ET (A, B, C, D, or 'no grade listed') and is listed in Appendix A. In situations where the grade of evidence differed between guidelines for the same indicator, the highest grade was selected.

Phase 2: Development of quality indicators

Step 3. Round one voting

Panellists were asked to use the supplementary document to assist in rating each proposed indicator on a Likert scale of 1–9 (1 = not important and 9 = very important) according to how important the indicator was in measuring quality of radiotherapy care and its association with improved patient outcomes. Indicators were presented in chronological order in terms of management – Pre-treatment; Treatment; Salvage treatment; Post-treatment/ Outcomes; and Information and Support. Panel members had the option in round one of not voting if the indicator was not within their expertise or they had difficulty understanding it. Panellists were also welcome to suggest QIs to be considered in round two of voting. Panellists were given 10 days to complete the round one voting process.

Step 4. Data analysis of round one voting and preparation for round two

Data were analysed according to the RAND criteria [10], and a traffic light system of *green*, *amber*, and *red* classified each indicator by their Median score (M) and Disagreement Index (DI), described in Table 1. The RAND DI quantified the level of disagreement between panellists for each of the indicators, with a lower score indicating a higher degree of agreement, and a DI $\geq$ 1 indicating disagreement. Indictors were colour coded as green if they were considered highly important (M $\geq$ 8) with little disagreement among panel members (DI < 0.75). Where panellists selected 'unable to comment' this was considered a null vote and the denominator was adjusted accordingly.

Step 5. Round two face-to-face meeting

Considering the Delphi method is an iterative process, results from the first round informed the key points of discussion and rating in the subsequent face-to-face round. All proposed indicators were discussed and addressed in isolation at this meeting, even if there was agreement in round one determining the QIs' inclusion or exclusion. At the end of each section panellists re-rated the importance for all indicators. Panellists were also asked to score the feasibility of collecting the data required to construct the numerator and denominator for the indicator, using the same Likert scale (1–9). As with round one, panellists were invited to nominate new indicators in round two. Inclusion, exclusion and the need for further discussion of each indicator was reviewed and confirmed during this round.

Step 6. Data analysis of round two voting and final confirmation

Provision existed for a third round of online voting on residual concerns or issues relating to proposed QIs. Panellists were given the opportunity to review the set of indicators after the second and third round of voting, along with their definition of numerators and denominators for final confirmation of the QI set.

Table 1
The criteria for indicator classification after round one voting.

Median	1–5.5	6–7.5	8–9
Agreement DI $\leq$ 0.75	Excluded (Red)	To be discussed (Amber)	Included (Green)
Disagreement DI > 0.75	To be discussed (Amber)	To be discussed (Amber)	To be discussed (Amber)

DI: Disagreement Index.

Results

In total, 13 panel members were invited to participate in the study and 12 accepted the invitation. Table 2 outlines the relevant experience and treatment setting of the specialists involved. Each panellist completed the three rounds of voting.

144 proposed indicators were presented in the round one survey, including 114 derived from the review of international guidelines and 30 identified from previously developed indicators sourced from the literature.

The RAND criteria ($M \geq 8$ and $DI \leq 0.75$) identified 38 *green* indicators considered as being important QIs; most monitored quality of care at diagnosis ($n = 17$, 44.7%) and health outcomes ($n = 4$, 36.8%). There was consensus that three indicators were not important ($M \leq 5.5$ and $DI \leq 0.75$). There were 103 *amber* indicators where panellists remained in disagreement about the importance of the proposed indicator.

For round two, a face-to-face meeting was held in Melbourne, 2017, with nine panellists attending and three participating by teleconference. There were 19 indicators determined to be important with no or low disagreement at the end of round two discussion. However, the panel only agreed that 17 of the 19 were feasible to collect ($M \geq 7.5$ and $DI \leq 0.75$). The panel voted to spilt one proposed indicator into two indicators (indicators 2.3 & 2.4) and a new indicator was suggested (indicator 4.2).

The panel modified the wording to provide clarity to a number of proposed QIs and collapsed others considered duplicative. Where indicators required that men be categorised according to their risk of disease progression ($n = 5$, 29.4%), the panel agreed to use the National Comprehensive Consortium Network (NCCN) risk groups, given that the PCOR-ANZ used this model.

Round three was undertaken to provide clarity on one indicator which demonstrated disagreement of its importance ($DI = 2.54$) after round two of voting. Opinions dispersed about the length of time that Androgen Deprivation Therapy (ADT) should be administered post treatment (indicator 2.7, table 3). The third round of voting resolved dispersion of opinion and resulted in the inclusion of this indicator.

Of the 144 proposed QIs, the panel approved a consensus set of 17 (11.8%) (Table 3). Most assessed a process of care ($n = 16$, 94.1%) with the remaining indicator assessing a health outcome. Indicators assessing processes at diagnosis ($n = 5$) and treatment ($n = 8$) were the most prevalent. No QIs were included from the support and information section because the panel felt it would be infeasible to collect information on these indicators at a population level. Fig. 1 displays the distribution and progression of QIs. A full list of proposed QIs and their relevant scoring is outlined in Appendix B.

Table 2
The experience and treatment setting of specialists involved in the Delphi panel.

Characteristic		Mean	(Range)
Experience	No. prostate cancer patients treated annually	95.5	(30, 200)
	Years of experience treating prostate cancer	15.8	(7, 30)
Characteristic		*N*	%
Brachytherapy	Currently performs brachytherapy	2	16.7
	Brachytherapy training	5	41.7
Treatment setting	Public	5	41.7
	Both Private & Public	7	58.3
	Metropolitan	3	25
	Rural / Regional	3	25
	Both Metropolitan & Rural / Regional	6	50

Discussion

Through a modified Delphi process, consensus was reached on a comprehensive set of 17 QIs endorsed as valid and assessing important aspects of radiotherapy care. The set of QIs are inclusive of all stages of CaP management – from diagnosis to treatment outcomes and follow up care – and monitors all forms of radiotherapy used in primary and salvage settings. It is overwhelmingly comprised of process-of-care indicators, with only one outcome indicator included, monitoring patient reported disease-specific quality of life. Although structure indicators formed part of the proposed set and are relatively easy to measure, the Delphi panel did not endorse any for collection, failing to support their association with improved quality of care and outcomes. This view supports that of Hayman that the association between structural indicators and quality is often inferred rather than proven [32].

The introduction of new radiotherapy technologies requires monitoring of quality and safety standards [33]. Due to older planning and imaging techniques still being delivered, a number of technical parameters of treatment were nominated by the panel ($n = 4$, 23.5%) to encourage use of contemporary radiotherapy techniques. These included metrics of the recommended prescription dosage, and the use of contemporary EBRT techniques such as Intensity Modulated Radiation Therapy (IMRT), Volumetric Arc Therapy (VMAT) and daily Image-Guided Radiation Therapy (IGRT).

The panel recognised daily IGRT as a better care process than older imaging techniques, such as bone matching, as daily IGRT using fiducial markers, CT or MRI imaging can increase the agreement between the planned and delivered dosage [34].

Discourse surrounding the length of ADT in high-risk patients undergoing EBRT led to a third round of voting. While there was agreement that this group of men should receive a long course (18–36 months) of ADT, the most practical way to measure this indicator was to document if ADT was ongoing at 12 months post treatment. This indicator belonged to a sub-set containing eight other QIs with a range of recommendations. The NCCN and European Association of Urology (EAU) recommend that patients with high-risk CaP receive ADT with radiotherapy [13,27]. In a population study from 2003 to 2009, it was found that adherence to this recommendation was sub optimal and decreased over time (75% and 58% respectively) [35]. This is despite evidence from a number of recent randomised controlled trials indicating that using radiotherapy and ADT in men with high-risk CaP offers a survival advantage when compared with radiotherapy as monotherapy [36–38]. The panel agreed with the current available evidence, and reached a consensus endorsing the indicators' inclusion.

Although not identified in international guidelines or the literature, panellists acknowledged the relationship between continuity of care and improved clinical outcomes and agreed that men required at least one consultation visit within the 12 months following completion of treatment. CaP care can be transferred to the general practitioner (GP) in an effort to reduce the workload in specialist care, reduce health costs and increase the accessibility of follow up care [39]. However, a recognised risk in this model is that GPs may not identify radiotherapy-specific adverse events or understand how to address recognised post treatment complications. It was determined that delivering high quality care does not cease when treatment is completed. Therefore, the proportion of men with CaP who received radiotherapy who had a follow up appointment with their treating radiation oncologist will be assessed and its correlation to quality of life will be monitored.

Similar to indicators previously developed by PCOR-ANZ, a comprehensive disease specific quality of life measure – the Extended Prostate Index Composite-26 (EPIC-26) [40], collected

Table 3
Summary of the final set of quality indicators after two rounds of voting.

No.	Quality indicator	Evidence level	Guideline/Reference	Dimension	Domain	Importance		Importance		Feasibility	
						M	DI	M	DI	M	DI
1. Pre-treatment/diagnosis						Round 1		Round 2			
1.1	Documentation of PSA level in pre-treatment assessment	Grade B (2A) & Delphi	Litwin et al. (2000) Spencer et al. (2003) Danielson et al. (2012) National Comprehensive Cancer Network 2017	Effective	Process	9	0.13	9	0.75	9	0.13
1.2	Documentation should include the clinical stage of the tumour (cT)*	No grade listed	Optimal Care Pathway for men with prostate cancer 2015	Effective	Process	8.5	0.69	9	0	9	0.13
1.3	Documentation of Gleason primary grade and secondary/tertiary grade**	Grade A & Delphi	European Society of Medical Oncology 2015 Litwin et al. (2000) Spencer et al. (2003) Danielson et al. (2012)	Effective	Process	9	0.12	9	0	9	0
1.4	Documentation of risk specific staging investigations in men with high risk localised CaP+	Grade A	European Society of Medical Oncology 2015, European Association of Urology 2015, National Cancer Control Program 2015 New Zealand Prostate Cancer Taskforce 2013	Equitable	Process	8.5	0.27	9	0	9	0.13
1.5	Documentation of TNM staging in pre-treatment assessment	Delphi	Danielson et al. (2012)	Effective	Process	8	0.97	9	0	9	0.13
2. Treatment						Round 1		Round 2			
2.1	Men with high risk localised CaP receiving active local treatment +	Grade A	Belgian Heath Care Knowledge Centre 2014	Effective	Process	8	2.02	9	0	9	0.29
2.2	Men undergoing EBRT standard conventional fractionation (1.8–2 Gy per fraction) should receive a dose of ≥74 Gy to the prostate	Grade A	European Association of Urology 2015 National Institute for Health and Care Excellence 2016 Belgian Heath Care Knowledge Centre 2014	Effective	Process	9	0.13	9	0	9	0.12
2.3^	(1) Men undergoing EBRT should receive contemporary techniques of IMRT/VMAT	No grade listed	New Zealand Prostate Cancer Taskforce 2013	Effective	Process	9	0.27	9	0	9	0.26
2.4	(2) Men undergoing EBRT, should have daily image guidance (IGRT), using either fiducial markers or (CT/ MRI) imaging			Effective	Process						
2.5	Men with high risk localised CaP should not receive low dose rate brachytherapy as monotherapy +	No grade listed	National Institute for Health and Care Excellence 2016	Effective	Process	8	1.56	9	0.66	8	0.75
2.6	Men undergoing low dose rate brachytherapy as monotherapy, should receive a recommended prescription dose of 144–145 Gy using Iodine 125	No grade listed	National Cancer Centre Singapore (Hong Gee Sim et al.) 2013	Effective	Process	8	0.29	9	0.13	8.5	0.69
2.7	Men with low-risk CaP undergoing EBRT should not receive ADT ++	Grade C	National Comprehensive Cancer Network 2017 National Cancer Control Programme 2015	Safe	Process	8	0.69	9	0.13	8	0.75
2.8	Men with high risk CaP undergoing EBRT should be on ongoing ADT at 12 months post treatment +	Grade A	European Society of Medical Oncology 2015	Effective	Process	7.5	1.05	9	2.54	8	0.47
3. Salvage treatment						Round 1		Round 2			
3.1	Men with disease progression and absence of metastatic disease (M1) post RP, should receive salvage RT	Grade C	American Urological Association 2013 Nag et al. (2016)	Effective	Process	8	0.13	9	0.13	7.5	0.47
4. Post-treatment/treatment outcomes						Round 1		Round 2			
4.1	Documentation of PSA taken within 12 months post RT (EBRT, BT)	No grade listed	National Cancer Institute 2016 National Institute for Health and Care Excellence 2016	Effective	Process	8	0.27	9	0	9	0.13

(*continued on next page*)

Table 3 (*continued*)

No.	Quality indicator	Evidence level	Guideline/Reference	Dimension	Domain	Importance		Importance		Feasibility	
						M	DI	M	DI	M	DI
4.2	Patient is seen in clinic for follow-up assessment within 12 months post treatment	*New indicator developed by panel*		Patient-centred / Effective	Process						
4.3	Assessment of disease-specific quality of life at 12 months post RT/BT using a validated instrument	No grade listed	Nag et al. (2016) Quality of life assessing urinary function (incontinence and obstruction), urinary bother, bowel function, sexual function and impact of hormones using the EPIC 26 [40] instrument	Patient-centred	Outcome	7	0.49	9	0.13	7.5	0.75
Total = 17 Quality indicators											

*Clinical T is defined as physical examination, imaging, endoscopy and biochemical tests (UICC 8th edition); **This is the information required to derive to Gleason score and the ISUP grade grouping; †High risk prostate cancer definition: T3a, N0, M0 or PSA > 20 ng/m or GS 8–10 (NCCN); ††Low Risk prostate cancer definition: T1c-T2a, N0, M0 and GS $\leq$6 and PSA < 10 ng/mL; ^Indicator split into two separate indicators. BT: Brachytherapy; CaP: Prostate Cancer; CT: Computed Tomography; DI: Disagreement Index; EBRT: External Beam Radiotherapy; CaP: Prostate Cancer; IGRT: Image-Guided Radiotherapy; IMRT: Intensity Modulated Radiotherapy; MRI: M: Median; Magnetic Resonance Imaging; PSA: Prostate Specific Antigen; RP: Radical Prostatectomy; RT: Radiotherapy; TNM: Tumour, Node Metastases; VMAT: Volumetric Arc Therapy.

as a patient reported outcome measure (PROM), forms part of our final set. Other measures to assess patients' perceptions of the support, information and care they receive were not endorsed for collection by the panel. While there was recognition of the importance of patient-centred QIs, this was shrouded by concerns regarding the feasibility of routine data collection such as inadequate infrastructure, ambiguity and difficulty in quantifying abstract concepts, and validity in measuring quality. There is strong evidence that PROMs can improve patient satisfaction and patient-provider communication if they are well-implemented [41]. There is also emerging evidence that ongoing collection and feedback of PROMs to healthcare providers can provide a survival benefit to cancer sufferers [42]. Considering this, further research is required to examine how these patient-reported-outcome and -experience measures might be incorporated into routine data collection and incorporated into future QI reports.

Three indicators classified as important measures of quality for radiotherapy were omitted from the final core set due to issues persisting on the feasibility of data collection at a population level. Documenting pre-treatment disease-specific quality of life would provide a valuable comparison to 12 months post radiotherapy. Similarly, the measurement of patient satisfaction with treatment choice was determined an additional burden on both the patient and provider and there was consensus it will not be feasible to collect.

Due to the complexity of CaP and the varying treatment options, there is evidence that multidisciplinary team (MDT) meetings positively impact the management and assessment of cancer patients [43]. While endorsing MDT discussions could provide an incentive to change and improve practice, the panel questioned the feasibility of accurately collecting the information required to develop the indicator and the absence of a universal method for defining MDT meetings. As a result, the indicator was determined not currently feasible to collect and report on in an Australian and New Zealand context. The three indicators will require future investigations to understand how the data are (or can be) captured, and the contribution required from the service provider to increase their feasibility.

There are a number of limitations to our study. Our literature search was restricted to OVID Medline and may have failed to identify all existing QIs. Risk of omitting indicators was mitigated by the expertise of the panel who were given the opportunity to suggest additional indicators and were likely to be familiar with the relevant literature.

Secondly, while the Delphi panel was purposively limited in number and the majority of panellists were radiation oncologists, the lack of a multidisciplinary panel for the development of indicators may mean opinions were dominated by a narrower view. We acknowledge that other radiation oncologists, urologists and surgeons may have opposing views and that these QIs do not necessarily represent uniform consensus across all radiation oncologists. Notwithstanding these limitations, the benefit of having a panel who are radiotherapy content experts is that there is robust discussion of indicators assessing technical decisions and aspects of treatment. It is noteworthy that panel members represented each Australian jurisdiction and practiced in public/private and regional/rural settings.

These QIs were developed with the intention of being implemented in Australia and New Zealand. While quality indicators were identified from numerous international guidelines, it may be that a Delphi panel comprising members from other geographic regions may have prioritised indicators differently. However, even though health systems are heterogeneous, the challenges and needs of patients and providers across countries are likely to be similar.

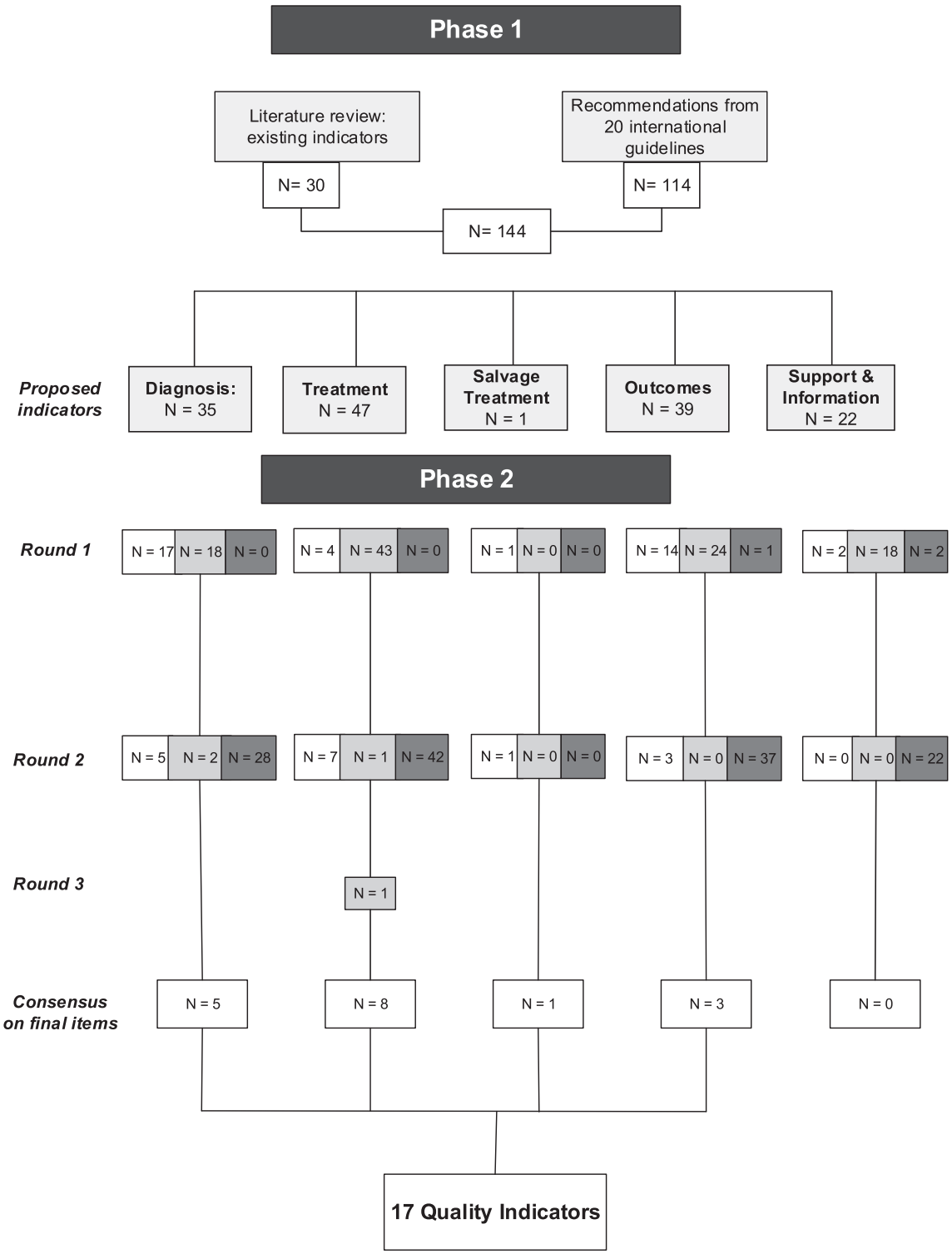

Fig. 1. Flow diagram of the development of quality indicators from Phase 1 (Literature Review), through to Phase 2 (Rounds 1–3 voting on quality indicators). Consensus that they are important/feasible; Disagreement as to whether the indicators are important or not; Consensus that indicators are not important/feasible

The strength of this research is that a comprehensive and contemporary indicator set could be proposed because, unlike earlier research to develop indicators, we did not impose dataset restrictions. This aided identification of the most important and valid indicators of quality, not just those that were feasible to collect.

We anticipate that the consensus QIs will be used for routine benchmarking of clinicians and providers around Australia and New Zealand. By providing ongoing feedback in a quality improvement cycle, it is expected to influence decision-making and identify potential initiatives to improve areas of poorer quality. Future research will assess the quality of data required to develop these indictors in radiotherapy centres, and will explore how to collect the three indicators which the panel found important but not currently feasible to collect. In addition, future indicators of quality care should incorporate aspects of care that are most important to patients. By addressing these factors, we can ensure that the care we are providing is regarded as high quality according to both patients and clinicians.

Conflict of interest disclosure

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.radonc.2018.04.017.

Appendix B. Supplementary data

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