

# Appropriateness Criteria for Active Surveillance of Prostate Cancer



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**Purpose:** The adoption of active surveillance varies widely across urological communities, which suggests a need for more consistency in the counseling of patients. To address this need we used the RAND/UCLA Appropriateness Method to develop appropriateness criteria and counseling statements for active surveillance.

**Materials and Methods:** Panelists were recruited from MUSIC urology practices. Combinations of parameters thought to influence decision making were used to create and score 160 theoretical clinical scenarios for appropriateness of active surveillance. Recent rates of active surveillance among real patients across the state were assessed using the MUSIC registry.

**Results:** Low volume Gleason 6 was deemed highly appropriate for active surveillance whereas high volume Gleason 6 and low volume Gleason 3+4 were deemed appropriate to uncertain. No scenario was deemed inappropriate or highly inappropriate. Prostate specific antigen density, race and life expectancy impacted scores for intermediate and high volume Gleason 6 and low volume Gleason 3+4. The greatest degree of score dispersion (disagreement) occurred in scenarios with long life expectancy, high volume Gleason 6 and low volume Gleason 3+4. Recent rates of active surveillance use among real patients ranged from 0% to 100% at the provider level for low or intermediate biopsy volume Gleason 6, demonstrating a clear opportunity for quality improvement.

**Conclusions:** By virtue of this work urologists have the opportunity to present specific recommendations from the panel to their individual patients.

## Abbreviations and Acronyms

AA = African-American  
AS = active surveillance  
LE = life expectancy  
MUSIC = Michigan Urological Surgery Improvement Collaborative  
PC = prostate cancer  
PSA = prostate specific antigen  
PSAD = prostate specific antigen density  
RAM = RAND/UCLA Appropriateness Method  
SDM = shared decision making

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Community-wide efforts aimed at increasing rates of active surveillance and reducing practice and physician level variation in the choice of active surveillance vs treatment are warranted.

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**Key Words:** watchful waiting, counseling, decision making, prostatic neoplasms, program evaluation

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RECENT studies indicate increased adoption of AS.<sup>1,2</sup> However, most AS series emanate from academic institutions, large hospitals or prospective trials with defined AS protocols. Very little data exist regarding the adoption of AS across diverse communities in nonprotocol settings.

In the MUSIC, a statewide consortium of academic and community urologists, we reported that 49% of patients with low risk PC were on initial conservative management. However, the rate was highly variable across practices, ranging from 27% to 80%.<sup>2</sup> Data from SEER (Surveillance, Epidemiology, and End Results) cancer registries suggest that initial adoption of AS varies widely in the community.<sup>3,4</sup> In fact, it seems that provider preference accounts for more variation than tumor related factors in the decision of initial treatment vs initial observation.<sup>4</sup>

These studies highlight a need for strategies to disseminate information to the broader urological community about the safety and value of AS. The high variability in the adoption of AS also suggests a need for more consistency in counseling and SDM. One approach is to use guidelines from professional medical societies. However, available guidelines generally provide high level recommendations based mostly on tumor factors and in most cases are not sufficiently granular to apply to the wide variety of individual clinical scenarios seen in everyday clinical practice.

An alternative approach is the RAM,<sup>5</sup> a method originally developed to measure the overuse and underuse of surgical procedures. RAM combines available data with the experience and insight of experts in order to provide guidance at a more detailed level than can be achieved with guidelines. Using RAM, appropriateness criteria with high internal validity have been developed for many procedures.<sup>6</sup>

We used the RAM to 1) review published data and guidelines on AS, 2) develop a list of tumor and patient based parameters that providers consider when counseling, 3) rate the appropriateness of AS for all possible combinations of these parameters and 4) create a counseling guide based on appropriateness scores. We also assessed recent rates of AS in real patients across the state of Michigan with respect to patient and tumor related factors.

## METHODS

The proper conduct of the RAM requires several steps, including panelist selection, information synthesis,

theoretical scenario development, scenario scoring and analysis. Scores can then be used prospectively or retrospectively to assess practice patterns.

The MUSIC was established in 2011 to improve the quality of prostate cancer care in Michigan. MUSIC now includes 42 community and academic urology practices comprising nearly 90% of urologists in the state. Each participating practice obtained exemption or approval for participation from a local institutional review board.

Previously we found a high degree of variability regarding the use of AS.<sup>2</sup> This was first discussed in a statewide meeting in October 2014. In January 2015 we formed an AS appropriateness criteria panel. A chair (MLC) and co-chair (BRL) were selected, and MUSIC urologists from around the state were asked to nominate themselves for participation in the panel. Final panelists were chosen with a goal of having broad representation from academic and community practices, a stated interest in AS, geographic spread and the availability to participate in several face-to-face meetings.

Practice settings and locations of panelists are described in Appendix 1. A RAM expert (SJB) and 2 patients (1 who underwent radical prostatectomy and 1 on AS) participated in discussions but did not score scenarios. At a preliminary meeting recent data on AS were reviewed with a recognized AS expert (L. Klotz, University of Toronto), and AS guidelines from multiple professional societies including the American Urological Association, National Comprehensive Cancer Network®, American Cancer Society, European Association of Urology, European Society for Medical Oncology, and Agency for Healthcare Research and Quality were presented. For the development of appropriateness criteria the panel agreed on definitions of AS and watchful waiting (Appendix 2). The panel elected to focus on men with low to low-intermediate risk PC and life expectancy greater than 10 years. The most relevant patient and tumor based parameters to be used in the construction of clinical scenarios were discussed.

With input from panelists the chair and co-chair chose tumor and patient based parameters likely to influence counseling (table 1 and Appendix 3). Biopsy tumor burden was based on Gleason score and number/maximal percent involvement of cores. We used PSAD because it appeared to correlate with AS outcomes better than PSA.<sup>7</sup> Patient based parameters included race, LE and sexual importance/function. AA men were given a separate category because of concerns regarding increased oncologic risk.<sup>8,9</sup> Sexual importance/function was included because baseline erectile function and the value or importance a man places on sexual activity can vary highly from one patient to the next. Therefore, the possibility of decreased erectile function associated with treatment may be a highly important consideration for some men but not others. Combining all parameters yielded 160 theoretical clinical

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