# National consensus quality indicators to assess quality of care for active surveillance in low-risk prostate cancer: An evidence-informed, modified Delphi survey of Canadian urologists/radiation oncologists

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## Abstract

**Introduction:** Although many low-risk prostate cancer (PCa) patients worldwide currently receive active surveillance (AS), adherence to clinical guidelines on AS and variations in care at the population level remain poorly understood. We sought to develop system-level quality indicators (QIs) and performance measures for benchmarking the quality of care during AS.

**Methods:** Convenience sampling methods were used to identify an expert panel among practicing urologists and radiation oncologists across Canada. QI development involved two phases: 1) proposed QIs were identified through a literature search and published clinical guidelines on AS; and 2) indicators were selected through a modified Delphi process during which each panelist independently rated each indicator based on clinical importance. QI items were chosen as appropriate measures for quality of AS care if they met prespecified criteria (disagreement index <1 and median importance of ≥7 on a nine-point scale).

**Results:** Among 42 invited expert panel members, the response rate was 45% (n=19). Expert panel members were well-represented by type of physician (84% urologists, 16% radiation oncologists) and practice setting (79% academic, 21% non-academic). The expert panel endorsed 20 of 27 potential indicators as appropriate for measuring quality of AS care.

**Conclusions:** We developed a set of QIs to measure AS care using published guidelines and clinical experts. Use of the indicators will be assessed for feasibility in healthcare databases. Reporting quality of care with these AS indicators may enhance adherence, reduce variation in care, and improve patient outcomes among low-risk PCa patients on AS.

## Introduction

At diagnosis, most Canadian men have localized prostate cancer (PCa), with 40–60% harboring low-risk, indolent tumors that will either take many years to manifest aggressive disease or will never require treatment.[1-3] Active surveillance (AS) has emerged as a management strategy for low-risk PCa. Recent studies suggest growing acceptance of AS worldwide, with data from population studies reporting 49–74% AS uptake from 2011–2014.[4-6]

The first quality indicators (QIs) for PCa were developed over a decade ago by investigators at the Research ANd Development (RAND) Corporation, and have subsequently been used to demonstrate widespread variation in the quality of early-stage PCa care.[7-9] The RAND QIs focused on PCa care broadly and were not specific to AS. A separate study from Michigan examined the frequency of followup prostate-specific antigen (PSA) testing and prostate biopsy among men treated with AS.[10] One recently published commentary proposed six quality measures that include four pertaining to initial selection phase and two to the surveillance phase.[11] Although potentially useful, this study has several limitations; it does not include all relevant processes of AS care measures, features no structures of care or outcomes based measures, and did not go through a formal development process. Another study used a modified Delphi approach to develop a practical guide for initial patient selection for AS.[12] This study used a formal QI development process; however, the study focused only on criteria for initial AS selection. Importantly, no study has formally developed and validated QIs to evaluate the quality of care in the AS population.

Substantial variation in quality of care among AS patients, specifically during AS followup (e.g., timing of confirmatory biopsy and followup biopsies after diagnosis, urologist followup during AS, digital rectal exam [DRE] and PSA measurement) across Canada and elsewhere,[11,13] suggest gaps in quality of care. To close the gaps, quality of care in

AS needs to be measured before it can be monitored and improved. Previous QIs were targeted mostly for curative intervention (i.e., radiation therapy, radical prostatectomy, or brachytherapy) in low-risk PCa and often do not apply to AS. Additionally, the feasibility of measuring QIs using large administrative databases, which provide insights at a broad healthcare system level, has not been shown. Further, it is presently unclear how often patients receive high-quality AS care in community settings (almost all published data come from academic centers), yet the majority of AS occurs in community settings. Therefore, there is significant interest in developing system-level QIs and performance measures for benchmarking the quality of healthcare patients are receiving during AS followup.

The purpose of this study was to employ rigorous methods to develop QIs for AS in low-risk PCa.

## Methods

### Overall approach

To generate national consensus about QIs for AS in low-risk PCa, we used a modified Delphi technique — a methodologically rigorous way to review and synthesize the evidence with a consensus-based approach to inform clinical decision-making.[14] The development processes involved two phases: 1) proposed QIs were identified from a literature search and published clinical guidelines on AS; and (2) the indicator selection process, conducted in two Delphi rounds.

### Phase 1: Literature review, framework, and proposed list of QIs

#### *Information sources*

A search of published literature was performed with the aid of a medical librarian using the following terms (exp "Prostate cancer" [Mesh] OR "Prostate Neoplasms" OR "Prostate malignancy") AND (exp "Quality indicators" or "Quality of care" or "Health Care"), from literature published between January 2005 and September 2019 (Medline, Embase, CINAHL, and the Cochrane Library). We identified published QIs in AS or general PCa treatment (Supplementary Fig 1; available in the Appendix at *cuaj.ca*). We also searched existing clinical guidelines on AS from published literature and professional network recommendations,[15] and searched AS eligibility criteria, patient and tumor characteristics, surveillance protocol during followup, triggers for curative treatment, long-term oncological outcomes, and key predictor variables that play a role in initial selection or discontinuation of AS.[16,17]

#### *Framework for identifying potential QIs in AS*

The foundation for quality assessment is based on the structure-process-outcome paradigm by Donabedian.[18] Wang et al published a quality-of-care framework in urological cancers that suggests ideal QIs need to incorporate a combination of structural, process, and outcome indicators determined by each procedure.[19] We also followed the framework of Birkmeyer et al and Miller et al for quality assessment and selection of QIs based on risk of procedure and volume of cases.[19,20]

#### *Proposed list of AS-specific QIs*

Based on the literature search, the RAND study,[13,21] and key guidelines (e.g., Cancer Care Ontario [CCO],[15] National Institute for Heath and Care Excellent[22]), we proposed an AS-specific set of QIs.[16] After an initial list of possible QIs was generated, we consulted with clinical leaders in PCa and AS from the Princess Margaret Cancer Centre (PM) and also considered broader theoretical concepts on QIs, then proposed possible AS-specific QIs by category. Several factors may affect the use of initial AS and discontinuation with change in risk status after initial diagnosis (i.e., age, PSA, and Gleason score at diagnosis; comorbidity status prior to diagnosis) that are important to adjust for when measuring quality of care at a health-system level.[23] These key predictors/explanatory covariates were selected based on published AS cohort studies or guidelines.[16,17]

#### *Selection of the Delphi expert panel members*

Individuals were eligible as panelists if they were practicing urologists or radiation oncologists from any province in Canada. We excluded any physician who was no longer registered with the regulatory body or doctors with concerns or pending discipline hearings. We followed convenience sampling methods, with multiple considerations, such as currently managing patients on AS, reachable, type of practice, and prior participation in PCa studies. With n=42 potential panelists, we anticipated 12–18 specialists (urologists/radiation oncologists) who would respond and agree to participate in this study.[24,25] A prior systematic review study stated that 8–12 expert panel members are appropriate to minimize errors and maximize reliability.[26] A final list of expert panel members was identified.

### Phase 2: Selection of QIs

#### *Pilot testing*

We pilot tested the potential QIs among five urologists and senior uro-oncology fellows at PM who were not members of the expert panel. We gathered information regarding the clarity of each proposed indicator, burden of data collection, and length and ease of survey completion. We modified the wording of QIs, layout of the Delphi questionnaire, the online QI rating form, and supplemental materials prepared for the expert panel based on feedback from pilot testing.

### *Rating of QIs by the expert panel using modified Delphi process*

The list of proposed QIs was presented to the expert panel to establish consensus on importance of these QIs to patients' quality of care at the population level. We measured the panel's rating of each indicator using a nine-item importance rating scale and disagreement index (DI) (details in supplementary Tables 1, 2; available in the Appendix at *cuaj.ca*). A low DI (<1) indicates a better level of consensus, whereas DI ≥1 indicates extreme variation in ratings. Consensus refers to QIs with ratings by the expert panel of ≥7 on the importance scale and a DI <1.[27] We used the 90$^{th}$ percentile for the upper interpercentile range (IPR) and the 10$^{th}$ percentile as the lower IPR for DI calculations to account for expected variabilities of expert panel responses. The expert panel was able to suggest modifications to proposed QIs or propose new indicators.

### Delphi first round

We sent expert panel members the rating form, a list of indicators, definitions of terms, and instructions for rating. Two followup emails were sent to non-responders two weeks apart. After receiving first-round rating scores for QIs, ratings were entered into a database and responses were analyzed. Then, thematic analysis of comments to modify or change any QIs was performed. We defined consensus to retain QIs as a median score of at least 7 on the Likert scale (1–9) and DI <1.

### Delphi second round

For the second round, the summary results from the first round of the modified Delphi (including frequency of each rating per indicator, individual's own ratings, percentage of agreement scores, DI scores for each indicators, and list of accepted indicators), along with a summary of the comments were shared with members of the expert panel for a second round of rating. Uncertain indicators or newly proposed indicators from the first round were modified and key recommendations were added before resubmitting to the expert panel. The expert panel was then asked to re-rank each QI that did not achieve consensus (<7 on the importance scale and DI <1) in the first round using the same nine-point Likert scale. A similar approach was followed for data analysis as the first round to accept or reject individual QIs. The same approach was used for key predictors/explanatory variables. All expert panel members (n=19) responded to the second round of the survey.

## Results

### Participants

Among 42 invited expert panel members, two could not be reached and 19 of the remainder (45%) agreed to participate in the modified Delphi process. Panel members were well-represented by type of physician (n=16 [84%] urologists, n=3 [16%] radiation oncologists) and practice setting (n=15 [79%] academic, n=4 [21%] non-academic). The expert panel had representation from five of 10 Canadian provinces (British Columbia n=1; Alberta n=2; Ontario n=10; Quebec n=5; and Newfoundland n=1) (Supplementary Table 3; available in the Appendix at *cuaj.ca*).

On the initial round, out of 27 indicators identified, the expert panel endorsed 20 (Fig. 1). The set includes indicators covering structure of care (n=1), process of AS care (n=13), and outcomes (n=6). In the second round, after modification and addition of QIs based on first-round feedback, six QIs were sent for expert panel rating. However, none of the newly suggested or modified QIs achieved consensus (Supplementary Table 4; available in the Appendix at *cuaj.ca*).

### Structure indicators

Of three proposed structure indicators, only one reached consensus: "Managed by PCa specialist vs. another physician (e.g., family physician, medical oncologist)," with a median importance score of 8, DI of 0.74, and percentage of consensus as a valid measure of 74% (Table 1).

### Process indicators

The list of process indicators (out of 17 QIs initially proposed) that achieved consensus is presented in Table 1. A total of 13 indicators (four QIs at the time of diagnosis plus two QIs measuring AS eligibility criteria, four measures during AS followup, and three QIs during switching to definitive treatment) reached consensus. All process indicators that were appropriate for measuring AS quality based on expert panel rating had a consensus ranging from 69–95% (Table 1). Three indicators were rated as uncertain, with median score 4–6, and one proposed QI (low-risk patients received AS at age ≥80 years) had a median importance of 7 but a DI >1.

### Outcome indicators

Out of seven nominated QIs, six achieved consensus (details in Table 1). However, the QI, "Five-year treatment-free survival" had only 53% consensus; similarly, "Five-year metastasis-free survival" also had a low level of consensus as a valid measure (47%). These two were retained, given their

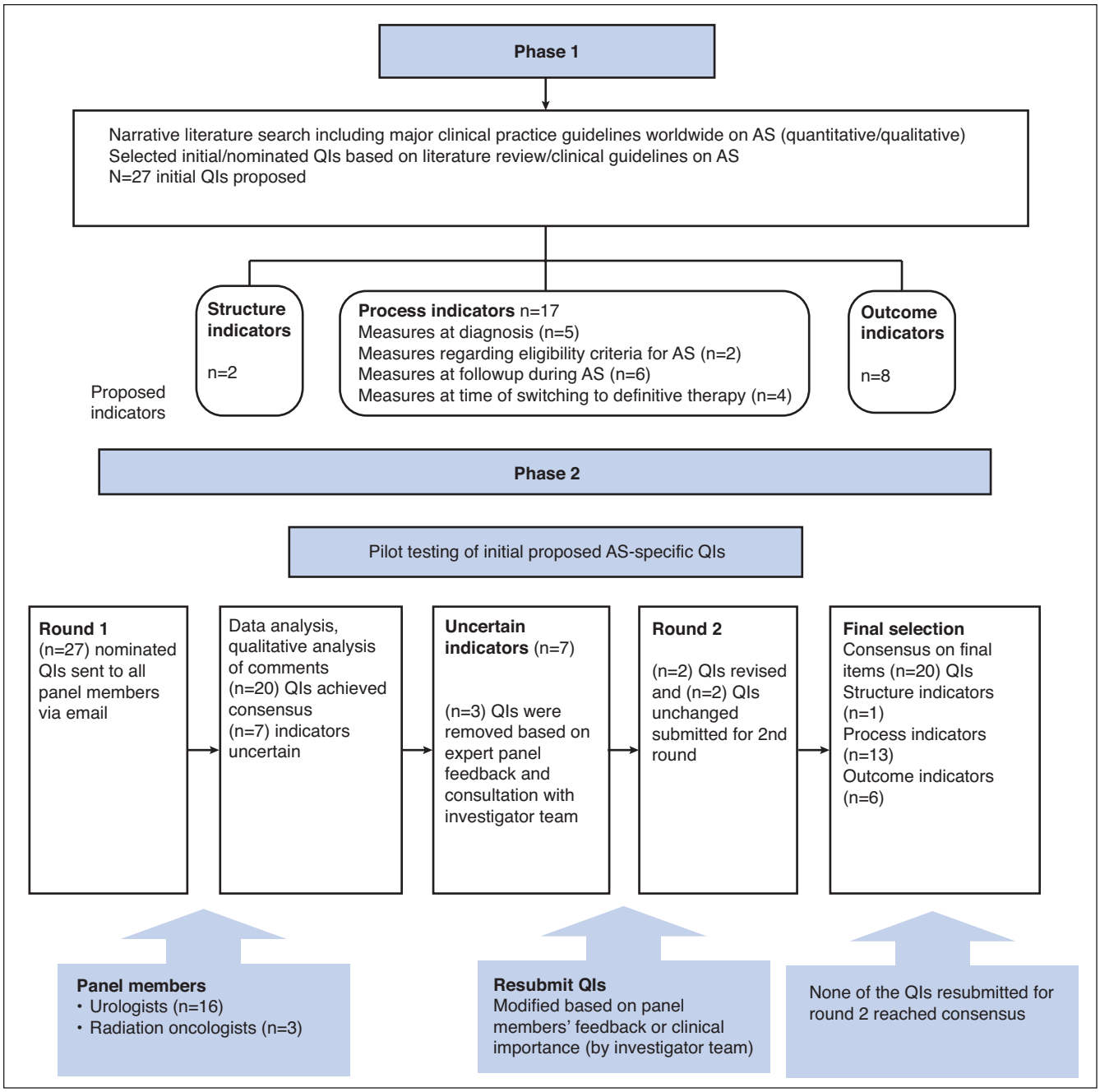


***Fig. 1.*** Flow diagram of the development of quality indicators on active surveillance for low-risk prostate cancer. AS: active surveillance; QI: quality indicator.

widespread reporting in AS outcome studies. The QI, "10-year treatment-free survival" had only 47% consensus, with median importance 6 and DI 1.55, which indicated it was an inappropriate measure.

## Key predictor/explanatory variables

Of seven key predictor/explanatory variables proposed, four were accepted in the first round of the Delphi, two were uncertain, and one variable was rejected (Supplementary Table 5; available in the Appendix at *cuaj.ca*). The expert panel suggested two additional variables as key predictor/explanatory variables, however, neither achieved consensus in the second round.

**Table 1. Final recommended quality indicators for active surveillance for low-risk prostate cancer patients**

| Indicators | Definition | Median (IQR) [range] | DI | Consensus (% with 7, 8, 9) | Consensus (% with 6, 7, 8, 9) |
|---|---|---|---|---|---|
| **I. Structure indicators** | | | | | |
| Managed by PCa specialist vs. another physician (e.g., family physician) | Percentage of AS patients managed by a urologist/ radiation oncologist among all low-risk AS patients | 8 (6–8) [1–9] | 0.74 | 74% | 84% |
| **II. Process indicators** | | | | | |
| **(A) Measures at diagnosis** | | | | | |
| Initial PSA measured at diagnosis | Percentage of all newly diagnosed patients with initial PSA measurement at diagnosis | 8 (7–9) [3–9] | 0.75 | 79% | 84% |
| T stage (DRE) is measured | Percentage of all newly diagnosed patients with clinical T-stage measured at diagnosis | 8 (7–9) [3–9] | 0.57 | 89% | 89% |
| Proportion of patients with PCa and 8 or more cores on diagnostic biopsy | Number of patients with PCa who underwent at least e core TRUS-guided biopsy | 9 (8–9) [6–9] | 0.53 | 95% | 100% |
| In men with low-risk PCa bone scan is not conducted | Percentage of low-risk patients for whom a bone scan is not conducted (bone scan not recommended for low-risk patients) | 8 (7–9) [2–9] | 0.47 | 86% | 86% |
| **(B) Measures regarding eligibility criteria for AS** | | | | | |
| Proportion of low-risk patients undergoing AS | Percentage of patients receiving initial AS (as compared to BT, RT, RP, or others) | 8 (7–9) [2–9] | 0.98 | 84% | 89% |
| Proportion of low-volume (with ≤3 positive cores and <50% of max percent core) patients undergoing AS | Percentage of low volume patients (with ≤3 positive cores and <50% of max percent core) who receive AS | 8 (7–9) [1–9] | 0.49 | 84% | 95% |
| **(C) Measures at followup during AS** | | | | | |
| Urologist/radiation oncologist followup as per CCO guidelines on AS | Percentage of patients on AS who had regular followup with urologist/ radiation oncologist every 6 months until definitive treatment or AS cessation | 8 (7–8) [4–9] | 0.68 | 79% | 89% |
| PSA test every 3–6 months | Percentage of patients on AS who had PSA test every 3–6 months until definitive treatment or AS cessation | 8 (6–9) [5–9] | 0.72 | 69% | 89% |
| Confirmatory biopsy done within 6–12 months | Percentage of patients on AS who had a confirmatory biopsy within 6–12 months from diagnosis | 9 (6–9) [4–9] | 0.57 | 74% | 89% |
| Serial biopsy every 2–5 years (based on CCO guidelines on AS) | Percentage of patients on AS who had serial biopsies every 2–5 years following a confirmatory biopsy while on AS | 7 (6–9) [3–9] | 0.68 | 74% | 84% |
| **(D) Measures at time of switching to definitive therapy** | | | | | |
| PCa specialist visits prior to switching to definitive therapy | Percentage of patients on AS who had switch to definitive therapy who visited a PCs specialist (urologist or radiation oncologist) – within 6 months prior to treatment | 7 (5–8) [1–9] | 0.65 | 63% | 68% |
| Biopsy prior to definitive treatment (within 6 months) | Percentage of patients on AS who had a biopsy prior to switch to definitive therapy | 7 (6–9) [1–9] | 0.87 | 68% | 79% |
| Active treatment initiated after upgrade in clinical stage or Gleason score | Percentage of patients on AS who had switch to definitive therapy after upgrade in clinical stage or Gleason score | 8 (7–9) [5–9] | 0.65 | 79% | 95% |
| **III. Outcome indicators** | | | | | |
| 5-year treatment-free survival | Percentage of patients on AS who discontinue AS within 5 years from diagnosis | 7 (5–8) [3–9] | 0.70 | 53% | 74% |
| 5-year metastasis-free survival | Number of AS patients who developed metastases within 5 years from diagnosis | 7 (5–9) [1–9] | 0.90 | 47% | 74% |
| 10-year metastasis-free survival | Number of AS patients who developed metastases within 10 years from diagnosis | 8 (5–9) [1–9] | 0.60 | 69% | 74% |
| 5-year disease-specific death | Number of AS patients who died due to PC within 5 years from diagnosis after initial AS | 7 (4–8) [7–9] | 0.90 | 58% | 69% |

ACG: adjusted clinical groups; ADT: androgen deprivation therapy; AS: active surveillance; BT: brachytherapy; CCO: Cancer Care Ontario; DI: disagreement index; DRE: digital rectal examination; IQR: interquartile range; MRI: magnetic resonance imaging; PCa: prostate cancer; PSA: prostate specific antigen; RP: radical prostatectomy; RT: radiation therapy; TRUS: transrectal ultrasound.

**Table 1 (cont'd). Final recommended quality indicators for active surveillance for low-risk prostate cancer patients**

| Indicators | Definition | Median (IQR) [range] | DI | Consensus (% with 7, 8, 9) | Consensus (% with 6, 7, 8, 9) |
|---|---|---|---|---|---|
| **III. Outcome indicators (cont'd)** | | | | | |
| 10-year disease-specific death | Number of AS patients who died due to PC within 10 years from diagnosis after initial AS | 7 (6–9) [4–8] | 0.65 | 74% | 79% |
| 10-year overall survival | Number of AS patients who died within 10 years from diagnosis | 7 (5–9) [1–9] | 0.80 | 69% | 74% |

ACG: adjusted clinical groups; ADT: androgen deprivation therapy; AS: active surveillance; BT: brachytherapy; CCO: Cancer Care Ontario; DI: disagreement index; DRE: digital rectal examination; IQR: interquartile range; MRI: magnetic resonance imaging; PCa: prostate cancer; PSA: prostate specific antigen; RP: radical prostatectomy; RT: radiation therapy; TRUS: transrectal ultrasound.

## Discussion

We developed QIs for AS that can be implemented to measure quality of care. After a careful review of the literature and use of a modified Delphi consensus process, our national expert panel of clinicians from urology and radiation oncology identified 20 QIs as important indicators for measuring quality of AS care. The final selected QIs included items that measure quality of care during initial selection for AS, processes of care during AS, and relevant outcome indicators.

### How can the QIs on AS be used to improve quality of AS care

The importance of measuring the quality of AS care has been increasingly recognized, and calls to monitor oncological outcomes and quality at a population level have become more common.[28] Given that a large number of QIs are being proposed as performance measures without knowledge of their validity, substantial concerns have arisen as to whether their use justifies the substantial financial and administrative resources required for their implementation in QI initiatives.[20] Based on the recommended matrix by Birkmeyer et al to choose the right measures for measuring quality and developing policy,[20] process indicators are considered most important for quality improvement in AS and represented the largest number of QIs approved by our expert panel.

### Implementation of QIs

CCO published AS clinical guidelines in 2015, with the aim of improving patterns of care and outcomes for men diagnosed with low-risk PCa;[15] however, no data are available to understand how AS care is being delivered in Ontario, and all published data are from outside Canada.[9,15,21,29-32] Development of our QIs is an important step in systematically assessing quality of care at a population level and identifying possible gaps in quality of care.

The field of AS is evolving rapidly. Of note, our expert panel members rated the use of magnetic resonance imaging (MRI) during AS enrollment to be of low importance and were uncertain (only 58% considered it an appropriate measure at this time) about the use of MRI during AS followup. Very few of the clinical guidelines we identified recommended the use of MRI for patient selection on AS and during followup.[17] Although there is ongoing debate about the use of MRI in AS, a recent clinical trial found that MRI followed by selected targeted biopsy is non-inferior to initial systematic biopsy in men at risk for PCa in detecting grade group 2 or greater cancers.[33] Similarly, studies also suggested that MRI use is beneficial for risk stratification and recommended use of MRI for men on AS before confirmatory biopsy.[33,34] As implementation of MRI in AS is just beginning in Canada based on recent guidelines,[35,36] MRI-related QIs would likely be added to the next update of the QIs. With rapidly changing AS practices using genomic and biomarkers, selecting current metrics that correlate to clinically meaningful outcomes is challenging. This reinforces the need to re-evaluate QIs on a regular basis as the field evolves.

### Prior published QIs in AS

A recently published commentary on quality metrics for AS had proposed six quality measures. Of the six measures, four related to the initial AS selection phase and two measures intended to measure quality during surveillance phase.[11] Another study, by Merriel et al, used a modified Delphi approach to develop a practical guide for initial implementation of AS and has contributed to this field. In this study, an expert panel that included largely urologists (75%) from a range of geographic regions (four U.S., four Europe, four Australia) reached an agreement on key principles for AS initial selection (reasonable state of health, life expectancy, medical comorbidities, suitability for radical treatment, and treatment preferences) and identified minimum diagnostic test requirements (PSA, PSA density, multiparametric MRI, and systematic biopsy).[12] In our study, PSA density and multiparametric MRI had moderately high disagreement among the expert panel members about the importance of the indicator. This may be due to lack of consistency in the practice guidelines of AS between countries or healthcare systems. It may also reflect respondent bias, since only four physicians represented each geographic region and only one was a radiation oncologist.

## Strengths and limitations of QIs

Strengths of this study include a careful literature search for QIs in PCa and use of a modified Delphi approach to obtain consensus in an area where clinical guidelines may be imperfect. Our expert panel consisted of urologists and radiation oncologists who were directly involved in managing AS patients, and represented different types of practice (academic and community-based) from across Canada. Our study identified expert-nominated process of AS care indicators that are also concordant with guidelines on AS. As a limitation, the level of data available in various databases (e.g., provincial administrative data, Surveillance, Epidemiology, and End Results-Medicare data) could play a critical role in applying our QIs to measure quality of AS care at the population level. Additional limitations include the fact that even if identified through expert consensus, not all QIs predict clinical outcomes;[9,20,32] we also did not include quality-of-life or cost-effectiveness measures among our selected indicators. These are likely of interest to patients and policymakers and should be considered in subsequent versions of our QIs.

Currently, we lack understanding of whether these selected QIs are predictive of clinical outcomes, hence, in the future, we aim to test feasibility, predictive validity, and subsequently establish benchmarks for quality improvement. We acknowledge the possibility of selection bias in that most of our respondents were practicing in an academic setting, had few radiation oncologists, and a moderate response rate (42%). Also, there was no way of determining if our respondents' rating scores on quality indicators were differed from non-respondents. Finally, as practice guidelines are changing rapidly, particular indicators may be eliminated or new, more appropriate QIs (e.g., use of MRI) introduced for measuring the right QIs specific to the policy context.

## Conclusions

Even though AS use has grown in PCa management, there is limited information on the quality of AS care. We developed a set of QIs to measure AS care using published guidelines and clinical expertise. The next step is to determine the feasibility of capturing each QI at a population level and identify highly impactful QIs for measuring quality of AS care. Reporting quality of care on these indicators will help enhance adherence, reduce variation in care, and improve outcomes among low-risk PCa patients on AS. Future efforts can focus on quality improvement initiatives and measure appropriateness of care according to AS guidelines. Future research should also evaluate variations in quality of care by region and hospital type (academic vs. community, cancer center vs. other) implementing AS and ensure QIs reflect evolving practice and can be targeted by interventions aimed at improving quality.

**Competing interests:** The authors do not report any competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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