

Clinical-Kidney cancer

# Development and acceptability testing of a patient decision aid for individuals with localized renal masses considering surgical removal with partial or radical nephrectomy

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## Abstract

**Introduction:** Patient decision aids are structured clinical tools that facilitate shared decision-making. In urology, the decision between partial and radical nephrectomy for a renal mass can be difficult. We sought to develop and evaluate a decision aid for patients with a localized renal mass considering surgery. This paper describes the development process and acceptability testing of our patient decision aid.

**Material and methods:** A decision aid was systematically created using the International Patient Decision Aids Standards. Review of the literature identified evidence regarding patient-important outcomes of partial and radical nephrectomy. A mixed methods survey was designed to assess acceptability of the decision aid. Kidney cancer survivors, patient advocates, methodological experts, and urologists were recruited to evaluate the decision aid. The primary outcome was the acceptability of the decision aid reported by survey responders.

**Results:** An evidence-based decision aid was created. Included benefits were overall survival, cancer-free survival, and length of hospital stay. Included harms were postoperative bleeding, urine leak, stage 3 renal failure, renal replacement therapy, and flank bulge. The decision aid met the International Patient Decision Aids Standards defining (6 of 6), certification (6 of 6), and quality criteria (21 of 23). Results of acceptability testing were highly favorable. Responders ( $n = 22$ ) reported the decision aid had acceptable language (91%), an appropriate length (82%), and presented balanced options (91%). Nine of 11 urologists (82%) reported intended use with future patients.

**Conclusions:** A novel, evidence-based decision aid was created for patients with renal masses considering surgery. The decision aid is available at <https://decisionaid.ohri.ca/AZsumm.php?ID=1913>. A separate decision aid addressing the management of small renal masses is currently under development. © 2019 Elsevier Inc. All rights reserved.

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## 1. Introduction

In urology, one of the most challenging decisions patients and clinicians face is the choice between radical nephrectomy and partial nephrectomy for renal masses. For patients facing this decision, radical nephrectomy is

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typically done laparoscopically with a quicker recovery [1]. Partial nephrectomy may require an open surgical approach with a longer recovery, or a complex minimally-invasive surgery (MIS), each of which has increased risk of postoperative bleeding and urine leak compared to radical nephrectomy [2]. However, patients who undergo partial nephrectomy may have less risk of developing renal failure [1]. The only randomized controlled trial (RCT) that compared survival outcomes of partial and radical nephrectomy, showed no benefit to partial nephrectomy at 10 years [3]. For many patients, the choice between partial and radical nephrectomy is straightforward based on patient and tumor factors and does not pose a clinical challenge. However, some tumors demand a more complex excision/reconstruction, and in these cases offering patients either surgical approach is usually reasonable provided both procedures are technically feasible. Navigating this challenging decision can be a time-consuming and difficult process.

Patient decision aids (PtDAs) are clinical tools used to facilitate shared decision-making for a specific population of patients who face a challenging decision [4]. When compared to standard counselling, PtDAs improve patients' knowledge, their accuracy of risk perception, and the congruency of their choice to their personal values [4]. Patients who use a PtDA are usually less indecisive and are more satisfied with their choice [4]. At a minimum, a PtDA must: (1) explicitly state the decision to be made, (2) present the management options available including benefits and harms, and (3) help patients clarify their values and preferences [1].

Although PtDAs are available for various populations, there has never been a PtDA published for patients with localized renal masses. This population is in high need of decisional support [5]. Creating decision aids for patients with renal masses has been identified as one of the top 10 research priorities in kidney cancer by the Kidney Cancer Research Network of Canada [5]. As such, we sought to develop and evaluate a PtDA for individuals with localized renal masses considering surgical removal. This PtDA was not meant to address the decision on management for patients with small renal masses (SRM) who are deciding between active surveillance or intervention (surgery or ablation) because this is a distinct decision. We are developing a separate decision aid for patients with SRM. This paper describes the development process and acceptability testing of a PtDA for patients with localized renal masses considering surgical removal.

## 2. Material and methods

### 2.1. Study design

This study was approved by The Ottawa Hospital Research Ethics Board. The Ottawa Decision Support Framework and the International Patient Decision Aid Standards were used to structure the development of the PtDA (Fig. 1) [6–8]. The International Patient Decision Aid Standards are

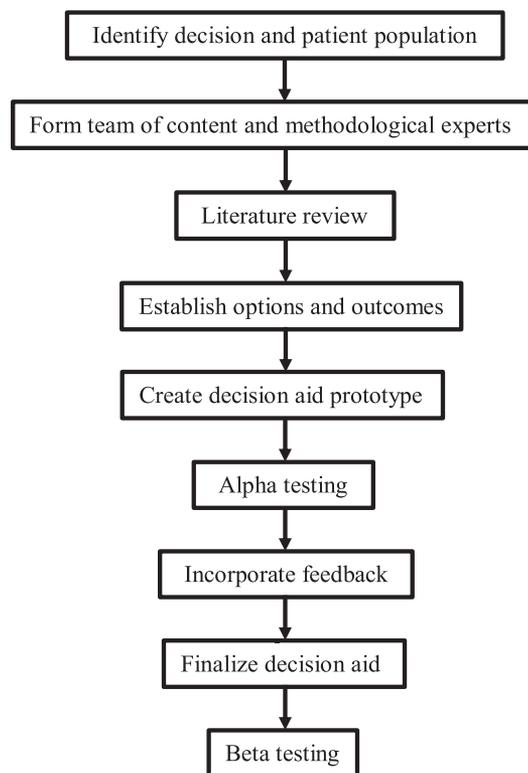


Fig. 1. Development process of patient decision aid. Recreated from Coulter et al. (2013) [8].

an evidence-based framework of criteria that were created to standardize the content, development and evaluation of PtDAs [6]. The development process includes: (1) determining the target population and performing a needs-assessment for decisional supports, (2) forming a steering committee of experts, (3) completing a literature review of management options and their outcomes, (4) creating a PtDA prototype, (5) alpha testing the prototype to assess acceptability, (6) updating the PtDA with alpha testing results to create final product, (7) beta testing final PtDA for effectiveness [6,9].

### 2.2. Population

The target population was patients with renal masses considering surgical options for treatment. Generally, these patients have localized tumors that are larger or more complex to remove due to their location in the kidney. Patients with a renal mass amenable to a straightforward partial nephrectomy were not the target population. A separate PtDA is currently under development for patients with SRM deciding between surveillance and different invasive treatments.

### 2.3. Steering committee

A steering committee of content and process experts was assembled. This included 5 uro-oncologists who routinely perform both partial and radical nephrectomies, an international leader in PtDA development, a urology resident, and

a research assistant. Patient advocates and survivors (patients with previous surgery for renal masses) also provided critical guidance on content and format.

#### 2.4. Exposures (treatments) and outcomes

After a literature review, the steering committee discussed the content (exposures and outcomes) of the PtDA using an iterative feedback process. The options felt to be most commonly performed for treatment of renal masses targeted by this PtDA were open partial nephrectomy and laparoscopic radical nephrectomy. Outcomes of patients receiving observation were included to provide context as this is an important criterion for high quality PtDAs [6]. Other treatment options including ablation and active surveillance, were briefly outlined. These were not reviewed in detail as they were not felt to be standard of care for the target population.

#### 2.5. Literature review

Summary-of-evidence tables were created to describe the outcomes (incidence of benefits and harms) of each surgical approach (Appendix 1). When possible, outcomes from RCTs or matched prospective cohorts were given more weight to minimize confounding and bias. In addition, given advancements in surgical technique, more weight was assigned to contemporary studies and to those that included multiple institutions to improve external validity. The data were reviewed by the steering committee and consensus was reached on the content.

#### 2.6. Prototype development

A prototype of the PtDA was created using the Ottawa Decision Support Framework template [7]. Plain language was used to permit use by patients with various educational backgrounds. Images and diagrams were included throughout the PtDA to illustrate each management option and to pictorially present the incidence of each outcome to improve patient understanding.

#### 2.7. Alpha testing

Alpha testing was performed by surveying stakeholders on the acceptability of the PtDA. Acceptability testing entails assessing the comprehensiveness of a PtDA with respect to its length, content, balance of information, and its ability to address the targeted decision [10]. This is a standard step in PtDA development and provides feedback to improve the final product. A 10-question, mixed-methods survey was created based on a validated acceptability scoring system (Appendix 2) [10]. Patients who had previously undergone surgery for kidney masses (survivors), patient advocates (identified through international kidney cancer associations), methodological experts (individuals with training in PtDA

development), and urologists were approached to complete the survey after reviewing the PtDA prototype. Alpha testing was completed by 11 urologists, 3 patient advocates, 1 methodological expert, and 7 survivors. Feedback provided through the completed surveys was reviewed by the steering committee and incorporated into the final product by consensus.

Validation of the final PtDA with new patients referred with localized renal masses, is performed in beta-testing. Previous articles describing the PtDA development process suggest beta-testing is not required for all PtDA prior to implementation, when a validated process is used for development [8]. Beta-testing (validation testing) was not the objective of this manuscript.

### 3. Results

The literature review identified 1 RCT, 4 systematic reviews, and numerous observational studies summarizing the outcomes of interest [2,3,11–19]. The included benefits on the PtDA were overall survival at 10 years, cancer-free survival at 10 years, and length of hospital stay. Included harms were postoperative bleeding (including rate of transfusion), postoperative urine leak, incidence of  $\geq$ stage 3 renal failure within 10 years (glomerular filtration rate  $<60$ ml/min), risk of renal replacement therapy (dialysis) at 10 years, and prevalence of postoperative flank bulge. There were different strengths of evidence between outcomes. One RCT compared partial and radical nephrectomy. For several outcomes (e.g., flank bulge) data were derived from published cohorts. An example of the pictorial diagrams used to present outcomes is provided in Fig. 2. The pictorial representation was included with the number of 100 faces shaded to indicate the percentage of patients who would be expected to have each outcome. A validated screening tool (SURE test) was included to assess patients' decisional conflict [20]. Knowledge questions were included to verify patients' understanding. For example, "Which option has the lowest risk of complications around the time of the surgery?". The answer is found in the reported risks with the correct answer of "laparoscopic radical nephrectomy."

All 22 participants completed the 10-question survey. All 4 groups felt the information presented on the PtDA was well-balanced (91%, 20 of 22), adequate in length (82%, 18 of 22), and useful for future patients (91%, 20 of 22). The language of the PtDA was felt to be appropriate (95%, 21 of 22). Responding urologists were in agreement with the quoted rates of outcomes (82%, 9 of 11) and intended to use the tool with future patients (82%, 9 of 11).

Narrative feedback revealed positive comment about the PtDA from all stakeholder groups. Urologists' suggestions focused on technical aspects of surgical approaches offered. For example, an important discussion among urologists was the inclusion of MIS partial nephrectomy as an option for management. Narrative feedback from survivors and patient advocates focused more on clarity of language. Images and pictorial diagrams were described as strengths by all groups.

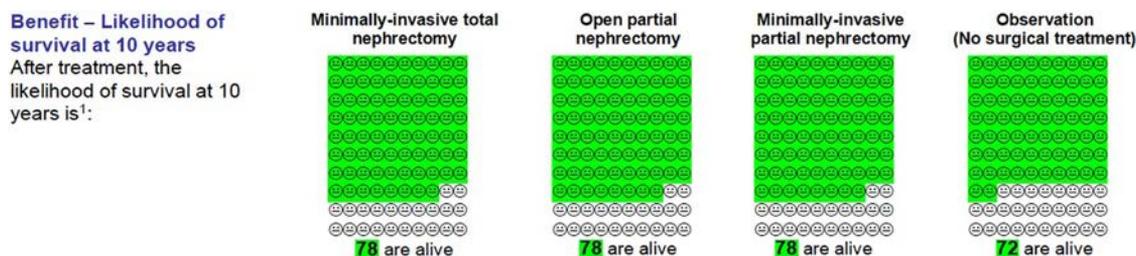


Fig. 2. Diagram of overall survival outcomes at 10 years. An example of pictorial presentation of outcomes on patient decision aid following each option for management of localized renal masses.

Results of the alpha testing were used to modify the PtDA prototype to create a finalized version (Appendix 3). The largest change to the prototype, was adding MIS partial nephrectomy as an option for management. This was not included on the prototype as it is not an approach offered by all urologists or institutions internationally. The inclusion of MIS partial nephrectomy places the impetus on the physician to outline to the patient what treatments are options for them based on their tumor complexity, medical history, and available regional resources. The PtDA met the International Patient Decision Aid Standards defining criteria (6 of 6), certification criteria (6 of 6), and quality criteria (21 of 23) (Table 1). Two criteria not met were specific to evaluating the effect on decision quality and patients' knowledge. The PtDA is freely available at: <https://decisionaid.ohri.ca/AZsumm.php?ID=1913>. The number of International Patient Decision Aid Standards criteria that are met by this PtDA are very high in comparison to PtDAs addressing other health care decisions also found at <https://decisionaid.ohri.ca/AZsumm.php>.

#### 4. Discussion

PtDAs are available for a wide range of health care decisions, however there has never been a PtDA created for localized renal masses. In fact, in urology, there are very few published PtDAs and the majority of those that are available focus on prostate specific antigen testing or treatment of localized prostate cancer [21–24]. This gap in decisional tools for urology patients is well recognized. In 2016, a multidisciplinary group of kidney cancer experts and patients were surveyed and identified the development of decisional tools for all stages of kidney cancer as a top priority in kidney cancer research [5]. Included in this recommendation was a call for a PtDA to help patients decide between partial and radical nephrectomy regardless of technical concerns [5]. In this study, we used a systematic method to create a PtDA to directly address this gap in patient-centered care.

The primary reason to surgically treat a renal mass is to render a patient cancer free. However, given that partial and radical nephrectomy offer equivalent oncological outcomes, the decision of which surgical approach is optimal for a

patient can be a preference-based decision which should be guided by patients' values [3,25]. In cases where a partial nephrectomy is deemed straightforward, partial nephrectomy is the standard of care. However, some tumors demand a more complex excision, and in these cases often partial and radical nephrectomy are reasonable treatment options. Where some patients may value a lower risk and more rapid recovery expected after a laparoscopic radical nephrectomy, others patients may accept some increased risk from partial nephrectomy to avoid chronic renal failure. By clarifying patients' values, PtDAs encourage patient-centered care.

PtDA are used to facilitate shared decision-making but do not replace the need for patient-physician consultation. Management options available to an individual vary based on patient factors, tumor characteristics, physician training, and/or equipment available at an institution. For example, not all patients are candidates for MIS partial nephrectomy based on tumor characteristics and many institutions do not have the facilities to offer this option. The term MIS partial nephrectomy was used to encompass laparoscopic and robotic surgery to make the PtDA as broadly applicable as possible. Treatment options still need to be explained to patients, and it is expected that urologists may indicate that some surgical approaches are not feasible for some patients. PtDAs are not meant to limit risk-stratified counselling. Risk assessment scoring systems, such as RENAL nephrometry or PADUA, may be used to further counsel patients regarding their risk of each outcome using the PtDA as a guide [26,27]. In the future, we hope to create an online platform that incorporates a risk assessment scoring system with patient-specific information to allow for a personalized experience. We also plan to create PtDAs for other patient populations, including those with SRMs who are often candidates for various forms of management.

Despite the availability of hundreds of PtDAs, few authors have published their development process [8]. This leaves users uncertain about the reason for inclusion of content and about the acceptability of the PtDA. Using the Ottawa Decision Support Framework and the International Patient Decision Aid Standards, we created our PtDA with a systematic approach [6–8]. The Ottawa approach to PtDA development, has been thoroughly tested with the

Table 1  
International Patient Decision Aid Standards criteria met by patient decision aid [6].

Item dimension	Qualifying criteria	Certification criteria	Quality criteria
Information	Describes the health condition or problem for which decision is required Explicitly states decision that needs to be considered Describes the options available for the index decision Describes positive features of each option Describes negative features of each option	Shows the negative and positive features of options with equal detail	Describes the natural course of the health condition or problem if no action is taken
			Makes it possible to compare the positive and negative features of available options
Probabilities			Provides information about outcome probabilities associated with the options Specifies the defined group of patients for whom the outcome probabilities apply Specifies the event rates for outcome probabilities Allows the user to compare outcome probabilities across options using the same time period Allows the user to compare outcome probabilities across the same denominator Provides more than 1 way of viewing the probabilities (e.g., words, numbers, and diagrams) Asks patients to think about which positive and negative features of options matter most to them
Values	Describes what it is like to experience consequence of the options.		Asks patients to think about which positive and negative features of options matter most to them
Guidance			Provides a step-by-step way to make a decision Includes tools like worksheets or lists of questions to use when discussing options with a practitioner
Development			Development process included a needs assessment with clients or patients Development process included a needs assessment with health professionals Development process included review by clients/patients not involved in producing the decision support intervention Development process included review by professionals not involved in producing the decision support intervention Field tested with patients who were facing the decision. Field tested with practitioners who counsel patients who face the decision
Evidence		Provides citations to the evidence selected Provides a production or publication date Provides information about the update policy Provides information about the levels of uncertainty around the event or outcome probabilities	Describes how research evidence was selected or synthesized Describes the quality of the research evidence used
Disclosure		Provides information about the funding source used for development	Includes authors’/developers’ credentials or qualifications
Plain language			Reports readability levels
Evaluation		Describes what the test is designed to measure <sup>a</sup>	Evidence improved match between preferences of the informed patient and the option chosen Evidence patient decision aid helps patients improve their knowledge about options’ features

<sup>a</sup> Not applicable for current decision aid. Green boxes indicate criteria met by patient decision aid, Yellow boxes indicate criteria to be complete with effectiveness testing, Grey boxes indicate criteria not applicable to current decision aid.

development of dozens of PtDAs [28]. The evidence supporting this approach is available at <https://decisionaid.ohri.ca/methods.html>. Researchers who are interested in developing PtDAs, can access published protocols, such as our own, to guide their development process [8].

This manuscript explains the development process of a novel PtDA for patients with localized renal masses considering partial or radical nephrectomy. We performed acceptability testing (alpha testing) with stakeholders including patients who have previously faced the target decision, kidney cancer patient advocates, surgeons who routinely perform partial and radical nephrectomy and PtDA methodological experts. We followed the criteria for evidence-based PtDA development that has been established by the International Patient Decision Aid Standards [6]. In these criteria, there are many aspects of the PtDA development process that contribute to a high-quality PtDA (Table 1) [6]. Our PtDA met 33 of 35 International Patient Decision Aid Standards criteria which is high in comparison to many other PtDAs currently in use. This manuscript does not report on validation testing (beta testing) of this PtDA. Beta testing is performed to prove the PtDA changes some aspect of the patients' decision-making experience (e.g., knowledge, decisional conflict, and choice) but is not essential to complete prior to use of a PtDA [6,8]. Our alpha testing results show this PtDA is an acceptable and valued clinical tool among patients previously facing this decision, surgeons, and methodological experts.

The strengths of this PtDA development process are its structured approach and its focus on a patient population in high need of decisional support. Our PtDA has been strongly supported by urologists, methodological experts, and most importantly patients. This study has limitations. First, the rates quoted for each outcome were based on the best available evidence, then by steering committee and expert consensus. Despite this, there is a range of rates reported in the literature that differ based on study design and tumor complexity. For example, some outcomes reported in cohorts of MIS partial nephrectomy are more favorable than cohorts receiving open partial nephrectomy or laparoscopic radical nephrectomy. This may be due to selection bias. Additionally, each point estimate on the PtDA would ideally be accompanied by a 95% confidence interval because a point estimate does not completely capture the ranges of outcomes. While a 95% confidence interval could be calculated for each outcome, this was not presented because it was felt this may increase confusion for patients. Narrative text on the PtDA encourages physicians to review this concept with patients. Second, information desired in rural locations or other countries may differ, potentially making the PtDA less applicable in these settings. Third, we included outcome data to 10 years' postoperative as this is the data from the longest follow-up available for a high-quality study. For young patients, this time-interval may be insufficient and urologists need to clarify this with individual patients.

As kidney cancer research continues, it is possible that new studies will be published with outcome rates different than those included on this PtDA. Additionally, future users may have further feedback. Ongoing updates incorporating new research and user feedback will allow the PtDA to remain current. Beta-testing with future patients will also address the 2 remaining International Patient Decision Aids Standards criteria to validate the PtDA and confirm effectiveness. This can be done by comparing patients' knowledge and/or decisional conflict scores before and after PtDA use.

## 5. Conclusions

We have created a novel PtDA for individuals with localized renal masses deciding between partial and radical nephrectomy. This clinical tool is acceptable to patients, patient advocates, methodological experts, and urologists and addresses an important need for kidney cancer patients. We are also currently developing a PtDA for patients with SRMs who are deciding between active surveillance and invasive treatments.

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## Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urolonc.2019.08.014>.

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