Building a Roadmap for Surveillance of Renal Masses Using a Modified Delphi Method to Help Achieve Consensus

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OBJECTIVE To establish a consensus for initial evaluation and follow-up of patients on active surveillance (AS) for T1 renal masses (T1RM).

METHODS A modified Delphi method was used to gather information about AS of T1RM, with a focus on patient selection, timing/type of imaging modality, and triggers for intervention. A consensus panel of Michigan Urological Surgery Improvement Collaborative-affiliated urologists who routinely manage renal masses was formed. Areas of consensus (defined > 80% agreement) about T1RM AS were established iteratively via 3 rounds of online questionnaires.

RESULTS Twenty-six Michigan Urological Surgery Improvement Collaborative urologists formed the panel. Consensus was achieved for 321/587 scenarios (54.7%) administered through 124 questions. Life expectancy, age, comorbidity, and renal function were most important for patient selection, with life expectancy ranking first. All tumors < 3 cm and all patients with life expectancy < 1 year were considered appropriate for AS. Appropriateness also increased with elevated perioperative risk, increasing tumor complexity, and/or declining renal function. Consensus was for multiphasic axial imaging initially (contrast CT for GFR > 60 or MRI for GFR > 30) with first repeat imaging at 3-6 months and subsequent imaging timing determined by tumor size. Consensus was for chest imaging for tumors > 3 cm initially and > 5 cm at follow up. Renal biopsy was not felt to be a requirement for entering AS, but useful in several scenarios. Consensus indicated rapid tumor growth as an appropriate trigger for intervention.

CONCLUSION Our consensus panel was able to achieve areas of consensus to help define a clinically useful and specific roadmap for AS of T1RM and areas for further discussion where consensus was not achieved. UROLOGY 180: 168–175, 2023. © 2023 Published by Elsevier Inc.

In the United States, renal cell carcinoma is the sixth most frequently diagnosed cancer in men and ninth in women.[1] Given the rise in utility and quality of imaging available, an increasing number of renal masses are detected at an earlier and often asymptomatic stage. Over 40% of newly diagnosed renal tumors are localized and less than 4 cm in size (clinical stage T1a).[2,3] Reported rates of metastatic progression in this subset of tumors are low, ranging between 0% and 6%.[4] Although the risk of metastatic progression is higher in clinical T1b renal tumors, which are localized and 4.1-7.0 cm in size,

Abbreviations: T1RM, T1 renal masses; RCC, Renal Cell Carcinoma; AS, Active surveillance; AUA, American Urological Association; NCCN, National Comprehensive Cancer Network; ASCO, American Society of Clinical Oncology; MUSIC, Michigan Urological Surgery Improvement Collaborative; MUSIC-KIDNEY, Michigan Urological Surgery Improvement Collaborative—Kidney mass: Identifying & Defining Necessary Evaluation & therapY; QI, Quality Improvement

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the likelihood of metastasis at presentation is still low, ranging between 3% and 7%.[5]

Surgical excision remains the gold standard for management of clinical T1 renal masses (T1RMs). However, active surveillance (AS) is an increasingly utilized management strategy, particularly in patients with multiple comorbidities and/or increased age.[6] AS has been shown to have non-inferior oncological outcomes when compared with other invasive treatment strategies for T1RMs in well selected patients.[7-9] Current National Comprehensive Cancer Network guidelines provide AS as an option for patients with T1RMs.[10] American Urological Association (AUA) guidelines currently include AS as an option for initial management for all patients with small (< 2 cm) solid or Bosniak 3/4 complex cystic renal masses. AS is also mentioned as an option when "the anticipated risk of intervention or competing risks of death outweigh the oncologic benefit of active treatment." Repeat imaging in 3-6 months can be performed to assess interval growth and growth kinetics for patients in whom the risk/benefit analysis for treatment is equivocal and for others who prefer AS.[6] Absolute indications for AS per the American Society of Clinical Oncology guidelines include high risk for anesthesia and intervention, or life expectancy (LE) < 5 years. Relative indications per American Society of Clinical Oncology included patients with significant risk of end-stage renal disease if treated, renal mass < 1 cm, and/or LE < 10 years.[11]

The aim of the Michigan Urological Surgery Improvement Collaborative (MUSIC) is to improve the quality of care for patients with urological conditions by leveraging the data in our state-wide registry to affect change through multiple quality improvement initiatives.[12,13] The collaborative initiated Michigan Urological Surgery Improvement Collaborative—Kidney mass (MUSIC-Kidney mass): Identifying and Defining Necessary Evaluation and therapY (KIDNEY), a prospective kidney mass registry in September 2017. Across MUSIC-KIDNEY practices, 46% of T1RM are managed initially without immediate intervention (ie, partial/radical nephrectomy, ablation, and stereotactic body radiation therapy), highlighting the growing acceptance of AS and other non-interventional approaches (expectant management, less-AS) for cT1RM.[14] Significant practice-level variation in the use of non-interventional approaches prompted us to engage MUSIC urologists in a panel to collect opinions and come to consensus when feasible. Our intent was to build upon the current guidelines and address the nuances associated with selecting patients for AS. Our study goal was to investigate initial evaluation, patient selection, and follow-up of patients considered for AS in order to build consensus, decrease variability, and generate a roadmap for use in clinical practice. Our approach was to form a consensus panel of urologists and establish consensus iteratively using a modified Delphi methodology.

METHODS

The Delphi methodology is a well-recognized technique that was originally developed for forecasting events using a series of intensive questionnaires with controlled and structured feedback.[15,16] The major difference in the modified Delphi technique is the initial use of direct interaction amongst participants. The Delphi method structures group communications so that the process is effective in allowing a group of individuals to deal with a complex problem. This structured and systematic information gathering from a group of experts on a specific topic using a series of questionnaires is eventually used to achieve consensus.

This project consisted of three phases, where each phase informed the subsequent phase. First, the available evidence was reviewed, which then informed the Delphi consensus questionnaire development. The consensus process then resulted in the formulation of a roadmap for AS of T1RMs, which was distributed broadly to MUSIC practices.

Formal Evidence Synthesis and Content Development

A set of carefully selected items was drawn from the various sources, including prior literature and several experts, to provide a solid basis in previously established work. The AUA, National Comprehensive Cancer Network, and American Society of Clinical Oncology guidelines were extensively reviewed to establish the baseline of current expected practice for patients.[6,10,11] Additionally, a review of the literature using PubMed and Medline databases was performed using keywords, including "kidney mass," "renal mass," and "AS." The available evidence was used to guide the development of the initial set of questions.

The aim of the evidence synthesis work was to identify questions relevant to the following 6 categories:

1) Patient selection
2) Renal mass biopsy
3) Initial evaluation
4) Follow up testing
5) Delayed Intervention
6) Completion of AS/(graduation)

Consensus Panel Formulation

MUSIC-KIDNEY was established in 2017 with each practice obtaining approval or exemption for collaborative participation from a local institutional review board. A total of 19 practices have contributed data regarding T1RM patients, and quality improvement activities have been performed at and between collaborative-wide meetings since 2018.

An advisory panel was formed, consisting of 26 MUSIC-affiliated urologists in the state of Michigan who actively manage patients with kidney tumors. The panel was chaired by Dr. Amit Patel, with presentations on current evidence and findings from the review processes. Discussion during briefing at the culmination of the project allowed for valuable interaction between urologists and dissemination of existing data from MUSIC-KIDNEY.

Consensus Process

A modified Delphi process was conducted to drive consensus among the participants. An Internet survey (Qualtrics) was generated based on the current literature and expert opinion

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and sent to the 26 committee members between November 2020 and December 2020. Participants indicated their level of agreement with statements relating to patient selection for AS via online questionnaires either as binary answers or on a 9-point appropriateness scale. Using the RAND/UCLA Appropriateness Method, combinations of important factors were also evaluated when appropriate, such as for patient selection. Panelists were instructed to use the available scientific evidence and their best clinical judgment to rate every scenario on a scale of 1-9, where 1 indicated that the harms of AS outweighed the benefits, and 9 signified that the benefits of AS outweighed the harms. The scores were associated with terminology ranging from highly inappropriate (score 1) to highly appropriate (score 9).

The panelists were given 7 days to complete each survey round. Reminder e-mails were sent to maintain panel participation at second and third rounds. All responses were kept anonymous, and questionnaires were individually administered to minimize bias due to "bandwagon" or "halo" effects.

Process Progression and Statistical Analysis

An independent coordinator collected the responses and comments from each participant. The level of agreement necessary to achieve consensus was set at 80%. In the Delphi process, the finding of "consensus" is more relevant than the level of consensus. Questions in which this level of consensus was achieved were removed from the next round of the survey. Repeated iterations of anonymous voting continued over 3 rounds. Factors not achieving consensus were iteratively developed between the 3 rounds of questionnaires incorporating feedback obtained from participants' comments. Outcomes of each round were displayed as histograms and available to participants to better inform their votes in the subsequent rounds. For inclusion in the final recommendations, each survey item was required to have reached group consensus.

Debriefing and Pathway Development

The consensus panel was reconvened 2 weeks after the 3 rounds of questionnaires to summarize the findings and solicit feedback.

RESULTS

Content Development and Validation

In total, 26 MUSIC urologists participated in the Delphi panel. The majority of the panel was fellowship-trained (69%) and in community practice (73%). Demographic information gathered regarding respondents is shown in Supplementary Table 1.

Consensus

A total of 124 questions were administered over 3 rounds. Several questions included multiple clinical scenarios to evaluate. Participant response rates were 100% in the first round, 85% in the second, and 88% in the third round. Results of the 3 rounds are summarized in Supplementary Figure 1. By the end of the Delphi process, consensus was achieved in 321 of 587 (54.7%) scenarios evaluated. The main statements of the consensus process are summarized in Tables 1 and 2. A detailed summary of the statements and responses is provided in Supplementary material 1. The consensus panel findings were used to create a roadmap for approaching decisions of AS for T1RM that was distributed to the MUSIC collaborative (Supplementary material 2).

Patient Selection

Panelists reached consensus that appropriateness of AS increases with advancing age, increasing comorbidity, decreasing LE, and decreasing renal function. LE ranked first among these drivers. Combination of LE with tumor size revealed that any patient with tumors < 3 cm and patients with LE < 1 year with asymptomatic T1RM were appropriate for AS (Fig. 1). Additional combinations of factors revealed that consensus for AS increased with increasing tumor complexity, elevated perioperative risk, or declining renal function. Tumor factors with low consensus (< 20%) for AS, that is, treatment is indicated, were cT3a masses, infiltrative masses, symptomatic masses, biopsy grade 4, and variant histology (Table 1). Details regarding how variations in combinations of factors affected decision-making and consensus for AS are available in Supplementary material 1.

Follow-up

Consensus was reached that first AS axial imaging should be 3-6 months after initial staging, with timing of subsequent studies (axial or ultrasound) according to tumor size. As panelists did not reach consensus on the exact timing of follow-up studies, ranges were used in the created roadmap (Supplementary material 2). Figure 2 highlights the proposed follow-up strategy based on tumor size. Details regarding the spread of responses on timing of follow up imaging and the interaction with tumor size are shown in Supplementary material 1. Consensus was that chest imaging was indicated for tumors > 3 cm at diagnosis, and during follow up for tumors > 5 cm.

Consensus was not reached that renal mass biopsy should be mandatory for initiation of AS; however, it was felt that biopsy should be offered to patients with rapid tumor growth who are considering continued AS. There was no consensus regarding specific kinetics constituting "rapid" tumor growth. There was a lack of consensus with regards to imaging modality to be used (renal ultrasound vs CT vs MRI), chest imaging for 3.1-5.0 cm tumors, the frequency of renal function assessments during AS, and the role of molecular imaging.

Delayed Intervention and Completion of Active Surveillance

Tumor growth rate and tumor size were considered as triggers for intervention. Consensus was not achieved regarding a specific growth rate or tumor size as a universal trigger for intervention. The most common cut points were > 0.5 cm/y (64%) and > 3 cm (46%) (Supplementary Figure 2); these cut points were found to vary based on LE (Supplementary material 1).

No overall consensus was reached for duration of AS following diagnosis with T1RM. Consensus was achieved that healthy individuals should be surveilled for at least 5 years and patients with significant comorbidities for at least 3 years. Consensus was not reached regarding the role of biopsy or specific imaging modalities required to graduate a patient from AS. Several noteworthy comments were made regarding the role of medico-legal issues, patient preference, and definitive evidence of benign pathology that hinted toward an understandable lack of comfort in this area amongst some panelists.

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Table 1. Summary of Consensus View on Appropriateness of Active Surveillance (AS) for Renal Masses

Consensus for AS	Consensus against AS
• All patients with LE < 1 y • All patients with ≤3 cm tumors • Some patients with larger tumors (≥4 cm) and even ≥7 cm for limited LE • Single, sporadic mass, and for: o Bilateral masses o Multifocal masses o Hereditary cancers o Heterogenous masses • Biopsy shows: o Grade 1-2 RCC o Clear cell RCC o Papillary RCC o Chromophobe RCC o Oncocytic RCC o Benign mass (Oncocytoma, angiomyolipoma, etc.) • Incidental or symptomatic detection, including o Microscopic hematuria o Flank pain, unrelated to renal mass	• Biopsy shows: o Grade 4 RCC o Sarcomatoid RCC o Rhabdoid RCC o Sarcoma o Renal medullary carcinoma o Collecting duct carcinoma • Symptomatic patients with: o Flank pain related to the renal mass o Suspected paraneoplastic syndrome • Infiltrative tumors and cT3a disease

LE, life expectancy; RCC, renal cell carcinoma.

Table 2. Summary of Consensus View on Initial Evaluation, Follow up, and Triggers for Intervention During Active Surveillance (AS) of Renal Masses

Initial Evaluation
• Renal function assessment needed
• Axial imaging with and without contrast should be performed
o MRI with contrast safe for GFR ≥30 ml/min/1.73 m^2
o CT with contrast safe for GFR ≥45 ml/min/1.73 m^2*
• Tumor complexity should be assessed
• Chest imaging needed for tumors > 3 cm
o X-Ray for 3.1-4.0 cm
o X-Ray or CT thorax for 4.1-7.0 cm (23%-77%)
o CT thorax for > 7.0 cm
• Chest imaging unnecessary for tumors ≤3 cm
• Renal mass biopsy not mandatory to initiate surveillance
Follow Up
• Renal function assessment needed
• Chest imaging needed for tumors > 5 cm
• Chest imaging not needed for tumors < 3 cm
• First imaging study during surveillance should be axial between 3 and 6 mo after diagnosis, with timing of subsequent scans varying by tumor size (second study within 18 mo)
• RMB should be offered to patients with rapid tumor growth who are considering continued AS
• RMB not mandatory to continue AS
• For patients with a known malignant mass, RMB not needed during AS
Delayed Intervention
• Tumor growth rate is a trigger for intervention.†

* Consensus was reached for GFR ≥60, and discussion during debriefing established that iodinated contrast is safe for GFR ≥45 ml/min/1.73 m^2.

† Exact cut point did not reach consensus, however > 0.5 cm/y was the most common response (64%).

DISCUSSION

Unlike prostate cancer, for which numerous centers have been employing various protocols for AS for decades, there is less information in the published literature to guide clinicians and patients regarding AS for localized renal cell carcinoma. While guidelines exist regarding AS for patients with T1RM, our panel of urologists found value in exploring specific nuances in management when integrating guideposts for decision making set by these guidelines. We have previously described significant variability in the management of real masses across our statewide collaborative[13] and that about 50% of MUSIC-KIDNEY patients are managed without immediate intervention.[14] Our goal was to conduct a formal approach to ascertain opinions of urologic surgeons on the appropriateness of AS for cT1RM and establish areas of consensus to build upon current available guidelines. We herein report the outcomes of this consensus panel, which include several novel findings and recommendations regarding the selection, evaluation, and follow-up of patients undergoing AS of cT1RM.

While AS has been increasingly regarded as an option for T1RM, patient selection for AS can be complex, with multiple factors (patient, tumor, and physician) going into the decision-making process. Our panel of urologists was able to identify factors impacting the decision, and the modified Delphi process helped our panel to achieve areas of consensus in this complex decision process. We feel these findings could help reduce variability within our collaborative and could help others evaluate their own practice patterns. Panelists regarded LE and age as being of primary importance for patient selection for AS. Several studies have shown a lack of benefit to surgery over AS in older individuals (≥75 years) with T1RM.[9,17] The preference of our urologists for LE (over age) in considering AS is a novel finding of our study. We have developed an easy-to-use tool to achieve this purpose and made it readily available at https://askmusic.med.umich.edu/tools/kidney-cancer-mortality-tool. (Lane et al., manuscript under consideration).

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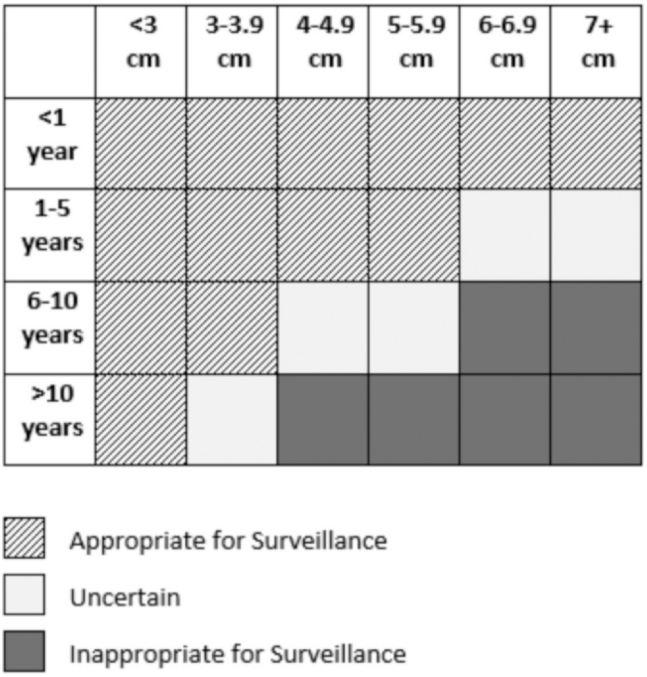

Figure 1. Appropriateness of active surveillance based on combination of life expectancy and size.

Our panel also achieved areas of consensus regarding the role of imaging and RMB when considering AS. Confirming that appropriate imaging has been obtained, even when it requires that additional studies be performed, can reduce the risk of mischaracterization of indeterminate renal masses as suspicious.[18] Cross-sectional abdominal imaging with contrast can be obtained in the majority of patients with T1RM; responses from our panelists indicated there may be an opportunity to address perceptions with regards to contrast induced nephropathy. It should be highlighted that statements issued by the American College of Radiology and National Kidney Foundation highlight an extremely low risk of acute kidney injury with iodinated contrast for patients with eGFR >45 ml/min/1.73 m^2 and certain patients with eGFR 30-44 ml/min/1.73 m^2.[19] Similarly, for contrast MRI, the risk of nephrogenic systemic fibrosis with second- and third-generation gadolinium based agents is so low, even for patients with eGFR <30 ml/min/1.73 m^2, that the potential harm of omitting the contrast may outweigh the risk of using contrast in almost all clinical situations.[20] Renal mass biopsy may also impact management for a given patient's T1RM.[6,21] Although there was not consensus in our panel for biopsy to be a requirement for entering AS, it was felt to be useful in several scenarios when AS and interventional management are under consideration.

Based on areas of consensus reached through the modified Delphi process, we were able to propose a roadmap for AS of T1RM. This roadmap is available for clinical use at https://musicurology.com/resources/provider-educational-materials. Several of our findings parallel the AUA guidelines, including similar recommendations regarding the frequency and modality of follow-up studies and the need to consider a multitude of factors to individualize AS.[6] We feel the proposed AS strategy from our consensus panel will help us to address AS in a more structured manner within our collaborative. Our recommendations and roadmap are not intended to replace current guidelines, but rather to provide specific information during the decision-making process for individual patients. Guidelines provide tumor and patient related factors that would favor AS and our findings parallel many of these recommendations. Guidelines provide guideposts for decision making, but judgment is required for individual decisions about AS with individual patients. Our study explores how a collaborative prioritizes such factors in real world scenarios when integrating guidelines into decisions. Nevertheless, there remains a lack of consensus with regards to several areas of AS, such as the utility of axial imaging at the second and subsequent AS visits, the role of chest imaging during AS of tumors 3.1-5 cm in size, frequency of renal function assessment, and the duration of AS. These are areas where further study is indicated. The use of renal ultrasound during AS is growing due to its low cost and lack of radiation.[8,22,23] Given that the risk of thoracic metastasis in renal tumors less than 3 cm is extremely low, we feel that routine annual chest imaging for these patients can generally be avoided.[24,25]

There was consensus in our panel for rapid tumor growth as a trigger for intervention, though consensus was not achieved regarding a specific growth rate as a universal trigger. The AUA guidelines discuss tumor size, tumor growth rate or a change in patient preference as potential triggers for intervention while on AS.[6] Tumor size is known to be a predictor of malignancy and increased oncologic risks.[26] While growth rate is often used as a trigger for further evaluation and/or intervention, some reports have questioned the reliability of growth rate to predict oncologic risk.[7,27] Reported tumor size and growth rate may be influenced by interobserver variability and change of imaging modality. Histological characterization and genetic definition of T1RM could be a trigger for intervention, compared with growth rate alone, suggesting value of RMB to obtain additional information to inform the decision to continue or abandon AS.[28,29]

Using the modified Delphi methodology, we were able to better understand different opinions and move toward consensus for AS of T1RMs. By including experienced kidney surgeons from both academic and community practices, the panelists represented a broad spectrum of U.S. urologic practice. We were able to achieve consensus regarding many details of AS that have not been addressed in prior guidelines. The methodological nature of this process, including multilevel question-making,

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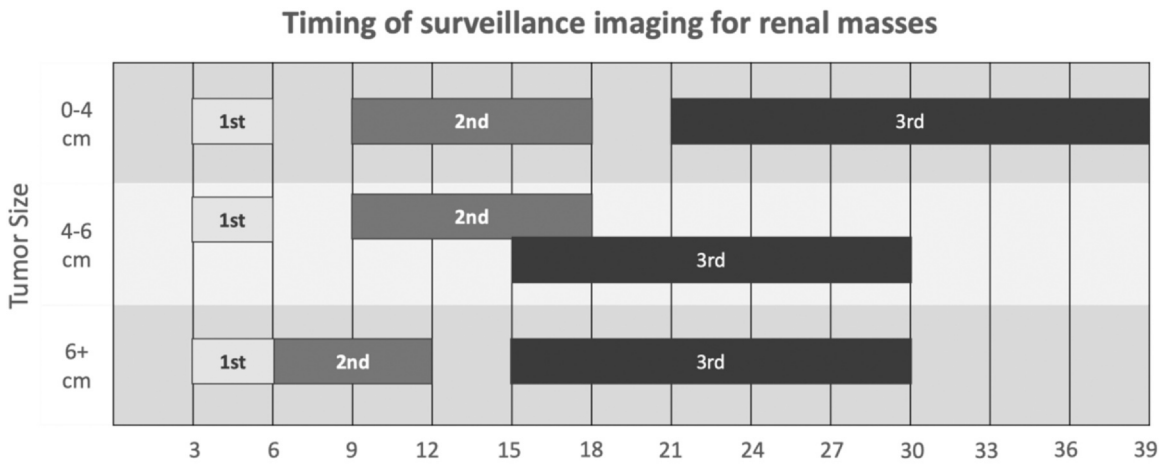

High Intensity vs Low Intensity Surveillance

High Intensity Surveillance Plan

Tumor Size	1st Surveillance Imaging	2nd Surveillance Imaging	3rd Surveillance Imaging
0 - 4 cm	3 months after diagnosis	9 months after dx (6mo after previous imaging)	21 mo after dx (12mo after previous)
4 - 6 cm			15 mo after dx (6mo after previous)
> 6 cm		6 months after dx (3mo after previous)	12 mo after dx (6mo after previous)

Low Intensity Surveillance Plan

Tumor Size	1st Surveillance Imaging	2nd Surveillance Imaging	3rd Surveillance Imaging
0 - 4 cm	6 months after diagnosis	18 months after dx (12mo after previous imaging)	30 mo after dx (12mo after previous imaging)
4 - 6 cm			
> 6 cm		12 months after dx (6mo after previous)	24 mo after dx (12mo after previous)

Figure 2. **(A)** Proposed follow-up strategy for active surveillance based on tumor size. **(B)** Proposed follow-up strategy based on size varied by intensity.

anonymous voting, multiple rounds of discussion and feedback, and the ability to perform several iterations of questionnaires, helped our panel to achieve consensus in multiple areas. The statements upon which consensus was reached will help guide patient selection, evaluation, and follow-up during AS; areas that did not achieve consensus can be investigated in the future. Based on our consensus panel findings, we describe a roadmap for approaching decisions of AS for T1RM that we have distributed to our statewide MUSIC collaborative. We anticipate future studies comparing data from the MUSIC-KIDNEY registry with other registries, such as DISSRM and the Renal Cell Consortium of Canada, to better understand differences between AS models and implement changes to improve the quality of care patients with T1RM receive.[8,30]

While the modified Delphi approach was a useful tool for helping to achieve consensus and highlight some gray areas in the AS of renal masses, there are limitations to this study. As our consensus panel of urologists who manage patients with renal masses consisted of voluntary participants and were not selected at random, there is a possibility that these results are not representative of the practices and determinations of all urologists who manage

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renal masses. Although panels are often conducted with even smaller sample sizes, our panel is relatively small in comparison with other types of surveys of physician opinion. In addition, participants outside of Michigan (and the United States) were not included. Additional limitations of this work are the inclusion of only urologists, without other specialists that are commonly involved in the care of T1RM patients, such as oncology and radiology. We acknowledge that the roadmap used in our collaborative will require auditing and continuous evaluation as to whether modifications are necessary.

CONCLUSION

The modified Delphi approach was successfully used to systematically gather information from a group of experienced kidney surgeons and identify areas of consensus regarding AS for patients with T1RM, including evaluation and follow-up. These statements can serve as a roadmap to help guide clinicians and patients and could potentially minimize the distress that patients may experience with AS. Finally, we identified a number of areas where consensus was not achieved; these should be the subject of further quality improvement initiatives.

Declaration of Competing Interest

None.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.urology.2023.06.010.

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