Shared decision-making in renal cell carcinoma

Cato Caroline Bresser

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Cato Caroline Bresser
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Promotor:

Prof. dr. P.B. van der Nat

Copromotoren:

Dr. M.M. Garvelink (St. Antonius Ziekenhuis)

Dr. H.H.E. van Melick (St. Antonius Ziekenhuis)

Manuscriptcommissie:

Prof. dr. P.F.A. Mulders

Prof. dr. W.J.W. Bos (Universiteit Leiden)

Dr. A.H. Pieterse (Leids Universitair Medisch Centrum)

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Chapter 1
General Introduction

Mr. de Vries, a 72-year-old man, was diagnosed with a small renal mass while undergoing imaging for unrelated abdominal complaints. During the consultation, his urologist explained that there were several possible treatment options: partial nephrectomy, thermal ablation therapy, or active surveillance. The urologist emphasized that the most suitable treatment option depends on what matters most to Mr. de Vries in life, as each option carries its own balance of risks and potential benefits. Surgery offers the greatest certainty of removing the tumor but involves perioperative risks. Active surveillance avoids immediate intervention but introduces uncertainty about future tumor behavior. Confronted with these trade-offs, Mr. de Vries is wondering how to choose between the options and which would best suit his situation.

Throughout the history of healthcare, it has been common practice for healthcare professionals (HCPs) to decide on a patient's diagnosis or treatment plan based on their expert opinion only. This paternalistic approach, in which the HCP decides what is best for a patient, aims to ensure that patients receive care that promotes their health and wellbeing[1]. However, this approach limits patients' autonomy in the decision-making process, resulting in decisions that often do not reflect their preferences and values. Furthermore, this may result in overtreatment and increased healthcare costs. Therefore, it is becoming increasingly important to ensure that patients receive healthcare that is tailored to their individual needs. The concept of shared decision-making (SDM) was first introduced by Robert Veatch in 1972 and subsequently embraced by the United States President's Commission in 1982[2,3]. However, it is only in more recent years that SDM has been increasingly adopted and implemented as a means of ensuring that healthcare decisions reflect patient's individual circumstances, preferences and values. With SDM, the decision-making process shifts from a paternalistic model to a patient-centered approach, with HCPs actively eliciting patients' perceptions and preferences and incorporating these into the decision. Research has shown that the majority of patients want to be involved in the decision-making process[4]. Moreover, there is growing evidence that this approach, in which patients take a more active role, is associated with greater satisfaction with the decision-making process and the decision itself, improved treatment adherence, and improvements in both patient-reported and clinical outcomes[5,6].

The need for shared decision-making in clinical practice

Shared decision-making can be defined as the process in which patients are actively involved in the decision-making process[7,8], and is increasingly recognized as a cornerstone of high-quality, patient-centered care. In SDM, patients and HCPs collaborate to choose the most appropriate option that fits the patient best. Next to informing about treatment options and possible outcomes in different scenarios, HCPs and patients discuss preferences and values with regard to the options[7]. It is the HCP's task to support patients in this process and help them find the option that best fits the patient's needs. Shared decision-making is considered to be appropriate in most decisions, especially preference-sensitive decisions, decisions with multiple options, and situations of equipoise. In addition, SDM seems relevant when the impact of the decision is high, when patient commitment is needed to carry out the decision, and when there is uncertainty of evidence or outcomes[9]. Considerable efforts have been made globally to promote SDM, including national awareness campaigns and legislative measures mandating its implementation[10]. These efforts target all stakeholders involved in the decision-making process, including patients, HCPs and the organizational context in which decisionare made. Examples are SDM training and the integration of tools to support SDM for both patients and HCPs[6,11–13].

The four shared decision-making steps

Shared decision-making is a continuous process involving four key steps, in which patients and HCPs can engage at various points in the care trajectory, as they move from diagnosis towards making a decision (Figure 1)[8,14]. In the first step, the HCP creates awareness of the fact that a decision needs to be made. Recent research among HCPs showed that only 45% of HCPs report making it clear during the consultation that a decision has to be made (step 1)[15]. Another observational study found that in 47% of encounters, HCPs did not foster choice awareness. Creating choice awareness is an important first step, in which the patient is activated, and is associated with a better SDM process afterwards[16]. In step 2, the treatment options are described, each with their own consequences (i.e. pros and cons). This step is known to be routinely practiced by most of the HCPs[17,18]. However, substantial inconsistencies have been observed in the treatment outcomes and risks communicated, between and even within individual HCPs, as well as in the manner in which these are presented to patients[19]. For example, some patients receive only a brief description of the potential benefits and a limited set of risks, while others are provided with a far more extensive overview of possible outcomes and uncertainties. In the third step, the patient's preferences in relation to the options (and their consequences) are discussed. This step is not routinely performed, as research shows that in only few consultations, patient preferences

were elicited or discussed[20–22]. In the fourth step, a decision is made (or deferred). In this final step, it is important to acknowledge that, if the three previous steps of the decision-making process have been carried out accurately, and this information is integrated into the decision, it does not matter who makes the decision (i.e. the patient or the HCP). Following the four SDM steps ensures that the final decision is aligned with the patient's values. Step 4 involves explicitly stating the decision and explaining why this option is appropriate (i.e. summarizing the considerations involved). In practice, this step is often carried out implicitly. However, it could benefit from being stated more explicitly as patients may feel uncertain about the chosen treatment if the decision is not clearly explained. This could reduce the benefits of SDM, such as decisional clarity, satisfaction and treatment adherence[23]. Clearly communicating the decision and its rationale gives patients a clear understanding of the chosen treatment plan and the next steps in the treatment process.

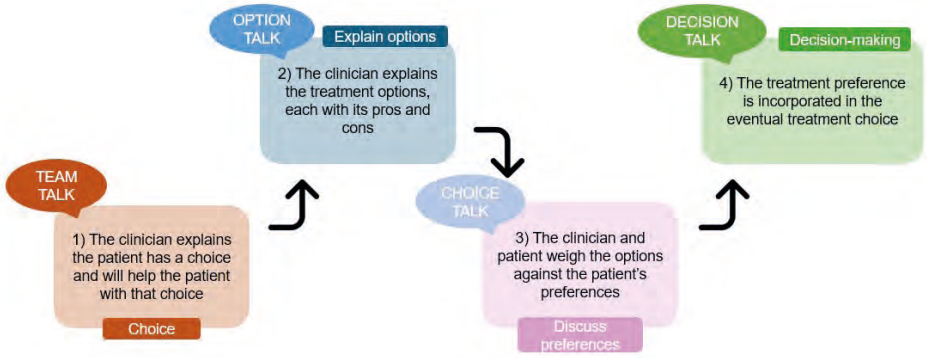

Figure 1. Concept of shared decision-making by Stiggelbout et al. and Elwyn et al[8,14]

Most patients prefer shared decision-making, but do not experience it

Recent studies indicate that both patients and HCPs increasingly recognize the importance of SDM, as 70% of both groups consider SDM to be important[22,24]. Most patients prefer to make decisions together with their HCPs, and this preference for SDM appears to be increasing over time[25]. Furthermore, many HCPs report that SDM is their preferred approach during clinical encounters[15]. However, similar reports reveal that many patients still do not experience SDM in practice, suggesting a discrepancy between HCP's perception and actual behavior[26]. Although many HCPs believe they routinely engage in SDM, observational research demonstrates that this is not the case, indicating considerable room for improvement[8,17,20].

In The Netherlands, a nationwide SDM awareness campaign was launched in 2021. It aimed to stimulate SDM among both patients and HCPs. However, research showed no difference in SDM compared to the period before the campaign started[27]. These findings highlight that simply raising awareness is not enough; SDM requires structural facilitation within clinical workflows and the active involvement of both patients and HCPs. Moreover, the increasing focus on SDM in national policy documents and healthcare strategies indicates a wider societal shift towards patient-centered care, emphasizing the importance of integrating SDM into routine practice[28]. In the current era, when the healthcare system is under increasing pressure, SDM should not simply be seen as an extra task for HCPs, but it should be recognized as a collaborative process in which patients are also responsible for active engagement[29]. Although the widely used four-step SDM model is grounded in observational research and incorporates patients' perspectives, the model mainly focuses on the communicative tasks of HCPs during the consultation. Consequently, the ways in which patients can engage or prepare are not explicitly articulated, even though patient activation is essential in the bilateral decision-making process.

Known barriers for shared decision-making

Several barriers for implementation of SDM in healthcare have been reported in the literature. Overall, barriers can be present at multiple levels and can be roughly divided into three categories: patient-, HCP-, and organizational- or system-level factors. At a patient-level, research has shown that a key barrier is the perceived power imbalance in the HCP-patient relationship[30]. This can make patients hesitant to express their preferences or ask questions. Furthermore, many patients report feeling uncertain about how to participate in SDM or lacking the knowledge and confidence to do so[31]. In addition, patient characteristics such as poor health, emotional distress or cognitive impairment are known barriers to participate in SDM[30,31]. At a HCP level, HCPs often believe that they are already practicing SDM, even when observational research indicates that key steps are missing[17]. Other barriers include a lack of skills when it comes to eliciting patient preferences, insufficient access to supporting resources such as patient decision aids (PtDAs), and variability in HCP communication styles[32]. At the organizational level, a frequently mentioned barrier for SDM is time pressure[30,32,33]. In order to implement SDM in consultations, HCPs might need to adapt their approach to the consultation and the way they communicate with patients. However, recent research has showed that applying SDM does not necessarily require more time[34]. There may be evidence of a training effect over time, in which consultation length may initially increase during the training period, but later decreases as the HCP becomes more skilled. Furthermore, it is unclear to what extent HCP's claims of a lack of time reflect an absence of autonomy in managing their available time[35]. Last, an overarching barrier is that both HCPs

and patients lack a clear understanding of what the concept of SDM really involves, and how it can be integrated into clinical consultations[36].

Tools to support shared decision-making in clinical practice

Several tools to support SDM exist, targeting patients, HCPs or both patients and HCPs[6]. Examples of available tools are PtDAs and patient- or HCP training. Combining HCP training with the implementation of tools to support SDM is known to promote the skills, confidence and cultural change needed for SDM adoption in clinical practice[37]. Patient decision aids are evidence-based tools designed to support SDM by presenting balanced information about treatment options, including active treatment, surveillance and no immediate intervention, alongside associated risks, benefits and uncertainties[23]. Interactive websites and digital tools are often used to provide information and exercises to help patients think about their values and preferences regarding the available options. In order to be considered a PtDA, the tool must include the following three elements, as defined by the International Patient Decision Aids Standards (IPDAS) minimum criteria: 1) an explicit statement that a decision needs to be considered for a specific patient population; 2) evidence-based, balanced information about the condition, options, and the associated benefits and harms; and 3) support for patients to clarify their values with respect to the benefits and harms of each option[23,38]. For the development of SDM support tools, it is recommended to co-create together with stakeholders to ensure that the tool aligns with the needs and preferences of end users and to improve implementation in clinical practice[39].

Patient decision aids are available for multiple diseases, covering both benign and malign conditions. There are more than 400 PtDAs listed in an online international database of PtDAs[40]. These tools help patients clarify their personal values and preferences, enabling them to make more informed and deliberative choices. Extensive research has shown that the use of PtDAs to support SDM is known to lead to patients making informed values-congruent choices, and patients feeling informed and clear about their personal values. In addition, PtDA use leads to increased patient knowledge and patients taking an active role in the decision-making process[23]. However, less than half of the newly developed PtDAs are used in clinical practice after implementation in a research context. Reported barriers to implementation include a lack of structured implementation strategies and organizational support, limited sustainability of tools (e.g. outdated or poor accessibility), resistance or low prioritization among HCPs, insufficient financial resources, and the absence of policy-level incentives[13]. These challenges highlight the importance of addressing implementation requirements already during the development of the tool[12]. Furthermore, HCPs often request evidence of the impact of each new PtDA, even though the effects can be difficult to measure reliably, which further complicates implementation.

Measuring shared decision-making

Shared decision-making can be measured with several validated tools, including perspectives of the patient, HCP and independent observers[41]. Available tools measure the quality of the decision-making process (e.g. perceived and observed levels of SDM, preparation for decision-making), and decision quality (e.g. effective decision-making, patient knowledge). In addition, quality of care delivery can be measured (e.g. quality of life, healthcare utilization). As decision-making processes are complex and involve multiple stakeholders with specific behaviors, it is important to consider all three perspectives (i.e. those of the patient, HCP and observer).

Observer-based tools measure SDM from an observer's point of view, adding to the patient's and HCP's perspective. The most commonly-used observer measure is the Observing Patient Involvement in Decision Making (OPTION) instrument, measuring the extent to which HCPs involve patients in decision-making[42]. The OPTION-12 instrument consists of twelve items focusing on HCP behavior[43]. An average level of 23 out of 100 was found by Couët et al in 2015, indicating a generally low level of patient involvement as measured with OPTION-12[20]. Over the past decade, there has been an increasing interest in SDM and the tools that support it, offering chance for improvement of OPTION-scores. In addition, a shorter version, OPTION-5, was introduced in 2013, providing a more efficient measure that focuses on the core components of SDM. OPTION-5 consists of five items and focuses specifically on assessing patient preferences[44].

Although the OPTION-5 tool has been widely used in many studies to evaluate SDM, a systematic synthesis of the available evidence has yet to be conducted. Consequently, there is no internationally recognized cut-off value for interpreting OPTION scores, hindering conclusions on what constitutes a 'good' level of SDM. A benchmark is essential for enabling comparisons across studies, evaluating the effectiveness of interventions and providing HCPs with clear guidance on SDM quality in daily practice.

Shared decision-making as a key component of value-based healthcare

Value-based healthcare (VBHC) is an approach to healthcare in which value is defined by outcomes in relation to the costs required to achieve them[45]. Unlike traditional healthcare models, which focus on the healthcare delivery process (measures) and the volume of care, VBHC puts the patient at the center of care delivery. As such, the aim of VBHC is not only to measure outcomes, but also to organize care in a way that ensures clinical decisions and care processes align with patients' values and preferences. This represents a fundamental shift from historically provider-driven care towards a patient value-driven system in which patients play an active role in decision-making about their treatment.

Porter developed a strategic agenda for improving value to facilitate its implementation in clinical practice[46]. This agenda includes key elements such as measuring outcomes and costs, organizing care around medical conditions, and using outcome data to improve value. More recently, a broader strategic agenda has been introduced which explicitly incorporates integrating value in patient communication, including SDM, as an integral component of VBHC[47]. While the initial strategic agenda focused primarily on improving care at a collective level, this broader agenda recognizes that realizing value also requires attention to communication and decision-making at an individual patient level. This comprehensive VBHC approach is becoming increasingly important in light of the major challenges facing healthcare systems, including population ageing, rising healthcare costs and a growing shortage of HCPs[28].

Shared decision-making is widely regarded as a key component of VBHC as it provides a structured approach to aligning clinical decisions with what matters most to patients[47]. Shared decision-making brings together clinical expertise, outcome information and patients' values and preferences. The shift towards VBHC has resulted in the collection of more outcome data, which can be used to improve care. Shared decision-making ensures these data are applied not only to improve care collectively, but also to support better treatment decisions for individual patients. In this way, the different elements of VBHC reinforce each other: outcome data support SDM, and SDM promotes more appropriate, and often more conservative treatment choices. Evidence suggests that SDM improves patient-reported outcomes, reduces unnecessary healthcare utilization and may reduce HCPs' workload, thus contributing directly to VBHC's goals[23,48,49].

In the Netherlands, the growing focus on outcome-driven, patient-centered care is evident in policy initiatives over the past decade, such as the Integral Care Agreement (Integraal Zorgakkoord, IZA)[28]. Within the IZA, multiple elements of VBHC are promoted in themes such as 'Appropriate care' (Passende Zorg), digitalization and data exchange, and regional

collaboration. These policy priorities are intended to support the transition towards VBHC. While this transition is ongoing, the Netherlands' strong and coherent national policy focus has positioned it as an international frontrunner in VBHC, including SDM.

Why advancing SDM requires further research

In summary, although SDM is widely regarded as an essential component of high-quality, value-driven care, its application in clinical practice remains inconsistent. Key steps are often overlooked, and there is a lack of understanding among patients and HCPs regarding what SDM entails. Structural barriers also continue to hinder its routine use. These shortcomings highlight the need for context-specific insights into how patients and HCPs can engage effectively with SDM, as well as the need to develop tools and strategies to support this process in daily practice. This need is particularly apparent in clinical areas with complex treatment pathways, such as renal cell carcinoma (RCC).

Renal cell carcinoma

Renal cell carcinoma is the most common type of kidney cancer[50]. In the Netherlands, yearly approximately 2700 patients are diagnosed with RCC. This number is expected to increase by 31% over the next decade, due to increasing incidence of risk factors such as smoking, hypertension, and obesity[51]. Renal cell carcinoma can be staged into four stadia, according to tumor size: cT1 tumors are smaller than 7 cm and located in the kidney only, cT2 tumors are bigger than 7 cm, and cT3 tumors grow outside the kidney. In cT4 RCC, the tumor has grown beyond Gerota fascia and/or is metastasized to regional lymph nodes and/or other organs[52]. In 20% of patients, the tumor has metastasized at initial diagnosis[53].

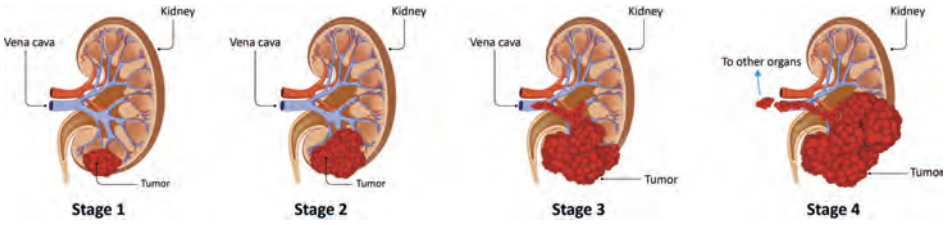

Figure 2. Renal cell carcinoma disease stages

In the Netherlands, RCC care is mostly organized within regional collaborative networks that aim to centralize complex treatments while ensuring accessible, coordinated care across institutions. Treatment is concentrated: partial nephrectomies (PN) and thermal ablation

(TA) techniques are performed only in selected hospitals with the necessary expertise. Nevertheless, notable variation in the availability and delivery of treatment options persists even within these regional structures[54]. The IZA has set volume standards for RCC treatments, requiring hospitals to perform at least 50 procedures per year (including surgery, TA techniques, and radiation therapy), in order to improve quality of care in the Netherlands[55]. For more advanced treatments, including immunotherapy combinations, patients are referred to specialized hospitals. Treatment plans for patients with RCC are discussed at a network level in centralized multidisciplinary team (MDT) meetings. The advice that results from these meetings is then communicated back to the referring hospital. National coordination of RCC care is facilitated through initiatives such as the Dutch Renal Cancer Group (DRCG) and the Netherlands Comprehensive Cancer Organization (IKNL), which support the collection and analysis of data, contribute to quality monitoring, and research related to RCC[56].

Tailoring treatment strategies in renal cell carcinoma

The management of RCC is guided by disease stage, various clinical and patient-related factors, including tumor characteristics, comorbidities and individual treatment preferences. For localized (cT1-2) RCC, surgical resection of the tumor, TA techniques (e.g. cryoablation, microwave ablation (MWA), and radiofrequency ablation (RFA)), and active surveillance (AS) are available[57]. Recently, emerging options such as stereotactic body radiation therapy (SBRT) are becoming more widely accepted[58,59]. For metastatic clear-cell RCC, there has been a significant evolution in the treatment landscape over the past years. Until 2019, tyrosine kinase inhibitors (TKIs) such as sunitinib and pazopanib were the standard of care. However, the introduction of immunotherapy, particularly combination therapies like nivolumab and ipilimumab, has resulted in a shift in treatment strategies[53,57]. These developments have led to a more personalized approach to treatment, based on individual risk profiles and expected survival benefits.

In both localized and metastatic RCC treatment, multiple treatment options are available, each with its own consequences. For example, patients with small renal tumors (cT1a), have multiple treatment options, including PN, TA or AS[60,61]. Each treatment has its own benefits and risks, and the best option for each patient depends on their individual preferences and clinical characteristics. With a growing range of treatment options for both localized and systemic RCC, it is important to weigh these options together with the patient to choose the most appropriate option.

Partial nephrectomy, the standard surgical option, is performed with the aim of removing the tumor while preserving as much kidney function as possible. Although it offers excellent long-term oncological outcomes, it is associated with a longer recovery time, surgical risks (e.g. bleeding or infection) and potential loss of renal function[57]. Thermal ablation techniques, such as cryoablation or RFA, are minimally invasive and usually result in shorter hospital stays and faster recovery. However, they may carry a slightly higher risk of local recurrence compared to surgery[62]. Active surveillance, which involves regular imaging and monitoring without immediate intervention, is a viable strategy, particularly for patients with limited life expectancy or significant comorbidities. Furthermore, there is an increasing tendency to adopt AS for small renal tumors, given the low risk of these tumors progressing to metastatic disease and the presence of competing mortality risks[63–65]. However, AS can lead to increased anxiety and stress for some patients, as well as the burden of having to come to the hospital regularly.

The way in which specific considerations regarding RCC treatment are weighed, such as side effects or recovery time, varies from person to person. For example, a physically active patient with a cT1a renal tumor who values a rapid return to daily activities, such as someone who participates in competitive sports, may strongly prefer TA over surgery due to the shorter recovery period and lower physical burden. In such cases, the perceived importance of functional recovery may outweigh small differences in oncological outcomes or recurrence risk. Therefore, the decision-making process for RCC treatment must be tailored to the individual, taking into account tumor characteristics, clinical guidelines and the patient's lifestyle, values and preferences. The decision-making process for metastatic RCC, which involves palliative rather than curative treatment goals, requires weighing potential benefits of treatment against toxicity profiles, the patient's overall condition, comorbidities and personal preferences. For example, some patients may prioritize quality of life and wish to avoid severe immune-mediated side effects, favoring TKIs. Conversely, others may accept a higher risk of immune toxicity in exchange for a chance at longer remission with immunotherapy.

Understanding variation in renal cell carcinoma treatment

Variation in treatment for RCC can be considered a sign of differences in quality of care. If certain treatment options are offered less frequently in each setting, it may suggest that patients are not consistently informed about the full range of available options, indicating suboptimal implementation of SDM. Recent research in the Netherlands has revealed significant variation in the initial management of cT1 RCC across hospitals in the Netherlands[54]. This indicates that the treatment approach selected may depend largely on the hospital or region where a patient is diagnosed. Some variation is acceptable, as it may reflect personalized care, HCP experience or SDM, but not when treatment decisions are influenced

by non-clinical factors, such as unequal access to treatment options across institutions[66]. Disparities in local treatment availability can lead to inconsistent care, potentially affecting both patient outcomes and healthcare costs. Although referral to specialized hospitals is possible within the Dutch healthcare system, such referrals appear to be underutilized in practice, contributing to unequal treatment. To ensure equitable and evidence-based treatment, it is essential that all patients are informed of all medically appropriate options, regardless of their availability at the diagnosing hospital.

The need for shared decision-making about renal cell carcinoma treatment

The dilemmas presented at the beginning of the introduction, in the case of Mr. de Vries, are common among patients with RCC and illustrate the complexity of treatment decision-making. The presence of equipoise, the absence of clear, evidence-based selection criteria and the fact that treatment choices are preference-sensitive make SDM particularly important in RCC to ensure delivery of high-quality, patient-centered care[9]. In urology, international guidelines recommend using SDM in clinical decision-making [57,60]. Nevertheless, many RCC patients still report limited involvement in decisions about their treatment[67]. Research has shown that SDM in urology has not improved in recent years[68]. To date, no research has specifically explored the reasons behind this stagnation.

To support patient's active participation in the decision-making process, it is essential to ensure that patients receive consistent information about all possible treatments, including their respective consequences. Patient decision aids could support this process. Although some PtDAs for RCC exist internationally, they are not tailored to the Dutch healthcare context and do not provide personalized summaries to facilitate discussion during clinical consultations[69,70]. Currently, there are no Dutch-language PtDAs available for RCC patients. Due to differences in treatment guidelines and availability across countries, direct translation of existing tools is not possible. These findings emphasize the need to develop and implement PtDAs that support SDM about RCC treatment in the Netherlands. However, the development of a PtDA requires insight into the needs of both RCC patients and HCPs. Little is known about how Dutch RCC patients and HCPs experience the decision-making process, what information they consider essential, and what barriers hinder the balanced and consistent presentation of treatment options. Furthermore, the extent to which regional variation in treatment exists is unclear. Understanding these factors is crucial for designing a PtDA that is context-appropriate and can be implemented in Dutch RCC care. Furthermore, there is limited evidence regarding the specific effects of PtDAs in RCC care. While international studies suggest potential benefits, the impact of PtDAs on SDM, consultation dynamics, and treatment decisions within the Dutch RCC setting has

not yet been established. As healthcare organizations and HCPs increasingly request context-specific evidence before adopting new SDM interventions, dedicated research is needed. These knowledge gaps demonstrate the necessity of systematically investigating the current decision-making context, co-developing PtDAs that align with end users' needs, and evaluating their impact and implementation in clinical practice. Addressing these issues is crucial for improving SDM in RCC care in the Netherlands.

Aim of this thesis

The aim of this thesis is to improve SDM in treatment decision-making for RCC. We have formulated five main objectives:

1. To evaluate the level of observed patient involvement in the decision-making processes by gaining insight into the current application of SDM in clinical practice.
2. To evaluate treatment patterns for cT1a RCC across Dutch hospitals to better understand the current clinical context.
3. To develop two PtDAs tailored to RCC to support SDM in clinical consultations.
4. To assess the effectiveness of the PtDAs as part of a SDM intervention in order to determine its value in clinical practice.
5. To evaluate the use of the SDM intervention and its implementation into routine care by exploring the experiences of patients and HCPs.

Outline of this thesis

This thesis is structured in four parts.

Part I reports on two studies that measured the current state of SDM in clinical practice, as well as treatment variation among patients with cT1a RCC in the Netherlands. **Chapter 2** presents a systematic review and meta-analysis examining the extent to which HCPs actively involve patients in the decision-making process, using the validated OPTION-12 and OPTION-5 instruments. **Chapter 3** analyses variation in treatment patterns for cT1a renal cancer tumors across seven Dutch Santeon hospitals. Together, these chapters highlight the current variability in both patient involvement and the clinical management of RCC.

Part II outlines the development process for two PtDAs for RCC. In **Chapter 4**, the development of a PtDA for cT1 renal masses is described. **Chapter 5** focuses on the development of a PtDA for metastatic clear cell RCC.

Part III evaluates the effectiveness of the developed PtDAs. **Chapter 6** describes the study protocol of the SDM-RCC study. In **Chapter 7**, the results of the SDM-RCC study are presented, evaluating the impact of the SDM intervention on the decision-making process and decision quality. This multicenter prospective study investigated the effect of a multifaceted SDM intervention (i.e. PtDA and HCP training) using a pretest-posttest study design. Patients with localized and metastatic clear cell RCC were included in this study. Data was collected through audio-recordings of consultations, using the OPTION-5 scale, as well as through questionnaires for patients and HCPs.

Part IV covers the implementation process. **Chapter 8** reports on the implementation of the intervention and investigates how and to what extent the SDM intervention was implemented and used. In addition, the experiences of patients and HCPs with the implementation process and use of the SDM intervention were investigated.

Chapter 9 provides a summary of this thesis, followed by a general discussion. Finally, implications for future research and clinical practice are presented.

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PART I

The current situation

Chapter 2

Assessing shared decision-making in clinical practice: A systematic review and meta-analysis of studies using OPTION-12 and OPTION-5.

C.C. Bresser*
A. Duarte-Díaz*
H. González-Pacheco
A. Rivero-Santana
Y. Ramallo-Fariña
H.J. Westerink
L.M. Dijksman
H.H.E. van Melick
P.B. van der Nat
F. Légaré
G. Elwyn
M.M. Garvelink**
L. Perestelo-Pérez**

*Authors contributed equally and share first authorship
**Authors contributed equally and share last authorship

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Abstract

Objectives: Observing Patient Involvement in Decision Making (OPTION)-12 and OPTION-5 assess the extent to which observers score healthcare professionals' (HCPs) involvement of patients in shared decision-making (SDM). We systematically reviewed studies measuring the extent to which HCPs involve patients in decision-making process using the OPTION instrument.

Design: Informed by Preferred Reporting Items for Systematic Reviews and Meta-Analyses, we updated a previous systematic review and included new studies reporting OPTION-12 or OPTION-5 scores from recordings of real-world clinical encounters, involving patients and HCPs making healthcare-related decisions. Searches were conducted across PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science databases (2012–2025), supplemented by citation screening and outreach to professional networks. We extracted study characteristics, OPTION version, psychometric data, and item-level score details. We also assessed the study quality using the reports of rating procedures and conducted meta-analyses, subgroup analyses using a priori hypotheses and completed meta-regressions.

Results: In total, 174 studies were included, comprising almost 20,000 clinical consultations: 102 studies used only OPTION-12 and 64 used only OPTION-5, while four studies reported using both scales. Mean OPTION-12 and OPTION-5 score for studies unaffected by interventions were 25.1 (95% CI: 22.1-28.2, k=76, I^2=99.71%) and 31.83 (95% CI: 26.6-37.1, k=42, I^2=99.55%) respectively. Subgroup analyses revealed significantly higher scores in studies with post-intervention OPTION-scores for both OPTION-12 (38.4 vs. 25.1, p<0.001, k=91, I^2=99.55%) and OPTION-5 (47.7 vs. 31.8, p<0.001, k=65, I^2=99.39%). In univariable meta-regression, longer consultation duration and female patient percentage (only for OPTION-12) were associated with higher scores. However, multivariable meta-regression revealed that clinical setting was the sole independent predictor for OPTION-12 (p=0.007), whereas consultation duration remained the primary independent predictor for OPTION-5 (p=0.003).

Conclusions: Since the 2015 previous review, little overall improvement has been observed. This limited progress raises important questions about how we interpret changes in observed SDM. Specifically, it remains unclear what degree of change in OPTION-12 scores reflects a meaningful improvement. Our multivariable findings provide a more nuanced perspective: while consultation duration remains the primary independent predictor for patient involvement when measured with OPTION-5, clinical setting emerges as a more critical independent driver for OPTION-12. These results suggest that the influence of time is not uniform across assessment tools and that structural barriers in different clinical environments must also be addressed to foster SDM effectively.

PROSPERO registration number: CRD42022332231.

Introduction

Shared decision-making (SDM) is a collaborative process in which patients are actively involved in making healthcare decisions about their own care[1]. In this process, healthcare professionals (HCPs) and patients work together to make decisions based on the best available evidence, weighing the benefits and risks of each option while incorporating patients' preferences and values to identify the most appropriate option. The SDM process can be divided into three key steps: (a) team talk, in which available options and roles in decision-making are discussed; (b) option talk, in which the options are discussed and compared; and (c) decision talk, where decisions are made that align with patients' informed preferences[2]. Patient involvement fosters informed and personalized care and has favorable impact on the quintuple aim (improve patient experience[3], health outcomes[4], HCPs' experience[5], efficiency[3] and equity[6]).

Several tools are available to measure SDM, covering both patient, HCP and observer perspectives[7,8]. Observer-based tools, in particular, offer unique advantages as they provide an objective measurement of the SDM process. These tools rely on trained assessors who evaluate behaviors during recorded encounters, making them less prone to biases like halo effects, and social desirability biases[9]. Observer-based tools can be used for evaluation of SDM processes in research, benchmarking, and when applied in training, feedback, or quality improvement initiatives, they can support efforts to improve SDM in clinical practice.

An often cited instrument to measure the extent to which HCPs involve patients in decision-making is the Observing Patient Involvement in Decision Making (OPTION) instrument[10]. Two versions of the OPTION exist: The original OPTION-12[10] and the shorter OPTION-5[11]. Both OPTION-12[12] and OPTION-5[13–16] have been widely applied across diverse clinical settings and healthcare disciplines. Over a decade has passed since a 2015 systematic review on the OPTION-12[12] provided the first comprehensive exploration of how HCPs involve patients in decision-making. Couët et al[12] found an overall mean of 23 (0-100 scale), with mean total scores of studies with post-intervention OPTION-scores of 34[12]. Evolving practices in patient involvement and decision-making underscore the need for an updated review of OPTION-12 studies to assess current evidence and address remaining research gaps. In addition, no systematic review has yet been conducted to summarize evidence on the use of OPTION-5 across multiple clinical specialties and settings. Therefore, this study aims to systematically review the extent to which HCPs actively involve patients in the decision-making process based on the OPTION-12 and OPTION-5 instruments.

Methods

Study design

We conducted a systematic literature review and meta-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines[17] (Appendix I). The protocol for this systematic review and meta-analysis was prospectively registered on PROSPERO on May 23th, 2022 (CRD42022332231).

The Observer OPTION instrument

The original OPTION-12 instrument consists of 12 items that describe key behaviors regarding patient involvement in decision-making. Each item is scored on a 0-4 scale by independent raters, with the total score standardized to 0-100 scale. The observer OPTION-5 was designed to enhance reliability by simplifying the scale, improving the clarity of behaviors assessed and reducing the time required for evaluation[11]. OPTION-5 comprises five items, each scored on a 0-4 scale, with a greater focus on eliciting and integrating patient preferences into the decision-making process (Appendix II)[9].

Search strategy

An electronic literature search was conducted on 19 June 2025. To update the 2015 systematic review by Couët et al.[12] which included studies published up to 2012, we limited our search to studies published from 2012 onward. A comprehensive search strategy, developed with the assistance of an experienced medical librarian, was used to identify references from PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL) and Web of Science (Appendix III). In order to assess if the search strategy was sufficient, we checked if it could identify the studies included in the previous OPTION-12 review[12]. In addition, references citing the validation studies of the OPTION-12 instrument (first and second versions)[10,18] were identified. Next, authors likely to have recently used the OPTION-5 or OPTION-12 instrument were contacted via the International Society for Medical Decision Making (ISDM) mailing list and the 'Shared@ Shared Decision-Making Network' Facebook page. Finally, a reference screening of relevant literature reviews was performed.

Inclusion criteria

Studies involving HCPs, patients and caregivers facing a real healthcare-related decision and reporting OPTION-12 or OPTION-5 scores were included in this review. Studies that did not report OPTION scores as an outcome measure or utilized the dyadic version (Dyadic-OPTION) were excluded. We included studies that involved HCPs, patients with any clinical condition, or surrogates (e.g., parents making decisions about their child's health). We did not impose any restrictions on the language of the studies, the age of participants, the setting (inpatient or outpatient), or the severity of the disease. Randomized and non-randomized

controlled trials, as well as observational studies (i.e., prospective, retrospective, or cross-sectional) that addressed patient involvement in decision-making using the OPTION scale, were included. Studies with simulated patients were excluded. In addition, we excluded conference abstracts, letters, commentaries, essays, book chapters, study protocols, and reviews.

Study selection

The results of the electronic literature search were downloaded to a reference database and duplicates were removed. The citations were loaded into Rayyan[19]. Potentially relevant studies were screened by title and abstract by two independent reviewers from a group of four researchers (CCB, ADD, MMG and LPP). Afterwards, two reviewers from a group of five researchers (CCB, MMG, HJW, LMD, or ADD) independently screened the included full texts for eligibility. Reasons for exclusion were recorded. Disagreements between the two reviewers on inclusion were discussed in several meetings and consensus was reached on the final set of included articles. For this update, we limited our data collection to newly published studies and analyzed these together with the studies included in the previous Couët review[12]. A detailed overview of the study selection process is presented in the PRISMA flow diagram (Figure 1).

Data extraction

Characteristics from the included studies were extracted in Excel by one independent researcher from a group of five researchers (CCB, MMG, HJW, LMD, or ADD) and double-checked by an independent researcher to increase the reliability of data extraction (CCB, MMG, or ADD). Any discrepancies were resolved in consensus meetings. The extraction file was pilot tested by CCB and MMG to ensure that all relevant data were captured. Data that were extracted included: (1) study characteristics (e.g., author, year, country, design); (2) consultation characteristics (e.g., decision type, consultation duration); (3) patient characteristics (e.g., sex, age, clinical condition); (4) HCP characteristics (e.g., sex, age, years of experience); and (5) OPTION-12 and OPTION-5 outcomes (mean, standard deviation (SD), range) (Appendix IV).

Quality assessment

The methodological quality of the studies was assessed by one independent researcher (CCB, MMG, HJW, LMD, ADD, LPP, ARS or YRF) by documenting a set of reporting guidelines for the rating procedure, psychometric data and OPTION-12 and OPTION-5 item-level data, developed by Couët et al[12]. This assessment focused specifically on the transparency and completeness of reporting regarding the use of OPTION scales, as these factors are critical for the reliability of observed SDM scores. The quality criteria were used to describe the state of the literature rather than as a basis for excluding studies or conducting sensitivity analyses, as the primary objective was to provide a comprehensive overview of how patient involvement is currently measured and reported across diverse clinical settings. Extracted

data were double-checked by an independent researcher (CCB or ADD). Discrepancies were resolved in consensus meetings.

Data analysis

Study characteristics were analyzed using descriptive statistics. Frequencies, averages (mean or median), and dispersion measures (SD, and interquartile range (IQR)) were reported. For studies reporting median scores, data skewness was checked[20] and sample means were estimated using a validated method (https://www.math.hkbu.edu.hk/~tongt/papers/median2mean.html)[21–23].

A meta-analysis was performed to obtain pooled mean estimates for OPTION-12 and OPTION-5 total scores, providing a summary of the level of observed patient involvement in clinical practice. Given the expected heterogeneity, these pooled estimates were primarily descriptive and aimed at summarizing mean levels as well as exploring moderators through subgroup analyses and meta-regressions. The primary meta-analysis included studies that reported the number of consultations, mean OPTION scores, and SD, standard error (SE), or 95% confidence interval (CI). Only non-intervention observations were included, defined as cross-sectional studies without interventions and the control/usual-care arms of RCTs and controlled before-after (CBA) studies. For these studies, a meta-analysis of means was conducted separately for OPTION-12 and OPTION-5, using a random-effects model. The restricted maximum-likelihood estimator was applied to estimate between-study variance ($\tau 2$). A leave-one-out sensitivity analysis was performed to assess the stability of the pooled estimates and to evaluate whether the high heterogeneity was driven by individual outlier studies. To explore the sources of heterogeneity, we adopted a two-step analytical approach: we first used univariable subgroup analyses and univariate meta-regressions as exploratory tools, and then ran a confirmatory multivariable meta-regression including only significant covariates ($p<0.05$) and excluding overly complex categorical variables to control for multiple testing, confounding, and overfitting (Appendix V). The meta-analysis was performed in Stata V.17 using the meta package and forest plots for subgroup analyses were generated using RStudio.

Results

Study and sample characteristics

A total of 174 studies were included (Figure 1). Of these 174 studies, 102 studies evaluated SDM using the OPTION-12 instrument (124 citations)[24–151], 64 studies using the OPTION-5 instrument (70 citations)[13–16,152–216], including four studies evaluating both instruments[59,85,136,144]. Tables 1 and 2 in Appendix VI present the study characteristics of studies using OPTION-12 and OPTION-5.

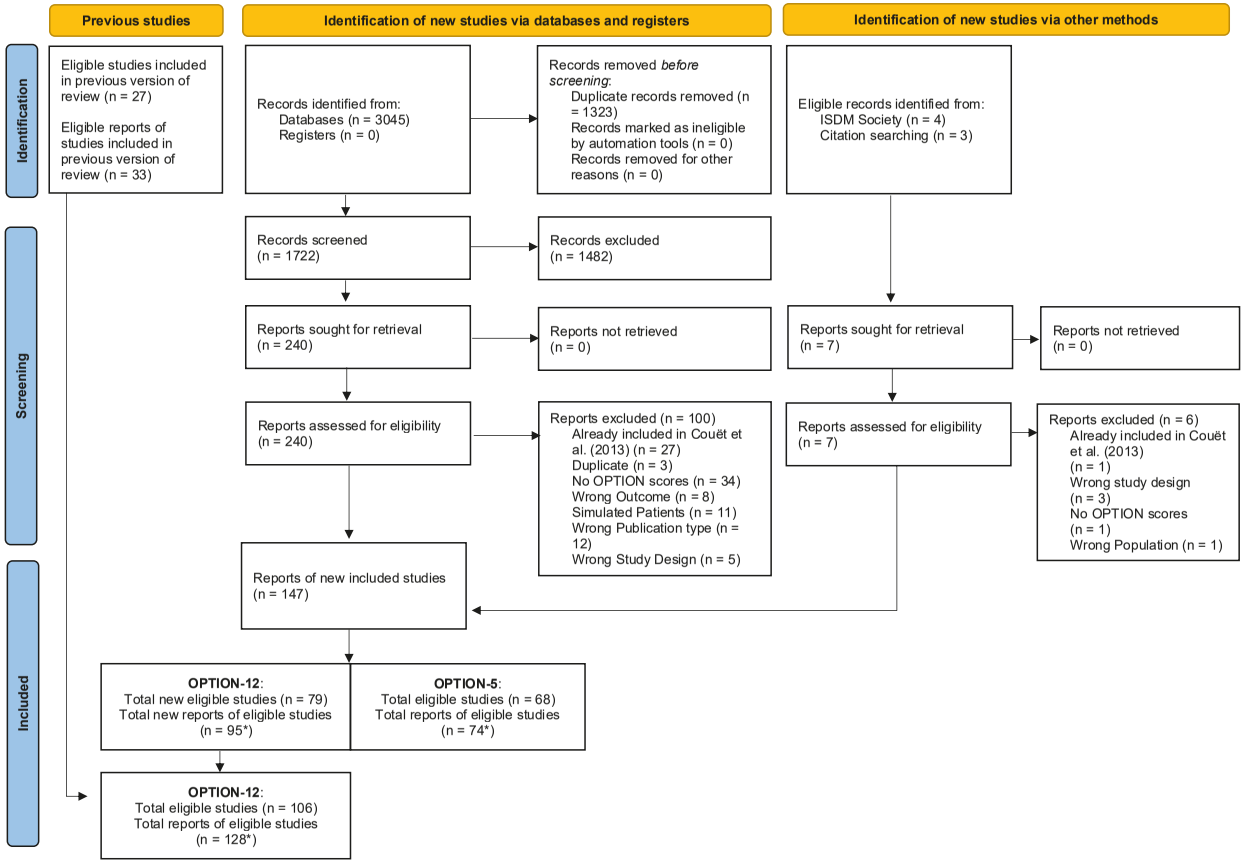


Figure 1. Flow diagram of the studies included.
* Four studies reported both OPTION-5 and OPTION-12 scores.
OPTION, Observing Patient Involvement in Decision Making

Total mean OPTION-scores

The main characteristics of studies included in the meta-analyses are summarized in Table 1.

For OPTION-12, of the 106 studies identified, 71 studies (76 groups) comprising 6,794 consultations were included in the meta-analysis. The mean consultation length was 23.07 minutes, with 66% female patients (mean age 46 years). Among HCPs, 49% were female, with a mean age of 42 years and a mean of 14 years of professional experience. The pooled OPTION-12 score was 25.1 (95% CI: 22.1–28.2, k=76, I^2=99.71%).

For OPTION-5, of the 68 studies identified, 41 studies (42 groups) comprising 3,578 consultations were included in the meta-analysis. The mean consultation duration was 25.2 minutes, with 61% female patients (mean age 55 years). Healthcare professionals were 50% female, with a mean age of 43 years and about 10 years of experience. The pooled OPTION-5 score was 31.8 (95% CI: 26.6–37.1, k=42, I^2=99.55%).

The robustness of the pooled estimates and the stability of the statistical heterogeneity were confirmed through leave-one-out sensitivity analyses for both scales. For OPTION-12 (k=76), the I^2 remained consistently between 99.6% and 99.7%, while for OPTION-5 (k=42), it remained between 99.4% and 99.6% across all iterations. These results indicate that the extreme heterogeneity is a systemic feature of the evidence base and is not driven by any single outlier study.

Table 1. Main characteristics of studies included in the meta-analyses

Variable	OPTION-12	OPTION-5
Number of studies	71	41
Number of groups within studies	76	42
Number of consultations	6794	3578
Mean duration ± SD (minutes)	23.1 ± 15.4	25.2 ± 21.7
% of females ± SD (patients)	66.4 ± 23.9	61.4 ± 24.1
Mean age ± SD (patients)	46.2 ± 15.8	55.1 ± 23.6
% of females ± SD (HCPs)	49.3 ± 23.3	49.7 ± 31.5
Mean age ± SD (HCPs)	41.8 ± 6.4	42.8 ± 10.8
Years of experience ± SD (HCPs)	14.2 ± 4.2	10.4 ± 4.8
Pooled mean OPTION score	25.1 (95%CI: 22.1-28.2)	31.8 (95%CI: 26.6-37.1)

SD, standard deviation

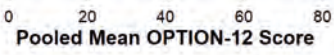
Exploration of heterogeneity

Subgroup analyses

Several a priori defined subgroup analyses were conducted to examine OPTION scores in several subgroups (Figures 2 and 3).

For OPTION-12 studies, significant differences in scores were observed across clinical conditions ($p<0.001$), with neurological conditions showing the highest mean score (47.8) and traumatic care (13.3) and respiratory conditions (20.4) among the lowest. Care setting also emerged as a significant moderator ($p=0.026$), with higher scores in secondary care (27.3) compared to primary care (20.7). No significant differences were found for continent ($p=0.281$), with scores of 22.9 in Europe and 28.5 in North America. Similarly, no significant variations were observed by rated media ($p=0.899$), type of decision ($p=0.598$), involvement of residents in training ($p=0.664$), or publication period relative to Couët et al's review ($p=0.399$). Regarding the secondary analysis of interventions for OPTION-12, scores were significantly higher in the intervention groups (mean 38.4; 95% CI: 35.1–41.7; k=91; $I^2=99.6\%$) compared with non-intervention observations (mean 25.1; 95%CI: 22.1–28.2; k=50; $I^2=98.0\%$; $p<0.001$).

Group / Subgroup	k	Tau	I2 (%)	Mean (95% CI)	P-diff
Continent					p=0.281
Europe	41	178.60	99.70	22.91 (18.78-27.05)	
North America	25	203.60	99.60	28.53 (22.89-34.17)	
Other	10	82.50	99.50	25.68 (19.95-31.41)	
Setting					**p=0.026**
Primary Care	29	121.20	99.70	20.69 (16.63-24.74)	
Secondary Care	43	192.40	99.60	27.30 (23.12-31.48)	
Condition					**p<0.001**
Cancer	8	336.80	99.50	24.70 (11.93-37.48)	
Cardiovascular	7	118.80	99.60	21.53 (13.41-29.64)	
Endocrine & Metabolic	5	36.40	95.00	23.92 (18.42-29.42)	
Mental Health	8	62.50	95.20	29.61 (23.94-35.27)	
Multiple	28	140.20	99.80	19.64 (15.22-24.06)	
Musculoskeletal	5	46.40	93.60	30.27 (23.97-36.56)	
Neurological	4	336.30	98.50	47.78 (29.49-66.11)	
Orthodontics	1	0.00		42.60 (36.48-48.73)	
Prenatal Screening	3	193.20	99.00	34.97 (19.15-50.79)	
Reproductive Health	2	87.70	94.90	28.15 (14.84-41.47)	
Respiratory	3	31.40	92.60	20.39 (13.74-27.04)	
Traumatic	1	0.00		13.30 (12.49-14.11)	
Rated media					p=0.899
Audio	25	130.20	99.80	22.93 (18.41-27.44)	
Transcripts	21	118.00	99.10	23.26 (18.54-27.99)	
Video	18	90.40	98.50	24.37 (19.88-28.69)	
Type of decision					p=0.598
Screening/Diag.	4	275.00	99.10	28.95 (12.58-45.33)	
Treatment	68	177.90	99.70	24.46 (21.26-27.66)	
Residents					p=0.664
No	74	186.60	99.70	25.08 (21.90-28.27)	
Yes	4	8.10	82.80	26.09 (22.87-29.30)	
Publication					p=0.399
Before Couet	19	206.50	99.80	22.76 (16.25-29.27)	
After Couet	57	167.90	99.60	25.92 (22.52-29.32)	



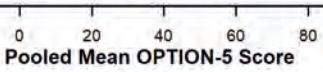
Note: k = number of studies; Tau = between-study variance; I2 = index of heterogeneity; CI = confidence interval.
OPTION = Observing Patient Involvement in Decision Making

Figure 2. Subgroup analyses for OPTION-12 studies

Similar patterns were observed in OPTION-5 studies (Figure 3). Siginificant differences were found across care settings (p=0.008), with lower scores in primary care (20.3) and higher scores in secondary care (34.0). Clinical condition also remained a significant moderator (p<0.001), with the highest OPTION-5 scores observed in respiratory conditions (65.6) and kidney diseases (47.3), whereas the lowest scores were reported in dermatological conditions (10.7). Furthermore, decision type showed significant variation (p<0.001), with diagnostic decisions yielding higher scores (60.6) than treatment-related decisions

(33.0). In contrast to the initial findings, no significant differences were observed across continents (p=0.614), with scores of 33.9 in Europe and 28.7 in North America. Similarly, rated media did not show significant association with scores (p=0.783) when comparing audio (32.8), transcripts (39.3) and video (34.8). No differences were found regarding the involvement of residents in training (p=0.904). In the secondary subgroup analyses including post-intervention observations, similar results to OPTION-12 were observed: scores were significantly higher in the intervention groups (mean 47.7; 95% CI: 39.6–55.9; k=23; I^2=99.4%) compared with non-intervention observations (mean 31.8; 95% CI: 26.6–37.1; k=42; I^2=99.6%; p<0.001).

Group / Subgroup	k	Tau	I2 (%)	Mean (95% CI)	P-diff
Continent					p=0.614
Europe	25	341.72	99.47	33.92 (26.62-41.21)	
North America	15	226.85	99.51	28.65 (20.87-36.44)	
Other	2	378.52	99.53	28.66 (1.63-55.69)	
Rated media					p=0.783
Audio	21	140.48	98.38	32.80 (27.66-37.95)	
Transcripts	8	681.01	99.66	39.30 (21.02-58.86)	
Video	7	386.35	99.30	34.84 (20.12-49.56)	
Setting					**p=0.008**
Primary Care	5	88.91	98.67	20.26 (11.93-28.59)	
Secondary Care	36	301.12	99.51	34.00 (28.26-39.74)	
Condition					**p<0.001**
Cancer	7	594.48	99.62	34.35 (16.22-52.48)	
Cardiovascular	4	137.05	97.21	30.49 (18.76-42.23)	
Dermatological	1	0.00		10.70 (7.98-13.43)	
Hematological	2	111.57	95.32	35.51 (20.52-50.50)	
Kidney Diseases	3	454.04	98.33	47.32 (22.93-71.70)	
Mental Health	2	372.01	99.61	19.11 (-7.67-45.90)	
Multiple	11	143.88	98.96	26.78 (19.43-34.12)	
Musculoskeletal	5	136.01	99.48	29.89 (19.59-40.19)	
Neurological	1	0.00		22.50 (18.57-26.43)	
Reproductive Health	3	525.83	96.36	39.10 (13.05-65.16)	
Respiratory	1	0.00		65.60 (62.55-68.65)	
Urological	1	0.00		41.80 (39.47-44.13)	
Type of decision					**p<0.001**
Diagnostic	1	0.00		60.56 (55.86-65.26)	
Treatment	36	285.70	99.50	33.00 (27.41-38.59)	
Residents in training					p=0.904
No	40	302.63	99.57	31.83 (26.45-37.34)	
Yes	2	260.06	98.49	30.57 (7.95-52.99)	



Note: k = number of studies; Tau = between-study variance; I2 = index of heterogeneity; CI = confidence interval.
OPTION = Observing Patient Involvement in Decision Making

Figure 3. Subgroup analyses for OPTION-5 studies

Meta-regression

Univariate meta-regression analyses explored potential continuous moderators of OPTION scores, including consultation length, patient- and HCP-demographics, HCP experience, and publication year (Table 2). Bubble plots of univariate meta-regression are shown in Appendix VII.

For OPTION-12, consultation length showed a significant positive association with scores (β=0.32, p=0.001, R^2=20.4%), as did the proportion of female patients (β=0.17, p=0.038, R^2=6.1%) (Table 2, Appendix VII). No other moderators, including publication year, patient age, HCP gender or age, or years of HCP experience, were significantly associated with OPTION-12 scores.

For OPTION-5, consultation length was again the only significant moderator (β=0.54, p<0.001, R^2=38.5%), indicating higher mean OPTION scores in longer consultations (Table 2, Appendix VII). Other variables, including patient- and HCP-demographics, years of HCP experience, and publication year, were not statistically significant.

Table 2. Univariate meta regression analyses

Moderator	K	Number of consultations	Coefficient (β)	95% CI	SE	P value	R-squared (%)
OPTION-12							
Consultation length (minutes)	38	2879	0.32	0.12-0.51	0.10	**0.001**	20.36
Females (%) – Patients	53	4102	0.17	0.01-0.32	0.08	**0.038**	6.14
Mean age – Patients	41	3278	-0.05	-0.35-0.25	0.15	0.737	0.00
Females (%) – HCPs	40	3693	0.05	-0.13-0.23	0.09	0.595	0.00
Mean age – HCPs	27	2324	-0.62		0.34	0.065	8.37
Years of experience – HCPs	13	975	-1.45	-1.28-0.04	0.78	0.065	16.62
Publication year	76	6794	0.28	-0.34-0.90	0.31	0.376	0.00
OPTION-5							
Consultation length (minutes)	20	1854	0.54	0.25-0.85	0.15	**0.000**	38.52
Females (%) – Patients	36	3143	0.03	-0.21-0.27	0.12	0.791	0.00
Mean age – Patients	27	2259	0.13	-0.11-0.37	0.12	0.280	0.44
Females (%) – HCPs	21	2260	-0.16	-0.21-0.27	0.11	0.131	6.29
Mean age – HCPs	12	1943	0.39	-0.42-1.20	0.41	0.344	0.00
Years of experience – HCPs	6	708	-1.65	-4.16-0.85	1.28	0.196	11.74
Publication year	42	3578	-2.02	-4.16-0.12	1.09	0.064	5.58

HCP, healthcare professional; K, number of groups within studies; OPTION = Observing Patient Involvement in Decision Making; R-squared, % of the variance explained by the moderator; SE, standard error.

In the univariate analyses, clinical setting, clinical condition, and duration were identified as significant predictors of OPTION-12 scores. However, clinical condition was excluded from the final multivariate meta-regression due to the high number of categories (12) which, given the limited number of studies, resulted in an unstable model with multiple empty cells. The final multivariate model thus included clinical setting, duration, and gender. The final multivariate meta-regression model explained 28.1% of the between-study heterogeneity (p=0.0027). Clinical setting remained the only significant independent predictor of SDM. After adjusting for consultation duration and patient gender, secondary care settings achieved significantly higher scores than primary care facilities (β=9.66; 95%CI [2.58-16.74]; p=0.007). Conversely, consultation duration (β=0.09; p=0.471) and the proportion of female participants (β=-0.03; p=0.684) did not significantly influence OPTION-12 scores in the multivariate context (Table 3).

The multiple meta-regression model for OPTION-5 accounted for 43.4% of the observed heterogeneity (p=0.0012). In this multivariate context, consultation duration was identified as the only significant independent predictor (β=0.45; 95%CI [0.16-0.75]; p=0.003), indicating that higher mean OPTION-5 scores were independently associated with longer clinical encounters. Clinical setting (β=21.43; p=0.136) and decision type (β=-17.49; p=0.222), which were significant in univariate analyses, did not retain their independent predictive value after adjusting for duration (Table 3).

Table 3. Multiple meta regression analyses

Moderator	Coefficient (β)	SE	P-value	95% CI
OPTION-12				
Secondary Care (vs. Primary)	9.66	3.61	**0.007**	2.58-16.74
Consultation length (min)	0.09	0.13	0.471	-0.16-0.34
Females (%) – Patients	-0.03	0.08	0.684	-0.19-0.13
Intercept (Constant)	10.43	6.74	0.122	-2.77-23.63
Model Statistics				
Number of studies (k)	31			
R-squared (%)	28.08%			
Wald Test (p-value)	0.003			
OPTION-5				
Consultation length (min)	0.45	0.15	**0.003**	0.16-0.75
Secondary Care (vs. Primary)	21.43	14.38	0.136	-6.74-49.61
Treatment Decision (vs. Screening/Diagnosis)	-17.49	14.33	0.222	-45.58-10.60
Intercept (Constant)	19.54	40.39	0.629	-59.63-98.71
Model Statistics				
Number of studies (k)	18			
R-squared (%)	43.40%			
Wald Test (p-value)	0.001			

Note. Models adjusted for all moderators simultaneously. Clinical condition was excluded due to the high number of levels relative to the number of studies to prevent model instability.

Quality assessment

Appendix IX shows the quality assessment of all included studies, reporting on the extent to which the authors reported sufficient information on the rating procedure, psychometric data and OPTION-12 and OPTION-5 level data as defined by Couët et al[12].

For OPTION-12, 74 studies (70%) reported using two or more raters to assess consultations, and 21 (20%) reported that a part of the consultations was assessed by two raters. Intra-rater reliability measures were reported in 12 studies (11%), inter-rater reliability in 68 studies (64%), and internal consistency in 19 studies (18%). Regarding item-level data, 14 studies (13%) detailed the response rate of each score on the 5-point scale for each item, 44 studies (42%) reported scores for all rated items, 24 studies (23%) provided the range of scores by item, and 23 studies (22%) reported the standard deviation for each item's score.

For OPTION-5, 42 studies (62%) reported that two or more raters assessed the consultations. Nineteen studies (28%) reported that a part of the consultations was assessed by two raters. Five studies (7%) reported intra-rater reliability measures, 45 studies (66%) reported measures of inter-rater reliability, and two studies (3%) reported internal consistency measures. In terms of OPTION-5 item-level data, nine studies (13%) reported the response rate of each score on the 5-point rating scale by item, 37 studies (54%) reported scores for all rated items, 18 studies (26%) reported the range of scores by item and 22 studies (32%) reported the SDs of scores by item.

Discussion

This systematic review and meta-analysis provides an updated synthesis of evidence on SDM in clinical practice using the OPTION-12 and OPTION-5 scales, spanning 174 studies, almost 20,000 consultations, and diverse clinical contexts. The pooled results show high heterogeneity, that could only be partially explained by the evaluated moderators. For both instruments, groups that received SDM-interventions achieved significantly higher scores compared to those without interventions, a finding also reported by Couët et al.[12] with OPTION-12, a result that supports the validity of the measures.

In non-interventional studies, both instruments consistently show higher scores in secondary care than in primary care, although evidence for OPTION-5 in primary care remains limited, with only a small number of observational studies available. This pattern may be explained by the nature of specialist consultations, which more frequently involve complex, preference-sensitive decisions characterized by explicit trade-offs and multiple reasonable options, thereby making SDM behaviors more visible and easier to observe using observer-based instruments. In addition, secondary care encounters often allow for more structured discussions, such as treatment escalation, diagnostic pathways, or risk–benefit considerations, whereas primary care consultations are commonly time-constrained[217,218] and address multiple problems within a single visit, limiting the opportunity for detailed and observable SDM behaviors. Within secondary care, some variability across clinical specialties was observed, with the highest OPTION-12 scores reported in neurological consultations and the highest OPTION-5 scores in respiratory and kidney disease consultations, suggesting that the type of clinical condition and decision context may further influence the extent to which SDM behaviors are expressed and captured by different observer-based instruments.

Another significant positive predictor for both scales, also observed by Couët et al.[12] for the OPTION-12, was the consultation length. It is not strange that, in non-interventional studies, more available time relates to greater observed SDM. However, this does not imply

that structured interventions to promote SDM necessarily require more time. Indeed, the latest update of the Cochrane review on DAs[3] found a significant but small increase in consultation length (1.5 min) when DAs were used during consultations, and no significant increase when used in preparation for the consultation. This aligns with the previous review by Dobler et al.[219], which reported no increase in consultation duration in 9 out of 13 trials. Another recent systematic reviews, not restricted to DA use, concluded that SDM does not necessarily require longer consultations[220,221]. This is an important finding because a key barrier to effective SDM implementation is the perception among HCPs that SDM is time-consuming, adding strain to already constrained schedules[220]. While time investment may initially pose a challenge, evidence suggests these skills integrate seamlessly into routine practice over time, mitigating such concerns[222].

For the OPTION-12, a higher proportion of female patients was associated with significantly higher scores in the univariate analysis, suggesting greater involvement of women in SDM. This finding aligns with earlier communication studies showing that female patients tend to ask more questions, express preferences more openly, and generally engage more actively in medical encounters[223–225]. However, a pooled secondary analyses of individual data (n=1,614) from 10 studies using OPTION-12, Keij et al.[226] found no association between patient gender and the extent to which clinicians involved patients in SDM, with most sociodemographic characteristics showing no association. Future research should continue to examine how patient and clinician's gender interact in shaping SDM processes, and whether interventions can ensure equitable involvement for all patients.

Consistent with previous research[227,228], OPTION-5 yielded systematically higher scores than OPTION-12, likely because it more explicitly targets core SDM components and may better differentiate between low and high SDM engagement[227]. Moreover, OPTION-5 places greater emphasis on integrating patient preferences, has a shorter structure that may reduce rater fatigue and improve scoring consistency, and allows positive scoring of clinician responses to patient-initiated contributions, whereas OPTION-12 mainly captures clinician-initiated behaviors. These findings highlight the importance of considering instrument design when interpreting and comparing SDM scores across measures. In this review, cross-study comparability was limited by inconsistent reporting of scale versions/languages and modifications, including modifications to the manual[220,227,229–233], and by variability across clinical contexts. Additionally, internal consistency was inconsistently reported, and modifications or translations may have led to over- or underestimation of scores. Future research should assess whether these score differences reflect meaningful improvements in SDM from the patient's perspective.

Regarding the temporal evolution of OPTION-12 results, subgroup analysis did not find a significant difference between studies published before and after Couët et al's review[12] (22.76 vs. 25.92), and the year of publication was not significantly related to the scores, suggesting limited change in observed SDM over the past decade. This is concerning, since the observed values are low compared to the theoretic range of scores (0-100), even after the implementation of SDM interventions (38.39 for OPTION-12 and 47.74 for OPTION-5). A recent systematic review focused on primary care[221], which integrated results from both OPTION-12 and OPTION-5 versions, also reported low levels of SDM (a median baseline score of 16). This persistent finding of low observed SDM scores, even following interventions, also raises questions about how SDM interventions are currently evaluated. Importantly, many SDM interventions continue to prioritize downstream outcomes such as patient knowledge, decisional conflict, or satisfaction, without systematically assessing whether SDM behaviors during the clinical encounter have actually changed. Our findings support a shift toward the routine inclusion of SDM process measures, alongside patient-reported outcomes, in the evaluation of SDM interventions. Combining observer-based measures (e.g., OPTION) with patient-reported outcomes may provide a more complete understanding of how interventions work, for whom, and under which conditions. This perspective aligns with ongoing international efforts to develop core outcome sets for SDM intervention research, which aim to balance process fidelity with patient-centered outcomes[234].

On the other hand, since there are no established cut-off values, it remains unclear whether observed differences in OPTION scores translate into meaningful variations in patient experience and decision quality. In this systematic review, only two studies suggested cut-off points for OPTION-12[235,236], but no consensus exists on the optimal threshold. While the right amount of SDM will always vary depending on the individual interaction and context, the OPTION items capture core elements, such as invitation and support, provision of information and explanation, and elicitation of views or preferences, that can be considered a minimal signal of reasonable SDM effort. It is difficult to imagine clinical encounters where these elements are not relevant, even if patients prefer clinicians to take a more directive role. From the large body of data and available transcripts, it may be possible to define such a "signal" score that reflects at least an attempt to address these principles. Instead of focusing solely on total scores, examining individual items of the OPTION scales may be more effective in identifying areas for improvement and enhancing SDM practices. Future research should prioritize defining clinically relevant thresholds to improve interpretability and application in both research and practice.

Strengths and limitations

This review provides a comprehensive synthesis of 174 studies evaluating patient involvement using both OPTION-12 and OPTION-5 tools from a wide range of clinical contexts and geographical regions. We have established a comprehensive database that includes an updated set of studies using OPTION-12 and a decade of research using OPTION-5, enabling robust quantitative meta-analyses. This database may serve as a valuable resource for future systematic reviews, particularly those focusing on specific contexts, specialties or conditions. We performed detailed subgroup and univariate meta-regression analyses to explore variability in OPTION score. Although multivariable models are generally preferred, we prioritized a univariable approach as the primary exploratory step because the number of studies reporting complete data across all potential moderators was limited. Relying solely on a multivariable model from the outset would have necessitated the exclusion of numerous studies, significantly reduced statistical power and increased the risk of selection bias. Subsequently, multivariable meta-regression was performed only for variables demonstrating significance in the univariable analysis to maintain a balance between model complexity and data representativeness.

Nevertheless, this review was subject to some limitations. The quality of included studies varied, with some lacking detailed reporting on rating procedures or consultation characteristics. In addition, differences in study designs, clinical settings, and intervention types may have influenced results. Most studies were conducted in high-income countries, potentially limiting generalizability to lower-income settings. Furthermore, a potential source of selection bias in our meta-analysis stems from the exclusion of identified studies that did not provide sufficient numerical data (e.g., mean scores or measures of dispersion) for pooling. Specifically, 35 out of 106 identified OPTION-12 studies and 27 out of 68 OPTION-5 studies could not be included in the quantitative synthesis. While the large volume of consultations included (nearly 20,000) provides a robust foundation, the pooled estimates essentially represent a synthesis of the available reported evidence, which may differ from the findings of studies with less rigorous reporting standards. The validity of the results is limited by the high statistical heterogeneity observed in the meta-analyses, which remained substantial even after subgroup and univariate meta-regression analyses. Given the high statistical heterogeneity (I^2>99%), the pooled estimates should be interpreted as a summary of the available evidence base rather than a universal standard for SDM. Moreover, subgroup analyses based on comparisons across studies rather than within studies should be interpreted with caution due to the potential for ecological bias. Quality assessment was conducted using the tool developed by Couët et al., which was suitable for comparison, but is less widely used than the Cochrane risk of bias tool[237], although it provided a more tailored assessment for the specific reporting of SDM instruments.

Future research

This review highlights several priorities for future research and practice: (1) reaching consensus on when to use OPTION-12 versus OPTION-5, given their different scoring patterns and applications in research and practice; (2) establishing context-specific thresholds or reference points to interpret OPTION scores, so that observed differences can be meaningfully linked to patient experience and decision quality; (3) investigating the structural and cultural factors that may explain the wide variability in SDM implementation observed across countries, settings, and clinical conditions; (4) developing and testing targeted interventions to sustain the higher SDM-levels observed after interventions.

Conclusion

We identified 106 studies using OPTION-12 and 68 studies using OPTION-5, from over sixteen different countries, and over fourteen clinical conditions from 2012 to 2023. This work updates the previous systematic review published by Couët et al[12] on studies using OPTION-12 and represents the first comprehensive systematic review of studies using OPTION-5 across diverse clinical conditions. SDM-interventions and longer consultations contributed to higher mean OPTION scores. Across studies, OPTION-5 consistently yielded higher mean OPTION scores than OPTION-12, reflecting differences in the tools' focus. With the results of this study, we can better evaluate and interpret both research and practice on SDM in different contexts.

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Appendix I: PRISMA checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	p. 1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	p. 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	p. 4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	p. 4
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	p. 5
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	p. 5
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix III
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	p. 5
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	p. 5-6
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	p. 6-7 + Appendix IV
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Appendix IV
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	p. 5-6 + Appendix IV

Section and Topic	Item #	Checklist item	Location where item is reported
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	p. 6 + Appendix V
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	p. 6 + Appendix V
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	p. 6
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	p. 6
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	p. 6 + Appendix V
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	p. 6 + Appendix V
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	p. 7 + Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Figure 1
Study characteristics	17	Cite each included study and present its characteristics.	Appendix VI (Table 1 + 2)
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	p. 10 + Appendix VIII
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	p. 7-10 + Appendix VI + Appendix VII

Section and Topic	Item #	Checklist item	Location where item is reported
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	p. 10 + Appendix VIII
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	p. 7-10
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	p. 8-10
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	p. 11-13
	23b	Discuss any limitations of the evidence included in the review.	p. 13
	23c	Discuss any limitations of the review processes used.	p. 13
	23d	Discuss implications of the results for practice, policy, and future research.	p. 13-14
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	p. 4
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	p. 4
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	p. 14
Competing interests	26	Declare any competing interests of review authors.	p. 14
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	p. 14

Appendix II: OPTION-12 and OPTION-5 items and scale design

OPTION-12		OPTION-5	
Item	**Behavior description**	**Item**	**Behavior description**
1	The clinician **draws attention to** an identified problem as one that requires a decision-making process.	1	For the health issue being discussed, the clinician **draws attention to or confirms** that alternate treatment or management options exist or that the need for a decision exists. If the patient rather than the clinician draws attention to the availability of options, the clinician responds by agreeing that the options need deliberation.
2	The clinician **states** that there is more than one way to deal with the identified problem ('equipoise').		
3	The clinician **assesses** the patient's preferred approach to receiving information to assist decision making (e.g. discussion, reading printed material, assessing graphical data, using videotapes or other media).	2	The clinician reassures the patient or re-affirms that the clinician **will support the patient to become informed or deliberate** about the options. If the patient states that they have sought or obtained information prior to the encounter, the clinician supports such a deliberation process.
4	The clinician **lists** 'options', which can include the choice of 'no action'.		
5	The clinician **explains** the pros and cons of options to the patient (taking 'no action' is an option).	3	The clinician **gives information or checks understanding about the options** that are considered reasonable (this can include taking no action), to support the patient in comparing alternatives. If the patient requests clarification, the clinician supports the process.
6	The clinician explores the patient's **expectations** (or ideas) about how the problem(s) are to be managed.		
7	The clinician explores the patient's **concerns** (fears) about how problem(s) are to be managed.	4	The clinician makes an effort to **elicit the patient's preferences** in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive.
8	The clinician checks that the patient has **understood** the information.		
9	The clinician offers the patient explicit **opportunities** to ask questions during the decision-making process.	5	The clinician makes an **effort to integrate the patient's elicited preferences** as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician makes an effort to do so.
10	The clinician elicits the patient's **preferred level of involvement** in decision-making.		
11	The clinician indicates the need for a **decision making** (or **deferring**) stage.		
12	The clinician indicates the need to review the decision (or **deferment**).		

Scoring OPTION-12: 0 = the behavior is not observed, 1 = a minimal attempt is made to exhibit the behavior, 2 = the behavior is observed and a minimum skill level achieved, 3 = the behavior is exhibited to a good standard, 4 = the behavior is exhibited to a very high standard
Scoring OPTION-5: 0 = no effort, 1 = minimal effort, 2 = moderate effort, 3 = skilled effort, 4 = exemplary effort

Appendix III: Search strategy (deducted on 19-6-2025):

Database	Search strategy	# Papers
Pubmed	("OPTION 5"[tiab] OR "OPTION 12"[tiab] OR "OPTION-5"[tiab] OR "OPTION-12"[tiab] OR "OPTION5"[tiab] OR "OPTION12"[tiab] OR "OPTION scale"[tiab:~1] OR "OPTION scales"[tiab:~1] OR "OPTION-scale*"[tiab] OR "observer OPTION"[tiab:~1] OR "OPTION-instrument*"[tiab] OR "OPTION instrument"[tiab:~1] OR "OPTION instruments"[tiab:~1]OR "OPTION-score*"[tiab] OR "OPTION score" [tiab:~1] OR "OPTION scores" [tiab:~1] OR "OPTION-questionnaire*"[tiab] OR "OPTION questionnaire" [tiab:~1] OR "OPTION questionnaires" [tiab:~1] OR "Elwyn G"[Author] OR "Elwyn G"[Investigator]) AND ("2012/01/01"[Date - Publication] : "2030/12/31"[Date - Publication])	576
Embase	('OPTION 5':ti,ab OR 'OPTION 12':ti,ab OR 'OPTION-5':ti,ab OR 'OPTION-12':ti,ab OR 'OPTION5':ti,ab OR 'OPTION12':ti,ab OR ('OPTION' NEXT/2 'scale'):ti,ab OR ('OPTION' NEXT/2 'scales'):ti,ab OR 'OPTION-scale*':ti,ab OR ('observer' NEXT/2 'OPTION'):ti,ab OR 'OPTION-instrument*':ti,ab OR ('OPTION' NEXT/2 'instrument'):ti,ab OR ('OPTION' NEXT/2 'instruments'):ti,ab OR 'OPTION-score*':ti,ab OR ('OPTION' NEXT/2 'score'):ti,ab OR ('OPTION' NEXT/2 'scores'):ti,ab OR 'OPTION-questionnaire*':ti,ab OR ('OPTION' NEXT/2 'questionnaire'):ti,ab OR ('OPTION' NEXT/2 'questionnaires'):ti,ab OR 'Elwyn G':au) AND [2012-2023]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it OR 'preprint'/it)	455
Cochrane CENTRAL database	(('OPTION' NEXT '5'):ti,ab OR ('OPTION' NEXT '12'):ti,ab OR 'OPTION-5':ti,ab OR 'OPTION-12':ti,ab OR 'OPTION5':ti,ab OR 'OPTION12':ti,ab OR ('OPTION' NEXT/2 'scale'):ti,ab OR ('OPTION' NEXT/2 'scales'):ti,ab OR 'OPTION-scale*':ti,ab OR ('observer' NEXT/2 'OPTION'):ti,ab OR 'OPTION-instrument*':ti,ab OR ('OPTION' NEXT/2 'instrument'):ti,ab OR ('OPTION' NEXT/2 'instruments'):ti,ab OR 'OPTION-score*':ti,ab OR ('OPTION' NEXT/2 'score'):ti,ab OR ('OPTION' NEXT/2 'scores'):ti,ab OR 'OPTION-questionnaire*':ti,ab OR ('OPTION' NEXT/2 'questionnaire'):ti,ab OR ('OPTION' NEXT/2 'questionnaires'):ti,ab)	124
Web of Science	TS=((“OPTION 5” OR “OPTION 12” OR “OPTION-5” OR “OPTION-12” OR “OPTION5” OR “OPTION12” OR (“OPTION” NEAR/1 “scale”) OR (“OPTION” NEAR/1 “scales” OR “OPTION-scale*” OR (“observer” NEAR/1 “OPTION”) OR “OPTION-instrument*” OR (“OPTION” NEAR/1 “instrument”) OR (“OPTION” NEAR/1 “instruments”) OR “OPTION-score*” OR (“OPTION” NEAR/1 “score”) OR “OPTION” NEAR/1 “scores”) OR (“OPTION-questionnaire*”) OR (“OPTION” NEAR/1 “questionnaire”) OR (“OPTION” NEAR/1 “questionnaires”)) OR (AU=“Elwyn G”)	1120

Database	Search strategy	# Papers
Web of Science - citations	• Elwyn et al., 2003 (Elwyn, G., et al., Shared decision making: developing the OPTION scale for measuring patient involvement. Qual Saf Health Care, 2003. 12(2): p. 93-9. doi 10.1136/qhc.12.2.93)	394
	• Elwyn et al., 2005 (Elwyn, G., et al., The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. Health Expect, 2005. 8(1): p. 34-42. doi 10.1111/j.1369-7625.2004.00311.x)	376
TOTAL	**Including duplicates**	**3.045**
TOTAL	**Without duplicates**	**1.722**

Appendix IV: Data extraction tool

Characteristics:

Study characteristics:

- Reference
- Publication year
- First author
- Country
- Language of the paper
- Study design (RCT/cross-sectional/pre-post)
- Setting (primary/secondary care)
- Specialism

Consultation characteristics:

- Number of consultations
- Mean consultation duration (minutes)
- Clinical condition
- Rated media (audio/video/transcripts/observations)
- Decision type (treatment/diagnostic/both)

Patient characteristics:

- Number of patients
- Patient gender
- Patient mean age

Healthcare professional (HCP) characteristics:

- Number of HCPs
- HCP gender
- HCP age
- HCP mean experience (years practice)

OPTION scores:

- Mean OPTION-12 or OPTION-5 score, standard deviation, 95% confidence interval
- Intervention type (decision aid, HCP training, patient communication tool, patient activation, feedback, revision of quality management documents, reflection on MDTMs, HCP feedback, redesign care pathways, HCP interviews, logbook)
- Cut-off values

Quality assessment:

Rating procedure and psychometric data (yes/no):

- Two raters or more assessed the consultations
- Intra-rater reliability measures reported?
- Inter-rater reliability measures reported?
- Internal consistency measures reported?

OPTION item-level data (yes/no):

- Response rate of each value on the 5-point rating scale (0, 1, 2, 3, 4) by item reported?
- Scores for all rated items reported?
- Ranges of scores by item reported?
- Standard deviations reported of scores by item reported?

Appendix V: Data analysis

To explore the sources of heterogeneity, we adopted a two-step analytical approach:
First, univariable analyses (including both subgroup analyses for categorical variables and univariate meta-regressions for continuous variables) were used as exploratory tools. This allowed us to maximize the use of available data for each moderator, as a full multivariable model from the outset would have restricted the analysis only to the small subset of studies reporting on every covariate, resulting in a significant loss of statistical power and a high risk of selection bias. Subgroup analyses were performed primarily on non-intervention observations only, to assess whether OPTION mean scores differed by categorical variables (Chi-square test). These included continent, care setting, clinical condition groups, decision type, rated media, involvement of residents in training, and publication period. Subgroup categories were defined a priori based on clinical relevance and consistency with previous reviews. To ensure sufficient statistical power and allow for meaningful comparisons, certain categories were refined based on data availability: continent was categorized into Europe, North America, and other; care setting into primary vs. secondary care; rated media into audio, transcripts, and video; and decision type into treatment vs. screening/diagnosis. Additionally, a secondary subgroup analysis was conducted that included intervention arms (i.e., post-intervention scores for intervention groups in RCTs, CBAs, and cross-sectional intervention studies) to explore whether OPTION scores differed when SDM interventions were present. Univariate meta-regression analyses were also performed on non-intervention observations to explore the association between the OPTION-12 and OPTION-5 total scores and the covariates of interest, such as patient demographics (i.e., percentage of females, mean age and education level), HCP characteristics (i.e., percentage of females, mean age, and years in practice) and consultation length. To visually illustrate these relationships, bubble plots were generated.

Second, to mitigate the risk of Type-1 errors associated with multiple testing and to control for confounding, a multivariable meta-regression model was conducted as a confirmatory step. This model included only those covariates that demonstrated statistical significance ($p<0.05$) in the preliminary univariate analyses. To maintain model simplicity and ensure sufficient statistical power, we specified that categorical variables with an excessive number of levels relative to the sample size (potentially leading to overfitting) would be excluded from the multivariate analyses.

Appendix VI: Table 1 & Table 2

Table 1. Study and sample characteristics – OPTION-12.

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics					
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min.)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported	Average OPTION-12 total score ± SD (range 0-100)
Abukmail [24]	2024	Australia	English	Cross-sectional	No intervention	55	Primary Care	11.7	Multiple	Transcripts	t60	NR	General Practitioners	54.5	NR	NR	No	25.20 ± 7.40
Advani [25]	2023	Ghana	English	Cross-sectional	No intervention	20	Secondary Care	N/R	Reproductive health	Transcripts	100	NR	NR	NR	NR	NR	No	34.79 ±7.16
Alegria [26]	2018	USA	English	Cross-sectional	No intervention	312	Secondary Care	NR	Mental health	Audio	67.9	44.0	Multiple	75.7	39.8	NR	No	33.00 ± 15.43
Ampe [27,28]	2017	Belgium	English	Controlled Before and After Study	No intervention	10	Nursing Home	N/R	Neurological Conditions	Transcripts	NR	NR	Multiple	NR	NR	NR	No	Pre-intervention: 47.61 ± 20.54 Post-intervention: 40.10 ± 9.46
					Intervention	11												Pre-intervention: 41.32 ± 10.48 Post-intervention: 38.82 ± 14.01
Amundsen [29,30]	2018	Norway	English	Controlled Before and After	No intervention	31	Secondary Care	36	Cancer	Transcripts	64.5	57	Oncologists	NR	NR	NR	No	Post-intervention: 12.10 ± 7.90
					Intervention	62		43			50	59						Post-intervention: 14.80 ± 9.20
Anixt [31]	2018	USA	English	Cohort Study	No intervention	45	Secondary Care	NR	Mental health	Video	NR	NR	Multiple	100	NR	NR	No	24.50 ± 9.70
Bakhit [32]	2018	Australia	English	RCT	No intervention	21	Primary Care	NR	Respiratory Conditions	Audio	NR	NR	General Practitioners	NR	NR	NR	No	22.70 ± 11.50
					Intervention	15												38.89 ± 6.50
Basile [33]	2018	USA	English	Before and After Study	Intervention	38	Secondary Care	NR	Respiratory Conditions	Transcripts	50	66.60	Multiple	72.70	43.60	17.60	No	66.73 ± 19.31
Birch [34]	2018	Canada	English	Cross-sectional	No intervention	27	Secondary Care	34	Reproductive health	Transcripts	100	NR	Genetic Counsellors	NR	NR	NR	No	42.40 ± 9.00
Branda [35]	2022	USA	English	RCT	Intervention	53	Secondary Care	6	Cardiovascular Diseases	Video	30	66	Cardiologists	NR	NR	NR	No	53.00 ± 12.00
Brenner [36]	2018	USA	English	Cross-sectional	No intervention	14	Primary Care	13.11	Cancer	Transcripts	64.0	63.9	General Practitioners	30.00	NR	NR	No	6.00 ± NR
Brinkman [37,38]	2013	USA	English	Before and After Study	No intervention	20	Primary Care	41	Mental health	Video	62	7.90	Pediatricians	0	NR	NR	No	31.20 ± 16.55
					Intervention	33		42			64	8.40		0	NR	NR	No	43.80 ± 32.17
Brito [39]	2015	USA	English	Controlled Before and After	No intervention	26	Secondary Care	NR	Endocrine & metabolic diseases	Video	NR	NR	Endocrinologists	NR	NR	NR	No	30.00 ± 8.00
					Intervention	82												35.00 ± 9.00
Burton [41]	2010	UK	English	Cross-sectional	No intervention	85	Secondary Care	NR	Cardiovascular Diseases	Video	38.82	NR	Cardiologists	NR	NR	NR	No	23.30 ± NR
Butow [42]	2010	Australia	English	Cross-sectional (Secondary analysis of an RCT)	No intervention	55	Secondary Care	NR	Cancer	Transcripts	100	52.50	Oncologists	45	47	19.90	No	23.44 ± 9.17

Table 1 *Continued*

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics					
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min.)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported	Average OPTION-12 total score ± SD (range 0-100)
Chad [43]	2025	Canada	English	RCT	No intervention Intervention	50 51	Secondary Care	NR	Respiratory Conditions	Video	38 38	4.3 4.8	Pediatric otolaryngologists	NR	NR	NR	No	14.25 ± 5.38 18.53 ± 4.24
Coutu [44]	2015	Canada	English	Cross-sectional	No intervention	37	Secondary Care	NR	Musculoskeletal Conditions	Transcripts	40.5	44.51	Occupational Therapists	91	36.80	NR	No	53.94 ± 9.68
Coylewright [45]	2016	USA	English	RCT	No intervention Intervention	22 34	Secondary Care	NR	Cardiovascular Diseases	Audio or Video	NR	NR	Multiple	NR	NR	NR	No	16.00 ± 10.10 21.30 ± 10.10
Dicé [46]	2016	Italy	English	Cross-sectional	No intervention	163	Primary Care	NR	Multiple Conditions	Transcripts	NR	NR	Pediatricians	33	NR	NR	No	10.15 ± 11.81
Dicé [47]	2021	Italy	English	Cross-sectional	No intervention	185	Primary Care	12.72	Multiple Conditions	Transcripts	NR	NR	Pediatricians	36.84	NR	NR	No	3.71 ± 8.69
Dierckx [48]	2013	Belgium	English	Cross-sectional	No intervention	210	Secondary Care	NR	Multiple Conditions	Audio	55.70	46.40	Physical Therapists	38.46	43	NR	No	5.20 ± 6.80
Edwards [49]	2006	UK	English	Cross-sectional	No intervention	17	Primary Care	NR	Multiple Conditions	NR	NR	NR	General Practitioners	NR	NR	NR	No	62.80 ± NR
Elwyn [51]	2003	UK	English	Cross-sectional	No intervention	186	Primary Care	8.20	Multiple Conditions	Audio	68	43.30	General Practitioners	38	38	NR	No	16.90 ± 7.70
Elwyn [50]	2004	UK	English	RCT	No intervention Intervention	352	Primary Care	12.5	Multiple Conditions	Audio	NR	45-65 45-65	General Practitioners	40.00	38.00	NR NR	No No	29 ± 15 47 ± 12
Elwyn [52]	2005	UK	English	Cross-sectional	No intervention	186	Primary Care	8.20	Multiple Conditions	Audio	68	43.30	General Practitioners	38	38	NR	No	3.00 ± 2.00
Elwyn [54]	2013	Canada	English	Cross-sectional	No intervention	215	Primary Care	NR	Multiple Conditions	Audio	69	NR	General Practitioners	64	37	NR	No	24.96 ± 4.98
Elwyn [53]	2016	UK	English	Stepped wedge trial	No intervention Intervention	36 36	Secondary Care	29.90 29.43	Musculoskeletal Conditions	Audio	50 69	63.80 67.80	Physical Therapists	NR	NR	NR	No	29.40 ± 4.98
Engelhardt [55]	2020	The Netherlands	English	Cross-sectional	No intervention	101	Secondary Care	28.05	Cancer	Transcripts	100	60.60	Oncologists	NR	NR	NR	No	15.60 ± 11.60
Evong [56]	2019	Canada	English	Cross-sectional	No intervention	117	Secondary Care	NR	Otolaryngology conditions	Video	36.75	2.92	Otolaryngologists	33.33	NR	NR	No	NR
Fersini [57]	2019	Italy	English	Cross-sectional	No intervention	58	Secondary Care	27.00	Reproductive health	Audio	100	35.00	Obstetricians	40	48	NR	No	21.20 ± 19.84
Gagnon [58]	2010	Canada	English	Cross-sectional	No intervention	128	Primary Care	6.50	Reproductive health	Transcripts	100	29	General Practitioners	73	33	NR	No	19.00 ± 7.00
Geessink [59]	2018	The Netherlands	English	Cross-sectional	Intervention	80	Secondary Care	21.60	Cancer	Audio	45	71.80	Surgeons	36.40	NR	NR	No	15.70 ± 9.00
Goossens [60,61]	2020	Belgium	English	RCT	No intervention	NR	Nursing Home	NR	Neurological Conditions	Audio	NR	NR	Multiple	NR	NR	NR	No	Pre-intervention: 27.46 ± 11.74 Post-intervention: 26.59 ± 9.36
					Intervention	NR								NR	NR	NR	No	Pre-intervention: 26.59 ± 9.36 Post-intervention: 53.49 ± 13.16
Goossensen [62]	2007	The Netherlands	English	Cross-sectional	No intervention	61	Secondary Care	13.00	Mental health	Audio	28.00	37.00	Psychiatrists	50.00	31.00	NA	No	43.00 ± 13.00
Goss [63,64]	2007	Italy	Italian	Cross-sectional	No intervention	235	Primary Care	11.00	Multiple Conditions	Transcripts	68.51	45.00	General Practitioners	0.00	46.00	17.00	No	20.61 ± 9.12
Goss [65]	2008	Italy	English	Cross-sectional	No intervention	80	Secondary Care	40.00	Mental health	Transcripts	61.00	43.60	Psychiatrists	41.18	38.00	10.80	No	26.70 ± 13.00

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics					
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min.)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported	Average OPTION-12 total score ± SD (range 0-100)
Gurtner [66]	2022	Switzerland	English	Cross-sectional	No intervention	71	Secondary Care	A: 6; B: 8.4	Mental health	Live observation	A: 77%; B: 36%	A: 52; B: 41	Multiple	NR	NR	NR	No	25 ± NR
Hawke [69]	2024	Australia	English	Cross-sectional	No intervention	26	Primary Care	20.00	Maternity Care	Audio	100	32	Multiple	92	NR	NR	No	37.5 ± NR
Härter – Breast [67]	2015	Germany	English	RCT	No intervention Intervention	71 22	Secondary Care	NR	Cancer	Audio	100 100	60.40 55.70	Multiple	54.40 66.70	35.70 35.20	NA	No	24.20 ± 9.90 32.30 ± 11.90
Härter – Colon [67]	2015	Germany	English	RCT	No intervention Intervention	34 33	Secondary Care	NR	Cancer	Audio	57.10 52.00	69.50 71.30	Multiple	42.90 22.20	34.40 39.59	NA	No	16.50 ± 5.50 25.60 ± 9.50
Hausheer [68]	2021	Switzerland	English	Cross-sectional	No intervention	30	Secondary Care	NR	Musculoskeletal Conditions	Audio	27.10	48.10	Physical Therapists	NR	NR	NR	Yes*	Md: 50.5 (44-66)
Henselmans [71]	2020	The Netherlands	English	RCT	No intervention Intervention (decision aid) Intervention (physician training) Intervention (decision aid + physician training)	187	Secondary Care	NR	Cancer	Audio	49.0 48.0 52.2 55.3	62.1 63.6 67.4 61.3	Oncologists	NR NR NR NR	NR NR NR NR	NR NR NR NR	No	29.50 ± 4.40 29.88 ± 14.40 49.49 ± 14.19 49.83 ± 12.8
Hess [75]	2012	USA	English	RCT	No intervention	200	Secondary Care	NR	Cardiovascular Diseases	Video	NI: 59.00; I: 58.00	NI: 54.90; I: 54.50	Multiple	NR	NR	NR	No	7.00 ± 5.54
Hess [72,73]	2016	USA	English	RCT	No intervention	536	Secondary Care	NR	Cardiovascular Diseases	Audio and Video	NR	NR	Multiple	NR	NR	NR	No	7.90 ± 5.40
Hess [74]	2018	USA	English	RCT	No intervention	516	Secondary Care	NR	Traumatic Conditions	Audio and Video	NR	NR	Multiple	NR	NR	NR	No	13.30 ± 6.50
Hirsch [76]	2011	Germany	English	Cross-sectional	No intervention Intervention	40	Primary Care	NR NR	Cardiovascular Diseases	Video	NR NR	NR NR	General Practitioners	NR NR	NR NR	NR NR	No	15.43 ± 10.14 23.64 ± 8.16
Holzhüter [77]	2021	Germany	English	Cross-sectional	No intervention	62	Secondary Care	6.42	Mental health	Audio	61.00	45.00	Multiple	NR	NR	NR	No	29.17 ± 10.42
Huang [78]	2016	China	English	Prospective Cohort Study	No intervention	80	Secondary Care	Md: 15 (5-38)	Cardiovascular Diseases	Audio or Video	30.00	Md: 62 (41-79)	Cardiologists	57.14	29.86	7	No	Md: 44 (6-67)
Jones [79]	2014	UK	English	Cross-sectional	No intervention	80	Secondary Care	NR	Musculoskeletal Conditions	Transcripts	48.00	47.8	Physical Therapists	NR	NR	Md: 6	No	24 (10.4-43.8)
Kasper [80]	2011	Germany	English	RCT	Intervention	76	Secondary Care	15.8	Neurological Conditions	Video	65.00	40.00	Neurologists	75.00	NR	NR	No	10 ± NR
Keshtgar [82]	2021	UK	English	Cross-sectional	No intervention	31	Secondary Care	NR	Orthodontics	Audio	25.81	19.40	Orthodontist	71.43	NR	NR	No	42.60 ± 17.40
Kindler [83]	2005	Switzerland	English	Cross-sectional	No intervention	21	Secondary Care	NR	Surgery	Video	NR	NR	Anesthetists	NR	NR	NR	No	26.80 ± 16.80
Krishnamoorthi [84]	2021	USA	English	Before and After Study	Intervention	29	Secondary Care	NR	Gastrointestinal conditions	Video	NI: 37; I: 33	NI: 63.8; I: 63.2	Multiple	NR	NR	NR	No	19.20 ± NR
Kunneman [89]	2016	The Netherlands	English	Cross-sectional	No intervention	100	Secondary Care	NR	Cancer	Audio	Rectal: 50; Breast: 100	61.8	Oncologists	NR	NR	NR	No	10 (2-6)
Kunneman [87]	2020	The Netherlands	English	RCT	No intervention Intervention	411 419	Secondary Care	NR NR	Cardiovascular Diseases	Video	NR NR	NR NR	Multiple	NR NR	NR NR	NR NR	No	29.10 ± 13.10 33.00 ± 10.80
Kunneman [88]	2022	USA	English	RCT	No intervention Intervention	48 96	Primary Care	28 26	Endocrine & metabolic diseases	Video	NR NR	NR NR	Multiple	NR NR	NR NR	NR NR	No	17.00 ± 6.89 25.00 ± 9.87
Labrie [90]	2015	The Netherlands	English	Cross-sectional	No intervention	70	Primary Care	10.80	Multiple Conditions	Video	47.10	NR	General Practitioners	38.20	NR	NR	Yes**	14.02 ± 7.59

Table 1 *Continued*

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics					
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min.)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported	Average OPTION-12 total score ± SD (range 0-100)
Langseth [91]	2012	UK	English	Cross-sectional	No intervention	49	Secondary Care	16.2	Cardiovascular Diseases	Audio	46.94	61.00	Cardiologists	NR	NR	NR	No	49.00 ± NR
LeBlanc [92]	2015a	USA	English	RCT	Intervention	96	Primary Care	48	Mental health	Video	NR	NR	General Practitioners	NR	NR	NR	No	32.50 ± 12.34
LeBlanc [93]	2015b	USA	English	RCT	Intervention	38	Primary Care	NR	Musculoskeletal Conditions	Video	100	NR	General Practitioners	NR	NR	NR	No	43.00 ± 9.93
Lee [94]	2020	Malaysia	English	Cross-sectional	No intervention	199	Primary Care	NR	Multiple Conditions	Audio	52.80	NR	General Practitioners	64.50	NR	NR	No	16.25 ± 6.90
Loh [92]	2006	Germany	English	Cross-sectional	No intervention	20	Primary Care	16.10	Mental health	Transcripts	NR	NR	General Practitioners	44.44	45.40	11.70	No	14.70 ± 11.79
McCabe [96]	2013	UK	English	Cross-sectional	No intervention	72	Secondary Care	2.00	Mental health	Transcripts	41.67	45.00	Psychiatrists	40.00	NR	NR	No	12.37 (2-45.8)
McKinstry – telephone [97]	2010	UK	English	Cross-sectional	No intervention	47	Primary Care	4.60	Multiple Conditions	Audio	62	NR	General Practitioners	NR	NR	NR	No	16.00 ± 10.80
McKinstry - face-to-face [97]	2010	UK	English	Cross-sectional	No intervention	59	Primary Care	9.70	Multiple Conditions	Audio	68	NR	General Practitioners	NR	NR	NR	No	19.00 ± 9.40
Meier [98]	2019	The Netherlands	English	RCT	No intervention Intervention	38 48	Secondary Care	NR NR	Respiratory Conditions	Audio	NR NR	NR NR	Otolaryngologists	NR NR	NR NR	NR NR	No	24.90 ± 10.85 28.81 ± 10.92
Meijers – 2015 [99]	2019	The Netherlands	English	Cross-sectional	No intervention	50	Primary Care	9.24	Multiple Conditions	Video	64	49.20	General Practitioners	35.00	51.60	NR	No	14.10 ± 6.30
Meijers – 2017 [99]	2019	The Netherlands	English	Cross-sectional	No intervention	50	Primary Care	11.28	Multiple Conditions	Video	58	48.80	General Practitioners	53.00	45.50	NR	No	22.60 ± 11.70
Melong [100]	2019	USA	English	Prospective Cohort Study	No intervention	81	Secondary Care	NR	Surgery	Video	52.00	8.40	Surgeons	33.33	NR	NR	No	6.58 ± 11.31
Menear [101]	2017	Canada	English	Cross-sectional	No intervention	114	Primary Care	27.60	Multiple Conditions	Transcripts	79.80	53.50	General Practitioners	56.10	45.30	17.80	No	25.71 ± 9.79
Mertz [102]	2018	USA	English	Prospective Cohort Study	No intervention	117	Secondary Care	NR	Surgery	Unspecified	56.90	54.00	Surgeons	NR	NR	NR	No	28.70 ± 7.70
Milte [103]	2015	Australia	English	RCT	No intervention	59	Secondary Care	38.00	Multiple Conditions	Audio	59.40	85.00	Geriatricians	NR	NR	NR	No	41.00 ± 17.00
Misra [104]	2019	USA	English	Cross-sectional	No intervention	24	Primary Care	NR	Multiple Conditions	Live observation	41.60	50.50	General Practitioners	37.50	32.90	5.40	No	57.20 ± 12.79
Mongliardi – public [105]	2013	Peru	English	Cross-sectional	No intervention	30	Secondary Care	12.10	Multiple Conditions	Video	87.00	54.00	Internal Medicine	29.00	47.00	15.00	No	25.63 ± 12.71
Mongliardi – private [105]	2013	Peru	English	Cross-sectional	No intervention	28	Secondary Care	14.40	Multiple Conditions	Video	86.00	52.00	Internal Medicine	29.00	47.00	15.00	No	34.88 ± 15.21
Montori [106]	2010	USA	English	RCT	No intervention Intervention	32 38	Primary Care	NR NR	Musculoskeletal Conditions	Video	100 100	NR NR	General Practitioners	NR NR	NR NR	NR NR	No	27.30 ± 8.93 49.80 ± 18.93
Mullan [107]	2009	USA	English	RCT	No intervention Intervention	21 30	Primary Care	NR NR	Endocrine & metabolic diseases	Video	NR NR	NR NR	Multiple	NR NR	NR NR	NR NR	No	27.70 ± 11.75 49.70 ± 17.74
Nannenga [108]	2009	USA	English	RCT	No intervention Intervention	44	Secondary Care	NR NR	Endocrine & metabolic diseases	Video	48.00	65.00	Endocrinologists	5.00	NR	NR	No	4.00 ± NR 8.00 ± NR
Olling – oncology [110]	2019	Denmark	English	Cross-sectional	Intervention	54	Secondary Care	NR	Cancer	Audio	NR	NR	Multiple	NR	NR	NR	No	13.4 ± NR
Olling - internal medicine [110]	2019	Denmark	English	Cross-sectional	Intervention	54	Secondary Care	NR	Cancer	Audio	NR	NR	Multiple	NR	NR	NR	No	10.2 ± NR
Ospina [126]	2022	USA	English	Before and After Study	Intervention	65	Secondary Care	NR	Endocrine & metabolic diseases	Audio or Video	NR	NR	Multiple	NR	NR	NR	No	20.8 ± NR

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics					
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min.)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported	Average OPTION-12 total score ± SD (range 0-100)
Ospina [127]	2023	USA	English	Cross-sectional	Intervention	53	Secondary Care	NR	Endocrine & metabolic diseases	Audio or Video	NR	NR	Surgeons	NR	NR	NR	No	Md = 34 (31-38)
Ozanne [111]	2025	USA	English	Cluster RCT	No intervention	306	Secondary Care	20.5	Cardiovascular Diseases	Video	35	68.7	Multiple	NR	NR	NR	No	30.7 ± 12.36
					Intervention (patient decision aid)	285		20.4			34	68.9		NR	NR	NR		34.5 ± 13.57
					Intervention (encounter decision aid)	263		21.8			40	69.9		NR	NR	NR		43.7 ± 16.20
					Intervention (patient decision aid + encounter decision aid)	263		23.4			38	68.7		NR	NR	NR		42.5 ± 15.74
Pellerin [112]	2011	USA	English	Cross-sectional	No intervention	152	Primary Care	26.68	Multiple Conditions	Transcripts	61.00	46.70	Family Medicine Residents	70.00	30.58	NR	No	24.00 ± 8.00
Pietrolongo [114]	2013	Italy	English	Cross-sectional	No intervention	88	Secondary Care	NR	Neurological Conditions	Transcripts	66.00	37.50	Neurologists	50.00	NR	NR	No	29.60 ± 10.30
Politi [115]	2010	USA	English	Cross-sectional	No intervention	75	Secondary Care	NR	Cancer	Live observation	100.00	51.00	Surgeons	40.00	NR	NR	No	68.00 ± 18.30
Rajendran [117]	2019	Germany	English	Cross-sectional	No intervention	30	Secondary Care	NR	Musculoskeletal Conditions	Transcripts	57.00	50.6	Osteopathy students	66.60	29.4	NR	No	0.3 ± 0.6
Reitz [118]	2016	The Netherlands	English	Cross-sectional	Intervention	6	Nursing Home	NR	Neurological Conditions	Video	83.30	NR	NR	NR	NR	NR	No	10.5 ± 4.97
Sanders [121]	2017	The Netherlands	English	RCT	No intervention	89	Primary Care	13.10	Musculoskeletal Conditions	Video	48	44.53	General Practitioners	37.00	49.00	19.10	No	23.66 ± 16.19
					Intervention	86		15.80			53	45.48		52.00	52.70	18.80		38.53 ± 15.02
Santema [122]	2016	The Netherlands	English	Cross-sectional	No intervention	54	Secondary Care	19.40	Cardiovascular Diseases	Audio	42.60	69.10	Surgeons	NR	NR	NR	No	31.00 ± 11.00
Schapira – English [124]	2019	USA	English	Prospective Cohort Study	No intervention	32	Secondary Care	NR	Cancer	Audio	NR	NR	Oncologists	NR	NR	NR	No	Md: 31.3 (26.6-39.6)
Schapira – Spanish [124]	2019	USA	English	Prospective Cohort Study	No intervention	14	Secondary Care	NR	Cancer	Audio	NR	NR	Oncologists	NR	NR	NR	No	Md: 22.9 (17.7-27.1)
Scholl [125]	2015	Germany	English	Cross-sectional	No intervention	63	Multiple Settings	NR	Multiple Conditions	Transcripts	63.50	54.80	Multiple	42.90	48.80	10.20	No	11.60 ± 6.30
Siriwadena [128]	2006	UK	English	Cross-sectional	No intervention	252	Primary Care	NR	Multiple Conditions	Video	NR	NR	General Practitioners	63.89	33.60	NR	No	34 ± NR
Snijders [131]	2015	The Netherlands	English	Cross-sectional	No intervention	32	Secondary Care	NR	Cancer	Transcripts	NR	64	Surgeons	NR	43.7	8.7	No	7 ± NR
Sonntag [132]	2012	Germany	English	Cross-sectional	No intervention	58	Primary Care	9.17	Endocrine & metabolic diseases	Audio	65.00	57.00	General Practitioners	70.00	51.00	NR	No	18.00 ± 7.00
Spencer-Bonilla [133]	2022	USA	English	RCT	No intervention	411	Secondary Care	NR	Cardiovascular Diseases	Audio or Video	NR	NR	NR	NR	NR	NR	No	29.00 ± 13.00
					Intervention	419		NR			NR	NR	NR	NR	NR	NR	No	33.00 ± 11.00
Stevens [134]	2024	USA	English	Cross-sectional	No intervention	13	Primary Care	NR	Cancer	Audio	0	54	Multiple	100	46	NR	No	10.31 ± 11.48

Table 1 *Continued*

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics					
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min.)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported	Average OPTION-12 total score ± SD (range 0-100)
Strauss [135]	2015	Italy	English	Before and After Study	Intervention	9	Secondary Care	NR	Mental health	Audio or Video	NR	NR	Neuropsychiatrists	NR	NR	NR	No	Pre-intervention: 52.78 ± 2.55 Post-intervention: 74.31 ± 6.16
					Intervention	8	Secondary Care	NR	Mental health	Audio or Video	NR	NR	Neuropsychiatrists	NR	NR	NR	No	Pre-intervention: 51.52 ± 3.08 Post-intervention: 63.67 ± 6.56
Stubenrouch [136]	2016	The Netherlands	English	Cross-sectional	No intervention	60	Secondary Care	NR	Multiple Conditions	Audio	65.00	NR	Multiple	59.46	NR	NR	No	23.70 ± 7.70
Turner [137]	2019	Italy	English	Cross-sectional	No intervention	54	Secondary Care	NR	Neurological Conditions	Unspecified	100.00	31.20	Neurologists	NR	NR	NR	No	72.58 ± 14.13
Vaillancourt [138]	2012	Canada	English	Cross-sectional	No intervention	19	Secondary Care	50.00	Multiple Conditions	Audio	58.00	40.20	Dieticians	100.00	39.30	13.50	No	29.00 ± 8.00
Vaillancourt [139,140]	2015	Canada	English	Cross-sectional	No intervention	8	Secondary Care	56.00	Endocrine & metabolic diseases	Audio + Transcript	NR	NR	Dieticians	100.00	38.90	11.80	No	28.00 ± 6.00
van der Velden [141]	2022	The Netherlands	English	Cross-sectional (Secondary analysis of an RCT)	No intervention	173	Secondary Care	NR	Cancer	Audio	11	63.5	Oncologists	NR	NR	NR	No	38.9 ± 17.2
Verwijmeren [142]	2018	The Netherlands	English	Cross-sectional	No intervention	75	Secondary Care	40.10	Mental health	Live observation	NR	NR	Psychiatrists	NR	NR	NR	No	34.60 ± 16.40
Visser [143]	2019	The Netherlands	English	Before and After Study	No intervention	74	Secondary Care	NR	Neurological Conditions	Audio	NR	NR	Multiple	NR	NR	NR	No	16.6 ± 12.8
Vortel [144]	2016	USA	English	Cross-sectional	No intervention	27	Secondary Care	34.40	Reproductive health	Audio	100	NR	Genetic Counsellors	NR	NR	NR	No	43.75 ± 9.72
Warner [145]	2015	USA	English	RCT	No intervention	63	Secondary Care	NR	Surgery	Video	57.00	53	Multiple	NR	NR	NR	No	23.00 ± 17.00
					Intervention	66		NR			44.00	54		NR	NR	NR		46.00 ± 21.00
Weiss [146]	2008	UK	English	Cross-sectional	No intervention	123	Primary Care	8.50	Multiple Conditions	Audio	NR	NR	General Practitioners	33.30	42.00	NR	No	3.81 ± 3.14
Wiering [148]	2016	The Netherlands	English	Cross-sectional	No intervention	43	Secondary Care	59.50	Cancer	Audio	49.00	11.90	Oncologists	NR	NR	NR	No	27.50 ± 9.50
Wulff [150]	2022	Denmark	English	Before and After Study	Intervention	55	Secondary Care	NR	Cancer	Audio	NR	NR	Multiple	NR	NR	NR	No	37.97 ± NR
Zhang [151]	2021	China	English	Cross-sectional	No intervention	297	Secondary Care	NR	Multiple Conditions	Audio	NR	NR	Surgeons	29.00	NR	NR	No	9.61 ± 3.58

N, number of consultations rated; NR, not reported; Md, median; SD, standard deviation; RCT, randomized controlled trial.
* Low involvement if <35, good if 35–59 and excellent involvement if 60–100.
** Low involvement (1 < SD; OPTION-score lower than 7.32), medium involvement (1 < SD > 1; OPTION-score between 7.32 and 22.1), or high involvement (SD > 1; OPTION-score higher than 22.1).

Table 2. Study and sample characteristics – OPTION-5.

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics						
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	N	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported?	Average OPTION-5 total score ± SD (range 0-100)
Aarts [152]	2021	USA	English	Before and After Study	No intervention	24	Secondary Care	NR	Reproductive health	Audio	100	38.5	16	Medical specialists + medical specialists in training	75	NR	NR	No	42.08 ± 12.73
					Intervention: decision aid + HCP training	28	Secondary Care	NR	Reproductive health	Audio	100	40.6	16	Medical specialists + medical specialists in training	75	NR	NR	No	54.59 ± 12.24
Allen [153]	2022	USA	English	Cross-sectional	Intervention: deision aid	12	Primary Care	NR	Cancer	Transcipts	0	58.5	5	General practicioners	NR	NR	NR	No	67.1 ± 10.62
Ankersmid [155]	2024	The Netherlands	English	Cross-sectional	Intervention: decision aid + HCP training	64	Secondary Care	Md: 19	Cancer	Transcripts	100	NR	NR	NR	NR	NR	NR NR NR NR	No	Decision modality: Frecuency of screening: Md: 25 (20-45) Duration of surveillance: Md: 15 (0-30) Type of screening performed: Md: 25 (0-45) In-person vs telephone: Md: 25 (0-50)
Aubuchon [156]	2025	USA	English	Cross-sectional	No intervention	20	Secondary Care	NR	Cancer	Transcripts	60	NR	6	Medical specialists	33.3	NR	NR	No	3.37 ± 2.50
Baggett [157]	2022	USA	English	RCT	Overall	378	Secondary Care	23.70	Multiple	Audio + Transcripts	45	71.9	43	Medical specialists	19	46.1	NR	No	34.7 ± 20.6
					Intervention: patient communication tool	185	Secondary Care	NR	Multiple	Audio + Transcripts	NR	NR	43	Medical specialists	NR	NR	NR	No	36.7 ± 21.2
					No intervention	193	Secondary Care	NR	Multiple	Audio + Transcripts	NR	NR	43	Medical specialists	NR	NR	NR	No	32.9 ± 19.9
Baghus [158]	2024	The Netherlands	English	Cross-sectional	No intervention	98	Primary Care	13.8	Multiple	Video or audio	65	51	20	General practice residents	80	30	NR NR	No	19.1 ± 10.9
Barradell [159]	2024	United Kingdom	English	Cross-sectional	Intervention: decision coaching training HCPs, decision aid, consultation prompt	19	Secondary Care	5.80	Respiratory conditions	Audio	NR	NR	9	NR	78	NR	NR	No	36.97 ± 21.4

Table 2 *Continued*

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics						
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	N	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported?	Average OPTION-5 total score ± SD (range 0-100)
Chen [160]	2020	China	English	Cross-sectional	No intervention	209	Primary Care	5.13	Multiple	Audio	56	64.42	10	General practitioners	100	42.4	NR	No	Rater 1: Md: 35 (25-45) Rater 2: Md: 30 (25-45)
Coylewright [161]	2020	United Kingdom	English	Before and After Study	Overall	35	Secondary Care	NR	Cardiovascular disease	Audio	55.9	85.8	6	Medical specialists	0	NR	NR	No	NR
					No intervention	25	Secondary Care	NR	Cardiovascular disease	Audio	NR	85.1	6	Medical specialists	0	NR	NR	No	17.9 ± 7.6
					Intervention: decision aid	5	Secondary Care	NR	Cardiovascular disease	Audio	NR	92.8	6	Medical specialists	0	NR	NR	No	79 ± 8.4*
Den Ouden [162]	2022	The Netherlands	English	RCT	Intervention: decision aid + HCP training	9	Primary Care	NR	Endocrine and metabolic disease	Audio	46	70.0	9	General practicioners	NR	NR	NR	No	83 ± 1.4
Diendéré [163]	2021	Canada	English	Cross-sectional	No intervention	238	Primary Care	NR	Multiple	Audio	76	NR	71	Multiple	68	34.52	NR	No	26.75 ± 10.72
Dillon [164]	2017	USA	English	RCT	Overall	40	Primary Care	22.20	Multiple	Audio	65	NR	24	General practicioners	NR	NR	NR	No	26.5 ± 15.2
					No intervention	10	Primary Care	25.70	Multiple	Audio	80	59.5	24	General practicioners	NR	NR	NR	No	23.9
					Intervention: patient activation and HCP training	10	Primary Care	22.20	Multiple	Audio	30	51.4	24	General practicioners	NR	NR	NR	No	29.2
					Intervention: patient activation tool	10	Primary Care	20.50	Multiple	Audio	50	51.5	24	General practicioners	NR	NR	NR	No	28.8
					Intervention: patient activation + HCP training + patient activation tool	10	Primary Care	20.50	Multiple	Audio	100	60.4	24	General practicioners	NR	NR	NR	No	24.5
Doraiswamy [165]	2021	Bangladesh	English	Cross-sectional	No intervention	306	Secondary Care	NR	Reproductive health	Observations	100	NR	NR	Medical specialist	NR	NR	NR	No	14.92 ± 10.5
Driever [166]	2022	The Netherlands	English	Cross-sectional	No intervention	727	Secondary Care	15.00	NR	Video	52	48.6	41	Medical specialist	32	47.90	NR	No	16.8 ± 17.1
DuBenske [167]	2021	USA	English	Cross-sectional	Intervention: decision aid	53	Primary Care	7.67	Cancer	Transcipts	100	NA	11	General practicioners	91	NR	NR	No	53.6 ± 12.95
Durand [168]	2021	USA	English	RCT	Overall	311	Secondary Care	NR	Cancer	Audio	100	NR	16	Medical specialist	81	NR	23	No	NR
					Intervention: option grid + HCP training	NR	Secondary Care	NR	Cancer	Audio	100	NR	5	Medical specialist	NR	NR	NR	No	28.93
					Intervention: picture option grid + HCP training	NR	Secondary Care	NR	Cancer	Audio	100	NR	6	Medical specialist	NR	NR	NR	No	24.71
Fabricius [169]	2022	Denmark	English	Cross-sectional	No intervention	65	Secondary Care	NR	Multiple	Observations	NR	NR	31	Multiple	58	41.20	14.70	No	8.2 ± 16.2

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics						
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	N	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported?	Average OPTION-5 total score ± SD (range 0-100)
Fay [170]	2016	USA	English	Before and After Study	No intervention	NR	Secondary Care	8.97	Urological disorders	Video	NR	NR	4	Medical specialist + medical specialist in training	NR	NR	NR	No	16.1 ± 7.1
					Intervention: option grid + HCP training	NR	Secondary Care	8.45	Urological disorders	Video	NR	NR	4	Medical specialist + medical specialist in training	NR	NR	NR	No	33.9 ± 23.5
Forcino [171]	2024	USA	English	Before and After Study	No intervention	28	Secondary Care	NR	Reproductive health	Audio	NR	NR	NR	Multiple	NR	NR	NR	No	17
					Intervention: decision aid (option grid/ picture option grid) + training	29	Secondary Care	NR	Reproductive health	Audio	NR	NR	NR	Multiple	NR	NR	NR	No	16
Geessink [172]	2018	The Netherlands	English	Cross-sectional	Intervention: HCP training	80	Secondary Care	21.60	Cancer	Audio	45	71.8	19	Medical specialist + medical specialist in training	36	NR	NR	No	12.6 ± 13.3
Gionfriddo [173]	2018	USA	English	Cross-sectional	Overall	15	Tertiary Care	NR	Cancer	N/A	53	63.7	8	Medical specialist	NR	NR	NR	No	NR
					No intervention	NR	Tertiary Care	NR	Cancer	Audio + Video	NR	NR	NR	NR	NR	NR	NR	No	17.5
					No intervention	NR	Tertiary Care	NR	Cancer	Audio	NR	NR	NR	NR	NR	NR	NR	No	21.8
Hale [175]	2020	USA	English	RCT	Intervention: patient activation	100	Primary Care	NR	Mental health	Transcipts	100 (parents) NR (children)	NR	17	Multiple	NR	NR	NR	No	33.2 ± 17.36
Haquebord [174]	2025	The Netherlands	English	Cross-sectional	No intervention	100	Primary Care	30	Musculoskeletal Conditions	Audio	60	51	41	Physical therapists	37	37	NR	No	27
Horbach [176]	2017	The Netherlands	English	Cross-sectional	No intervention	55	Secondary Care	NR	Cardiovascular disease	Audio	58	26.8	6	Medical specialist	NR	NR	NR	No	31.3 ± 15.49
IJaz [177]	2018	USA	English	Cross-sectional	No intervention	29	Tertiary Care	7.40	Multiple	Observations	45	40.0	NR	NR	56	NR	NR	No	10.35
Jackson [178]	2020	USA	English	RCT	No intervention	105	Primary Care	29.00	Multiple	Transcipts	52	66.1	11	General practicioner	55	47.00	18.00	No	27.5
Jouni [179]	2016	USA	English	RCT	Intervention: decision aid without genetic-informed risk	NR	Secondary Care	NR	Cardiovascular disease	Video	NR	NR	NR	Multiple	NR	NR	NR	No	70.1 ± 7.4
					Intervention: decision aid including genetics-informed risk	NR	Secondary Care	NR	Cardiovascular disease	Video	NR	NR	NR	Multiple	NR	NR	NR	No	72.7 ± 6
Koning [181]	2024	The Netherlands	English	Cross-sectional	No intervention	29	Secondary Care	NR	Cancer	Audio	100	67.7	11	Medical specialists	NR	NR	NR	No	25.9 ± 13.4
Kölker [180]	2018	Germany	English	Cross-sectional	No intervention	79	Primary Care	NR	Multiple	Audio	65	54.7	24	General practicioners + medical specialists	54	49.40	NR	No	11.84 ± 11.92

Table 2 *Continued*

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics						
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	N	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported?	Average OPTION-5 total score ± SD (range 0-100)
Kriston [182]	2020	Germany	English	Cross-sectional	No intervention	80	Primary Care + Secondary Care	NR	Multiple	Audio	64	NR	24	General practicioners + medical specialists	46	NR	12.60	No	11.83
Landmark [183]	2017	Norway	English	Cross-sectional	No intervention	3	Secondary Care	NR	Multiple	Video	33	36.7	3	Medical specialists	0	42.00	NR	No	55.33
Lemos [185]	2024	USA	English	Cross-sectional	No intervention	132	Secondary Care	Increased PSE: 10.69 Without increased PSE: 10.1	Musculoskeletal Conditions	NR	53	55	NR	Medical specialists	NR	NR	NR	No	Increased PSE: 18.9 Without increased PSE: 18.55
Mathijssen [16]	2020	The Netherlands	English	Cross-sectional	No intervention	168	Secondary Care	9.04	Musculoskeletal Conditions	Audio	69	61.2	22	Multiple	27	48.00	15.70	No	28.3 ± 15.1
Marcellis [186]	2024	The Netherlands	English	Before and After Study	No intervention	36	NR	25.29 (Md: 26)	Cardiovascular disease	Audio	39	72	40	Multiple	39	42	NR	No	45.83 ± 9.45
					Intervention: personalized outcomes forecasts (POFs)	20	NR	17.72 (Md: 17)	Cardiovascular disease	Audio	60	73		Multiple	50	41	NR	No	53 ± 12.18
McCabe [14]	2019	United Kingdom	English	Cross-sectional	No intervention	74	Secondary Care	27.67	Neurological Conditions	Video	61	81.7	21	Multiple	NR	NR	NR	No	22.5 ± 17.25
Mekelenkamp [15]	2021	The Netherlands	English	Cross-sectional	No intervention	40	Secondary Care	56.00	Hematological disease	Audio + Transcripts	62	NR	12	Multiple	NR	NR	NR	Yes	43 ± 11
Mule [187]	2021	USA	English	Cross-sectional	No intervention	22	Secondary Care	NR	Mental health	Audio	Children: 18 (Parents: 77)	Children: 3.73	6	Medical specialists	83	NR	NR	No	5.45 ± 5.55
Muscat [188]	2019	Australia	English	RCT	No intervention	20	Primary Care	16.00	Multiple	Video	50	75.3	9	General practicioners	22	NR	NR	No	11.3
Nijhuis [189]	2025	The Netherlands	English	Before and After Study	No intervention	16	Secondary Care	NR	Neurological Conditions	Audio	NR	NR		Medical specialists + nurse specialists	NR	NR	NR	No	58
					Intervention: decision aid + training	8	Secondary Care	NR	Neurological Conditions	Audio	NR	NR	12	Medical specialists + nurse specialists	NR	NR	NR	No	55
Noordman [191]	2022	The Netherlands	English	Before and After Study	No intervention	19	Secondary Care	22.90	Multiple	Video	42	66.9	10	Multiple	70	NR	NR	No	38 ± 25.3
					Intervention: HCP training	20	Secondary Care	24.10	Multiple	Video	30	65.1	12	Multiple	67	NR	NR	No	41 ± 19.5
Noordman [190]	2024	The Netheralands	English	Cross-sectional	Intervention: visual decision aid	35	Seconday Care	Nephrology: 42.42; osteoarthritis: 12.15	Multiple	Video	66	67	10	Medical specialists + specialized nurses	NR	NR	NR	No	46
Osse [192]	2025	Canada, United Kingdom and the Netherlands	English	Cross-sectional	No intervention	125	Secondary Care	NR	Urological disorders	Audio	100	50	18	Medical specialists	70.6	44	NR	No	41.8 ± 12.8
Òverby [193]	2022	Norway	English	Cross-sectional	No intervention	18	Secondary Care	NR	Respiratory conditions	Video	22	47.8	4	Medical specialists	0	NR	NR	No	65.6 ± 6.6

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics						
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	N	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported?	Average OPTION-5 total score ± SD (range 0-100)
Prick [194]	2025	The Netherlands	English	Before and After Study	No intervention	16	Secondary Care	NR	Cardiovascular disease	Audio	NR	NR	NR	Medical specialists (in training)	NR	NR	NR	No	7.5
					Intervention: decision aid	14	Secondary Care	NR	Cardiovascular disease	Audio	NR	NR	NR	Medical specialists (in training)	NR	NR	NR	No	15
Probst [13]	2020	USA	English	RCT	Overall	50	Secondary Care	NR	Cardiovascular disease	Audio	58	58.9385	NR	Multiple	NR	NR	NR	No	NR
					No intervention	22	Secondary Care	3.67	Cardiovascular disease	Audio	65	60.1	NR	Multiple	NR	NR	NR	No	26.6 ± 21
					Intervention: decision aid	22	Secondary Care	2.42	Cardiovascular disease	Audio	50	55.3	NR	Multiple	NR	NR	NR	No	52 ± 18
Rake [195]	2024	The Netherlands	English	Cross-sectional	Intervention: decision aid	20	Secondary Care	32.4	Mutliple	Audio	75	41.8	4	Medical specialists (in training) + physician assistants	75	43.3	NR	No	57.5 ± 10.1
Roux [184]	2020	United Kingdom	English	Cross-sectional	No intervention	45	Primary Care	10.35	Dermatological conditions	Video	67	NR	23	General practitioners	NR	NR	NR	No	10.7 ± 9.39
Savelberg [197]	2019	The Netherlands	English	Cross-sectional	Intervention: decision aid + HCP training	33	Secondary Care	NR	Cancer	Audio	100	NR	NR	Multiple	NR	NR	NR	No	42 ± 10.8
					Overall	132	Secondary Care	NR	Cancer	Audio	56.5	58.6	NR	Multiple	NR	NR	NR	No	NR
Scholl [198]	2021	Germany	English	RCT	No intervention	69	Secondary Care	NR	Cancer	Audio	71	57.4	NR	Multiple	NR	NR	NR	No	21.3 ± 12.44
					Intervention: HCP training + patient activation + pt communication tools + decision aids + revision of quality management documents + reflection on MDTMs	63	Secondary Care	NR	Cancer	Audio	40	59.8	NR	Multiple	NR	NR	NR	No	16.71 ± 15.35
Schonberg [199]	2025	USA	English	Cross-sectional	Intervention: decision aid	30	Primary Care	8.5	Cancer	Transcripts	100	78.5	13	Medical specialists + nurse practitioner	70	NR	NR	No	77.9 ± 20.6

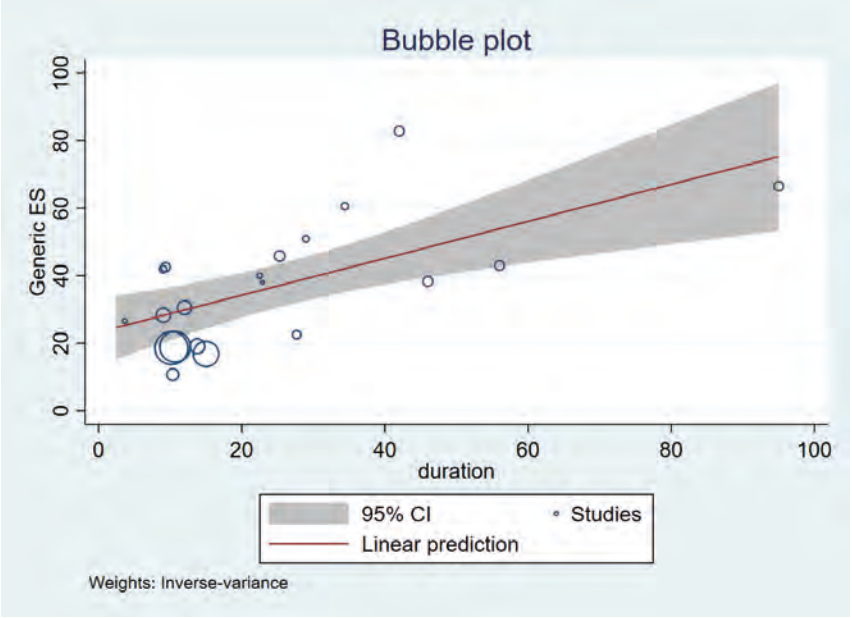
Table 2 *Continued*

Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics						
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	N	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported?	Average OPTION-5 total score ± SD (range 0-100)
Schultz [200]	2025	USA	English	Prospective Comparative Sequential Series	No intervention	64	Tertiary Care	NR	Multiple	Observation	46	54	5	Medical specialists	NR	NR	NR	No	13.1 ± 4.6
					Intervention: Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function form (PF-SF10a) score with the patient using a standardized script	64	Tertiary Care	NR	Multiple	Observation	33	55	5	Medical specialists	NR	NR	NR	No	12 ± 4.1
Stubenrouch [201]	2017	The Netherlands	English	Cross-sectional	No intervention	80	Secondary Care	12.00	Multiple	Audio	51	49.3	21	Multiple	61.9	NR	NR	No	30.5 ± 10.5
					Overall	395	Secondary Care	NR	Cardiovascular disease	Audio	40	NR	NR	NR	NR	NR	NR	No	NR
Stubenrouch [202]	2022	The Netherlands	English	RCT	No intervention	NR	Secondary Care	12.50	Cardiovascular disease	Audio	NR	62.0	NR	NR	NR	NR	NR	No	28.7 ± 12.4
					Intervention: decision aid + HCP training	NR	Secondary Care	16.50	Cardiovascular disease	Audio	NR	65.0	NR	NR	NR	NR	NR	No	37.8 ± 12.4
Stubenrouch [136]	2016	The Netherlands	English	Cross-sectional	No intervention	60	Secondary Care	NR (range 11-58 min)	Multiple	Audio	65	NR (range 47-77)	37	Multiple	60	NR	NR	No	39.3 ± 12.7
Taylor [204]	2017	USA	English	Before and After Study	No intervention	12	Tertiary Care	NR	Multiple	Transcipts	control: 25	78.3	17	Medical specialist	NR	NR	NR	No	44.66 ± 33.54
					Intervention: HCP training	20	Tertiary Care	NR	Multiple	Transcipts	intervention: 65	84.9	17	Medical specialist	NR	NR	NR	No	71.48 ± 16.75
ten Haaft [205]	2024	The Netherlands	English	Cross-sectional	No intervention	19	Secondary Care	22.61 (Md: 22)	Cancer	Audio	84	NR	6	Medical specialist	NR	NR	NR	No	35 ± 16.02
van Dulmen [206]	2022	The Netherlands	English	Cross-sectional	No intervention	29	Secondary Care	28.96	Chronic kidney disease	Video	48	71.4	15	Multiple	60	NR	NR	No	50.9 ± 14.4
van Hoorn [207]	2021	The Netherlands & USA	English	Cross-sectional	No intervention	123	Secondary Care	9.35	Hand conditions	Audio	50	52.6	6	Medical specialist	0	43.32	11.49	No	42.5 ± 20
van Rossenberg [208]	2021	The Netherlands	English	Cross-sectional	No intervention	63	Secondary Care	9.00	Hand conditions	Audio	52	54.0	3	Medical specialist	0	37.70	3.80	No	41.90 ± 18.45

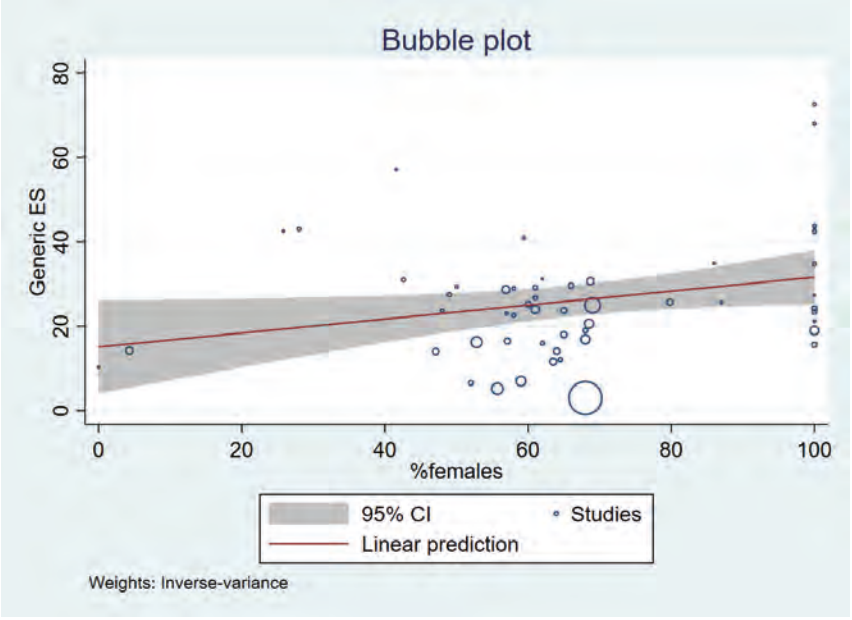
Study characteristics						Consultation characteristics					Patient characteristics		HCP characteristics						
1st author	Year	Country	Language	Design	Study arm	N	Setting	Average duration (min)	Clinical condition	Rated media	Gender (% females)	Mean age (years)	N	Profession	Gender (% females)	Mean age (years)	Years of practice	Cut-off value reported?	Average OPTION-5 total score ± SD (range 0-100)
van Veenendaal [209]	2022	The Netherlands	English	Before and After Study	Overall	112	Secondary Care	NR	Cancer	Audio	100	60.0	NR	Multiple	NR	NR	NR	No	NR
					No intervention	63	Secondary Care	NR	Cancer	Audio	100	NR	NR	Multiple	NR	NR	NR	No	33.9 ±14.8
					Intervention: HCP training + feedback + redesign care pathways + interviews HCPs	49	Secondary Care	NR	Cancer	Audio	100	NR	NR	Multiple	NR	NR	NR	No	54.3 ± 19.9
van Veenendaal [210]	2021	The Netherlands	English	Before and After Study	Overall	139	Secondary Care	47.70	Cancer	Audio	100	62.3	28	Multiple	NR	NR	NR	No	NR
					No intervention	80	Secondary Care	46.00	Cancer	Audio	100	NR	22	Multiple	NR	NR	NR	No	38.3 ± 15
					Intervention: HCP training + feedback + redesign care pathways + logbook with SDM activities	59	Secondary Care	50.10	Cancer	Audio	100	NR	6	Multiple	NR	NR	NR	No	53.2 ± 14.8
Vortel [144]	2016	Canada	English	Cross-sectional	No intervention	27	Secondary Care	34.40	Reproductive health	Audio	100	NR	8	Genetic counsellors	NR	NR	NR	No	60.56 ± 12.45
Wijngaarde [212]	2024	The Netherlands	English	Cross-sectional	No intervention	24	Secondary Care	24.14 (Md: 27)	Hematological disease	Audio	29	9.4	4	Medical specialist	100	NR	NR	No	27.7 ± 13.8
Wijngaarde [213]	2025	The Netherlands	English	Cross-sectional	Intervention: training + SDM cards + 3 good questions for children cards	18	Secondary Care	25.00 (Md: 25)	Hematological disease	Audio	50	7.32 (Md: 7.5)	3	Medical specialist	100	NR	NR	No	53.3 ± 15.9
Williams [214]	2019	United Kingdom	English	Cross-sectional	No intervention	25	Secondary	42,0	Cancer	audio + transcripts	100	NR	11	Multiple	NR	NR	NR	No	82,82 ± 8,54
					No intervention	26	Secondary	95	Chronic kidney disease	audio + transcripts	38	NR	4	Nurse specialist	NR	NR	NR	No	66,53 ± 9,16
Zimmermann [216]	2020	USA	English	Before and After Study	No intervention	13	Secondary	NR	Chronic kidney disease	transcipts	39	78,7	9	Multiple	NR	NR	NR	No	23,65 ± 16,61
					Intervention: patient communication tool	17	Secondary	NR	Chronic kidney disease	transcipts	65	NR	9	Multiple	NR	NR	NR	No	59,45 ± 8,08
Roodbeen [196]	2021	The Netherlands	English	Cross-sectional	No intervention	36	Secondary	22,50	Multiple	video	47	68,7	19	Multiple	53	NR	NR	No	40 ± 21,3
Wright [215]	2023	USA	English	Cross-sectional	No intervention	210	Primary	NR	Mental health	audio	46,79 (caregiver: 91,43)	8,3	62	Multiple	92	35,20	5.48	No	32,78 ± 17,79

N, number of consultations rated; SD, standard deviation; USA, United States of America; NR, not reported or unclear data; RCT, randomized controlled trial; HCP, healthcare professional.
*In the Coylewright study, OPTION-5 scores were reported after 5th use of the intervention

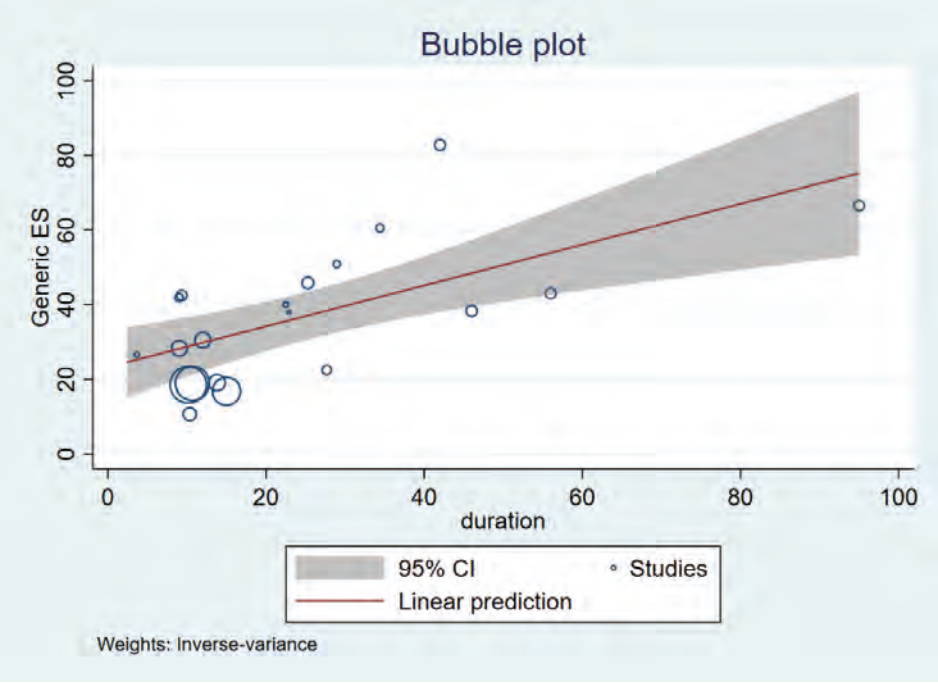
Appendix VII: Bubble plots of univariate meta-regression



OPTION-12: consultation length



OPTION-12: % of females



OPTION-5: consultation length

Appendix VIII: Table 3 & Table 4

Table 3. Quality assessment of outcomes reporting across peer-reviewed studies – OPTION-12

Study		Rating procedure and psychometric data				OPTION item-level data			
1st author	Year	Two raters or more assessed the consultations?	Intra-rater reliability measures reported?	Inter-rater reliability measures reported?	Internal consistency measures reported?	Response rate of each value on the 5-point rating scale (0, 1, 2, 3, 4) by item reported?	Scores for all rated items reported?	Ranges of scores by item reported?	Standard deviations of scores by item reported?
Abukmail	2024	Yes	No	No	No	No	No	No	No
Advani	2023	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Alegria	2018	Yes	No	Yes	No	No	No	No	No
Ampe	2017	Yes	No	No	No	No	Yes	No	Yes
Amundsen	2018	Partly (n = 82)	No	Yes	No	No	No	No	No
Anixt	2018	Partly (18%)	No	Yes	No	No	No	No	No
Bakhit	2018	Yes	No	No	No	No	No	No	No
Basile	2018	Yes	No	No	No	No	No	No	No
Birch	2018	Yes	No	Yes	No	No	No	No	No
Branda	2022	No	No	No	No	No	No	No	No
Brenner	2018	Yes	No	No	No	No	Yes	Yes	No
Brinkman	2013	Yes	No	Yes	No	No	Yes	Yes	No
Brito	2015	Yes	No	Yes	No	No	No	No	No
Burton	2010	Yes	No	No	No	No	No	No	No
Butow	2010	No	No	N/A	No	No	No	No	No
Chad	2025	Partly (20%)	No	No	No	No	No	No	No
Coutu	2015	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Coylewright	2016	Partly (n = 31)	No	Yes	No	No	No	No	No
Dicé	2016	Yes	No	No	Yes	No	No	No	No
Dicé	2021	Yes	No	Yes	Yes	No	Yes	No	Yes
Dierckx	2013	Yes	No	Yes	No	Yes	Yes	Yes	No
Edwards	2006	Yes	No	No	No	No	No	No	No
Elwyn	2003	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Elwyn	2004	Yes	No	No	No	No	No	No	No
Elwyn	2005	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Elwyn	2013	Yes	No	No	No	Yes	Yes	Yes	Yes
Elwyn	2016	Yes	No	No	No	No	No	No	No
Engelhardt	2020	Yes	No	Yes	Yes	No	No	No	No
Evong	2019	Yes	No	Yes	No	No	Yes	No	No
Fersini	2019	Partly (n = 15)	No	Yes	Yes	Yes	Yes	Yes	Yes
Gagnon	2010	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Geessink	2018	Yes	No	Yes	No	No	No	No	No
Goossens	2020	Yes	No	Yes	No	No	Yes	No	No
Goossensen	2007	No	No	N/A	Yes	No	Yes	No	No
Goss	2007	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Goss	2008	Partly (n = 30)	No	Yes	Yes	Yes	Yes	Yes	Yes
Gurtner	2022	No	No	No	No	No	No	No	No
Härter	2015	Yes	No	Yes	No	No	No	No	No
Hausheer	2021	Yes	No	Yes	Yes	No	No	No	No
Hawke	2024	Yes	No	Yes	No	Yes	Yes	Yes	No
Henselmans	2020	Yes	No	Yes	No	No	No	No	No
Hess	2012	Yes	No	Yes	No	No	No	No	No
Hess	2016	Yes	No	No	No	No	No	No	No

Study		Rating procedure and psychometric data				OPTION item-level data			
1st author	Year	Two raters or more assessed the consultations?	Intra-rater reliability measures reported?	Inter-rater reliability measures reported?	Internal consistency measures reported?	Response rate of each value on the 5-point rating scale (0, 1, 2, 3, 4) by item reported?	Scores for all rated items reported?	Ranges of scores by item reported?	Standard deviations of scores by item reported?
Hess	2018	Yes	No	Yes	No	No	No	No	No
Hirsch	2011	Yes	No	Yes	Yes	No	Yes	No	Yes
Holzhüter	2021	Yes	No	Yes	No	No	No	No	No
Huang	2016	Yes	No	Yes	No	No	Yes	Yes	No
Jones	2014	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Kasper	2011	Partly (n = 50)	Yes	Yes	No	No	Yes	No	Yes
Keshtgar	2021	Yes	No	Yes	No	No	No	No	No
Kindler	2005	Yes	No	Yes	No	No	Yes	Yes	Yes
Krishnamoorthi	2021	Yes	No	No	No	No	No	No	No
Kunneman	2016	Partly (n = 10)	Yes	Yes	No	No	No	No	No
Kunneman	2020	Yes	No	Yes	No	No	No	No	No
Kunneman	2022	Yes	No	No	No	No	No	No	No
Labrie	2015	Yes	No	Yes	Yes	No	No	No	No
Langseth	2012	No	No	N/A	No	Yes	Yes	Yes	No
LeBlanc	2015a	Yes	No	Yes	No	No	No	No	No
LeBlanc	2015b	Yes	No	No	No	No	No	No	No
Lee	2020	Yes	No	Yes	No	No	No	No	No
Loh	2006	Yes	No	Yes	No	No	Yes	Yes	Yes
McCabe	2013	Partly (20%)	No	Yes	No	No	No	No	No
McKinstry	2010	Yes	No	Yes	No	No	No	No	No
Meier	2019	Partly (20%)	No	No	No	No	No	No	No
Meijers	2019	Yes	No	Yes	No	Yes	No	No	No
Melong	2019	Yes	No	No	No	No	Yes	No	No
Menear	2017	Yes	No	Yes	No	No	Yes	Yes	Yes
Mertz	2018	Partly (n = 15)	No	Yes	No	No	Yes	No	Yes
Milte	2015	Yes	Yes	Yes	No	No	No	No	Yes
Misra	2019	No	No	No	No	No	Yes	No	Yes
Mongliardi	2013	Partly (n = 20)	No	Yes	Yes	No	Yes	No	No
Montori	2010	Yes	Yes	Yes	No	No	Yes	Yes	No
Mullan	2009	Yes	No	Yes	No	No	No	No	No
Nannenga	2009	Yes	No	No	No	No	No	No	No
Olling	2019	Yes	No	Yes	No	No	Yes	No	No
Ospina	2022	Yes	No	No	No	No	No	No	No
Ospina	2023	Yes	No	No	No	No	No	No	No
Ozanne	2025	No	No	No	No	No	No	No	No
Pellerin	2011	Partly (n = 20)	Yes	Yes	No	No	Yes	Yes	Yes
Pietrolongo	2013	Partly (n = 15)	No	Yes	No	No	No	No	No
Politi	2010	No	No	N/A	No	No	No	No	No
Rajendran	2019	Partly (10%)	No	Yes	No	Yes	Yes	Yes	No
Reitz	2016	Yes	No	Yes	No	No	No	No	No
Sanders	2017	Yes	Yes	Yes	Yes	No	Yes	No	Yes
Santema	2016	Yes	No	No	No	No	No	No	No
Schapira	2019	Partly (n = 5)	No	No	No	No	Yes	No	No
Scholl	2015	Yes	No	Yes	Yes	No	No	No	No
Siriwadena	2006	Yes	No	No	No	No	No	No	No
Snijders	2015	Partly (n = 10)	No	Yes	No	No	No	No	No
Sonntag	2012	Partly (25%)	No	Yes	No	No	No	No	No
Spencer	2022	Yes	No	Yes	No	No	No	No	No
Strauss	2024	Yes	No	No	No	No	No	No	No

Table 3 *Continued*

Study		Rating procedure and psychometric data				OPTION item-level data			
1st author	Year	Two raters or more assessed the consultations?	Intra-rater reliability measures reported?	Inter-rater reliability measures reported?	Internal consistency measures reported?	Response rate of each value on the 5-point rating scale (0, 1, 2, 3, 4) by item reported?	Scores for all rated items reported?	Ranges of scores by item reported?	Standard deviations of scores by item reported?
Strauss	2015	Yes	No	Yes	No	No	No	No	No
Stubenrouch	2016	Partly	No	Yes	No	No	No	No	No
Turner	2019	No	No	N/A	No	No	No	No	No
Vaillancourt	2014	Yes	No	Yes	No	No	Yes	No	No
Vaillancourt	2015	Yes	No	Yes	No	No	Yes	No	No
van der Velden	2022	Yes	No	Yes	No	No	No	No	No
Verwijmeren	2018	No	No	N/A	No	No	No	No	No
Visser	2019	Partly (n = 19)	No	Yes	No	No	No	No	No
Vortel	2016	Yes	No	Yes	No	No	Yes	Yes	Yes
Warner	2015	Yes	No	No	No	No	No	No	No
Weiss	2008	No	No	N/A	No	No	No	No	No
Wiering	2016	Yes	No	Yes	No	No	Yes	No	No
Wulff	2022	Partly	No	No	No	No	Yes	No	No
Zhang	2021	Partly (n = 30)	No	Yes	Yes	Yes	Yes	No	Yes

N/A, not applicable

Table 4. Quality assessment of outcomes reporting across peer-reviewed studies – OPTION-5

Study		Rating procedure and psychometric data				OPTION item-level data			
1st author	Year	Two raters or more assessed the consultations?	Intra-rater reliability measures reported?	Inter-rater reliability measures reported?	Internal consistency measures reported?	Response rate of each value on the 5-point rating scale (0, 1, 2, 3, 4) by item reported?	Scores for all rated items reported?	Ranges of scores by item reported?	Standard deviations of scores by item reported?
Aarts	2021	Yes	No	Yes	No	No	Yes	Yes	Yes
Ankersmid	2024	Yes	No	No	No	No	No	No	No
Allen	2022	Yes	No	Yes	No	No	Yes	No	Yes
Aubuchon	2025	Yes	No	No	No	No	No	No	No
Baggett	2022	Yes	No	Yes	No	No	Yes	No	Yes
Baghus	2024	Yes	No	Yes	No	No	Yes	Yes	Yes
Barradell	2024	Yes	No	Yes	No	No	Yes	Yes	Yes
Chen	2020	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Coylewright	2020	Yes	No	Yes	No	No	No	No	No
Den Ouden	2022	Yes	No	No	No	No	No	No	No
Diendéré	2021	Yes	No	Yes	No	No	No	No	No
Dillon	2017	Yes	No	Yes	No	No	Yes	Yes	Yes
Doraiswamy	2021	No	No	No	No	No	Yes	No	Yes
Driever	2022	Partly (n=29)	No	Yes	No	No	Yes	No	Yes
DuBenske	2021	Yes	No	No	No	No	Yes	No	Yes
Durand	2021	Yes	No	No	No	No	No	No	No
Fabricius	2022	Yes	No	No	No	Yes	Yes	Yes	No
Fay	2016	No	No	No	No	No	No	No	No
Forcino	2024	Yes	No	No	No	No	No	No	No
Geessink	2018	Yes	No	Yes	No	No	No	No	No
Gionfriddo	2018	Yes	No	Yes	No	No	Yes	Yes	No
Hale	2020	Partly (n=23)	Yes	Yes	No	No	Yes	No	No
Hacquebord	2025	Partly (n=12)	No	Yes	No	Yes	Yes	Yes	No
Horbach	2017	Yes	No	No	No	No	Yes	Yes	Yes
Ijaz	2018	No	No	No	No	Yes	Yes	Yes	Yes
Jackson	2020	Yes	No	Yes	No	No	No	No	No
Jouni	2016	No	No	No	No	No	No	No	No
Koning	2024	Yes	No	Yes	No	No	Yes	No	No
Kölker	2018	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Kriston	2020	Yes	Yes	Yes	No	No	No	Yes	No
Landmark	2017	Yes	No	No	No	No	No	No	No
Lemos	2024	Partly (n=15)	No	Yes	No	No	No	No	No
Marcellis	2024	Yes	No	Yes	No	No	Yes	No	Yes
Mathijssen	2020	Partly (n=10)	No	Yes	No	No	Yes	No	Yes
McCabe	2019	Partly (n=16)	No	Yes	Yes	No	Yes	Yes	Yes
Mekelenkamp	2021	Yes	No	Yes	No	No	No	No	No
Mule	2021	Yes	No	No	No	No	Yes	No	Yes
Muscat	2019	Partly (15%)	No	No	No	No	Yes	No	No
Nijhuis	2025	No	No	No	No	No	No	No	No
Noordman	2022	Yes	No	Yes	No	No	Yes	No	No
Noordman	2024	No	Yes	No	No	No	Yes	No	No
Osse	2025	Partly (n=100)	No	Yes	No	No	No	No	No
Överby	2022	Yes	No	Yes	No	No	No	No	No
Prick	2024	Yes	No	No	No	No	No	No	No
Probst	2020	Yes	No	Yes	No	No	No	No	No
Rake	2024	Yes	No	No	No	No	No	No	No
Roux	2020	Partly (n=9)	No	Yes	No	No	No	No	No

Table 4 *Continued*

Study		Rating procedure and psychometric data				OPTION item-level data			
1st author	Year	Two raters or more assessed the consultations?	Intra-rater reliability measures reported?	Inter-rater reliability measures reported?	Internal consistency measures reported?	Response rate of each value on the 5-point rating scale (0, 1, 2, 3, 4) by item reported?	Scores for all rated items reported?	Ranges of scores by item reported?	Standard deviations of scores by item reported?
Savelberg	2019	Yes	No	Yes	No	No	Yes	Yes	Yes
Scholl	2021	NR	No	No	No	No	No	No	No
Schoberg	2025	Yes	No	Yes	No	No	Yes	No	Yes
Schultz	2025	Yes	No	Yes	No	No	No	No	No
Stubenrouch	2017	Partly	No	Yes	No	No	Yes	No	No
Stubenrouch	2022	Partly	No	Yes	No	No	Yes	No	No
Stubenrouch	2016	Partly	No	Yes	No	No	No	No	No
Taylor	2017	Yes	No	Yes	No	No	No	No	No
ten Haaft	2024	Yes	No	No	No	Yes	Yes	No	No
van Dulmen	2022	Partly (n=4)	No	Yes	No	Yes	Yes	No	Yes
van Hoorn	2021	Partly (n=16)	No	Yes	No	No	No	No	No
van Rossenberg	2021	Partly (n=10)	No	Yes	No	No	No	No	No
van Veenendaal	2022	Yes	No	Yes	No	No	No	No	No
van Veenendaal	2021	Yes	No	Yes	No	No	No	No	No
Vortel	2016	Yes	No	Yes	No	No	Yes	Yes	Yes
Vijngaarde	2024	Partly (n=6)	No	Yes	No	Yes	Yes	Yes	No
Wijnaarde	2025	Partly (n=6)	No	Yes	No	No	Yes	Yes	No
Williams	2019	Yes	No	No	No	No	Yes	Yes	Yes
Zimmermann	2020	Yes	No	No	No	No	No	No	No
Roodbeen	2021	Partly (25%)	No	Yes	No	Yes	Yes	No	Yes
Wright*	2023	Partly (40%)	No	Yes	No	No	Yes	No	No

N/A, not applicable.
* In the Wright study, OPTION-5 scores by item were reported for 4 of the 5 items.

Chapter 3

Hospital variation in the treatment of cT1a renal cancer.

C.C. Bresser
P.B. van der Nat
H.Yildirim
B.J.P. Kersten
H.J.J. Leenarts
K.K.H. Aben
P.J. Zondervan
L.M. Dijksman
P.D. Polm
M.M. Garvelink*
H.H.E. van Melick* for the Santeon RCC Working Group**

*Authors contributed equally and share last authorship
**The Santeon RCC Working Group (collaborators) are:

W.A. Scheepens, Catharina Hospital, Eindhoven, The Netherlands;
S. Dijkstra, Canisius Wilhelmina Hospital, Nijmegen, The Netherlands;
M.J. Yska, Maasstad Hospital, Rotterdam, The Netherlands;
D. Luijendijk, Martini Hospital, Groningen, The Netherlands;
M. Asselman, Medisch Spectrum Twente, Enschede, The Netherlands;
A.E.C. Ruiter, OLVG, Amsterdam, The Netherlands.

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Abstract

Objectives: To evaluate treatment patterns and inter-hospital variation of cT1a renal cell carcinoma (RCC) in seven Dutch teaching hospitals.

Patients and methods: In this historical multicenter cohort study, adults diagnosed with cT1a renal cancer (2019-2022) were identified through the Netherlands Cancer Registry. Clinical data were extracted from electronic records. Primary outcome was initial treatment. Descriptive statistics and subgroup analyses assessed variation. Logistic regression analyses identified factors associated with active treatment.

Results: We included 501 patients with 544 cT1a renal cancer tumours. Mean age was 66 years, 40% were overweight (BMI 25-29.9), and 40% had severe comorbidity (CCI ≥ 5). Active treatment was initiated for 65% of tumours, ranging from 44 to 85% between hospitals ($p < 0.001$). The types of treatment modalities used differed significantly between hospitals. This variation persisted after stratifying for comorbidity and tumour complexity. Independent factors associated with active treatment were Charlson comorbidity index (CCI) (OR = 0.77 95%CI [0.72-0.83], $p < 0.001$) RENAL Nephrometry score (OR = 1.16 95%CI [1.04-1.28], $p = 0.006$), and hospital of diagnosis ($p < 0.001$). After adjustment for case mix, hospital of diagnosis remained a significant predictive factor ($p < 0.001$). Study limitations include potential selection bias and limited generalizability.

Conclusions: Substantial inter-hospital variation exists in cT1a RCC management, which is not fully explained by patient- or tumour characteristics. To reduce unwarranted variation and improve care, transparent care pathways, routine outcome measurement, shared decision-making and inter-hospital benchmarking are needed.

Introduction

Renal cell carcinoma (RCC) accounts for 3-5% of all new cancer cases in Europe each year and is therefore the sixth most frequently diagnosed cancer[1]. The number of new RCC cases in the Netherlands is expected to increase by 31% in the next decade, as risk factors such as hypertension and obesity are expected to rise further[2]. In addition, the rising incidence is attributable to the more frequent incidental detection of small renal masses (SRMs) during imaging performed for unrelated reasons[3]. In the Netherlands, more than half of the RCC diagnoses are cT1 tumours (located only in the kidney, <7 cm), of which 36% are cT1a tumours (≤4 cm)[4].

Treatment options for RCC depend on disease stage, tumour location, histopathology, patient factors (e.g. comorbidity and obesity) and patient preferences for treatment. The standard of care for the treatment of cT1a RCC is partial nephrectomy (PN), but thermal ablation (TA) and active surveillance (AS) are alternatives[5]. A 12-year prospective study has recently confirmed the safety and long-term oncological outcomes of AS[6]. In addition, radiotherapy (RT) is an emerging therapy for SRMs[7,8]. For some patients, watchful waiting (WW) or managing symptoms as they occur (best supportive care) are appropriate treatment options. In the Netherlands, the local availability of specific treatment modalities, such as surgery or TA, varies between hospitals. Ideally, the decision on the most appropriate treatment should be based on oncological efficacy, preservation of renal function, treatment-related complications and patient preferences for appropriate treatment options (e.g. impact on quality of life). In line with the concept of shared-decision making (SDM), all treatment options should be considered and discussed[9,10]. Patients should be referred if a particular required treatment modality is not available at the hospital of diagnosis.

A recent study has shown practice variation in the treatment of cT1 RCC in the Netherlands, with treatment strategies influenced by surgical hospital volume[11].Variation in treatment is, to some extent, inevitable and even necessary, as each patient has unique characteristics and needs. In some cases, variation may be unjustified[12].

For example, the range of treatment options available at a given hospital or in a certain region may be a factor. Currently, the treatment options offered to patients may depend on the hospital or region in which they are diagnosed. This could result in patients being over- or undertreated, or certain treatment options being withheld. In addition, variation could result in differences in outcomes or care costs between hospitals. Therefore, it is important to identify factors associated with variation in the treatment of cT1a RCC. In this way, unwarranted differences can be identified and reduced. The aim of this study is to analyse treatment variation for cT1a renal cancer in seven large teaching hospitals in the Netherlands. Additionally, we will investigate factors associated with this variation.

Patients and methods

Study design

This retrospective, multicenter cohort study was performed within a network of seven large non-academic teaching hospitals in the Netherlands, the Santeon hospital group: St. Antonius Hospital, OLVG, Catharina Hospital, Canisius Wilhelmina Hospital (CWZ), Martini Hospital, Maasstad Hospital, and Medisch Spectrum Twente (MST). These hospitals are geographically spread throughout the Netherlands and serve approximately 12% of the Dutch population. These hospitals collaborate to implement value-based healthcare (VBHC)[13,14].

The Medical Research Ethics Committee United (MEC-U) in Nieuwegein has confirmed that the Medical Research Involving Human Subjects Act (WMO) did not apply to this study (W24.115). The research protocol for this study was approved by the 'Santeon Beheercommissie' (SDB 2024-012). In addition, each participating hospital approved local feasibility. Pseudonymization was applied to all data for the hospitals involved.

Patient population and data collection

Patients aged -18 years diagnosed with cT1a renal cancer from 2019 to 2022 were identified by the Netherlands Cancer Registry (NCR). As the NCR includes both histologically confirmed and clinically diagnosed cases, this study population reflects SRMs that are suspected to be RCC, rather than only confirmed RCC. Patients diagnosed outside the Santeon hospitals were excluded. From the NCR, date of birth, gender, date of diagnosis, hospital of diagnosis, treatment, date of treatment, and tumour radius were collected and subsequently checked with the electronic patient record in each participating hospital. Next, complementary patient-, tumour- and treatment characteristics were extracted manually from the electronic patient records. Charlson comorbidity index (CCI) was categorized into three groups: no comorbidity (0), mild/moderate comorbidity (1-4) and severe comorbidity (-5). RENAL Nephrometry scores were categorized into two groups: low (4-6) and intermediate/high (7-12). Estimated glomerular filtration rate (eGFR) was collected around the date of diagnosis (range 4-8 months prior to treatment). Data were collected and managed using REDCap electronic data capture tools[15]. In addition, information on the available treatment options in each hospital was obtained from urologists at each hospital. Clinical follow-up was completed until February 2025.

Outcomes

The primary outcome of this study was the initial treatment received for the cT1a renal cancer. Treatment was categorized into six groups: PN, TA, AS, radical nephrectomy (RN), RT or WW/no treatment. Treatment was further categorized into active treatment, including PN, TA, RN and RT. No active treatment was defined as AS or WW/no treatment.

Statistical analyses

With descriptive analyses, we provided insight into patient- and tumour characteristic of the total population and by hospital. Continuous variables were presented as mean ± standard deviation (SD) or median with interquartile range (IQR). Categorical data were presented as frequencies with percentage and compared using Chi-square tests. Due to the limited sample size, no statistical testing was performed in small groups. Furthermore, treatment distributions across hospitals were visualized. Post-hoc analyses were conducted using standardized *z*-tests to identify significant deviations between observed and expected frequencies for each hospital-treatment combination.

In addition, we have stratified all analyses by CCI score (mild/moderate vs. severe) and RENAL Nephrometry score (low vs. intermediate/high). Next, analyses were repeated in tumours suitable for PN (RENAL Nephrometry score 4-6, CCI < 5, eGFR ≥ 60). Univariable and multivariable logistic regression was performed to determine which factors were associated with initiating active treatment. Missing values were handled using listwise deletion.

To evaluate how much of the variation in treatment decisions could be attributed to differences between hospitals, we calculated the intraclass correlation coefficient (ICC) using a null multilevel logistic regression model, with hospital included as a random intercept. A multilevel analysis was deemed necessary if the percentage was over 10%[16]. A *p*-value <0.05 was reported as a significant difference. Statistical analyses were performed with SPSS version 29.0.

Results

Tumour characteristics

Overall, 501 patients with 544 cT1a renal cancer tumours were diagnosed at the seven hospitals from 2019 to 2022. A total of 35 patients presented with more than one tumour. Mean age of patients was 66 years, 40% were overweight (body mass index [BMI] 25-29.9), and 40% had severe comorbidity (CCI ≥ 5). Mean eGFR was 69.4 ml/min/1,73m^2 and 48% of tumours presented in the left kidney. Mean tumour radius was 2.5 cm and the majority of tumours had a low RENAL Nephrometry score (4-6, n=283, 52%) (Table 1). Patient- and tumour characteristics differed minimally between hospitals.

Table S1 provides an overview of the treatment modalities available at each hospital (Supporting Information: Appendix I). There were few differences in the treatment options offered by the hospitals. None of the hospitals offered RT, and hospital C did not offer surgery in-house.

Table 1. Tumour characteristics in patients with cT1a renal cancer according to hospital site.

	Total (n=544)	Hospital A (n=60)	Hospital B (n=82)	Hospital C (n=45)	Hospital D (n=46)	Hospital E (n=61)	Hospital F (n=92)	Hospital G (n=158)
Sex (female), no. (%)	175 (32)	24 (40)	27 (33)	21 (47)	11 (24)	21 (34)	26 (28)	45 (29)
Mean age at diagnosis, years ± SD	65.6 ± 11.4	67.8 ± 10.9	67.7 ± 11.2	70.8 ±9.8	64.7 ± 11.1	63.7 ± 11.0	65.5 ± 12.0	63.4 ± 11.4
BMI, no. (%)								
Underweight (<18.5)	4 (1)	1 (2)	-	-	1 (2)	1 (2)	1 (1)	1 (1)
Normal (18.5-24.9)	164 (30)	19 (32)	24 (29)	9 (20)	12 (26)	20 (33)	29 (32)	51 (32)
Preobesity (25-29.9)	219 (40)	23 (38)	36 (44)	20 (44)	22 (36)	22 (36)	30 (33)	71 (45)
Obesitas class I (30-34.9)	101 (19)	12 (20)	13 (16)	5 (11)	14 (30)	10 (16)	18 (20)	29 (18)
Obesitas class II (35-39.9)	36 (7)	4 (7)	5 (6)	4 (9)	3 (7)	5 (8)	9 (10)	6 (4)
Obesitas class III (>40)	4 (1)	-	1 (1)	1 (2)	-	-	2 (2)	-
Missing	16 (3)	1 (2)	3 (4)	6 (13)	3 (5)	3 (5)	3 (3)	-
Charlson Comorbidity Index, no. (%)								
No comorbidity (0)	34 (6)	1 (2)	1 (1)	-	3 (7)	8 (13)	5 (5)	16 (10)
Mild (1-2)	129 (24)	14 (23)	17 (21)	6 (13)	12 (26)	15 (25)	24 (26)	41 (26)
Moderate (3-4)	162 (30)	18 (30)	28 (34)	9 (20)	20 (44)	17 (28)	21 (23)	49 (31)
Severe (≥5)	219 (40)	27 (45)	36 (44)	30 (67)	11 (24)	21 (34)	42 (46)	52 (33)

	Total (n=544)	Hospital A (n=60)	Hospital B (n=82)	Hospital C (n=45)	Hospital D (n=46)	Hospital E (n=61)	Hospital F (n=92)	Hospital G (n=158)
Smoking/history with smoking, no. (%)								
Yes	313 (58)	30 (50)	50 (61)	21 (47)	19 (41)	36 (59)	60 (65)	97 (61)
No	177 (32)	25 (42)	25 (31)	21 (47)	17 (37)	6 (10)	28 (30)	55 (35)
Missing	54 (10)	5 (8)	7 (9)	3 (7)	10 (22)	19 (31)	4 (4)	6 (4)
Hypertension, no. (%)								
Yes	316 (58)	38 (63)	59 (72)	28 (62)	16 (35)	22 (36)	48 (52)	105 (67)
No	185 (34)	20 (33)	19 (23)	16 (36)	24 (52)	13 (21)	44 (48)	49 (31)
Missing	43 (8)	2 (3)	4 (5)	1 (2)	6 (13)	26 (43)	-	4 (3)
eGFR, ml/min/1,73m², mean ± SD	69.35 ± 22.55	63.72 ± 22.5	66.70 ± 20.7	67.56 ± 21.5	77.89 ± 19.6	73.92 ± 22.1	66.43 ± 26.3	70.21 ± 21.5
Missing	n=36	n=13	n=13	n=0	n=1	n=1	n=2	n=6
Tumour location (left kidney), no. (%)	261 (48)	29 (48)	35 (43)	24 (53)	25 (54)	26 (43)	37 (40)	85 (54)
Tumour radius (mm), mean ± SD	24.8 ± 8.6	26.0 ± 8.3	23.7 ± 8.1	23.4 ± 9.2	27.3 ± 7.6	24.0 ± 8.2	26.3 ± 8.5	24.0 ± 9.2
RENAL Nephrometry score, no. (%)								
Low (4-6)	283 (52)	41 (68)	42 (51)	21 (47)	20 (44)	33 (54)	45 (49)	81 (51)
Intermediate (7-9)	242 (45)	18 (30)	38 (46)	20 (44)	26 (57)	23 (38)	43 (47)	74 (47)
High (10-12)	19 (4)	1 (2)	2 (2)	4 (9)	-	5 (8)	4 (4)	3 (2)

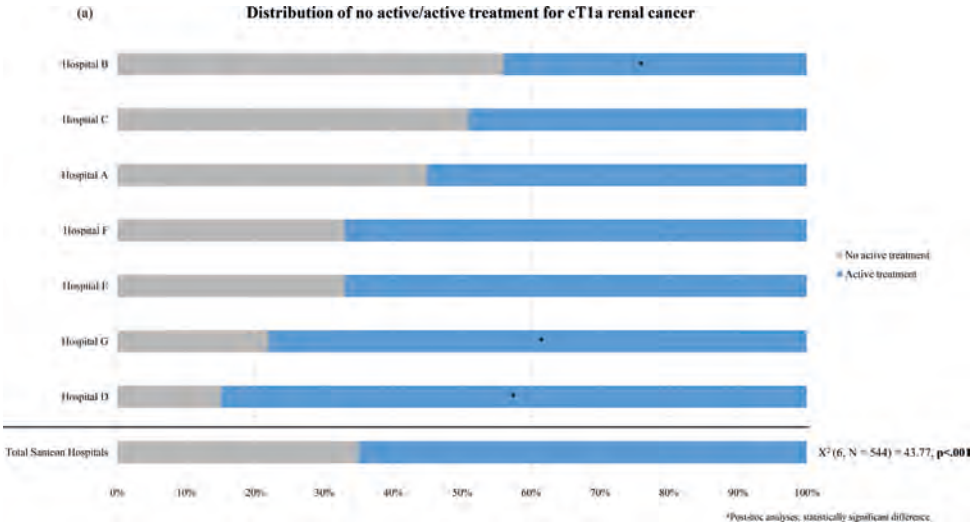
Abbreviations: BMI, body mass index; eGFR, estimated glomerular filtration rate; SD, standard deviation.

Active versus no active treatment

Figure 1 displays the distribution of active versus non-active treatment across hospitals. Overall, 65% of tumours were actively treated and this percentage varied largely across the seven hospitals (44-85%) (Figure 1A). Post-hoc analysis revealed that Hospital B performed significantly *fewer* active treatments than expected (z = -2.4). Hospitals D and G had significantly *more* patients receiving active treatment than expected (z = -2.2 and z = -2.7, respectively) ($p < 0.05$).

Specific treatment modalities

Significant differences were also observed between hospitals when specific treatment modalities were considered (Figure 1B). PN and TA were found to vary between hospitals from 20 to 54% and 0 to 39%, respectively. AS was chosen in 15-51% of tumours and RN was performed in 2-13% of tumours. Initial treatment rates for specific treatment modalities are presented in Table S2 (Appendix II). Post-hoc analyses showed that tumours in patients diagnosed in Hospitals A or E were *less often* managed with TA than expected (z = -3.2 and z = -2.0, respectively). Tumours diagnosed in Hospital B were managed significantly *more* with AS (z = 3.4) and significantly less with TA (z = -2.7). Patients with tumours diagnosed in Hospital C were *less often* managed with PN than expected (z = -2.1), while tumours in patients diagnosed in Hospital D were managed *more often* with TA (z = 3.6). Tumours in patients diagnosed in Hospital F were significantly *more likely* to be treated with radiotherapy, as these patients were referred to a regional hospital for this treatment (z = 3.5). In Hospital G, tumours were *less often* managed with AS than expected (z = -2.4) (p <0.05).



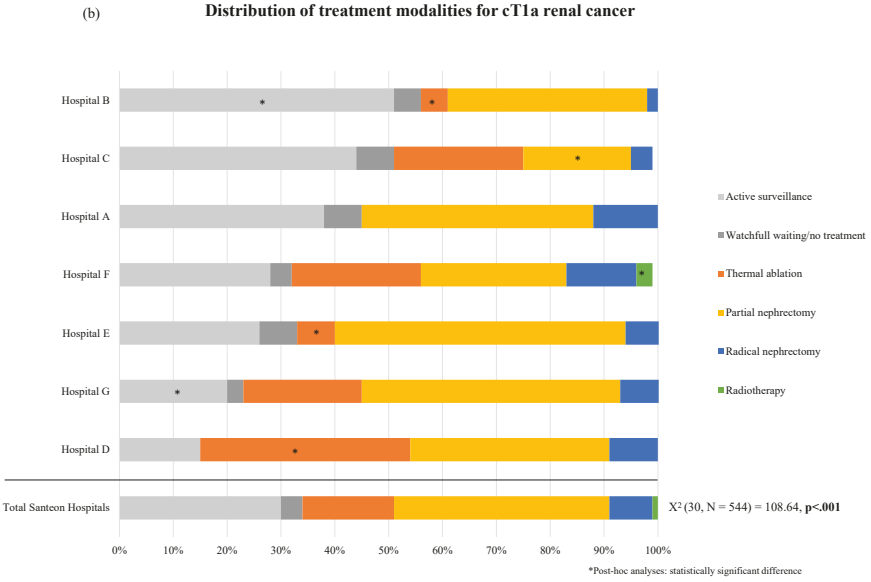


Figure 1. (**A, B**) Distribution of treatment modalities for cT1a renal cancer across hospitals, categorized by active/no active treatment (A) and specific treatment modalities (B).

After stratification by comorbidity and tumour complexity, significant variation in treatment across hospitals remained, as shown in Figure S1 (Appendix III) (p <0.001). In tumours from patients eligible for PN, the gold standard of therapy, 61% received PN, with hospital rates ranging from 43 to 71% (Figure S2, Appendix IV).

Factors affecting active treatment

Univariable logistic regression analysis revealed that CCI and RENAL Nephrometry score were independent significant predictive factors for receiving active treatment (Odds ratio (OR) = 0.77 95% CI [0.72-0.83], p < 0.001 and OR = 1.16 95% CI [1.04-1.28], p = 0.006, respectively). This indicates that tumours in patients with fewer comorbidities and more anatomically complex tumours were more likely to undergo active treatment. In addition, hospital of diagnosis was significantly associated with whether or not tumours were treated with active treatment (p < 0.001), indicating that treatment approach varied by hospital of diagnosis. Lastly, eGFR prior to treatment was a significant predictor of receiving active treatment (OR = 1.02 95% CI [1.00-1.02], p < 0.001).

Multivariable logistic regression analysis showed that the hospital of diagnosis remained significantly associated with active or no active treatment, even after correction for CCI, RENAL Nephrometry score, and eGFR (p < 0.001).

With an ICC of 0.081, it was found that around 8% of the total variation in treatment decisions could be attributed to the hospital of diagnosis. As this was below the predefined threshold of 10%, no further multilevel analysis was conducted.

Discussion

This study evaluated variation in the management of cT1a renal cancer in seven Dutch teaching hospitals. Significant differences in treatment distributions were found across hospitals, and differences persisted after stratifying for comorbidity and tumour complexity. Multivariable analyses showed that after case mix adjustment, hospital of diagnosis remained a significant factor associated with initiating active versus no active treatment.

First, although this study shows a treatment distribution comparable to previous studies on cT1 RCC[11,17], we observed substantial differences in treatment distributions across hospitals, even after adjustment for patient and tumour factors. Instead, our findings suggest the presence of unwarranted practice variation, whereby patients might not always receive care that aligns with their personal values and preferences[12]. This is of particular concern in the context of cT1a RCC, where several treatment options, including AS, TA, and PN, are

considered appropriate. In the absence of well-defined, evidence-based pathways, treatment decision-making may differ across hospitals. Variation in practice is not a new phenomenon within healthcare and has been observed in many different contexts[12]. Nevertheless, it is not necessarily considered problematic. However, the differences observed in our study are undesirable, as they suggest that treatment decisions depend on institutional factors, such as the availability of specific modalities, expertise, or clinician preferences. Our findings align with recent UK research, showing that hospitals with greater experience and higher surgical volumes are more likely to perform PN, regardless of tumour complexity[18]. Similarly, a recent study showed that the primary urologist was the key factor in determining cT1a RCC management decisions[19]. Our findings suggests that institutional factors may heavily influence treatment decisions, potentially resulting in under- or overtreatment and affecting patients' quality of life and clinical outcomes. A key objective of accessible healthcare is to ensure that patients receive the same standard of care, regardless of where they are diagnosed[20]. Therefore, it is essential to understand the causes of this variation in order to promote consistency in care.

Second, this analysis was conducted as part of the wider VBHC implementation in the Santeon network, aiming to improve RCC care[21]. To translate our findings into sustainable improvements, the next step in VBHC implementation is required: transitioning from individual, hospital-level initiatives to organized, collective learning. While individual participating hospitals have implemented VBHC principles, a structured framework for shared learning has been lacking. However, this structured framework has been successfully established for 16 medical conditions included in the Santeon 'Better Together' programme, with the number of included conditions continuing to grow. This program enables VBHC implementation by providing data insights, supporting multidisciplinary improvement teams and facilitating collaboration[13,14]. We therefore recommend incorporating RCC into this program to support standardized care pathways, inter-hospital benchmarking and the systematic implementation of improvements in line with the Santeon approach to standardizing care. Moreover, similar efforts have been done for prostate cancer, where similar patterns have been observed in prostate cancer management across Santeon hospitals, with variations in treatment, particularly among patients with localized prostate cancer[22]. Because of these findings, the Santeon hospitals have developed a uniform care pathway based on standardized diagnostics, aiming for accurate diagnoses and appropriate treatment.

This study has some limitations. First, the study population was derived from seven Dutch teaching hospitals and may not be representative of national practice. Nevertheless, their regional distribution is likely to improve the external validity of our findings. In addition, hospitals differed in treatment availability. Most had made regional agreements with other hospitals to streamline RCC care. For instance, at Hospital C, patients requiring active

treatment were often referred to a regional hospital specialized in RCC care not included in this study. This reflects real-world organizational variation, which should be considered when interpreting the findings. Consequently, cases involving active treatment may have been underrepresented in that hospital's data. Secondly, while the NCR includes both histologically and clinically diagnosed RCC cases, tumours without histological confirmation that are not actively treated, and with no clear clinical diagnosis of malignancy (e.g. those under AS/WW without diagnostic certainty), may be underrepresented. Treatment patterns for this subgroup could not be fully evaluated. Furthermore, a lack of data on patient outcomes and preferences limited insight into treatment rationale. Additionally, lacking data on clinician-related factors (e.g. experience) may influence treatment decision-making and contribute to variation. Finally, the retrospective design resulted in missing data, leading to exclusions in the multivariable analysis and potentially affecting the robustness of the findings. Nevertheless, observed hospital differences remain relevant, reflecting variations not fully explained by case mix. To address these limitations, a nationwide RCC registry has recently been initiated to enable more comprehensive analyses of practice variation and patient-centered outcomes[23]. Despite limitations, this study offers insights from a large multicenter cohort, highlighting substantial inter hospital variation in cT1a renal cancer management and the need for standardized care pathways. Future research should explore how institutional factors influence treatment decisions and outcomes, to help reduce unwarranted variation and improve collaborative learning in optimizing RCC management.

Conclusions

This study demonstrates substantial variation between hospitals in cT1a renal cancer management, which cannot be fully explained by differences in patient comorbidity or tumour complexity. Treatment decisions were significantly associated with the hospital of diagnosis, suggesting that institutional factors play a key role. In order to reduce unwarranted variation and improve the consistency and quality of care, transparent care pathways, standardized outcome measurement, shared decision-making and inter-hospital benchmarking are essential.

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Appendix I: Supplementary Table S1

Supplementary Table S1. Available treatment modalities performed at each hospital site (2019-2022)

Hospital	Partial nephrectomy	Radical nephrectomy	Thermal ablation	Radiotherapy	Active surveillance	Watchful waiting/ no treatment
A	✓	✓	✓[1]	✗	✓	✓
B	✓	✓	✓	✗	✓	✓
C	✗[2]	✗[2]	✓	✗	✓	✓
D	✓	✓	✓	✗	✓	✓
E	✓[3]	✓	✓	✗	✓	✓
F	✓	✓	✓	✗	✓	✓
G	✓	✓	✓	✗	✓	✓

[1]TA performed since June 2022
[2]Did not offer surgery in-house, but as part of a partnership in the region
[3]Robot-assisted partial nephrectomy offered since 2021; prior to that, only open partial nephrectomy was performed in-house.

Appendix II: Supplementary Table S2

Supplementary Table S2. Initial treatment ranges in % of tumours for cT1a renal cancer according to hospital site for all tumours and stratified by comorbidity, tumour complexity, and age.

	Total n=544	CCI<5 n=325	CCI≥5 n=219	RENAL 4-6 n=283	RENAL 7-12 n=261
Active surveillance	15-51	14-41	18-64	10-52	17-55
Partial nephrectomy	20-54	33-68	12-29	24-58	17-53
Radical nephrectomy	2-13	4-11	0-19	0-11	5-21
Thermal ablation	0-39	0-34	0-55	0-40	0-39
Radiotherapy	0-3	0-2	0-5	0-2	0-4
Watchful waiting/no treatment	3-7	0-4	0-14	0-10	0-7

CCI, Charlson Comorbidity Index.

Appendix III: Figure S1

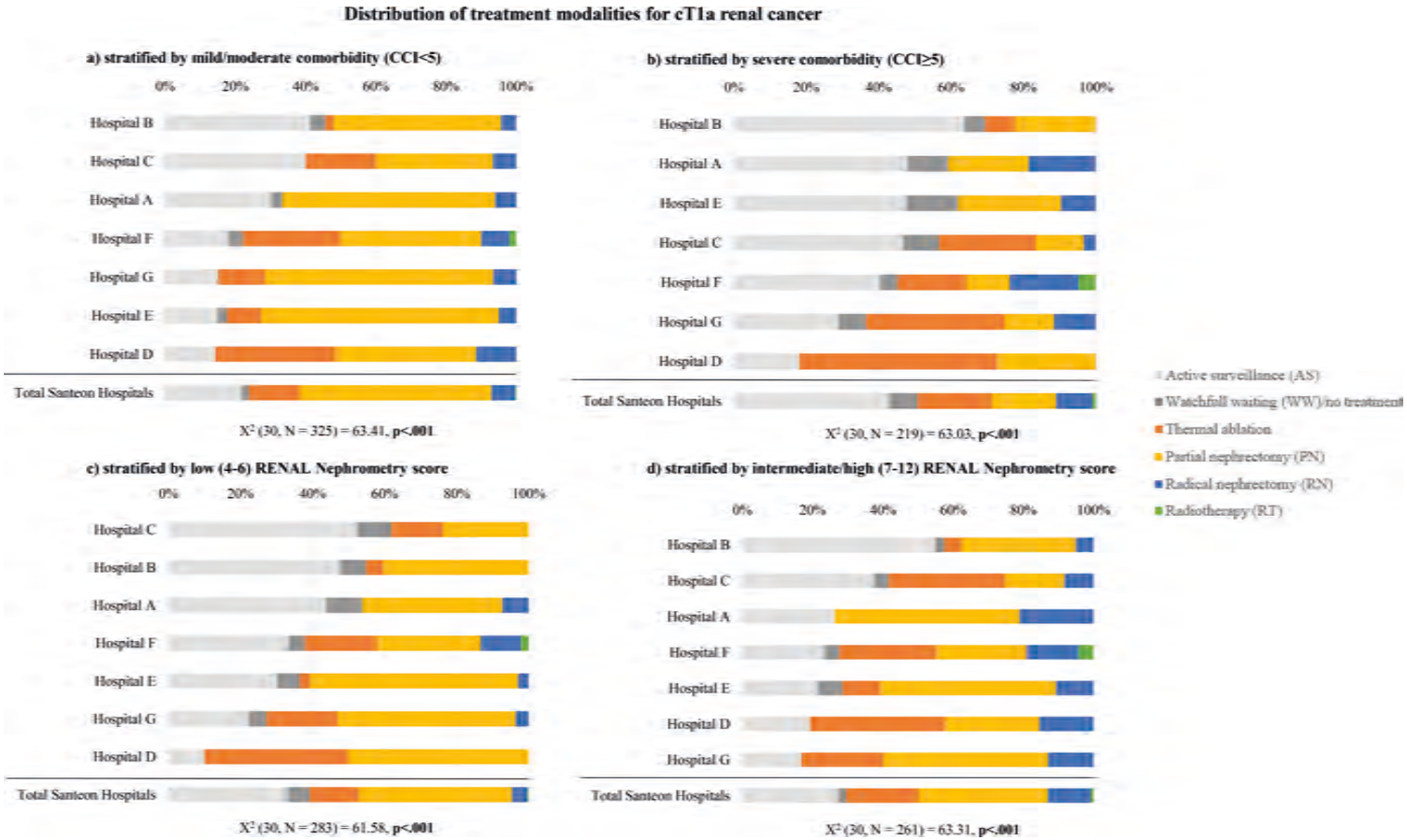


Figure S1. a, b, c, d. Distribution of treatment modalities for cT1a renal cancer across hospitals, stratified by mild/moderate comorbidity (CCI<5) (a) and severe comorbidity (CCI-5) (b), and by low (4-6) (c) and intermediate/high (7-12) RENAL Nephrometry score (d)

Appendix IV: Figure S2

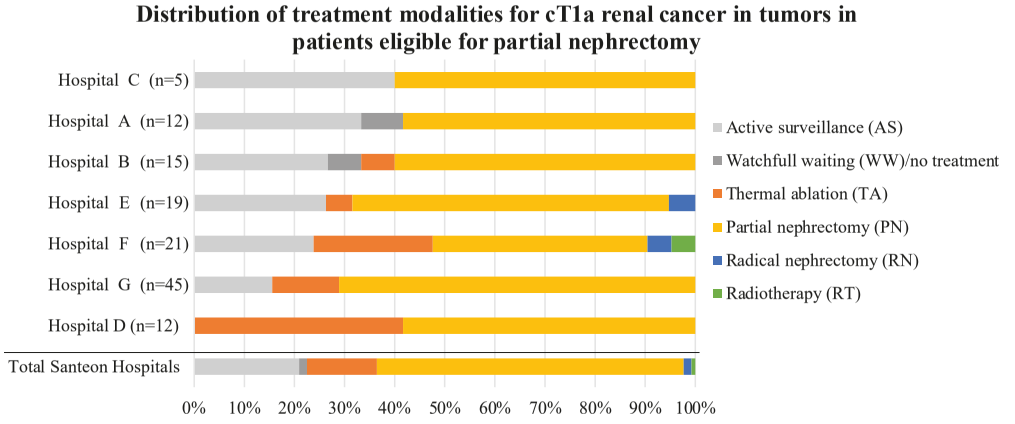


Figure S2. Distribution of treatment modalities for cT1a renal cancer across hospitals, only including tumours in patients eligible for partial nephrectomy.

PART II

Development of two patient decision aids for renal cell carcinoma

Chapter 4

Development of a patient decision aid for T1 renal cell carcinoma: A user-centered mixed methods study.

C.C. Bresser
H.H.E. van Melick
R. The
P. B. van der Nat
M.M. Garvelink

Urology Practice, 2025

Abstract

Introduction: It is important to actively involve patients with cT1 renal masses in treatment decision-making. Patient decision aids (PtDAs) support patients and healthcare professionals (HCPs) in shared decision-making. The aim of this study was to develop a Dutch PtDA for cT1 renal masses and to test its acceptability and usability.

Methods: This was a user-centered mixed-methods design. Cocreation process with HCPs from several hospitals and a patient representative, with input from (a) a needs assessment study (semistructured interviews and questionnaires) and (b) acceptability and usability testing (think-aloud sessions and semistructured interviews), guided by the International Patient Decision Aids Standards (IPDAS) criteria. Compatibility with the IPDAS criteria was evaluated (c).

Results: In total, 12 patients with cT1 renal masses and 56 HCPs participated. The PtDA consists of 3 components: (1) a decision aid handout demonstrating an overview of treatment options; (2) an online decision aid with information on renal cell carcinoma, treatment options, and values-clarification exercises; and (3) a personal decision aid summary. Both patients and HCPs highly appreciated the PtDA and were able to navigate through it. The PtDA fulfills all 12 IPDAS criteria.

Conclusions: We systematically developed a PtDA for cT1 renal masses. The PtDA was found acceptable and usable by patients and HCPs. The PtDA is currently being implemented in routine care.

Introduction

Renal cell carcinoma (RCC) represents 3-5% of cancer diagnoses in Europe yearly[1]. In the Netherlands, the incidence is expected to increase by 31% in a decade[2]. More than half of Dutch RCC diagnoses are cT1 tumors[3]. Approximately 80% of surgically excised tumors <4 cm are malignant[4]. As several treatment options for cT1 tumors exist, patients and healthcare professionals (HCPs) have the opportunity and responsibility to determine the best treatment option. There is no clear definition of evidence-based selection criteria. Accordingly, not only tumor characteristics, treatment outcomes and risks, and patient comorbidities but also patient's individual preferences and values must be taken into account. This process can be facilitated by shared decision-making (SDM).

SDM is a collaborative approach in which patients are actively involved in decision-making, to ensure informed decisions that align with their values and preferences[5,6]. SDM is known to lead to improved quality of life, reduced decisional conflict, improved patient satisfaction, and reduced healthcare utilization[7–9]. SDM is crucial when multiple treatment options exist, as is the case with RCC. The European Association of Urology RCC guidelines advocate SDM for treatment decisions[10]. However, a global survey shows nearly one third of RCC patients report no involvement in treatment decision-making, suggesting poor SDM implementation[11].

SDM can be supported by patient decision aids (PtDAs), which provide information about options and associated risks, helping patients clarify personal values in order to choose the most appropriate treatment[12]. PtDA use is known to result in patients taking an active role in decision-making, increased patient knowledge, and patients feeling informed and clear about their personal values[9].

In uro-oncology, the importance of SDM has been increasingly recognized, with some PtDAs available[13]. However, most focus on prostate cancer and few tools for RCC exist[14–16]. Given the complexity and impact of treatment decisions in RCC, it is important to integrate SDM in this setting. In addition, previous studies show variation in cT1 RCC treatment across geographical regions[17,18], highlighting the need for consistent patient guidance. SDM is essential to ensure that patients are informed about all appropriate options, regardless of local availability. Current tools lack a personalized overview of individual values and preferences, which could significantly improve decision-making. Effective implementation of a PtDA requires tailoring to tumor (sub)type, therapeutic options and language. Therefore, a country specific PtDA is needed. With rising RCC incidence worldwide[19] and new treatment options, there is a need for better SDM implementation in RCC care. This study aimed to develop a Dutch PtDA for cT1 renal masses.

Materials and Methods

User-centered mixed-methods development process based on the International Patient Decision Aids Standards (IPDAS)[20] criteria, consisting of cocreation sessions and three main elements: a needs assessment study (a), acceptability and usability testing (b), and compatibility evaluation with the IPDAS minimum criteria (c; Figure 1).

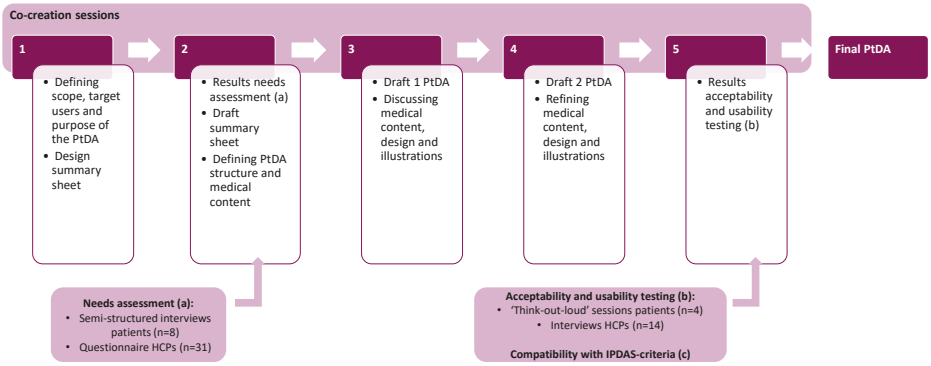


Figure 1. Development process of the cT1 renal masses patient decision aid (PtDA).
HCP indicates healthcare professional; IPDAS, International Patient Decision Aids Standards; a, needs assessment study; b, acceptability and usability testing; c, compatibility evaluation with IPDAS criteria.

Participants

HCPs specialized in RCC and patients with cT1 renal masses aged ≥ 18 years who were able to complete a telephone interview were included. Patients who were not fluent in Dutch or unable to answer interview questions independently were excluded. For the needs assessment study (a), patients were recruited by means of purposive sampling via working group members. Needs assessment study (a) participants who had consented to participate in follow-up research were included for acceptability and usability testing (b).

All patients signed informed consent. The Medical Research Ethics Committee United (MEC-U) in Nieuwegein has confirmed that the Medical Research Involving Human Subjects Act (WMO) did not apply to this study (Ref: AW23.027/W22.125). The study followed local laws and regulations, with local feasibility approved at each hospital. Data were collected from July 2022 to June 2023.

HCPs were recruited using purposive expert- and snowball sampling. For the needs assessment study (a), HCPs were invited via an e-mail distributed by the Dutch Renal Cancer Group/Dutch Urological Association. For acceptability and usability testing (b), HCPs

involved in RCC care, but not part of the working group, were selected through purposive sampling facilitated by working group members.

Cocreation sessions

Cocreation sessions were conducted with a multidisciplinary team of HCPs and a representative from the Dutch Kidney Cancer Patient Association (i.e. 'working group'). In collaboration with ZorgKeuzeLab, a company experienced in the development and implementation of PtDAs, the scope, target audience, objectives, format, and implementation strategy for the PtDA were defined.

Twelve HCPs from ten Dutch hospitals were invited to participate in the working group. Five cocreation sessions were planned. To ensure that the PtDA met the needs and preferences of both patients and HCPs, the results of the needs assessment study (a) were shared during the cocreation sessions and integrated in the development process. Draft versions of the PtDA were produced, reviewed, and evaluated during acceptability and usability testing (b). Feedback was used to refine and finalize the PtDA. Cocreation sessions took place both in person and online. Sessions were audio recorded for validation purposes and field notes were taken.

Needs assessment study

For patients, semistructured interviews were conducted using a predefined topic guide (Appendix I). All interviews were audio recorded, transcribed, and analyzed independently by two researchers (CB and MT) using an inductive thematic approach. Interviews continued until thematic saturation was reached.

For HCPs, data were collected using a 40-item online survey, collecting information on experience in RCC care, perspectives on SDM, and perceptions and requirements for the PtDA (Appendix II).

Acceptability and usability testing

Patients participated in online think-aloud sessions via Microsoft Teams. During these one-hour sessions, patients navigated through the online PtDA while articulating their thoughts aloud. Sessions were recorded and field notes were taken to document challenges and assess usability. Patients provided feedback on the content, design, and usefulness of the tool, and whether they would recommend it to others.

HCPs from different hospitals were interviewed by telephone to gain insight into the implementation of the PtDA in different workflows. During the interviews, HCPs shared their willingness to use the PtDA, their likelihood to recommend it (acceptability), and their

suggestions for improving the workflow and content (usability). Interviews were audio recorded and field notes were taken for verification purposes.

Suggestions for improvement were categorized and discussed with the working group in the fifth cocreation session. Feedback was reviewed, and consensus was reached on the final changes to be implemented in the PtDA.

Compatibility evaluation with IPDAS-criteria

The compatibility of the PtDA with the IPDAS criteria was evaluated based on the twelve minimum qualifying and certification criteria for decision aids[21].

Analysis

Patient and HCP characteristics were analyzed using descriptive statistics. Continuous variables were presented as mean with SD or median with IQR. Categorical variables were presented as frequencies (%) unless otherwise stated.

Qualitative feedback from acceptability and usability tests (b) was documented in Excel, categorized by the type of participant (patient/HCP) and the feedback topic. These data were analyzed by the authors (CB, MG, HvM, RT, AT) and reviewed during the cocreation session 5. Quantitative and qualitative data were processed and analyzed using Excel (version 2016).

Results

Cocreation sessions

Eleven HCPs from nine hospitals participated in the working group (Table 1). Additionally, a patient representative from the Dutch Kidney Cancer Patient Association participated. The average age of the working group was 49 years, with 15 years of experience in RCC care, and 55% worked in nonacademic teaching hospitals. Cocreation sessions of 2 to 3 hours each were held between June 2022 and June 2023, guided by the Dutch Urological Association and European Association of Urology guidelines to ensure alignment with current clinical practice[10,22].

Table 1. Baseline characteristics of healthcare professionals who participated in the working group, needs assessment study (a), and acceptability and usability testing (b)

HCP characteristic	Working group (n=11)	Needs assessment study (n=31)	Acceptability and usability testing (n=14)
Age, years - mean (SD)	49 [39-52][a]	45.1 (8.7)	46.3 (9.1)
Sex			
Male	6 (54.5)	13 (41.9)	8 (57.1)
Female	5 (45.5)	17 (54.8)	6 (42.9)
Other	-	1 (3.2)	-
Function			
Urologist	7 (63.6)	24 (77.4)	8 (57.1)
Resident urology	-	3 (9.7)	-
(Intervention) radiologist	2 (18.2)	1 (3.2)	1 (7.1)
Nurse specialist (in training)	1 (9.1)	3 (9.7)	2 (14.3)
Oncology nurse	-	-	3 (21.4)
Medical oncologist	1 (9.1)	-	-
Average professional experience with RCC, years – mean (SD)	15 [12-16][a]	12.5 (7.3)	7.5 (5.4)
Organization type			
Academic hospital	5 (45.5)	4 (12.9)	5 (35.7)
Non-academic teaching hospital	6 (54.5)	21 (67.7)	5 (35.7)
Non-teaching hospital	-	6 (19.4)	4 (28.6)

Abbreviations: HCP, healthcare professional; RCC, renal cell carcinoma.
[a]Age and average professional experience are presented as median [IQR] due to non-normal distribution.

Needs assessment study

Eight patients participated in the interviews. Mean age was 69 years, and 63% were male. Most patients had been diagnosed over a year ago, and 50% were highly educated (Table 2). Interviews lasted approximately one hour.

Table 2. Baseline characteristics of patients who participated in the needs assessment study (a) and acceptability and usability testing (b)

Patient characteristic	Needs assessment study (semi-structured interview, n=8)	Acceptability and usability testing (think-aloud session, n=4)
Age, years – mean (SD)	69.4 (7.4)	71.8 (5.0)
Male sex	5 (62.5)	3 (75.0)
Education level[a]		
High	4 (50.0)	2 (50.0)
Middle	2 (25.0)	2 (50.0)
Low	2 (25.0)	-
Treatment received[b]		
Partial nephrectomy	6 (60.0)	3 (60.0)
Radical nephrectomy	-	-
Thermal ablation therapy	3 (30.0)	2 (40.0)
Active surveillance	1 (10.0)	-
Number of months since diagnosis		
0-6	1 (12.5)	1 (25.0)
6-12	2 (25.0)	1 (25.0)
>12	5 (62.5)	2 (50.0)

[a]Education level was assessed during semistructured interviews based on highest level of completed education based on the International Standard Classification of Education.
[b]Treatment modalities were not mutually exclusive.

Patients reported that their diagnosis was often incidental (n=7). After diagnosis, patients mainly had questions about treatment options and life expectancy (n=4). Three patients experienced no real choice in treatment decision-making. Some patients reported that they were not informed on all available treatment options because they later heard of other existing treatment options (n=2). Patients differed in needs for additional information, with some patients highlighting the need for clear and consistent information, as they reported receiving conflicting advice about recovery after treatment (n=4) and one patient who was missing information on risk of recurrence of disease and metastasis. The tradeoffs involved in the decision-making process were: removal of the tumor from the body (n=4), renal function (n=1), oncological efficacy (n=2), and invasiveness of the treatment (n=1).

Thirty-one HCPs participated in the needs assessment study, with a mean age of 45 years. Forty-two percent were male, and the majority worked as a urologist (77%), with a mean experience of thirteen years, mostly working in nonacademic teaching hospitals (68%; Table 1).

Six HCPs (19%) agreed that patients with localized RCC should be more involved in decision-making. Eighteen HCPs were neutral (58%), and six disagreed (19%). Most HCPs (n=27, 87%) reported that the final treatment decision should be made by the patient and HCP together. Four HCPs (13%) stated that patients should make the final decision after considering the HCP's opinion. None of the HCPs stated that HCPs should make the final decision after considering the patient's opinion.

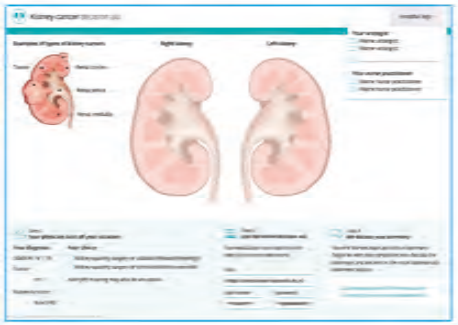
All HCPs reported that they were willing to make an effort for patient engagement in treatment decision-making. A PtDA for cT1 tumors was considered (highly) desirable by 80% of HCPs (n=25). Five HCPs (16%) were neutral on this topic. Expected benefits of the PtDA reported by HCPs were improved information provision (n=18), more patient engagement leading to improved decision-making (n=5), and patients receiving a treatment in line with their values (n=3). Expected disadvantages were confusion with patients because of too much information in the PtDA (n=8), increased consultation time (n=5), and low patient literacy (n=2).

The results of the needs assessments study were presented to the working group. In cocreation session 2, they discussed whether and how the needs could be incorporated in the PtDA.

The PtDA

A three-component PtDA was developed and evaluated for acceptability and usability testing, including (1) a decision aid handout outlining the treatment options; (2) an online PtDA with detailed information on RCC, treatment options, and values-clarification exercises; and (3) a personalized decision aid summary to facilitate decision-making during consultations (Figure 2, Appendix III).

1. Health care professional hands out decision aid



The health care professional explains the patient's diagnosis and treatment options using the decision aid handout. This sheet contains a unique login for the online patient decision aid.

2. Patient uses decision aid

The patient reads information in the online patient decision aid and lists their goals, considerations and treatment preferences.

3. Shared decision-making

The patient and health care professional discuss the patient's goals, considerations and preferences supported by the decision aid summary. Together they decide about the most suitable treatment.

Figure 2. The three-component cT1 renal masses patient decision aid and patient instructions for its use. Used with permission from ZorgKeuzeLab.

Acceptability and usability testing

Four patients participated, with a mean age of 72 years, 75% were male and 50% were highly educated (Table 2). Patients recognized that the PtDA addressed the information they were looking for (2/4). They valued the PtDA for providing a comprehensive overview and found the handout sheet helpful in summarizing treatment options (2/4). The PtDA summary was considered useful for preparing for follow-up consultations (2/4). However, one patient felt that the PtDA contained too much text.

Fourteen of the 23 invited HCPs took part in acceptability and usability testing. Mean age was 46 years, 43% were female, and 57% were urologists with a mean experience of 8 years in RCC care (Table 1). HCPs reported that the PtDA provided clear and concise information about the disease and treatment options, and served as a useful reference for patients and informal caregivers. They highlighted the values-clarification exercises as effective in identifying patient preferences and noted that the PtDA summary could improve SDM.

The results of the patient and HCP acceptability and usability testing were categorized (Appendix IV) and reviewed with the working group, leading to the final version of the PtDA.

Compatibility evaluation with IPDAS-criteria

All 16 qualifying and certification criteria for PtDAs were met (Appendix V).

Discussion

This study describes the structured development of a PtDA for cT1 renal masses with involvement of all relevant stakeholders. This is the first Dutch PtDA for cT1 tumors. By publishing this development process, we hope that HCPs will gain better understanding of the development of PtDAs and, as a result, increase their use of this tool. Our development process led us to do three observations:

Despite increasing attention to SDM, there is little focus on this topic in RCC management. International RCC guidelines recommend SDM in treatment decision-making[10]. A recent international study showed that one-third of RCC patients report no involvement in treatment decision-making[11]. Another study showed that this has not improved over the years[23]. The results of our needs assessment study highlight that some patients felt they had no real choice in their treatment. Moreover, HCPs had varying views on patient involvement in RCC treatment decisions. On the other hand, they were all willing to make an effort to involve patients in decision-making, and most of them preferred a PtDA to support this. Expected barriers and facilitators identified by HCPs are consistent with findings from the existing literature[24].

To successfully embed the PtDA in RCC care, a specific implementation strategy is recommended, with coproduction of PtDA content as an important first step[25]. As the availability of RCC treatment varies internationally, it is important to establish a national development process to match the available treatment options. However, RCC treatment options are changing rapidly over time, emphasizing the need for structural maintenance of the PtDA. Collaboration with an independent company ensures that updates are performed rapidly when guidelines change. A separate study is currently being conducted to investigate the implementation of the PtDA as part of a multifaceted SDM intervention[26].

In parallel with the development process of this PtDA, we have also developed a PtDA for metastatic clear cell RCC[27]. The approach is largely the same as for the current tool. However, the development process for cT1 renal masses was less complicated than for metastatic RCC because several types of systemic therapy are available. In the Netherlands, reimbursement for systemic therapy varies between hospitals, leading to differences in treatment availability. As mentioned before, our developed PtDA consists of three components, supporting different steps of the SDM process[28]. In SDM, the process of identifying patient's values is essential because it leads to better alignment of treatment decisions with patient's values and less decisional regret. PtDAs facilitate this through values-clarification methods. Internationally, only two-thirds of existing PtDAs provide explicit values-clarification methods[9]. We included an online slider in our PtDA in order to let patients think about their own values regarding treatment decisions[29].

This study has some limitations. First, the number of patients included in the needs assessment study and acceptability and usability testing is small, and patients were mostly highly educated. Given the small sample size and limited inclusion of patients with diverse ethnic and racial backgrounds, the generalizability of the PtDA is unknown. Additionally, digital/language skills were not assessed in our study. This may have introduced bias. However, patients with limited (health/digital) literacy skills are often accompanied by relatives who can assist them.

Conclusions

In this study, a three-component PtDA was developed to support SDM in cT1 renal masses treatment decision-making. The PtDA was found to be acceptable and usable by patients and HCPs. The existence and use of this PtDA could contribute to high-quality, patient-centered and appropriate care for RCC patients in the Netherlands. This PtDA is part of a multifaceted intervention, which is being investigated in a clinical trial (ClinicalTrials.gov NCT05548621)[26]. Afterward, the PtDA will be made available to all HCPs and patients in The Netherlands.

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Appendix I. Interview guide needs assessment study for patients with cT1 renal masses

Introduction:

- Age
- Sex
- Marital status
- Education, background
- Current occupation

Diagnosis:

- When were you diagnosed with kidney cancer?
- How did you discover that you had kidney cancer? Incidental finding?
- Who communicated the diagnosis to you?
- Who was with you when you received the diagnosis?
- What do you recall from the diagnosis consultation?
- What did you experience emotionally?
- What information were you provided with at that time?
- What were the key questions you had during and after this consultation?
- Did you have concerns after the diagnosis? If yes, what were they?
- Were there aspects missing during the diagnosis consultation?
- Were treatment options discussed during the diagnosis consultation?

Treatment options:

- What information were you given about the treatment options?
- What treatment options were available to you?
- Which treatment did you choose?
- Was it difficult for you to decide on the treatment? Why or why not?
- What was important to you in life? Which treatment option aligned with this? Did you choose this treatment?
- What information did you find unnecessary during the discussion of treatment options?
- What information was lacking during the discussion of treatment options?
- Did you seek additional information? Where? What were you looking for and why? (peer support: support groups, patient experiences, chats, blogs, discussion groups, patient associations, articles, etc.) Second opinion?
- Did you involve other individuals in your decision? Who? How did these discussions influence the treatment you ultimately chose?
- How did your doctor involve you in the treatment choice? How did you perceive this?

- Did you feel you had a choice regarding the treatment?
- Who, in your case, ultimately made the decision about your treatment?
- In your opinion, who should make the final treatment decision: the doctor, you together with the doctor, or you alone?

During treatment:

- Were you aware of the pros and cons of the treatment options? Were you aware of the risks associated with the treatment options (complications/side effects)?
- How did you experience the treatment?
- What deviated from your expectations?

After treatment:

- How was the recovery from the treatment? How long did it take? Did you receive additional assistance/care? What precautions did you need to take?
- How do you currently view your decision? Would you choose the same treatment now? Why or why not?

Tips:

- What advice would you give to patients going through a similar journey?
- Do you have any specific tips for the decision aid?

May we contact you in the future for follow-up research, during which we will present the decision aid developed for your feedback?

Appendix II: Questionnaire needs assessment study healthcare professionals

Introduction:

- Age
- Sex
- Profession
- Number of years of experience with RCC
- Hospital type
- Self-assessment knowledge on RCC (1-5: insufficient, moderate, sufficient, good, excellent)
- Yearly number of patients with RCC diagnosed in hospital
- RCC treatments performed in hospital
- Treatments requiring referral to other hospital

Experiences with RCC care:

- When are patients with (suspected) RCC informed about treatment options in your hospital? (multiple answers possible)
    - During the diagnostic consultation
    - During the policy discussion (after multidisciplinary team meeting (MTM))
    - Other, namely ...
- How are treatment options offered to patients decided upon in your hospital?
    - All treatment options that are medically feasible for the patient
    - A selection of treatment options that you as a physician consider appropriate
    - During a multidisciplinary team meeting (MTM)
    - All treatment options available in your hospital
    - Other, namely ...
- Who informs patients with (suspected) RCC about the different treatment options in your hospital? (multiple answers possible)
    - Urologist
    - Urology resident (in training)
    - Medical oncologist
    - Oncology resident (in training)
    - Nurse specialist
    - Oncology nurse
    - Other, namely ...
- How are patients informed about treatment options in your hospital? (multiple answers possible)
    - Verbal information
    - In writing: hospital information leaflet
    - In writing: leaflet(s) from institutions or practices

    - Referral to information on the internet: hospital website
    - Referral to information on the internet: other website, namely ...
    - Other, namely ...

- What do you miss in the decision-making process regarding treatment choice for patients with RCC?
- To what extent do you agree with the following statements: [1: completely disagree - 5: completely agree]

    - I believe that patients in my hospital are offered all possible treatment options for RCC
    - I believe that patients are sufficiently informed about treatment options in my hospital
    - I believe that the information about treatment options for RCC available to patients in the hospital is reliable
    - I believe that patients with (metastatic) RCC should be more involved in the decision-making process about treatment choice than we currently do

- Which of the following descriptions best fits you? (Check one box) (Control Preference Scale)

    - I prefer to let the patient decide on the treatment themselves
    - I prefer to let the patient mainly decide on the treatment, taking my opinion as a healthcare provider into consideration
    - I prefer to make a decision about the treatment together with the patient
    - I prefer as a healthcare provider to mainly determine the treatment, taking the patient's opinion into account
    - I prefer to make the decision about the treatment as a healthcare provider

Comments on these questions:

Opinion on shared decision-making:

- To what extent do you pay attention to the following elements of shared decision-making? [1: completely disagree - 5: completely agree]

    - I make it clear to patients that a decision needs to be made
    - I discuss the option of 'not (further) treating'
    - I ask what health goals/needs the patient has
    - I ask what is important in the patient's daily life
    - I give the patient time to discuss the decision for treatment choice together with a loved one
    - I thoroughly weigh the different treatment options with my patients
    - In my treatment advice, I integrate both the patient's values and the medical justification for a particular treatment
    - I ask which treatment option the patient prefers

- I believe that better-informed patients (and caregivers) complicate the decision-making process
    - Completely disagree
    - Disagree
    - Neutral
    - Agree
    - Completely agree
- To what extent are you willing to make an effort to involve patients more in decision-making about their treatments?
    - Not at all
    - Barely
    - A little
    - Mostly
    - Completely
    - I don't know / N/A
- What do you see as barriers or obstacles to involving patients in decision-making?

Comments on these questions:

Perceptions and desires regarding a PtDA:

- Do you already have experience with using decision aids? Yes/no
- If yes: How did you experience the use of decision aids?
- A decision aid for patients with (suspected) RCC about treatment options seems to me: 1: Not desired at all - 5: Very desired
- What benefits do you expect from kidney cancer decision aids?
- What disadvantages do you expect from kidney cancer decision aids?
- Which treatment options do you think should be included in the local RCC decision aid?
    - Partial nephrectomy
    - Radical nephrectomy
    - Cryoablation
    - Microwave ablation (MWA)
    - Radiofrequency ablation (RFA)
    - Radiotherapy
    - Active surveillance
    - Watchful waiting
    - I don't know
    - Other, namely: ...
- Which treatment options do you believe should be included in the decision aid for metastatic clear cell RCC?
    - Cytoreductive nephrectomy
    - Immunotherapy (monotherapy)
    - Combined immunotherapy

    - Targeted therapy
    - Radiotherapy
    - Embolization
    - Best supportive care
    - I don't know
    - Other, namely: ...

- What is the best time to offer such a decision aid to patients?
- Who is the most suitable healthcare professional to guide the patient in using the decision aid? (multiple options possible)

    - Physician
    - Nurse Specialist
    - Nurse
    - Outpatient clinic employee
    - General 'decision coach'
    - Other, namely: ...

- Which healthcare outcomes should definitely be addressed in the decision aid? (multiple options possible)

    - Survival
    - Response duration
    - Quality of life
    - Treatment side effects
    - Other, namely: ...

- Comments on these questions:
- Do you have any additional comments regarding this survey or regarding decision aids?

Appendix III: The three component decision aid: decision aid handout, online patient decision aid and decision aid summary

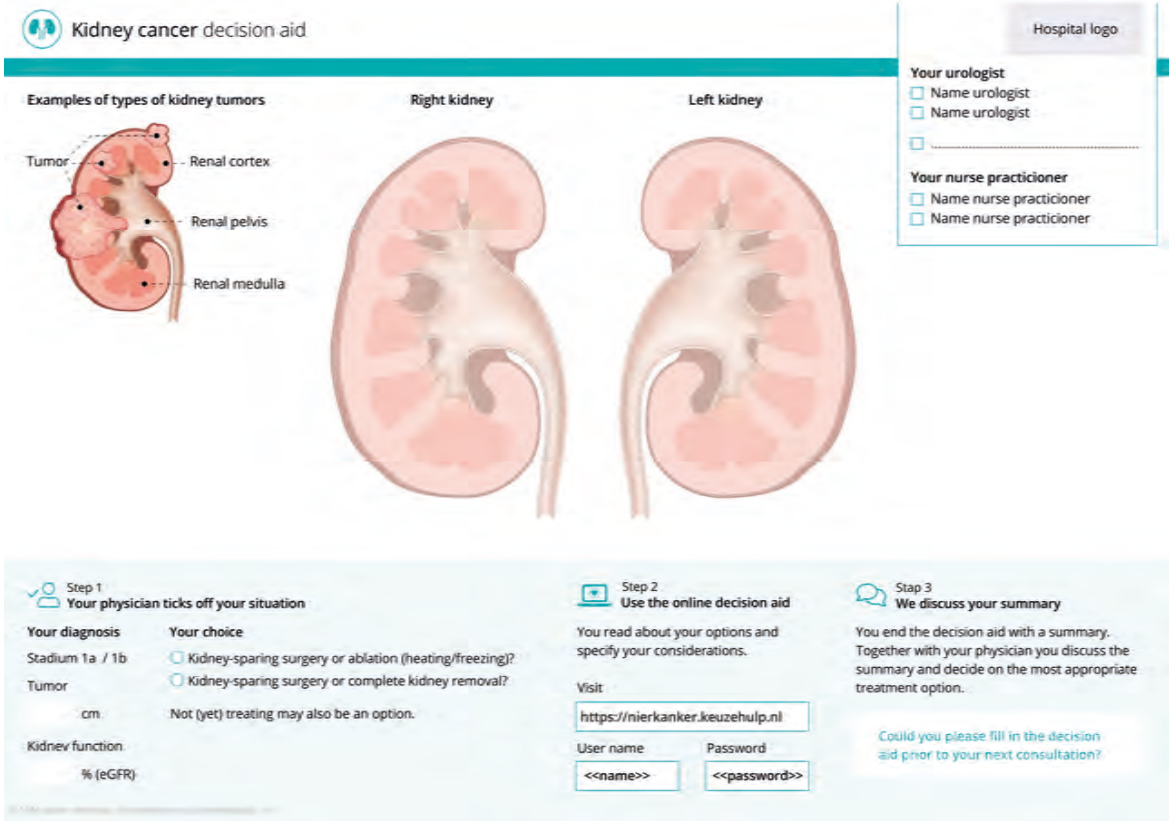

Figure 1. Decision aid handout. Used with permission from ZorgKeuzeLab.
*Note: this is a translation from Dutch to English

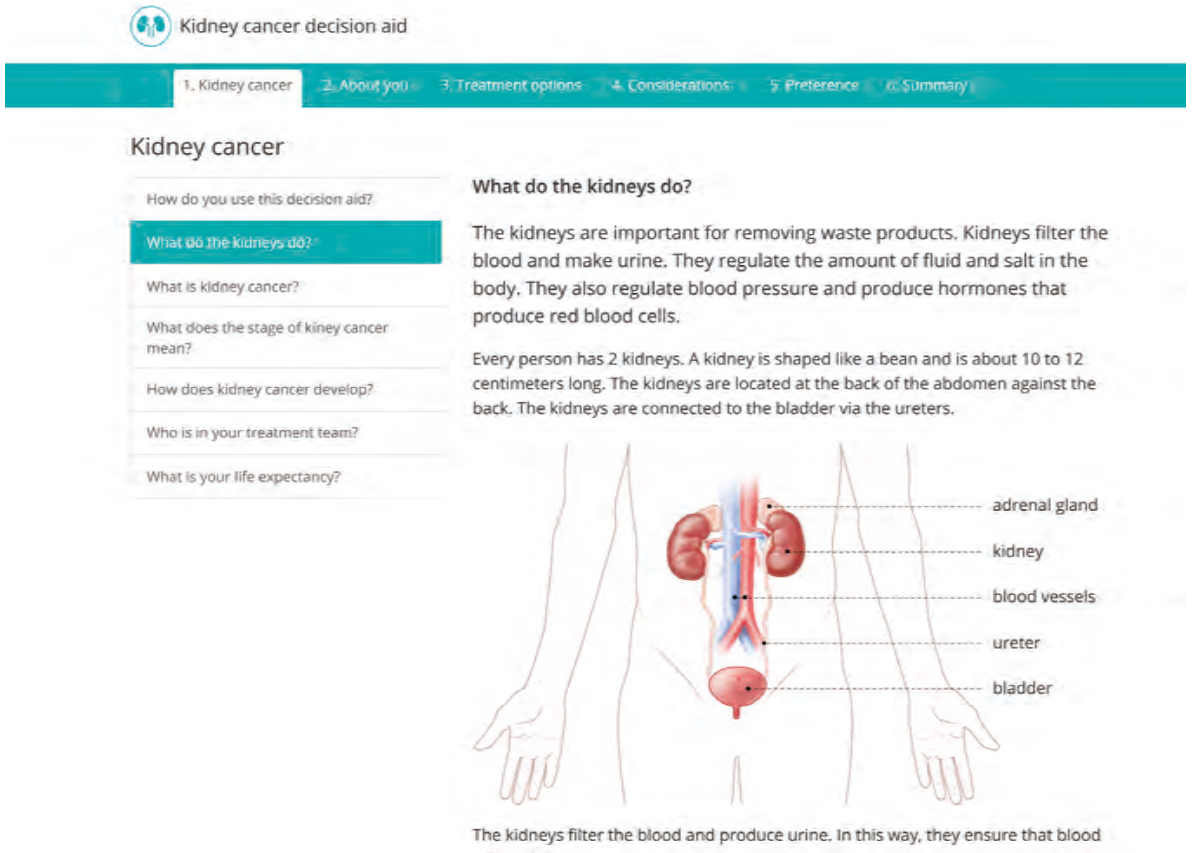

Figure 2. Online patient decision aid – screenshot. Used with permission from ZorgKeuzeLab.
*Note: this is a translation from Dutch to English

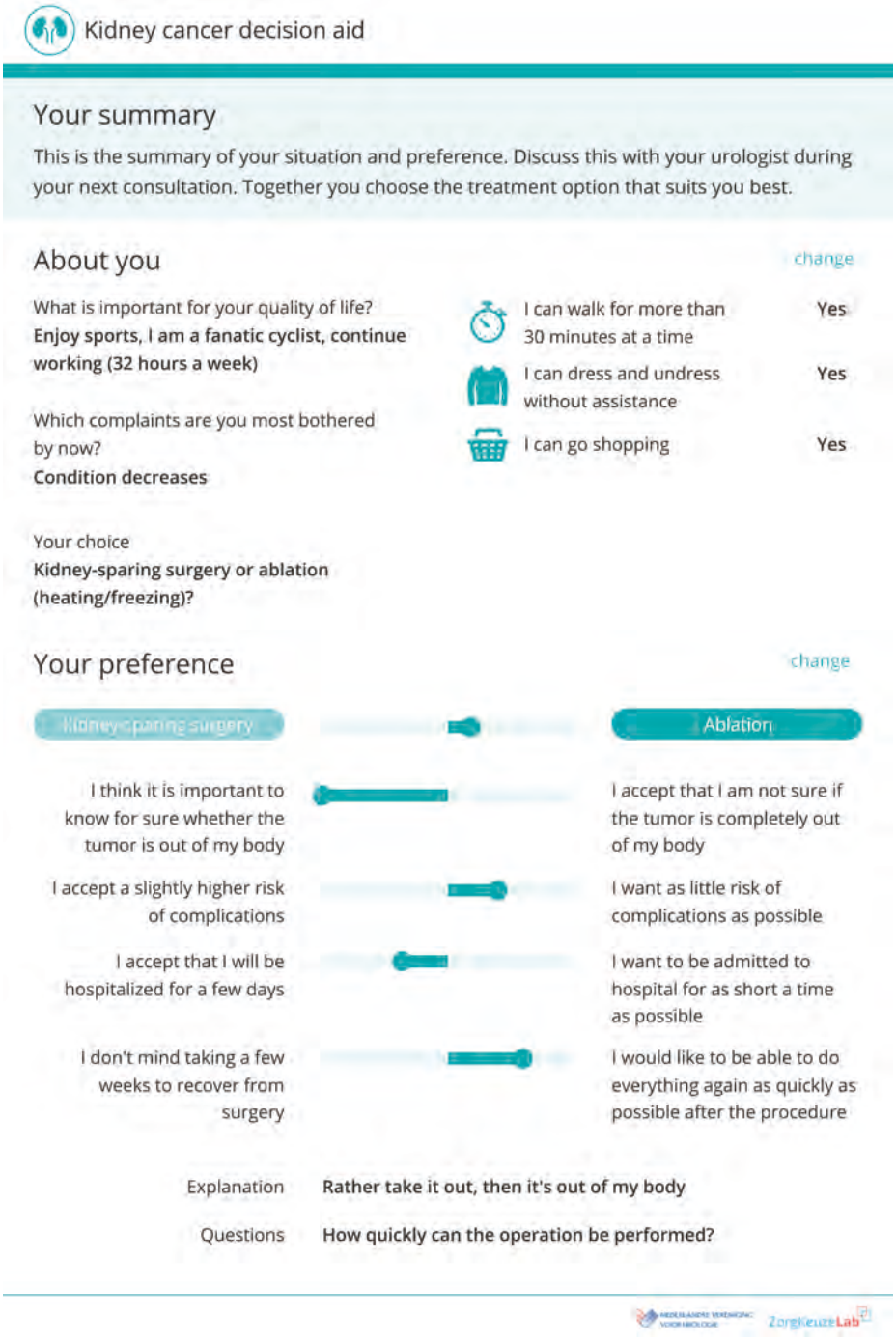

Figure 3. Decision aid summary. Used with permission from ZorgKeuzeLab.
*Note: this is a translation from Dutch to English

Appendix IV: Acceptability and usability testing - Suggestions for improvements to the PtDA

Suggestion for improvement	Category	Suggested by
Nuance role of renal biopsy	Textual modification	HCPs
Underexposed treatment option active surveillance	Treatment options	HCPs
Add information on loss of kidney function	Add information	Patients + HCPs
Explain that as a patient, you will not see every member of the multidisciplinary team	Add information	HCPs
Several linguistic textual modifications	Textual modification	Patients + HPCs
Add more figures into the decision aid	Add figures	Patients + HCPs

Appendix V: Compatibility evaluation with IPDAS-criteria

Table 3. IPDAS minimal qualifying and certification criteria for decision aids regarding treatment options[1]

Criterion			cT1 renal masses PtDA
Qualifying criteria	1	PtDA describes health condition or problem for which index decision is required	✓
	2	PtDA explicitly states the decision that needs to be considered (index decision)	✓
	3	PtDA describes the options available for the index decision	✓
	4	PtDA describes the positive features (benefits/ advantages) of each option	✓
	5	PtDA describes the negative features (harms, side effects, or disadvantages) of each option	✓
	6	PtDA describes what it is like to experience the consequences of the options (physical, psychological, social)	✓
Certification criteria	7	PtDA shows the negative and positive features of options in equal detail (using similar fonts, sequence, and representation of statistical information)	✓
	8	PtDA (or associated documentation) provides citations to the evidence selected	✓
	9	PtDA (or associated documentation) provides a production or a publication date	✓
	10	PtDA (or associated documentation) provides information about the update policy	✓
	11	PtDA provides information about the levels of uncertainty around event or outcome probabilities	✓
	12	PtDA (or associated documentation) provides information about the funding source used for development	✓

Abbreviations: PtDA patient decision aid

[1]Durand M-A, Witt J, Joseph-Williams N, et al. Minimum standards for the certification of patient decision support interventions: Feasibility and application. Med Decis Mak. 2014;98(4):462-468. doi:10.1016/j.pec.2014.12.00

Chapter 5

Improving value of care for renal cell carcinoma patients; development of a decision aid for metastatic clear-cell renal cell carcinoma. A user-centered mixed methods study.

C.C. Bresser
H.H.E. van Melick
R. The
P. B. van der Nat
M.M. Garvelink

Patient Education and Counselling, 2025

Abstract

Objective: Patient decision aids (PtDAs) can support shared decision-making (SDM) by providing information about options, pros and cons and eliciting personal preferences. The aim of this study was to develop and test the acceptability and usability of a PtDA for patients with metastatic clear-cell renal cell carcinoma (RCC), the most common type of metastatic kidney cancer.

Methods: User-centered mixed methods design. Co-creation process with stakeholders guided by the International Patient Decision Aids Standards (IPDAS) criteria, consisting of three main elements: (a) a needs assessment; (b) acceptability and usability testing; and (c) compatibility assessment with IPDAS criteria.

Results: Thirteen RCC patients and 29 healthcare professionals (HCP) participated in this study. Co-creation sessions were held with nine HCPs and a patient representative. Needs assessment (a) showed that patients lacked real treatment choices and wanted information on all treatment options, including life expectancy, side effects, psychological, and lifestyle advice. HCPs expect a PtDA to improve information delivery and patient engagement. A three-component PtDA was developed and tested (b), with positive feedback from both patients and professionals. The tool meets all 12 IPDAS criteria (c).

Conclusions: The web-based PtDA was developed and adapted to address unmet needs and found to be acceptable and usable by patients and HCPs.

Practice implications: The use of this tool could contribute to high quality, patient-centered and appropriate care for metastatic clear cell RCC patients in the Netherlands.

Introduction

Renal cell carcinoma (RCC) is the most common type of kidney cancer, accounting for 3-5% of new cancer diagnoses annually in Europe[1]. Clear cell RCC (ccRCC) is the predominant subtype, representing 75% of cases[2]. Treatment for metastatic ccRCC involves systemic therapy, including tyrosine kinase inhibitors, immunotherapy and combinations thereof[3]. Each treatment option has its own pros and cons, such as side effects or treatment duration, which should be weighed together with the patient. While the range of treatment options is growing, as several forms of systemic therapy show promising results, the local availability and provision of options varies between hospitals in the Netherlands. In addition, there is no transparency about regional treatment options offered. As a result, patients may not be offered all treatment options, leading to unwarranted practice variation. To ensure that the most appropriate treatment option is chosen, all relevant options should be discussed considering the patient's values, risks, benefits, and side effects, using a shared decision-making (SDM) process[4].

SDM involves collaboration between patients and healthcare professionals (HCPs) to make informed decisions aligned with patient's values and preferences[4,5]. Implementation of SDM has shown to reduce healthcare utilization, improve health outcomes, and lower the burden on HCPs[6–8]. Yet, 29% of RCC patients worldwide report no involvement in treatment decisions[9]. This, and the uncertainty around the best treatment option for an individual patient, emphasizes the need for SDM in RCC care[10].

SDM involves four key steps: (1) informing the patient of the decision; (2) explaining the options and consequences; (3) discussing preferences; and (4) making/deferring the final decision together[11]. Patient decision aids (PtDAs) support SDM by helping patients clarify their values to select the most appropriate treatment[7]. PtDAs are known to ensure patient activation and participation in the decision-making process, and lead to increased patient knowledge and patients feeling better informed and clearer about their values, contributing to patient-centered care[7].

Currently, the only PtDA for metastatic RCC is a paper-based decision support tool from the International Kidney Cancer Coalition (IKCC)[12]. Although the existing PtDA covers all treatment options, not all of these are available in every country due to differences in guidelines and reimbursement policies, which vary worldwide. Therefore, the existing PtDA cannot be easily used for different countries, even when translated. In addition, it also lacks a personalized summary for guiding treatment decisions. It is recommended that PtDAs are context specific and developed using a systematic, user-centered process based on the International Patient Decision Aids Standards (IPDAS)[13], including field testing with patients

and independent HCPs. It is of utmost importance to better involve RCC patients in SDM by systematic and transparent development of PtDAs.

The aim of this study was to develop a PtDA for Dutch patients with metastatic ccRCC to help improve care of RCC patients in the Netherlands, that may serve as a blueprint for similar developments internationally. Simultaneously, a PtDA was developed for Dutch patients with localized (cT1N0M0) RCC[14].

Methods

User-centered mixed methods design guided by the IPDAS criteria, consisting of five co-creation sessions and three main elements: (a) a needs assessment, and (b) acceptability and usability testing (Figure 1). The results of (a) and (b) were used as input for the co-creation sessions, as were several concepts of the PtDA. After reaching consensus on the PtDA, the (c) compatibility with the IPDAS minimum criteria was assessed.

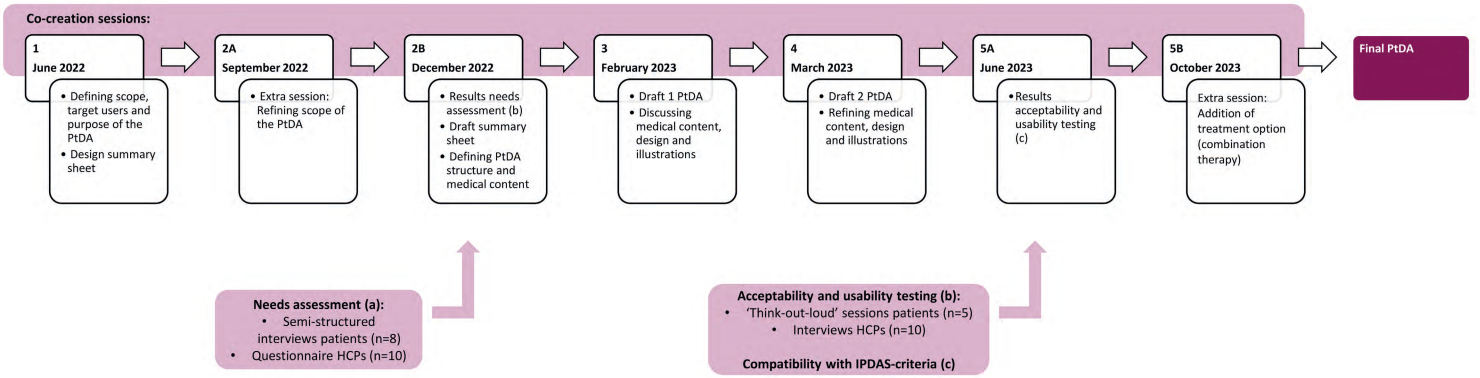

Figure 1. Development process of the metastatic ccRCC PtDA.
Abbreviations: PtDA patient decision aid, HCP health care professional, IPDAS International Patient Decision Aids Standards.

Participants

Working group

A multidisciplinary working group was established, consisting of HCPs involved in metastatic RCC care, and a patient representative from the Dutch Kidney Cancer Patient Association. HCPs were selected based on type of hospital in which they worked (i.e. academic or non-teaching), geographical distribution throughout the Netherlands and HCPs with opposing views on SDM/PtDAs. In addition, a minimum of two HCPs per discipline were aimed to be selected to participate. HCPs were recruited using purposive expert sampling and snowballing. Working group members received an honorarium for attending the co-creation sessions.

Patients

For the needs assessment (a), a purposive sample of patients with metastatic ccRCC was included, recruited via two working group members working in two different hospitals (University Medical Center Utrecht and St. Antonius Hospital Nieuwegein-Utrecht). Patients were included if they were over 18 years of age and able to complete a telephone interview. Patients who did not speak Dutch or were unable to answer the interview questions independently were excluded. For acceptability and usability testing (b), we included patients from the needs assessment who had agreed to follow-up studies.

All patients signed informed consent. The Medical Research Ethics Committee United (MEC-U) in Nieuwegein has confirmed that the Medical Research Involving Human Subjects Act (WMO) did not apply to this study (Ref: AW23.027/W22.125). The study followed local laws and regulations, with local feasibility approved at each hospital. Data were collected from July 2022-July 2023.

HCPs

HCPs from different hospitals across the Netherlands were recruited through purposive expert sampling and snowballing. For the needs assessment (a), HCPs were recruited via an e-mail sent by the Dutch Renal Cancer Group (DRCG) and the Dutch Urological Association (NVU). For acceptability and usability and testing (b), HCPs involved in RCC care who were not part of the working group were included, recruited by means of purposive sampling through working group members.

Co-creation sessions

Co-creation sessions with a multidisciplinary team of HCPs specializing in RCC care and a representative of RCC patients (i.e. the working group) took place. In collaboration with ZorgKeuzeLab, a company specialized in the development and implementation of PtDAs,

the scope, target group, purpose, format, and implementation strategy of the PtDA were determined. Initially, five co-creation sessions were planned to discuss the PtDA's aims, target population, purpose and scope, content and format.

In order for the PtDA to meet the needs and preferences of patients and HCPs, the results of the needs assessment study (a) were presented during the co-creation sessions and incorporated into the development process. Draft PtDAs were developed, discussed with the working group and tested for acceptability and usability testing (b). These results were used to optimize the final PtDA.

Co-creation sessions took place physically and online, moderated by the researcher (CB) together with the director of ZorgKeuzeLab (RT). Each session was audio recorded for verification purposes and field notes were taken.

Needs assessment

The needs assessment differed for patients and HCPs. For patients, semi-structured interviews were held to gather information about patients' needs for information to help them make informed treatment decisions. These interviews, conducted by a researcher (CB) using a pre-defined topic list (Appendix I), focused on the following topics: experiences of diagnosis and treatment, information provision, treatment decision-making, decision-making preferences and tips for the PtDA. Topics were chosen based on relevant SDM frameworks (i.e. Interprofessional-SDM, Ottawa Decision Support Framework). Interviews were audiotaped, transcribed and independently coded by two researchers (CB and MT) using an inductive approach to identify themes. Interviews were conducted until data saturation was reached.

For HCPs, a 40-item digital survey collected information on socio-demographic characteristics, experience with RCC care, SDM (including the Control Preference Scale (CPS)[15]), and perceptions and needs regarding the PtDA (Appendix II).

Acceptability and usability testing

Patients participated in an online think-out-loud session using Microsoft Teams with a researcher (CB) and a ZorgKeuzeLab staff member (AT). During these one-hour sessions, patients navigated through the online PtDA, while verbalizing their thoughts. Sessions were recorded and field notes were taken. Any challenges were noted to assess usability. Patients provided feedback on the content, presentation, usefulness, and whether they would recommend the tool.

HCPs participated in a telephone interview with the researcher (CB) and the director of ZorgKeuzeLab (RT). HCPs from several hospitals were included to collect data on implementation preferences with different workflows. During the interviews, HCPs were asked to express their willingness to use the PtDA themselves, to indicate whether they would recommend it to others (acceptability), and to provide feedback on workflow and content improvements (usability). Interviews were audio-recorded for verification purposes and field notes were taken.

Suggestions for improvements were categorized and discussed with the working group in co-creation session 5A, in which the feedback was discussed and consensus was reached on changes to be made to the PtDA.

Compatibility with IPDAS-criteria

The compatibility of the PtDA with the IPDAS-criteria was assessed by two authors (CB and MG) using the 12 minimum IPDAS criteria[16].

Analysis

Patient and HCP characteristics from co-creation sessions, needs assessment, and acceptability and usability testing were summarized using descriptive statistics. Continuous data were expressed as a mean with standard deviation (SD) or as the median (interquartile range (IQR)) where appropriate. Categorical data were expressed as frequencies (%) unless otherwise stated.

Qualitative feedback from acceptability and usability testing from patients and HCPs was entered into Excel, including information on the type of participant who brought it up (HCP or patient), topic of the feedback, and how it would be incorporated into the PtDA. Data were analyzed by the authors (CB, MG, HvM, RT, AT). The results were discussed in co-creation session 5A. Quantitative data and qualitative data were analyzed using Excel (version 2016).

Results

Co-creation sessions

Twelve HCPs from 8 Dutch hospitals were invited to participate in the working group, with 9 HCPs from 7 hospitals accepting (Table 1). A patient representative from the Dutch kidney cancer patient association also participated. The mean age of the working group was 52 years, with an average of 17 years of experience in RCC care, and most worked in academic hospitals (66.7%). Co-creation sessions lasted 2-3 hours. Two additional short sessions were needed to make substantive decisions about the treatments to be included in the

PtDA (Figure 1, session 2b + 5b). Co-creation sessions took place between June 2022 and October 2023, and were guided by the IPDAS criteria. The DRCG guideline was chosen to determine which options to present in the PtDA[17].

Table 1. Baseline characteristics of HCPs who participated in the working group, (a) needs assessment, and (b) acceptability and usability testing.

HCP characteristic	Working group (n=9)	Needs assessment (n=10)	Acceptability and usability testing (n=10)
Age, years – mean (SD)	52.3 (8.4)	51.7 (10.2)	47.3 (9.0)
Male sex	3 (33.3)	5 (50.0)	4 (40.0)
Function			
Nursing specialist (in training)	1 (11.1)	2 (20.0)	-
Oncology nurse	-	1 (10.0)	1 (10.0)
Oncologist	6 (66.7)	7 (70.0)	9 (90.0)
Urologist	2 (22.2)	-	-
Average professional experience with RCC – mean (SD)	16.6 (7.8)	16 (7.6)	8.8 (6.7)
Organization type			
Academic hospital	6 (66.7)	3 (30.0)	3 (30.0)
Non-academic teaching hospital	3 (33.3)	7 (70.0)	6 (60.0)
Non-teaching hospital	-	-	1 (10.0)

All data presented as n (%) unless otherwise specified
Abbreviations: HCP health care professional, SD standard deviation, RCC renal cell carcinoma

(a) Needs assessment

Patients

Eight patients participated in an interview (response rate 100%). Mean age was 64 years, and 62.5% were male. The majority had been diagnosed over a year ago, and 37.5% were highly educated (Table 2). The interviews lasted approximately one hour.

Table 2. Baseline characteristics of patients who participated in the needs assessment (a) and acceptability and usability testing (b).

Patient characteristic	Needs assessment (semi-structured interview, n= 8)	Acceptability and usability testing (think-out-loud session, n= 5)
Age, years – mean (SD)	63.6 (9.4)	67.2 (8.8)
Male sex	5 (62.5)	4 (80.0)
Education level[a]		
High	3 (37.5)	3 (60.0)
Middle	5 (62.5)	2 (40.0)
Low	-	-
Treatment received[b]		
Tyrosine kinase inhibitor (TKI)	4 (23.5)	3 (30.0)
Immunotherapy monotherapy	2 (11.8)	1 (10.0)
Immunotherapy doublet therapy	1 (5.9)	-
Immunotherapy + TKI	1 (5.9)	1 (10.0)
Watchfull waiting	1 (5.9)	1 (10.0)
Other (metastasectomy, radiotherapy, cytoreductive nephrectomy)	8 (47.1)	4 (40.0)
Number of months since diagnosis		
6-12	1 (12.5)	-
> 12	7 (87.5)	5 (100.0)

All data presented as n (%) unless otherwise specified
Abbreviations: SD standard deviation, RCC renal cell carcinoma, TKI tyrosine kinase inhibitor
[a]Education level was assessed during semi-structured interviews based on highest level of completed education
[b]Treatment modalities were not mutually exclusive

Patients' experiences with treatment decision-making

Interviews revealed that patients often felt overwhelmed by the diagnosis (n=7, Table 3, quote 1). Many patients felt that they had no explicit choice in their treatment plans (n=4, quote 2). When options were offered, patients were reassured and expressed a strong desire to be informed about all available treatment options. They had questions about their life expectancy and treatment options, with the option of no treatment not always clearly explained.

Patients' information needs for the PtDA

While patients reported receiving reliable information about their treatment, they reported different needs for additional information about the development of metastases, treatment side effects, and the recovery process, especially how these factors affect daily life (quote

3-4). Patients reported a lack of information about psychological support and lifestyle advice, and indicated that they would like to receive more information on these topics (quote 5). In addition, patients emphasized transparency in communication with their HCP (quote 6). None regretted their treatment choices.

Table 3. Patient's needs assessment – quotes

Quote number	Quote	Patient
1	*'It was a shock, being told you have kidney cancer while you were going for your heart. It was a diagnosis that I couldn't have thought of coming up. It was an unpleasant surprise and came totally out of the blue'*	1
2	*"The oncologist said: 'You can't have chemotherapy. You will have immunotherapy. They had already signed me up for that. It was basically bite-size."*	2
3	*"After surgery, no metastases were found. I knew the stage of the cancer, but I didn't know it could come back. I had not been told that before. Now it turns out that it can metastasize."*	2
4	*"I could not stand the medication very well. I thought: if this is it, I don't know if I'm going to make it. It was quite intense."*	4
5	*"You live with it every day, that's how it is. You have a kind of fear with everything you feel. I had lost that for a while, but now with every little thing I think there's something there again."*	3
6	*"I understood from the oncologist that it is best not to treat it for now because then you have the most pleasant life. And then I thought: look, there's nothing more to be done, it's done. Afterwards, when I spoke to my GP, I understood that something could actually be done about it if I developed symptoms."*	5

Abbreviations: GP general practitioner

HCPs

Ten HCPs participated, with a mean age of 52 years. 50% were male, 70% were oncologists, and their mean experience in RCC care was 16 years. Most worked in a teaching hospital (70%, n=7) (Table 1). Telephone interviews lasted approximately 30 minutes.

HCPs' experiences with treatment decision-making & the need for a PtDA

Thirty percent of HCPs (n=3) agreed that patients with metastatic RCC should be more involved in decision-making. 40% (n=4) were neutral, and 20% (n=2) disagreed. Most HCPs (n=5) stated decision-making should be shared between the HCP and the patient, 20% (n=2) stated that HCPs should make the final decision after considering the patient's opinion.

A PtDA for metastatic RCC was considered (highly) desirable by 40% (n=4) and neutral by 40% (n=4). HCPs reported expected benefits such as providing patients with accurate information (n=3), increasing awareness and deliberation (n=4), and better informed patients who can actively participate in their treatment decisions as result (n=2).

HCPs expected patients to be better prepared to make decisions, by using the value clarification exercises in the PtDA, probably leading to greater clarity about their options and more informed decisions. Expected disadvantages of using the PtDA were increased time, potential confusion, decision anxiety and the potential for patients to overlook important details amidst the variety of options presented.

HCPs expressed a desire for the PtDA to include outcome information on survival and duration of response, as well as information on the benefits and harms of treatment options and treatment sequences. Supplementary Table 1 (Appendix III) shows the full results of the needs assessment with HCPs.

An overview of the results of the needs assessment with patients and HCPs (Table 4) were presented to the working group in co-creation session 2b. During this session, incorporation of needs and preferences in the PtDA were discussed. Table 5 shows how the specific needs and preferences have been incorporated into the PtDA. Eventually, specific outcome information on survival and duration of response was not included because there was no scientific information available.

Table 4. Needs and preferences of patients and HCPs on treatment decision-making and the PtDA.

	Needs and preferences	
Topic	**Patients**	**HCPs**
Treatment decision-making	Did not have a real choice in their treatment	Patients should be more involved in the decision-making process
	Want to know all treatment options	Ideally, the doctor and patient should work together to decide which treatment to choose
	Have trust in the HCP's expertise and advice	Are divided over possible treatment options
		Do not always offer the option of no active treatment
PtDA	Information on prognosis and chance of recurrence of disease	Outcome information on survival and duration of response
	Information on psychological counselling and lifestyle advice	Information on benefits and harms of treatment options and treatment sequences

Abbreviations: *HCP* health care professional. *SDM* shared decision-making. *PtDA* patient decision aid

Table 5. Incorporation of needs and preferences in the final PtDA.

Topic	Identified needs and preferences	Incorporation in the final PtDA	PtDA component
Treatment decision-making	Patients felt they did not have an explicit choice in their treatment	Yes	PtDA handout (patient activation, (SDM step 1[11])), online PtDA (patient activation (SDM step 1), preference elicitation exercises (SDM step 3))
	Patients want to know all treatment options	Yes	PtDA handout (overview of treatment options (SDM step 2)), online PtDA (information on treatment options (SDM step 2))
	Patients have trust in the HCP's expertise and advice	N/A	Process around PtDA: PtDA does not replace consultation, but helps patients to become more informed in the treatment decision-making process
	HCPs report that patients should be more involved in the decision-making process	Yes	PtDA handout (patient activation (SDM step 1)), online PtDA (patient activation (SDM step 1), preference elicitation exercises (SDM step 3)), PtDA summary
	HCPs report that ideally, the doctor and patient should work together to decide which treatment to choose	Yes	PtDA handout (patient activation (SDM step 1)), online PtDA (patient activation (SDM step 1), preference elicitation exercises (SDM step 3)), PtDA summary
	HCPs are divided over possible treatment options to include in the PtDA	Yes	The DRCG guideline was leading in the treatment options included in the PtDA.
	HCPs do not always offer the option of no active treatment	Yes	PtDA handout (overview of treatment options (SDM step 2)), online PtDA (information on best supportive care (SDM step 2))
PtDA	Information on prognosis and chance of recurrence of disease	Yes	Online PtDA (SDM step 2)
	Information on psychological counselling and lifestyle advice	Yes	Online PtDA (SDM step 2)
	Outcome information on survival and duration of response	Partly included*	-
	Information on benefits and harms of treatment options and treatment sequences	Yes	PtDA handout (SDM step 2), online PtDA (SDM step 2)

Abbreviations: HCP health care professional, SDM shared decision-making, PtDA patient decision aid

*General information on survival is incorporated in the PtDA as no specific numbers for International mRCC Database Consortium (IMDC) criteria were available.

The PtDA

A three-component PtDA was drafted and used for acceptability and usability testing, consisting of: (1) a decision aid handout providing an overview of treatment options; (2) an online PtDA with information on RCC, treatment options and value clarification exercises; (3) a personal decision aid summary to support decision-making during the consultation (Figure 1-3, Appendix V).

(b) Acceptability and usability testing

Patients

Seven patients from the needs assessment were invited to a think-out-loud session (one had died). Five patients participated (71% response rate), one withdrew and one patient was ill. Mean age was 67.2 years, 80% were male, and 60% were highly educated (Table 2). Think-out-loud sessions lasted approximately 45 minutes. Patients recognized the information in the PtDA as the information they had searched for or missed since their diagnosis. They reported that the PtDA provided a complete and compact overview, and found the hand-out sheet a good overview of treatment options. They found the PtDA summary useful for preparing for follow-up consultations. Most patients felt that there was too much text and not enough pictures in the PtDA.

HCPs

Ten of 23 invited HCPs participated in acceptability and usability testing (43% response rate). The mean age was 47.3 years, 60% were female, and 90% were oncologists with an average of 8.8 years of experience in RCC care (Table 1). HCPs reported that the PtDA provided clear, concise information about the disease and treatment options and could be a reference for patients and caregivers. They reported that the value clarification exercises could help to elicit patient preferences and that the PtDA summary could be used as a tool during follow-up counselling for decision-making in a subsequent treatment line.

Results of the patient and HCP acceptability and usability testing were summarized into categories (Appendix IV) and discussed with the working group, leading to final changes in the PtDA.

(c) Compatibility with IPDAS-criteria

The PtDA met all 12 qualifying and certification criteria for decision aids (Appendix VI).

1. Health care professional hands out decision aid

The health care professional explains the patient's diagnosis and treatment options using the decision aid handout. This sheet contains a unique login for the online patient decision aid.

2. Patient uses decision aid

The patient reads information in the online patient decision aid and lists their goals, considerations and treatment preferences.

3. Shared decision-making

The patient and health care professional discuss the patient's goals, considerations and preferences supported by the decision aid summary. Together they decide about the most suitable treatment.

Figure 2. The three-component metastatic kidney cancer PtDA and instructions for its use.
*Note: this is a translation from Dutch to English

Discussion and Conclusion

Discussion

This paper outlines the systematic development of a PtDA for metastatic ccRCC using the IPDAS framework[18]. The PtDA is designed to support SDM regarding treatment. To our knowledge, this is the first online PtDA for this specific patient population, as existing tools are paper-based and don't provide a personalized summary[12]. Based on stakeholder input through needs assessment (a), co-creation sessions and acceptability and usability testing (b), the PtDA was fine-tuned to meet existing needs. The PtDA was found to be acceptable and usable by both patients and HCPs and met all IPDAS minimum qualifying criteria. The development process led us to make four observations.

First, the needs assessment (a) with patients highlighted the existing need for patient involvement in decision-making in metastatic ccRCC in the Netherlands. Despite the recognized importance of SDM, the level of patient reported involvement in RCC treatment has remained low since 2018[19]. The development of this PtDA aims to address this gap by supporting patients to make informed decisions when multiple treatment options are available[7]. Interestingly, 40% of surveyed HCPs expressed neutrality regarding the need for a PtDA for metastatic ccRCC. Yet, acceptability and usability testing (b) of the PtDA among other HCPs showed a big interest in using the PtDA in practice. This discrepancy may possibly be explained by the fact that HCPs were initially unsure of what to expect from a PtDA, but once they were able to see and interact with the tool during the acceptability and usability testing (b), they recognized its potential value in clinical practice. The willingness of HCPs to use the PtDA is of utmost importance, as it could support implementation and ensure its use in the future.

Secondly, previous research suggest that HCPs do not always make clear that a decision needs to be made (SDM step 1)[20], whereas creating choice awareness is essential for SDM[21]. The PtDA addresses this by providing a handout during initial consultations, encouraging patient engagement even when choice awareness is not explicitly facilitated by the HCP. In addition, the handout and online PtDA provide an overview of available treatment options (SDM step 2). The inclusion of preference elicitation exercises further supports patients in reflecting on their treatment values and preferences (SDM step 3). The PtDA's summary consolidates patient's goals, considerations, and preferences, supporting a collaborative decision-making process with the HCP in the final stage. During the next consultation, the patient and HCP make a decision or decide whether deferring is necessary (SDM step 4). Thus, the PtDA effectively supports all stages of the SDM process[11].

Thirdly, a very thorough development process has been followed in accordance with the IPDAS guidelines[18], which are important for quality assessment of PtDAs. As the use of PtDAs is known to reduce healthcare utilization and improves outcomes[6,7], it is crucial that they follow a robust development process to minimize potential bias. The establishment of minimum standards is essential if these tools are used to address unwarranted practice variation[16]. Part of the IPDAS minimum standards is evaluation of the PtDA by independent HCPs not involved in the development process, which is often overlooked in the development of existing PtDAs[22], leading to poorer implementation. By incorporating feedback from HCPs not involved in the initial development during acceptability and usability testing (b), we ensured a comprehensive assessment of the PtDA. While it is excellent that the PtDA is now available for use, we anticipate that additional measures may be required to fully achieve SDM in practice[23]. This includes its integration into clinical practice, ideally introduced early in the treatment discussion phase. To address this, HCPs in the working group were involved in thinking about the implementation of the PtDA. Combining the PtDA with HCP training in SDM and the use of the PtDA could improve the overall SDM process.

Finally, during the development process of the PtDA, we collaborated with the 'Easy-reading Foundation' (Stichting Makkelijk Lezen) to ensure that the information provided in the PtDA was accessible to all patients, including the 2.5 million people in the Netherlands with low literacy levels[24]. As few existing PtDAs recognize the challenges posed by low (health) literacy[7], we decided to focus on this topic. However, our acceptability testing included few patients with a low education level, which may have introduced a selection bias in the results as PtDAs are known to be difficult to understand[25]. During the development process of our PtDA, we took account of low literacy when writing the online PtDA text. We will also consider low literacy during the evaluation study.

Limitations

This study has some limitations. First, the selection of HCPs was based on their attitudes toward PtDAs or SDM. Although we tried to select HCPs with different attitudes, it is possible that the HCPs involved were more positive about SDM than other HCPs, which may have introduced selection bias. Second, patients were recruited using purposive sampling, which may have introduced selection bias. In addition, patients who participated in the needs assessment study also participated in the acceptability and usability tests. It is possible that patients who agreed to participate in the think-out-loud sessions were patients with a good prognosis and/or an open attitude towards SDM, and this may not be a good reflection of reality. Moreover, although patients verbalized their thoughts during the think-out-loud sessions, objective measures of their understanding or knowledge of the PtDA were not collected. Furthermore, the sample sizes of the needs assessment and acceptability and usability testing are small, potentially introducing bias to the validity of the results. Future

research should assess whether the PtDA improves patients' knowledge. In terms of the sustainability of this PtDA, the rapid evolution of treatment options for metastatic ccRCC will require regular updates. Proactive measures to update the PtDA will be considered to ensure its continued relevance and accuracy.

Conclusion

By co-designing a PtDA with stakeholders, we developed a tool that is acceptable and usable in supporting SDM for patients with ccRCC.

Practice implications

Given the potential benefits of consistent information provision and patient engagement, this PtDA is relevant to all those involved in the RCC care process and is a possible solution to existing unmet needs in the treatment decision-making process. Parallel to this development process, a PtDA for local RCC was developed, supporting SDM across the RCC care pathway[14]. The effect of both PtDAs on SDM is currently being evaluated in a clinical study (ClincalTrials.gov ID: NCT05548621)[26].

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Appendix I. Topic list needs assessment metastatic RCC patients

Introduction (Questions about sociodemographic characteristics, semi-structured):

- Age
- Sex
- Marital status
- Education, background
- Current occupation

Diagnosis:

- When were you diagnosed with kidney cancer?
- How did you discover that you had kidney cancer? Incidental finding?
- Who communicated the diagnosis to you?
- Who was with you when you received the diagnosis?
- What do you recall from the diagnosis consultation?
- What did you experience emotionally?
- What information were you provided with at that time?
- What were the key questions you had during and after this consultation?
- Did you have concerns after the diagnosis? If yes, what were they?
- Were there aspects missing during the diagnosis consultation?
- Were treatment options discussed during the diagnosis consultation?

Treatment options:

- What information were you given about the treatment options?
- What treatment options were available to you?
- Which treatment did you choose?
- Was it difficult for you to decide on the treatment? Why or why not?
- What was important to you in life? Which treatment option aligned with this? Did you choose this treatment?
- What information did you find unnecessary during the discussion of treatment options?
- What information was lacking during the discussion of treatment options?
- Did you seek additional information? Where? What were you looking for and why? (peer support: support groups, patient experiences, chats, blogs, discussion groups, patient associations, articles, etc.) Second opinion?
- Did you involve other individuals in your decision? Who? How did these discussions influence the treatment you ultimately chose?
- How did your doctor involve you in the treatment choice? How did you perceive this?

- Did you feel you had a choice regarding the treatment?
- Who, in your case, ultimately made the decision about your treatment?
- In your opinion, who should make the final treatment decision: the doctor, you together with the doctor, or you alone?

During treatment:

- Were you aware of the pros and cons of the treatment options? Were you aware of the risks associated with the treatment options (complications/side effects)?
- How did you experience the treatment?
- What deviated from your expectations?

After treatment:

- How was the recovery from the treatment? How long did it take? Did you receive additional assistance/care? What precautions did you need to take?
- How do you currently view your decision? Would you choose the same treatment now? Why or why not?

Tips:

- What advice would you give to patients going through a similar journey?
- Do you have any specific tips for the decision aid?

May we contact you in the future for follow-up research, during which we will present the decision aid developed for your feedback?

Appendix II: Questionnaire needs assessment HCPs

Introduction (Questions about sociodemographic characteristics, semi-structured):

1. Age
2. Sex
3. Profession
4. Number of years of experience with RCC
5. Hospital type
6. Self-assessment knowledge on RCC (1-5: insufficient, moderate, sufficient, good, excellent)
7. Yearly number of patients with RCC diagnosed in hospital
8. RCC treatments performed in hospital
9. Treatments requiring referral to other hospital

Experiences with RCC care:

10. When are patients with (suspected) RCC informed about treatment options in your hospital? (multiple answers possible)
    - During the diagnostic consultation
    - During the policy discussion (after multidisciplinary team meeting (MTM))
    - Other, namely ...
11. How are treatment options offered to patients decided upon in your hospital?
    - All treatment options that are medically feasible for the patient
    - A selection of treatment options that you as a physician consider appropriate
    - During a multidisciplinary team meeting (MTM)
    - All treatment options available in your hospital
    - Other, namely ...
12. Who informs patients with (suspected) RCC about the different treatment options in your hospital? (multiple answers possible)
    - Urologist
    - Urology resident (in training)
    - Oncologist
    - Oncology resident (in training)
    - Nurse specialist
    - Oncology nurse
    - Other, namely ...

13. How are patients informed about treatment options in your hospital? (multiple answers possible)

    - Verbal information
    - In writing: hospital information leaflet
    - In writing: leaflet(s) from institutions or practices
    - Referral to information on the internet: hospital website
    - Referral to information on the internet: other website, namely ...
    - Other, namely ...

14. What do you miss in the decision-making process regarding treatment choice for patients with RCC?

    - To what extent do you agree with the following statements: [1: completely disagree - 5: completely agree]

15. I believe that patients in my hospital are offered all possible treatment options for RCC
16. I believe that patients are sufficiently informed about treatment options in my hospital
17. I believe that the information about treatment options for RCC available to patients in the hospital is reliable
18. I believe that patients with (metastatic) RCC should be more involved in the decision-making process about treatment choice than we currently do
19. Which of the following descriptions best fits you? (Check one box) (Control Preference Scale)

    - I prefer to let the patient decide on the treatment themselves
    - I prefer to let the patient mainly decide on the treatment, taking my opinion as a physician into consideration
    - I prefer to make a decision about the treatment together with the patient
    - I prefer as a healthcare provider to mainly determine the treatment, taking the patient's opinion into account
    - I prefer to make the decision about the treatment as a healthcare provider

Comments on these questions:

Opinion on SDM:

- To what extent do you pay attention to the following elements of shared decision-making? [1: completely disagree - 5: completely agree]

20. I make it clear to patients that a decision needs to be made
21. I discuss the option of 'not (further) treating'
22. I ask what health goals/needs the patient has
23. I ask what is important in the patient's daily life
24. I give the patient time to discuss the decision for treatment choice together with a loved one
25. I thoroughly weigh the different treatment options with my patients
26. In my treatment advice, I integrate both the patient's values and the medical justification for a particular treatment
27. I ask which treatment option the patient prefers
28. I believe that better-informed patients (and caregivers) complicate the decision-making process

    - Completely disagree
    - Disagree
    - Neutral
    - Agree
    - Completely agree

29. To what extent are you willing to make an effort to involve patients more in decision-making about their treatments?

    - Not at all
    - Barely
    - A little
    - Mostly
    - Completely
    - I don't know / N/A

30. What do you see as barriers or obstacles to involving patients in decision-making?

Comments on these questions:

Perceptions and desires regarding a PtDA:

31. Do you already have experience with using decision aids? Yes/no

    If yes: How did you experience the use of decision aids?

32. A decision aid for patients with (suspected) RCC about treatment options seems to me: 1: Not desired at all - 5: Very desired
33. What benefits do you expect from kidney cancer decision aids?
34. What disadvantages do you expect from kidney cancer decision aids?
35. Which treatment options do you believe should be included in the decision aid for metastatic clear cell RCC?
    - Cytoreductive nephrectomy
    - Immunotherapy (monotherapy)
    - Combined immunotherapy
    - Targeted therapy
    - Radiotherapy
    - Embolization
    - Best supportive care
    - I don't know
    - Other, namely: ...
36. What is the best time to offer such a decision aid to patients?
37. Who is the most suitable healthcare professional to guide the patient in using the decision aid? (multiple options possible)
    - Physician
    - Nurse Specialist
    - Nurse
    - Outpatient clinic employee
    - General 'decision coach'
    - Other, namely: ...
38. Which healthcare outcomes should definitely be addressed in the decision aid? (multiple options possible)
    - Survival
    - Response duration
    - Quality of life
    - Treatment side effects
    - Other, namely: ...
39. Comments on these questions:
40. Do you have any additional comments regarding this survey or regarding decision aids?

Appendix III: Supplementary Table S1

Supplementary Table S1. Results from the needs assessment (a) questionnaire among HCPs

Item	HCPs (n=10)
Experiences with RCC care	
When are patients with (suspected) RCC informed about treatment options in your hospital?	
During the diagnostic consultation	5 (50.0)
During the policy discussion (after MTM)	8 (80.0)
How are treatment options offered to patients decided upon in your hospital?	
All treatment options that are medically feasible for the patient	3 (30.0)
A selection of treatment options that you as a physician consider appropriate	3 (30.0)
During a MTM	8 (80.0)
All treatment options available in your hospital	-
Other, namely ...**	1 (10.0)
Who informs patients with (suspected) RCC about the different treatment options in your hospital?*	
Urologist	8 (26.7)
Urology resident (in training)	4 (13.3)
Oncologist	8 (26.7)
Oncology resident (in training)	2 (6.7)
Nurse specialist	5 (16.7)
Oncology nurse	3 (10.0)
How are patients informed about treatment options in your hospital?*	
Verbal information	9 (42.9)
In writing: hospital information leaflet	3 (14.3)
In writing: leaflet(s) from institutions or practices	3 (14.3)
Referral to information on the internet: hospital website	2 (9.5)
Referral to information on the internet: other website, namely ...	3 (14.3)
Other, namely ...***	1 (4.8)
What do you miss in the decision-making process regarding treatment choice for patients with RCC?	
Clarity for patients	1 (33.3)
What matters to the patient	1 (33.3)
In the future, the choice of adjuvant/no adjuvant immunotherapy after resection of primary RCC will be a difficult decision point	1 (33.3)

Item	HCPs (n=10)
I believe that patients in my hospital are offered all possible treatment options for RCC.	
Strongly disagree	-
Disagree	-
Neutral	-
Agree	7 (70.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)
I believe that patients are sufficiently informed about treatment options in my hospital.	
Strongly disagree	-
Disagree	-
Neutral	-
Agree	8 (80.0)
Strongly agree	1 (10.0)
Missing	1 (10.0)
I believe that the information about treatment options for RCC available to patients in the hospital is reliable.	
Strongly disagree	-
Disagree	-
Neutral	2 (20.0)
Agree	5 (50.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)
I believe that patients with metastatic RCC should be more involved in the decision-making process about treatment choice than we currently do.	
Strongly disagree	-
Disagree	2 (20.0)
Neutral	4 (40.0)
Agree	3 (30.0)
Strongly agree	-
Missing	1 (10.0)

Supplementary Table S1 *Continued*

Item	HCPs (n=10)
Which of the following descriptions best fits you? (Control Preference Scale)	
I prefer to let the patient decide on the treatment themselves.	-
I prefer to let the patient mainly decide on the treatment, taking my opinion as a physician into consideration.	2 (20.0)
I prefer to make a decision about the treatment together with the patient.	5 (50.0)
I prefer as a healthcare provider to mainly determine the treatment, taking the patient's opinion into account.	2 (20.0)
I prefer to make the decision about the treatment as a healthcare provider.	-
Missing	1 (10.0)
Opinion on SDM	
I make it clear to patients that a decision needs to be made.	
Strongly disagree	-
Disagree	-
Neutral	-
Agree	7 (70.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)
I discuss the option of 'not (further) treating'.	
Strongly disagree	-
Disagree	-
Neutral	1 (10.0)
Agree	8 (80.0)
Strongly agree	-
Missing	1 (10.0)
I ask what health goals/needs the patient has.	
Strongly disagree	-
Disagree	-
Neutral	2 (20.0)
Agree	4 (40.0)
Strongly agree	3 (30.0)
Missing	1 (10.0)

Item	HCPs (n=10)
I ask what is important in the patient's daily life.	
Strongly disagree	-
Disagree	1 (10.0)
Neutral	1 (10.0)
Agree	5 (50.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)
I give the patient time to discuss the decision for treatment choice together with a loved one.	
Strongly disagree	-
Disagree	-
Neutral	-
Agree	7 (70.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)
I thoroughly weigh the different treatment options with my patients.	
Strongly disagree	-
Disagree	-
Neutral	-
Agree	7 (70.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)
In my treatment advice, I integrate both the patient's values and the medical justification for a particular treatment.	
Strongly disagree	-
Disagree	-
Neutral	1 (10.0)
Agree	6 (60.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)
I ask which treatment option the patient prefers.	
Strongly disagree	-
Disagree	-
Neutral	-
Agree	7 (70.0)
Strongly agree	2 (20.0)
Missing	1 (10.0)

Supplementary Table S1 *Continued*

Item	HCPs (n=10)
I believe that better-informed patients (and caregivers) complicate the decision-making process.	
Completely disagree	4 (40.0)
Disagree	1 (10.0)
Neutral	2 (20.0)
Agree	2 (20.0)
Completely agree	-
Missing	1 (10.0)
To what extent are you willing to make an effort to involve patients more in decision-making about their treatments?	
Not at all	-
Barely	-
A little	-
Mostly	3 (30.0)
Completely	5 (50.0)
I don't know/N/A	1 (10.0)
Missing	1 (10.0)
What do you see as barriers or obstacles to involving patients in decision-making?	
Increased consultation time	2 (25.0)
When patients want to continue treatment at all costs	1 (12.5)
Patient's ability to think along	2 (25.0)
A difference between what is possible and what is applicable to the patient	1 (12.5)
Complexity of the treatment landscape	1 (12.5)
Disinformation on the internet	1 (12.5)
Perceptions and desires regarding a PtDA	
Do you already have experience with using decision aids?	
Yes	4 (40.0)
No	4 (40.0)
Missing	2 (20.0)
If yes: How did you experience the use of decision aids?	
Excellent	1 (25.0)
Helpful	1 (25.0)
Contributing, but not playing a major role	1 (25.0)
Helpful, but can also create confusion	1 (25.0)

Item	HCPs (n=10)
A decision aid for patients with (suspected) RCC about treatment options seems to me:	
Not desired at all	-
Not desired	-
Neutral	4 (40.0)
Desired	3 (30.0)
Very desired	1 (10.0)
Missing	1 (10.0)
What benefits do you expect from kidney cancer decision aids?	
Accurate information	3 (33.3)
Increasing awareness and deliberation	4 (44.4)
Better informed patients who can actively participate in their treatment decisions as result	2 (22.2)
What disadvantages do you expect from kidney cancer decision aids?	
Increased time	3 (30.0)
Potential confusion (patient)	5 (50.0)
Decision anxiety (patient)	2 (20.0)
Which treatment options do you believe should be included in the PtDA for metastatic clear cell RCC?*	
Cytoreductive nephrectomy	6 (13.6)
Immunotherapy (monotherapy)	7 (15.9)
Combined immunotherapy	8 (18.2)
Targeted therapy	7 (15.9)
Radiotherapy	3 (6.8)
Embolization	3 (6.8)
Best supportive care	7 (15.9)
Other, namely: ...****	3 (6.8)
What is the best time to offer such a decision aid to patients?	
After the first consultation	2 (28.6)
After MDT	4 (57.1)
If there is a treatment indication	1 (14.3)
Who is the most suitable HCP to guide the patient in using the decision aid?*	
Physician	7 (46.7)
Nurse Specialist	6 (40.0)
Nurse	2 (13.3)
Outpatient clinic employee	-

Supplementary Table S1 *Continued*

Item	HCPs (n=10)
Which healthcare outcomes should definitely be addressed in the decision aid? *	
Survival	8 (25.0)
Response duration	7 (21.9)
Quality of life	8 (25.0)
Treatment side effects	8 (25.0)
Other, namely: ...*****	1 (3.1)

All data presented as n (%) unless otherwise specified
Abbreviations: *HCP*: health care professional; *RCC*: renal cell carcinoma; *MTM*: multidisciplinary team meeting; *SDM*: shared decision-making; *N/A*: not applicable; *PtDA*: patient decision aid.
*Answers were not mutually exclusive
**Open answer: 'In consultation with the patient and family'
***Open answer: 'Brochures from medical companies'
****Open answers: 'Watchful waiting', 'watch and wait' & 'Whatever the options really are, immune monotherapy is not in the first line, so it is not offered there either, so it has to be more personalized.'
*****Open answer: 'Logistics of treatment, what it means for a patient'

Appendix IV: Acceptability and usability testing - Suggestions for improvements to the PtDA

Suggestion for improvement	Category	Suggested by
Treatment option: immunotherapy combined with tyrosine kinase inhibitor should be added	Treatment options	HCPs
Include radiotherapy as palliative treatment option to control symptoms	Treatment options	HCPs
Information on the effect of each treatment on the disease should be added	Add information	HCPs
Add information on the development of kidney cancer	Add information	HCPs
Add explanation on value clarification exercises	Add information	HCPs
Side effects of dual immunotherapy and immunotherapy should be aggravated	Add information	HCPs
Explain that as a patient, you will not see every member of the treatment team	Add information	HCPs
Remove fabric names of medication, use medication group names instead	Textual modification	HCPs
Several linguistic textual modifications	Textual modification	Patients + HPCs
Add more figures into the decision aid	Add figures	Patients + HCPs
Specify survival rates by risk group	Specification of survival rates	HCPs

Appendix V: The three component decision aid: decision aid handout, online patient decision aid and decision aid summary

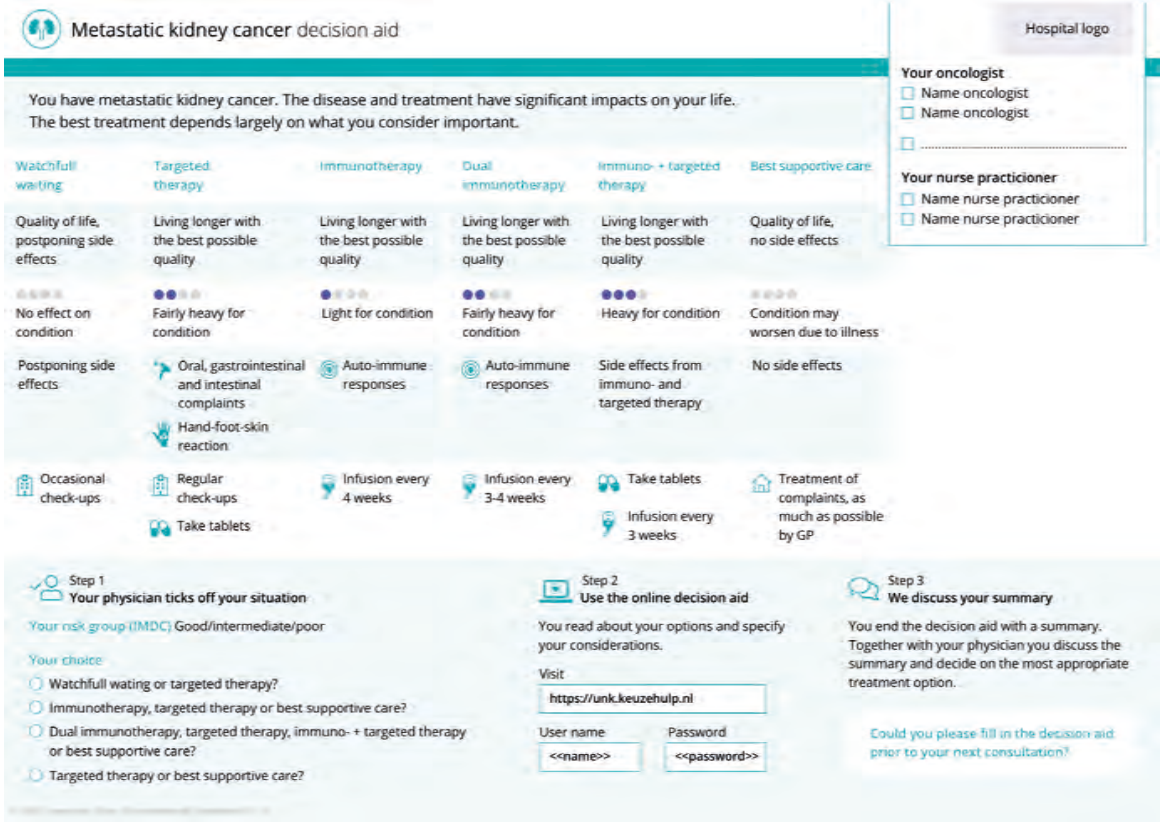

Figure 1. Decision aid handout
*Note: this is a translation from Dutch to English

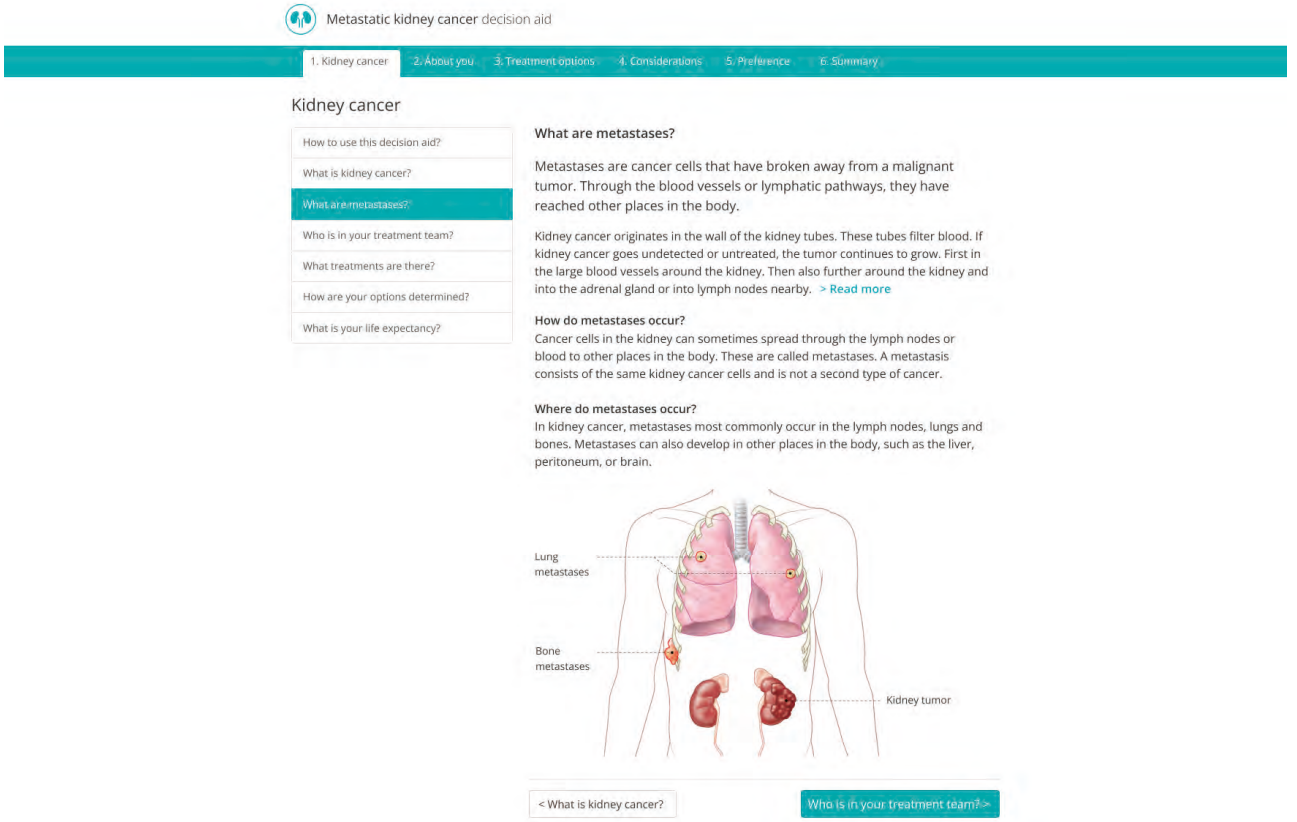

Figure 2. Online patient decision aid – screenshot
*Note: this is a translation from Dutch to English

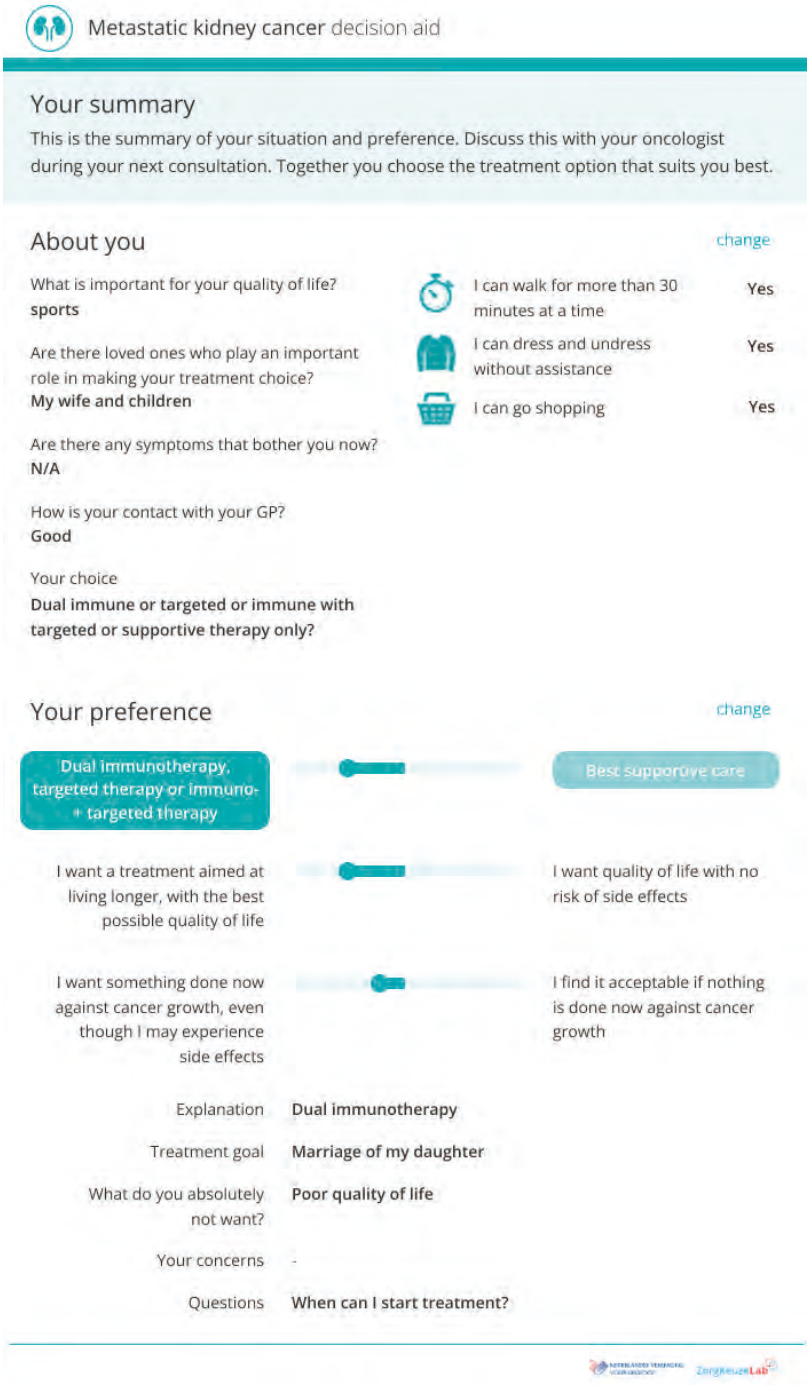

Figure 3. Decision aid summary
*Note: this is a translation from Dutch to English

Appendix VI: Compatibility with IPDAS-criteria

Table 4. IPDAS minimal qualifying and certification criteria for decision aids regarding treatment options[1]

Criterion			Metastatic clear cell RCC PtDA
Qualifying criteria	1	PtDA describes health condition or problem for which index decision is required	✓
	2	PtDA explicitly states the decision that needs to be considered (index decision)	✓
	3	PtDA describes the options available for the index decision	✓
	4	PtDA describes the positive features (benefits/ advantages) of each option	✓
	5	PtDA describes the negative features (harms, side effects, or disadvantages) of each option	✓
	6	PtDA describes what it is like to experience the consequences of the options (physical, psychological, social)	✓
Certification criteria	7	PtDA shows the negative and positive features of options in equal detail (using similar fonts, sequence, and representation of statistical information)	✓
	8	PtDA (or associated documentation) provides citations to the evidence selected	✓
	9	PtDA (or associated documentation) provides a production or a publication date	✓
	10	PtDA (or associated documentation) provides information about the update policy	✓
	11	PtDA provides information about the levels of uncertainty around event or outcome probabilities	✓
	12	PtDA (or associated documentation) provides information about the funding source used for development	✓

Abbreviations: PtDA patient decision aid

[1] Durand M-A. Witt J. Joseph-Williams N. et al. Minimum standards for the certification of patient decision support interventions: Feasibility and application. Med Decis Mak. 2014;98(4):462-468. doi:10.1016/j.pec.2014.12.009

PART III

Effects of the patient decision aids as part of a shared decision-making intervention

Chapter 6

Evaluating the impact of a shared decision-making intervention for patients with renal cell carcinoma: The SDM-RCC study protocol.

C.C. Bresser
M.M. Garvelink
B.M.M. van den Berg
F.C.K. Dolk
P.B. van der Nat
H.H.E. van Melick

European Urology Oncology, 2024

Abstract

The aim of the SDM-RCC study is to evaluate the impact of a comprehensive shared decision-making (SDM) intervention for patients with renal cell carcinoma (RCC) on the decision-making process and outcomes. The intervention includes online patient decision aids (PtDAs) and training of health care professionals (HCPs) in the use of PtDAs and SDM. The study is a multicenter, prospective pretest-posttest cohort in six Dutch hospitals, focusing on patients with localized or metastatic RCC. The primary outcome is the observed quality of the decision-making process, measured using OPTION-5 scores. Secondary outcomes include perceived quality of the decision-making process, decision quality, and implementation of the intervention (user statistics and interviews). Quantitative analysis will be performed on questionnaire data, while qualitative analysis will be performed on interviews using coding based on established frameworks. The study results could improve understanding of the decision-making process for RCC patients from patient, HCP, and observer perspectives. The SDM tool implemented is expected to support the decision-making process.

There are multiple treatment options for renal cell carcinoma (RCC), depending on the disease stage, tumor location, and patient preferences regarding treatment outcomes. Shared decision-making (SDM) is therefore recommended[1]. Treatment options include surgical resection, thermal ablation, and active surveillance (AS) for localized disease (T1 N0 M0). Systemic therapy, with options comprising targeted therapy, immunotherapy, and combination therapies, is recommended for metastatic RCC[2]. At present, the options offered to Dutch patients often depend on treatment availability and hospital preferences instead of patient preferences, leading to variations in practice.

Despite global efforts promoting SDM in urology, including guidelines encouraging SDM use[3], patients with RCC report limited involvement in decision-making[4]. For SDM, it is important that patients are aware of all medical appropriate options including no active treatment, irrespective of their local availability. Patient decision aids (PtDAs) are recognized tools supporting SDM that provide information on treatment options, risks, and benefits, can improve patient knowledge and informed decision-making, and may potentially reduce health care costs[1,5].

Existing PtDAs for RCC were developed for other contexts (other countries and languages)[6]. Since treatment options for RCC differ internationally, PtDAs cannot simply be translated for use in another context. Therefore, we developed two online PtDAs for localized RCC (cT1) and metastatic clear-cell RCC that align with the European Association of Urology guidelines (in press). PtDAs were established for cT1 and metastatic settings only, as these are the RCC stages for which multiple treatment options are available. These PtDAs are part of a multifaceted SDM intervention involving healthcare professional (HCP) training and feedback.

The aim of the SDM-RCC trial (ClinicalTrials.gov NCT05548621) is to evaluate the impact of the SDM intervention on RCC decision-making quality and the implementation process. Here we outline the protocol for this multicenter prospective cohort study with a pretest/posttest design. The pretest group receives no PtDA, while the post-test group, which is a separate patient cohort diagnosed after PtDA implementation, is offered PtDAs to support decision-making (Fig. 1).

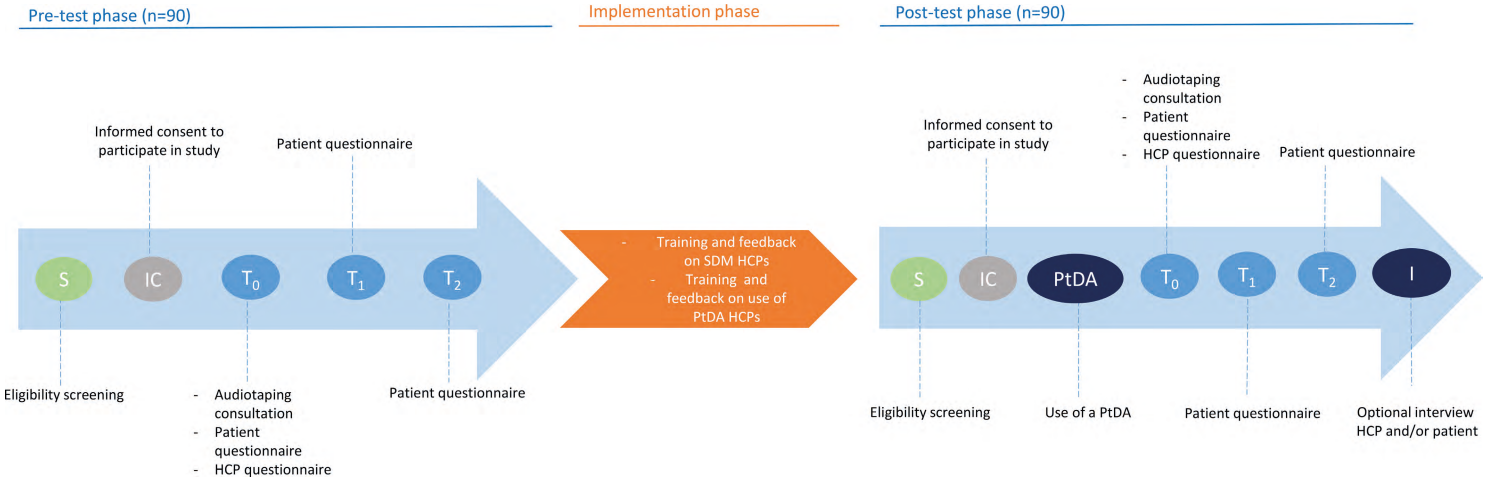

Figure 1. Flowchart SDM-RCC study.
S= screening; IC = informed consent; HCP = health care professional; PtDA = patient decision aid; SDM = shared decision-making. T0 = immediately after the consultation; T1 = after 2 wk; T2 = after 3 mo.

Conducted across six Dutch hospitals (academic and nonacademic) geographically distributed throughout the Netherlands, the study will include adults (age ≥ 18 yr) with clinically suspected localized (cT1) RCC or histologically proven metastatic clear-cell RCC. Participants must understand Dutch and be able to use a web-based PtDA (to be determined with their HCP). As part of the recruitment process, HCPs will provide information letters, obtain informed consent, and ensure confidentiality in accordance with data protection regulations.

The PtDAs guide patients through three steps: (1) the HCP provides a decision aid handout; (2) the online PtDA presents information and value exercises; (3) a personalized summary is generated to support SDM in subsequent consultations (Fig. 2).

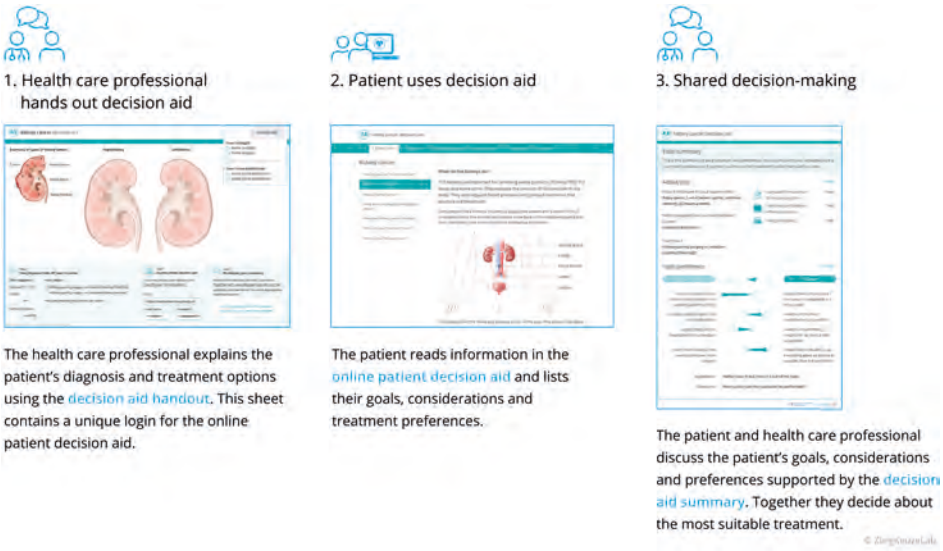

Figure 2. Overview of the three components of the patient decision aid for localized renal cell carcinoma.
Note: this is a translation from Dutch to English

The intervention involves PtDAs implemented using a strategy based on the Consolidated Framework for Implementation Research[7]. HCPs receive SDM training and feedback, and then use the PtDAs during consultations. Implementation is supported by hospital-specific strategies, a telephone helpdesk, and online dashboards with data on PtDA use that allow personalized feedback.

Data collection includes audio recording of consultations, questionnaires, medical record data for patients, and semi-structured interviews. Questionnaires are administered immediately after the consultation (T0) and at 2 wk (T1) and 3 mo (T2) after the consultation (Supplementary material).

For the primary outcome, the Observing Patient Involvement in Decision-making (OPTION)-5 instrument systematically assesses the extent to which HCPs involve patients in decision-making. OPTION-5 is measured from an observer's perspective of audio recordings of consultations[8]. Secondary outcomes are related to the quality of the decision-making process and the decision, and exploratory outcomes such as quality of life and process indicators (Supplementary material). Interviews will provide insight into HCP and patient experiences regarding implementation and use of the SDM strategy.

Quantitative analyses will compare OPTION-5 scores between pretest and post-test groups using a mixed regression model (with random effects for hospital and HCP). Similar statistics, including correlations, are used for secondary and exploratory outcomes. Qualitative analyses will include thematic evaluation of semi-structured interviews using Atlas.ti software (Atlas.ti, Berlin, Germany). Coding will be performed by two independent researchers using appropriate frameworks[1,8] and open coding, with discrepancies resolved in consensus meetings. Data will be triangulated using a convergent design to combine and compare patient, HCP, and observer findings to understand the decision-making process from all perspectives. Results will be reported in accordance with appropriate reporting guidelines.

According to a two-tailed t test with 90% power (b = 0.1, a = 0.05), a minimum sample size of 36 patients per period would be sufficient for detection of a clinically relevant difference of 10 points on the OPTION-5 scale (0–100). To adjust for potential confounding by covariates, we aim to include 90 patients per phase (180 in total). Interviews involve a minimum of 15 HCPs and 12 patients.

This study will evaluate the impact of a multifaceted SDM intervention for RCC on the quality of the decision-making process and decision quality. Previous research has highlighted potential benefits of PtDAs for other diseases[5], but there have been no studies for RCC. Therefore, the SDM-RCC study will add valuable insights into the effectiveness of PtDAs specifically for RCC and the implementation process. Post-trial use of newly developed PtDAs in medical practice is poor[9]. Therefore, we will use a multifaceted strategy that addresses important implementation factors to facilitate subsequent PtDA uptake in clinical practice. Our study design will allow us to assess whether this strategy is effective.

Strengths of the study include the exploration of decision-making from three perspectives (patient, HCP, observer) and the inclusion of patients from different hospital types, reflecting the diversity of Dutch RCC care. The inclusion of both local and metastatic RCC cases will provide insights into the effects of an SDM strategy at different disease stages.

Potential limitations include possible differences in enrolment pace between hospitals, especially for metastatic RCC cases. Efforts to address this include setting a minimum threshold of participants per hospital. In addition, the pretest/post-test design may introduce potential confounders if other changes in the care pathway occur. Proactive reminders and comprehensive electronic questionnaires will be used to support questionnaire completion and audio recording of follow-up consultations.

In conclusion, patients with RCC face complex treatment decisions that warrant SDM. We will assess whether our multifaceted intervention, which includes PtDAs and HCP training, improves SDM and decision quality, thereby addressing a critical aspect of RCC care. The study findings could significantly impact clinical practice across hospitals by standardizing the way treatment options are discussed and decided on via an SDM approach.

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Supplementary material

Outcomes for this study involve several validated instruments commonly used for SDM measurement[1]:

Secondary outcomes

The perceived quality of the decision-making process will be assessed using the following questionnaires (T_1):

- Decisional Conflict Scale (DCS) measures patients' self-reported evaluations about feeling informed and clear about personal values (0-100 scale)[2] (T_1 and T_2);
- Preparation for Decision Making (Prep-DM) scale assesses patients' perception of how useful the PtDA is in preparing for communication and decision-making (0-100 scale)[3] (T_1);
- Control Preference Scale (CPS) measures patients' preferred and actual roles in treatment decisions[4] (T_1);
- The SDM-Q-9 assesses perceived level of SDM. Measures the process of SDM in medical consultations and is available from the perspective of the patient (SDM-Q-9 patient; T_1) and of the HCP (SDM-Q-9 HCP; T_0) (0-100 scale)[5].

The quality of the decision will be assessed using the following measures:

- Patient satisfaction with the decision will be evaluated using effective decision-making items included in the DCS (T_1 and T_2);
- Patients' understanding of information relevant to treatment decisions will be objectively assessed using a knowledge questionnaire (T_1). This questionnaire consists of ten questions regarding RCC that can be answered as 'true', 'false' or 'I don't know': seven questions regarding RCC in general and 3 questions for local or metastatic disease. For each good answer, one point will be assigned, leading to a total knowledge score between 0-10, which will be transferred to a 0-100 score.

Exploratory outcomes

Quality of life is assessed using the EORTC QLQ-C30 version 3.0[6] and the Hospital Anxiety and Depression Scale (HADS)[7] (T_0 and T_2). The first subscale of the Assessing Communication about Evidence and Patient Preferences (ACEPP) tool is used to assess the quality of the decision-making process and score the use of outcome information during consultations (observed based on audiotape of the consultation)[8]. Finally, process indicators are derived from patient's medical files (e.g. number and duration of consultations needed for decision-making, chosen treatment, number of days from diagnosis to treatment and number of referrals to other hospitals for treatment).

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Chapter 7

Improved shared decision-making for patients with renal cell carcinoma: results of the SDM-RCC study.

C.C. Bresser
M.M. Garvelink
T. van Dijk
N. van der Linde
B.M.M. van den Berg
F.C.K. Dolk
H.H.E. van Melick*
P.B. van der Nat* for the SDM-RCC Study Group**

*Authors contributed equally and share last authorship
**The SDM-RCC Study Group (collaborators) are:

P.D. Polm, St. Antonius Hospital, Utrecht/Nieuwegein, The Netherlands; M. Los, St. Antonius Hospital, Utrecht/Nieuwegein, The Netherlands; K. Herbschleb, St. Antonius Hospital, Utrecht/Nieuwegein, The Netherlands; J. Hunting, St. Antonius Hospital, Utrecht/Nieuwegein, The Netherlands; B.B.M. Suelmann, University Medical Center Utrecht, Utrecht, The Netherlands; C.P. Bruijnen, University Medical Center Utrecht, Utrecht, The Netherlands; W.M. Brinkman, University Medical Center Utrecht, Utrecht, The Netherlands; S.J. Schraa, University Medical Center Utrecht, Utrecht, The Netherlands; S.F. Mulder, Radboud University Medical Center, Nijmegen, The Netherlands; J.F. Langenhuijsen, Radboud University Medical Center, Nijmegen, The Netherlands; M.D. Franken, Radboud University Medical Center, Nijmegen, The Netherlands; B.J. Koeneman, Radboud University Medical Center, Nijmegen, The Netherlands; W. van Kampen, Radboud University Medical Center, Nijmegen, The Netherlands; P.J. Zondervan, Amsterdam University Medical Center, Amsterdam, The Netherlands; S. Rynja, Spaarne Hospital, Hoofddorp/Haarlem, The Netherlands; J.M. Moll, Treant Hospital, Emmen, The Netherlands; M. Snijder, Treant Hospital, Emmen, The Netherlands; J. Bosschieter, Noord West Hospital group, Alkmaar, The Netherlands; S.G. van Ravensteijn, Catharina Hospital, Eindhoven, The Netherlands; M. Bloemendal, Gelre Hospital, Apeldoorn, The Netherlands.

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Abstract

Background and Objective: To improve shared decision-making (SDM) for renal cell carcinoma (RCC), we implemented a SDM intervention consisting of a patient decision aid and healthcare professional (HCP) training. This study evaluates its effectiveness.

Methods: Multicenter prospective pretest-posttest study including adults with localized RCC or metastatic clear cell RCC. The pretest group received standard care; the posttest group was included after SDM intervention implementation. The primary outcome was the Observing Patient Involvement in Decision-making (OPTION)-5 score, measuring patient involvement. Secondary outcomes included HCP- and patient-reported SDM and decision quality (e.g. decisional conflict scale (DCS), control preference scale (CPS)). Exploratory outcomes were quality of life, quality of the decision-making process (i.e. Assessing Communication about Evidence and Patient Preferences (ACEPP) subscale 1A), and process indicators (e.g. treatment decision). Mixed-effects regression model with random intercepts for hospital was used.

Key Findings and Limitations: Posttest, OPTION-5 scores increased significantly (47.2 to 60.5; mean difference 13.2; 95%CI [8.7-17.8]; p<.001), with improvements across most hospitals and all OPTION-5 items. HCP-reported SDM and ACEPP subscale 1A also increased (both p<.001), while patient-reported SDM remained unchanged. The number and duration of consultations increased, and DCS uncertainty scores showed more conflict, while the CPS remained unchanged. The pretest-posttest design minimized inter-hospital workflow variation and supported sustained behavioral change but limits causal inference.

Conclusions and Clinical Implications: Implementation of an SDM intervention was associated with higher levels of observed and HCP-reported SDM, while patient-perceived involvement remained similar. These findings suggest integrating the SDM intervention into routine RCC care in order to promote patient-centered decision-making.

Introduction

Renal cell carcinoma (RCC) treatment decisions require balancing oncological efficacy with potential morbidity and individual patient preferences. RCC is a heterogeneous disease ranging from localized to metastatic stages with multiple therapeutic options that vary in invasiveness, efficacy and impact on quality of life. Given the clinical uncertainty, evolving evidence and the preference-sensitive nature of many treatment choices that need to be made, shared decision-making (SDM) is essential to align disease management with patient values and ensure high-quality, person-centered care[1]. International guidelines advocate SDM for RCC treatment decision-making[2,3], emphasizing a collaborative process in which healthcare professionals (HCPs) and patients work together, with patients being actively engaged in selecting the most appropriate treatment[4,5]. SDM may also improve physical and mental health, reduce treatment variation through greater transparency of treatment options, and potentially lower healthcare costs[5,6]. However, despite improvements in oncology care, RCC patients report limited involvement in treatment decision-making, with little change over the past decade[7,8].

Implementation of practical tools to support SDM, such as patient decision aids (PtDAs), can support SDM and improve healthcare quality[9,10]. PtDAs are (online) tools that provide information about a (medical) problem, available options, associated risks and uncertainties, and a balanced overview of advantages and disadvantages[11]. These tools help patients clarify their values and preferences when considering treatment. PtDAs are known to increase patient knowledge, improve feeling informed and clear about personal values, lead to more accurate expectations of benefits and harms, and promote more active participation in decision-making[11].

Although the benefits of SDM interventions in other malignancies are well-established, evidence of their effect in RCC remains limited. Furthermore, the RCC setting presents specific challenges: treatment decisions are complex and involve rapidly evolving systemic options that require balancing survival benefits with treatment burdens and quality of life considerations. We have developed two PtDAs, one for localized cT1 RCC and one for metastatic clear cell RCC (ccRCC)[12,13], embedded in a multifaceted SDM intervention that includes skills and awareness training for HCPs. Such multifaceted approaches that address barriers for SDM at multiple levels are essential for effectively embedding SDM into routine practice[14,15], as is demonstrating the effectiveness of PtDAs in new contexts. This study aimed to evaluate the impact of the multifaceted SDM intervention for RCC on the quality of the decision-making process and the quality of the decision itself.

Material (Patients) and Methods

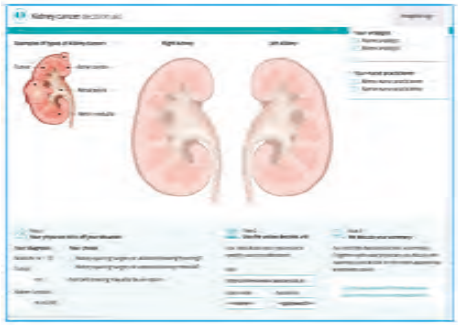
Study design

The study protocol is described in detail in a previous paper[16]. In this multicenter, prospective pretest-posttest cohort study in six Dutch academic and teaching hospitals, the pretest group received usual care. In the implementation phase, the SDM intervention was implemented in these same six hospitals. The posttest group received the PtDA corresponding to their disease stage to support treatment decision-making.

The SDM intervention

The intervention comprised a PtDA for localized RCC (Figure 1, Appendix I) or metastatic ccRCC (Appendix I) and an implementation strategy including SDM training for HCPs (i.e. urologists, oncologists, nurse(s) (specialists)), feedback on SDM, and training in PtDA use during consultations[12,13,17]. HCPs received feedback on their recorded pretest consultations and completed an accredited online training with preparatory e-learning. The strategy was tailored to each hospital to best incorporate the PtDAs in clinical practice. A helpdesk was available during implementation to address any questions, and HCPs received regular feedback on PtDA use (i.e. frequency of distribution, the HCPs involved, patient login activity).

1. Health care professional hands out decision aid



The health care professional explains the patient's diagnosis and treatment options using the decision aid handout. This sheet contains a unique login for the online patient decision aid.

2. Patient uses decision aid

The patient reads information in the online patient decision aid and lists their goals, considerations and treatment preferences.

3. Shared decision-making

The patient and health care professional discuss the patient's goals, considerations and preferences supported by the decision aid summary. Together they decide about the most suitable treatment.

Figure 1. Example of the localized RCC PtDA. RCC, renal cell carcinoma; PtDA, patient decision aid.

Participants and procedures

Patient eligibility criteria were: -18 years; a clinical suspicion of T1 renal masses or metastatic ccRCC; good understanding of Dutch in speech and writing. Participants were recruited by their HCP and provided with an information letter via (e)mail between November 2022 and August 2025. Figure 2 presents the start and end dates of the pretest, implementation, and posttest phases per hospital. Informed consent was obtained by the HCP. Patients could withdraw from the study at any time. Confidentiality was ensured through study ID use and handling of personal data complied with EU General Data Protection Regulation and any local regulations.

Figure 2. Study timeline per hospital
Abbreviations: RCC = renal cell carcinoma, ccRCC = clear cell renal cell carcinoma.
No major changes in RCC guidelines or systemic therapy paradigms relevant to counseling content occurred during the study period.

Data collection

Data was collected by means of 1) audio recordings of the consultations regarding treatment decision-making; 2) patient questionnaires right after the consultation in which a treatment decision was made (t_0), two weeks (t_1), and three months thereafter (t_2); 3) HCP questionnaires at t_0. Data regarding patient-, treatment- and care process characteristics were extracted from patient's electronic health records (EHRs). Data were collected and managed using REDCap electronic data capture tools[18].

Outcomes

Primary outcome

The 'Observing patient involvement in decision-making'(OPTION)-5 score was measured to systematically assess the degree to which HCPs involve patients in decision-making during audiotaped consultations from an observer perspective[19]. OPTION-5 consists of 5 items,

each scored from 0-4, summed, and converted to a 0-100 scale, with higher scores indicating greater levels of observed SDM (Supplementary Table S1, Appendix II). Only consultations that had been successfully recorded were available for analysis, and OPTION-5 scores were calculated based on these consultations. Consultations for which no recording was available were considered missing. The recorded consultations were aggregated per patient to derive a single, overall OPTION-5 score. Two out of three independent trained coders (TvD, NvdL or CB) scored the OPTION-5 and compared their codes during consensus meetings. If necessary, a third independent coder was assigned to reach consensus.

Secondary outcomes

Patient- and HCP-reported levels of SDM were assessed using the SDM-Q-9-patient and SDM-Q-9-Doc[20]. Patients' self-reported evaluations about feeling informed and clear about personal values were assessed using the Decisional Conflict Scale (DCS), with lower scores indicating less conflict and higher scores more conflict[21]. Patients' perception of how useful the PtDA is in preparing for communication and decision-making was assessed using the Preparation for Decision Making (Prep-DM) scale[22]. Patients' preferred and actual roles in treatment decisions were assessed using the Control Preference Scale (CPS)[23]. Patients' knowledge was assessed with ten questions regarding RCC that can be answered as 'true', 'false' or 'I don't know'. For each good answer, one point was assigned, leading to a total score between 0-10, which was transferred to a 0-100 score.

Exploratory outcomes

The first subscale of the Assessing Communication about Evidence and Patient Preferences (ACEPP) tool was used to assess the quality of the decision-making process and to score the use of outcome information during consultations (observed based on audiotapes of the consultations)[24]. Quality of life was assessed using the EORTC QLQ-C30 version 3.0[25] and the Hospital Anxiety and Depression Scale (HADS)[26]. Finally, process indicators were derived from patient's medical files (e.g. number and duration of consultations needed for decision-making, chosen treatment, number of days from diagnosis to treatment and number of referrals to other hospitals for treatment).

A detailed overview of the outcome measures of this study is presented in the protocol paper and in Supplementary Table S2 (Appendix III)[16].

Data analysis

Participants' baseline characteristics (i.e. age, sex, social economic statis, disease stage, World Health Organization (WHO) performance status (PS) and hospital) were compared using unpaired t-tests or Pearson's Chi-squared tests according to variable type and distribution of the data. These comparisons were performed to assess baseline comparability

between groups. Primary analyses were performed for all patients and, if clinically relevant, per patient group (i.e. patients with local or metastatic RCC). Consultation duration was measured as the time from the start of the first consultation until a definitive treatment decision was made. In cases involving multiple consultations, the consultation durations were summed. For this analysis, only patients from whom all consultations were audio recorded, were included. If patients were seen by different HCPs in consecutive consultations, all HCPs were asked to complete the t_0 questionnaire, and the highest item score was included in the analysis.

Differences in OPTION-5 scores between pretest- and posttest were assessed using a mixed regression model with random effects for hospital to account for clustering. Secondary continuous outcomes were analyzed using similar mixed-effects models. Categorical outcomes (e.g. chosen treatment or referral for treatment) were explored using group-level comparisons between the pretest and posttest groups with Chi-squared or Fisher's exact tests. Correction for covariates was considered for clinically relevant baseline variables, but WHO PS was the only differing variable and could not be included because of missing data. In case of missing data, questionnaire scores were calculated according to the instrument-specific scoring manuals, including predefined rules for handling missing items. P-values <.05 were reported as a significant difference. Statistical analyses were performed using SPSS version 29.0.

Results

A total of 206 unique patients were included in this study: 111 in the pretest group and 95 in the posttest group (Table 2). No differences were found in baseline characteristics between these groups, except for a slightly higher WHO PS in the posttest group. However, this variable had substantial missing data and should be interpreted with caution. In the pretest group, 130 of 137 consultations were available for OPTION-5 scoring, whereas 162 of 201 consultations were available in the posttest group.

Forty-five unique HCPs from six hospitals participated. Twenty-seven HCPs were involved in the pretest period, and 34 HCPs were involved in the posttest period. Sixteen HCPs participated in both the pre- and posttest measurements. HCP characteristics are presented in Table 2. HCPs' age and distribution across hospitals were comparable between groups. However, the posttest group comprised a higher proportion of female HCPs and nurses or nurse specialists.

Table 1. Pre- and posttest patient characteristics

	Pretest (n=111)	Posttest (n=95)	P-value[a]
Age (years), median [IQR]	66 [59-72]	67 [59-75]	0.47
Sex (male)	76 (69)	63 (66)	0.74
Social economic status			
Low	9 (8.1)	15 (16)	0.16
Moderate	25 (23)	23 (24)	
High	77 (69)	55 (58)	
Missing	-	2 (2.1)	
Disease stage			
Localized RCC	75 (68)	58 (61)	0.33
T1a RCC	50 (67)	43 (74)	0.35
T1b RCC	25 (33)	15 (26)	
Metastatic ccRCC	36 (32)	37 (39)	0.89
Good risk	7 (19)	8 (22)	
Intermediate risk	20 (56)	23 (62)	
Poor risk	6 (17)	5 (14)	
Missing	3 (8.3)	1 (2.7)	
WHO performance status			
0	51 (46)	33 (35)	**0.02**
1	18 (16)	27 (28)	
2	8 (7.2)	2 (2.1)	
3	-	-	
4	-	-	
Missing	34 (31)	33 (35)	
Hospital			
Hospital A	37 (33)	31 (33)	0.22
Hospital B	15 (14)	8 (8.4)	
Hospital C	24 (22)	21 (22)	
Hospital D	15 (14)	18 (19)	
Hospital E	11 (10)	15 (16)	
Hospital F	9 (8.1)	2 (2.1)	

All data are presented as n (%) unless otherwise specified
Abbreviations: WHO = World Health Organization, RCC = renal cell carcinoma, ccRCC = clear cell renal cell carcinoma, IQR = interquartile range
[a]Tests performed to compare groups: Pearson's Chi-squared test, unpaired t-test

Table 2. Pre- and posttest HCP characteristics

	Pretest (n=27)	Posttest (n=34)
Age (years), median [IQR]	40 [37-51]	43 [38-54]
Sex (male), n (%)	14 (52)	12 (35)
Hospital		
Hospital A	8 (30)	8 (24)
Hospital B	4 (15)	6 (18)
Hospital C	3 (11)	4 (12)
Hospital D	5 (19)	5 (15)
Hospital E	4 (15)	9 (27)
Hospital F	3 (11)	2 (5.9)
HCP type		
Medical specialist	21 (78)	19 (56)
Resident	4 (15)	5 (15)
Nurse specialist	2 (7.4)	4 (12)
Nurse	-	6 (18)

All data are presented as n (%) unless otherwise specified
Abbreviations: HCP = healthcare professional, IQR = interquartile range

The response rate for the pretest patient questionnaires was 95% (n=105) at t_0, 94% (n=104) at t_1 and 85% (n=94) at t_2. In the posttest phase, patient response rates were respectively 87% (n=83), 85% (n=81), and 66% (n=63). For HCP questionnaires, the corresponding rates were 97% pretest and 80% posttest.

Primary outcome: OPTION-5

Mixed-effects modelling with a random intercept for hospital revealed that the posttest group had significantly higher OPTION-5 scores than the pretest group (60.5 vs. 47.2; MD: 13.2; 95%CI: [8.7-17.8]; standardized mean difference (SMD) 0.81; p<.001). Around 12% of the variance in OPTION-5 scores was attributable to hospital clustering. The multilevel analysis was performed without adjustment for WHO PS due to missing data on this variable. In all hospitals, except for Hospital C and Hospital F, OPTION-5 scores increased after implementation of the SDM intervention. Baseline scores and the size of the effect varied across hospitals (Figure 3, Supplementary Table S3 (Appendix IV)).

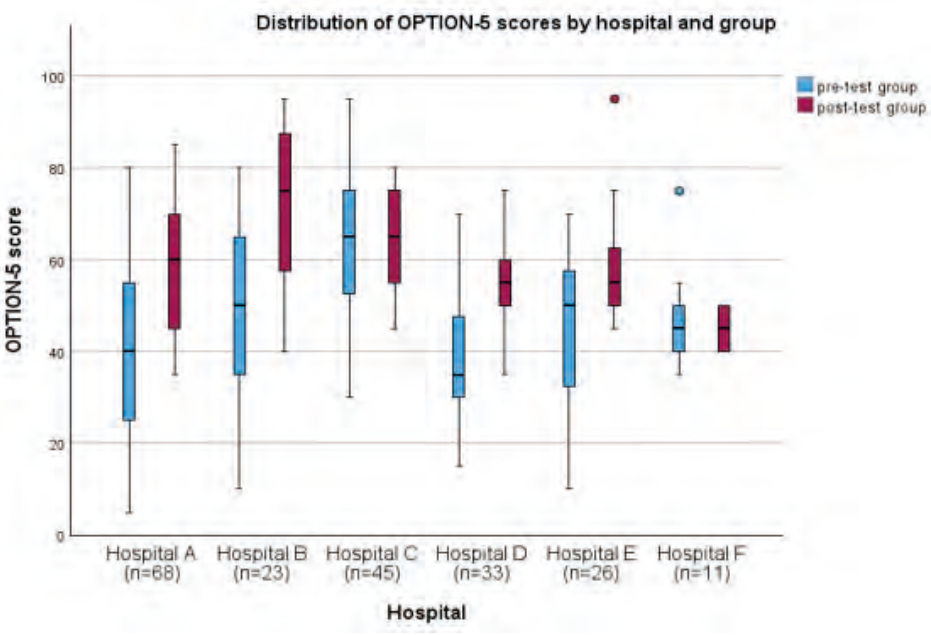


Figure 3. Distribution of OPTION-5 scores by ho spital and group.

In item-level multilevel analyses, the posttest group scored significantly higher on all OPTION-5 items compared to the pretest group, except for item 3 (information about options) (Table 3). The largest improvements were observed for item 2 (eliciting patient preferences), item 4 (integrating patient preferences), and item 5 (check decision).

Table 3. Multilevel analysis of OPTION-5 for pretest group and posttest group. Total score and score per item.

	Pretest (n=111)	Posttest (n=95)	Mean		Standardized	
	Mean ± SE	Mean ± SE	difference (β)	95% CI	mean difference	P-value
OPTION-5 item 1: presenting the decision (0-4)	2.41 ± 0.16	2.73 ± 0.17	+0.31	[0.03-0.60]	0.30	**p=0.032**
OPTION-5 item 2: eliciting patient preferences (0-4)	1.43 ± 0.25	2.14 ± 0.26	+0.71	[0.33-1.09]	0.52	**p<.001**
OPTION-5 item 3: information about options (0-4)	2.30 ± 0.09	2.34 ± 0.09	+0.05	[-0.14-0.24]	0.67	p=0.596
OPTION-5 item 4[a]: integrating patient preferences (0-4)	1.42 ± 0.07	2.16 ± 0.08	+0.73	[0.53-0.94]	0.98	**p<.001**
OPTION-5 item 5: check decision (0-4)	1.87 ± 0.18	2.70 ± 0.19	+0.83	[0.54-1.12]	0.79	**p<.001**
OPTION-5 total score (0-100)	47.25 ± 3.11	60.49 ± 3.21	+13.24	[8.68-17.79]	0.81	**p<.001**

[a]Model convergence issues caused by lack of hospital-level variance.

Secondary outcomes

SDM-levels reported by HCPs were significantly higher in the posttest group (pretest: 71.8 (n=108) vs. posttest: 78.7 (n=76); mean difference (MD) 7.0; 95%CI [4.06-9.88]; SMD 0.72; p<.001). In contrast, perceived levels of SDM as reported by patients did not significantly differ between groups (pretest: 80.0 (n=103) vs. posttest: 82.7 (n=80); MD 2.6; 95%CI [-3.19-8.47]; SMD 0.13; p=0.4). In addition, significant differences were found for the DCS uncertainty subscale at both t_1 and t_2 with scores showing more conflict in the posttest group (t_1: 20.5 vs. 28.0; MD 7.5; 95%CI [0.47-14.5]; SMD 0.32; p=0.04, and t_2:18.8 vs. 26.6; MD 7.7; 95%CI [1.23-14.2]; SMD 0.37; p=0.02). No significant difference was observed in patients' actual decision-making role (CPS actual) between the pre- and posttest assessments (p=0.066), although patients reported more active or shared participation posttest. For all other secondary outcomes (i.e. Prep-DM, CPS preferred, and patient knowledge), no significant differences were found after implementation.

In Supplementary Table S4 and S5, the results of the analyses of the secondary and exploratory outcomes are presented (Appendix V/VI).

Exploratory outcomes

Scores on ACEPP subscale 1A were higher in the posttest group compared to the pretest group (6.3 vs. 5.2; MD 1.09; 95%CI [0.65-1.52]; SMD 0.70; p<.001), indicating better decision-making quality and use of outcome information. In addition, significant differences were observed on two EORTC-QLQ-C30 subscales at t2. The posttest group had lower scores on the nausea and vomiting subscale (11.7 vs. 5.09; MD 6.61; SMD 0.32; p=0.04) and the dyspnea subscale (20.6 vs. 10.5; MD -10.4; SMD -0.44; p=0.01). Regarding process indicators, the number of consultations required for decision-making increased from 1.2 to 2.1 (pretest vs. posttest; MD 0.9; 95%CI [0.75-1.02]; SMD 1.78; p<.001), and consultation duration increased from 24 to 35 minutes (MD 11 minutes; 95%CI [06:49-15:38]; SMD 1.99; p<.001). No significant differences were observed in treatment choices between the pre- and posttest groups. However, greater use of active surveillance (AS) was observed among patients with localized RCC after implementation (Supplementary Table S5 (Appendix VI)).

Discussion

This study evaluated the impact of a SDM intervention consisting of a PtDA for localized or metastatic RCC, and training for HCPs in SDM and PtDA use, on the degree of SDM. This study found that the SDM intervention was associated with increased SDM-level observed during consultations. HCPs in the posttest group reported a higher perceived level of SDM. There were no clinically meaningful differences in patient-reported outcomes between

groups, except for the level of uncertainty about which option to choose, which increased after implementation. The number and duration of consultations increased after implementation. Finally, more cases of localized RCC were treated with AS after implementation, although this difference did not reach statistical significance. These results led us to make four main observations.

First, implementation of the SDM intervention was associated with higher observed levels of SDM, consistent with existing literature[9,15]. However, OPTION-5 scores did not increase in all hospitals. This hospital-level variability underscores the importance of contextual factors and suggests that the impact of SDM interventions is not consistent across settings. This is likely due to differences in the local implementation context, such as the extent of team engagement, the presence of SDM ambassadors and variations in workflow or clinical culture[27]. Differences in baseline SDM levels and HCP mix across hospitals may also have contributed to the observed heterogeneity. Hospitals with lower baseline scores tended to show greater improvement, suggesting a ceiling effect in centers where SDM was already partly embedded[28]. Additionally, differences in case mix (e.g. patient age, disease stage, HCP type) may have affected the observed effect by influencing the patient's ability or willingness to engage in SDM. To date, the OPTION-5 instrument has not yet been used to evaluate SDM behavior in RCC care. The mean posttest OPTION-5 score of 60.5 observed in this study indicates a moderate to high level of SDM behavior. This is comparable to, or slightly above, levels reported in other oncological studies following targeted SDM interventions[15,29–31]. Notably, provision of information about treatment options (OPTION-5 item 3) did not improve post-intervention, likely reflecting already high baseline performance, in contrast to the marked improvements observed in preference elicitation and integration (OPTION-5 items 4–5). Accordingly, the largest gains were observed in deliberative behaviors related to eliciting and integrating patient preferences and verifying the decision (OPTION-5 items 4-5). These are key markers of genuine SDM. These results imply that the intervention successfully reinforced the interactive and deliberative elements of the consultation, which are frequently the most difficult aspects of SDM to implement in routine oncological care.

Secondly, HCPs in the posttest group reported higher levels of perceived SDM, while patient-reported involvement did not differ between pre- and posttest groups. This is in line with other research[15,32] and suggests that HCP and patient experience of SDM are not clearly correlated. The mean level of perceived SDM for pretest patients was already high, leaving limited room for improvement compared to other studies reporting baseline mean scores of around 69[33], contributing to a ceiling effect. It is also possible that patients unconsciously associate SDM with their overall satisfaction with care rather than evaluating the decision-making process itself[34]. Taken together, these findings underscore that improvements in observed and HCP-reported SDM may not necessarily translate into changes perceived by patients and should

therefore be interpreted cautiously when considering patient-level impact. These findings suggest that the improvements observed by HCPs and observers may reflect aspects of SDM that are less immediately visible to patients. Future research could explore whether certain patient subgroups experience clearer benefits, or whether more sensitive, patient-centered measures are needed to capture changes in their experience.

Thirdly, unexpectedly, the DCS increased following the implementation of the SDM intervention, whereas previous studies have generally demonstrated a decrease[11]. This finding may indicate that patients became more aware of the need to make a decision and were therefore more actively engaged in the decision-making process. In this context, a temporary increase in decisional conflict could indicate successful patient activation, suggesting that patients are considering their options more critically and preparing for future consultations more effectively. Conversely, it could also indicate a temporary increase in perceived uncertainty as patients recognize the complexity of the decision[35]. However, these interpretations should be made cautiously, as an increase in decisional conflict does not necessarily reflect a beneficial or harmful effect. According to the DCS manual, scores <25 indicate decision readiness and scores >37.5 decision delay. In this study, all scores remained below the delay threshold, with only the post-implementation uncertainty subscale slightly exceeding 25. As an alternative explanation, the observed increase could be due to an increased information load and complexity, a greater awareness of trade-offs (particularly in the metastatic setting), anxiety caused by facing these trade-offs more explicitly, or the timing of the measurement in relation to the finalization of the decision. This unexpected increase indicates that further follow-up measurements may be necessary in order to establish whether this initial uncertainty continues or is resolved over time.

Fourth, as part of the intervention, patients were offered an additional consultation, leading to an increase in the total number of consultations. The duration of consultations also increased post-intervention, suggesting a more thorough deliberation process. However, previous reviews have shown that SDM interventions and PtDAs do not necessarily extend consultation duration[36,37]. This suggests that our findings may be influenced by local implementation factors rather than an inherent time burden of SDM. The increase in consultation time may also be related to the novelty of the tools and the associated learning curve. This would mean that consultation duration would decrease again over time, as efficiency is likely to improve as HCPs become more familiar with SDM-related behaviors[36]. At the same time, increased consultation number and duration may challenge feasibility, scalability, and resource utilization in routine clinical practice. However, longer or more frequent consultations should not be viewed as undesirable, as embedding SDM in clinical practice inherently requires additional time and organizational support. Instead, they may reflect more patient-centered discussions in which treatment options and values are explored

in greater depth. These conversations can also increase acceptance of treatment with AS and may, in theory, contribute to more efficient use of healthcare resources over time, for example by reducing overtreatment. However, this potential impact on healthcare costs warrants further study. In line with this, it was observed that AS was chosen more frequently in the posttest group. However, it is unclear whether this reflects the effect of the SDM intervention itself or a broader temporal shift towards the increased acceptance of AS in clinical practice. Notably, the implementation of the PtDA was accompanied by increased involvement of nurses in decision-making consultations. This indicates that additional consultation time is not solely the responsibility of physicians and does not necessarily require more time from medical specialists. Furthermore, the additional time invested may lead to improved outcomes for patients or HCPs at a later stage. This evolving, multidisciplinary approach may facilitate the sustainable integration of SDM into routine RCC care.

Strengths and limitations

This is the first study to investigate the RCC treatment decision-making process from the perspectives of patients, HCPs, as well as observers. RCC decision-making is complex and involves multiple stakeholders. We assessed the impact of the SDM intervention from patient, HCP, and observer perspectives. A major strength of this study is its inclusion of a diverse range of hospitals (academic and teaching hospitals) located across different regions of the Netherlands. This enhances the generalizability of the findings to routine clinical practice. Furthermore, the SDM intervention was evaluated in both localized RCC and metastatic ccRCC, enabling its impact to be assessed across the full disease spectrum. Last, a subsequent implementation study examined the integration of this SDM intervention into routine care[38]. This study also has limitations. Although the pretest-posttest design fits routine clinical care, it lacks the methodological strength of a randomized controlled trial and limits causal inference. The pretest-posttest design is inherently vulnerable to time effects, including potential changes in SDM awareness. Since no major guideline updates occurred during the study period, the potential impact of time-related effects and residual confounding on the observed findings is likely limited. Additionally, future research should include longitudinal study designs to better understand how patients' perceptions of SDM evolve over time. Although consultations were audiotaped, prior evidence suggests that recording has minimal impact on HCP or patient behavior and is therefore unlikely to have substantially influenced the results[39]. Nevertheless, repeated outcome measurement may have increased HCP awareness in the posttest period, potentially influencing communication behavior. Observers were not blinded to the study phase during coding, which could have introduced assessment bias. Clustering at the HCP level was not feasible because consultations were aggregated at the patient level and patients with multiple consultations were often seen by different HCPs. As decision-making outcomes are likely influenced by individual HCP communication styles, hospital level rather than HCP-level clustering may not have fully

captured within-HCP correlation and could have affected estimate precision. The uneven distribution of patients with localized RCC versus metastatic ccRCC limited the ability to draw stage-specific conclusions, particularly in the metastatic setting. Therefore, patients with both disease stages were analyzed together, in line with our aim to evaluate overall implementation rather than stage-specific effectiveness. However, this may have obscured stage-specific effects and limits the generalizability of the findings across the full spectrum of RCC care. Furthermore, awareness of the audio recording may have influenced HCP behavior during consultations, particularly before implementation. This could have improved pretest group performance and thereby underestimating the true effect of the SDM intervention. Selection bias may also have occurred if HCPs were more likely to introduce the PtDA to certain patients. Additionally, despite identical electronic questionnaire procedures, response rates were lower in the posttest phase, which may have affected the representativeness of the sample. Next, the presence of missing data due to unrecorded consultations, despite repeated reminders, which occurred predominantly in the posttest group, and the poorer WHO status in the posttest group, may have lowered the OPTION-5 scores. This suggests that the observed improvement could represent an underestimate. Finally, it is of upmost importance to regularly update PtDAs to keep pace with evolving evidence and emerging treatment options.

Conclusions

After implementation of the multifacted SDM intervention, higher SDM levels were observed, particularly regarding elicitation and integration of patient preferences into the decision-making process. Despite improvements in perceived patient involvement reported by HCPs, patients' perceived involvement was similar between pre- and posttest patients. Increased consultation frequency and duration suggest a more extensive deliberation process and increased application of SDM, with implications for time investment, staffing, and training in routine practice. This study suggests that structured support for SDM may improve the quality of the decision-making process in routine RCC care, while patient-level effects appear more limited and contextual factors may influence transferability beyond the Dutch healthcare setting. The approach is applicable to other genitourinary malignancies involving preference-sensitive decisions, although disease-specific and contextual adaptation will be required.

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Appendix I: The three component decision aids: decision aid handout, online patient decision aid and decision aid summary

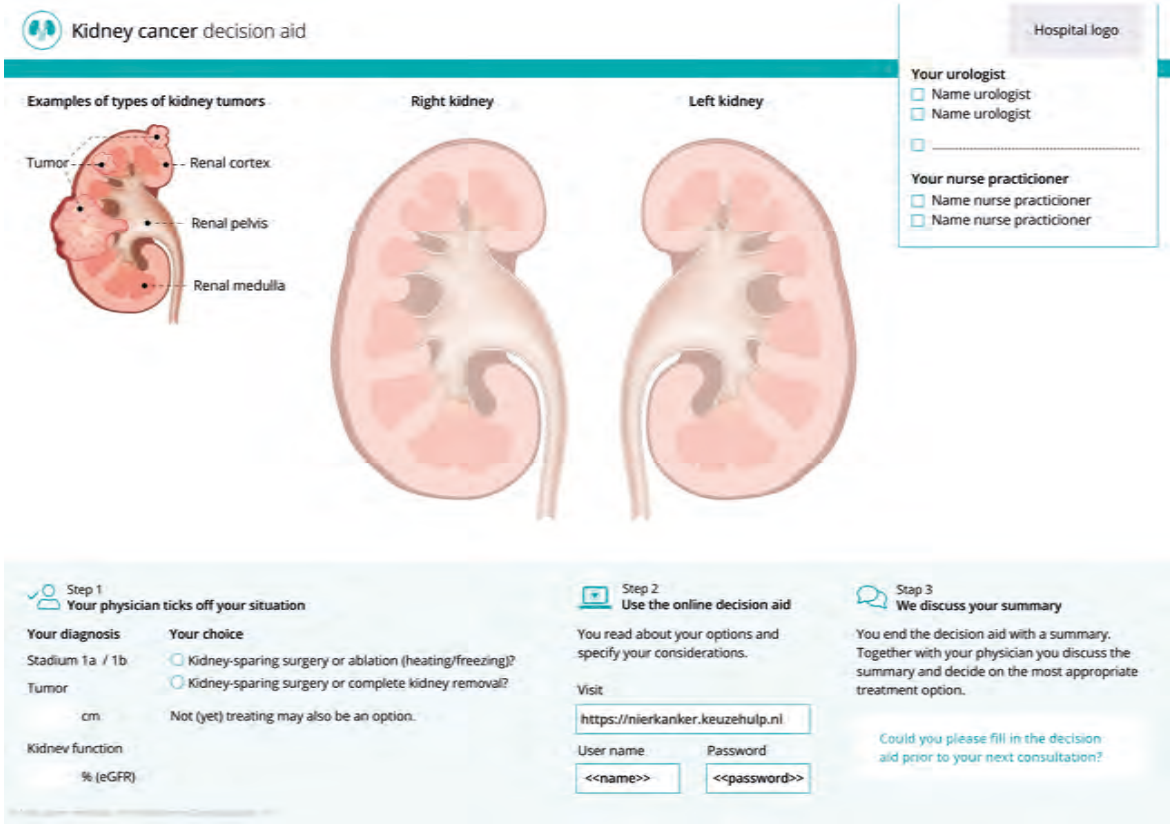

Figure 1. Decision aid handout for localized cT1 renal cell carcinoma.
*Note: this is a translation from Dutch to English

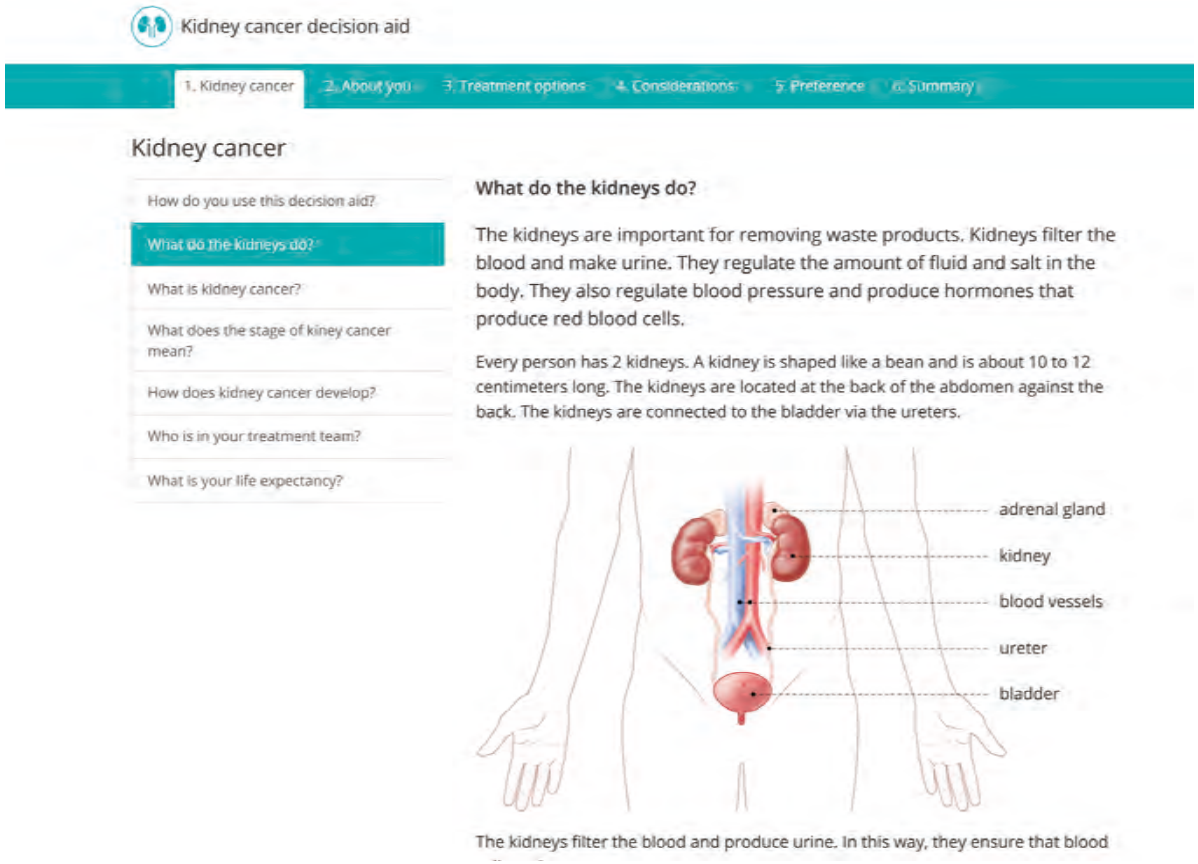

Figure 2. Online patient decision aid for localized cT1 renal cell carcinoma– screenshot.
*Note: this is a translation from Dutch to English

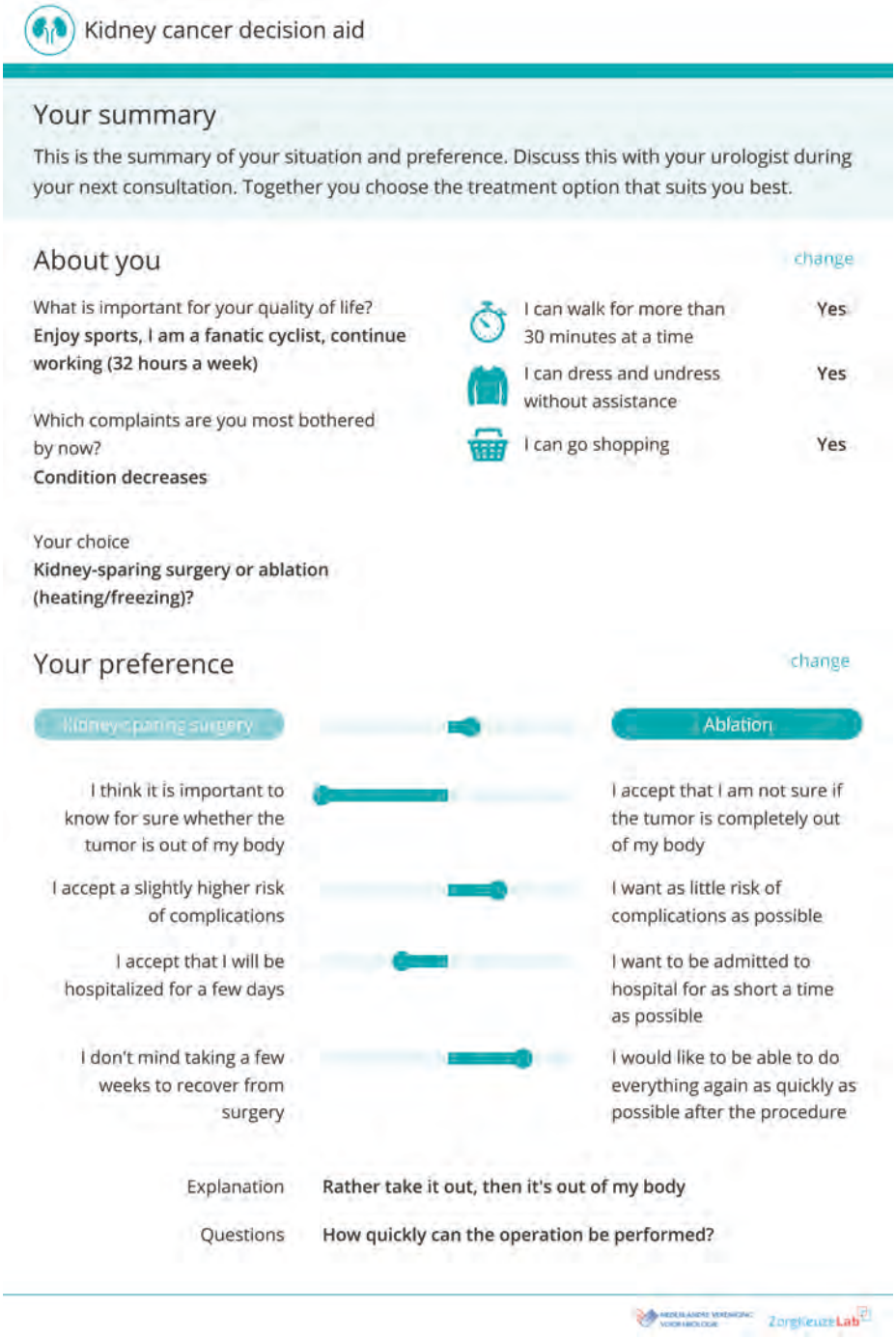

Figure 3. Decision aid summary.
*Note: this is a translation from Dutch to English

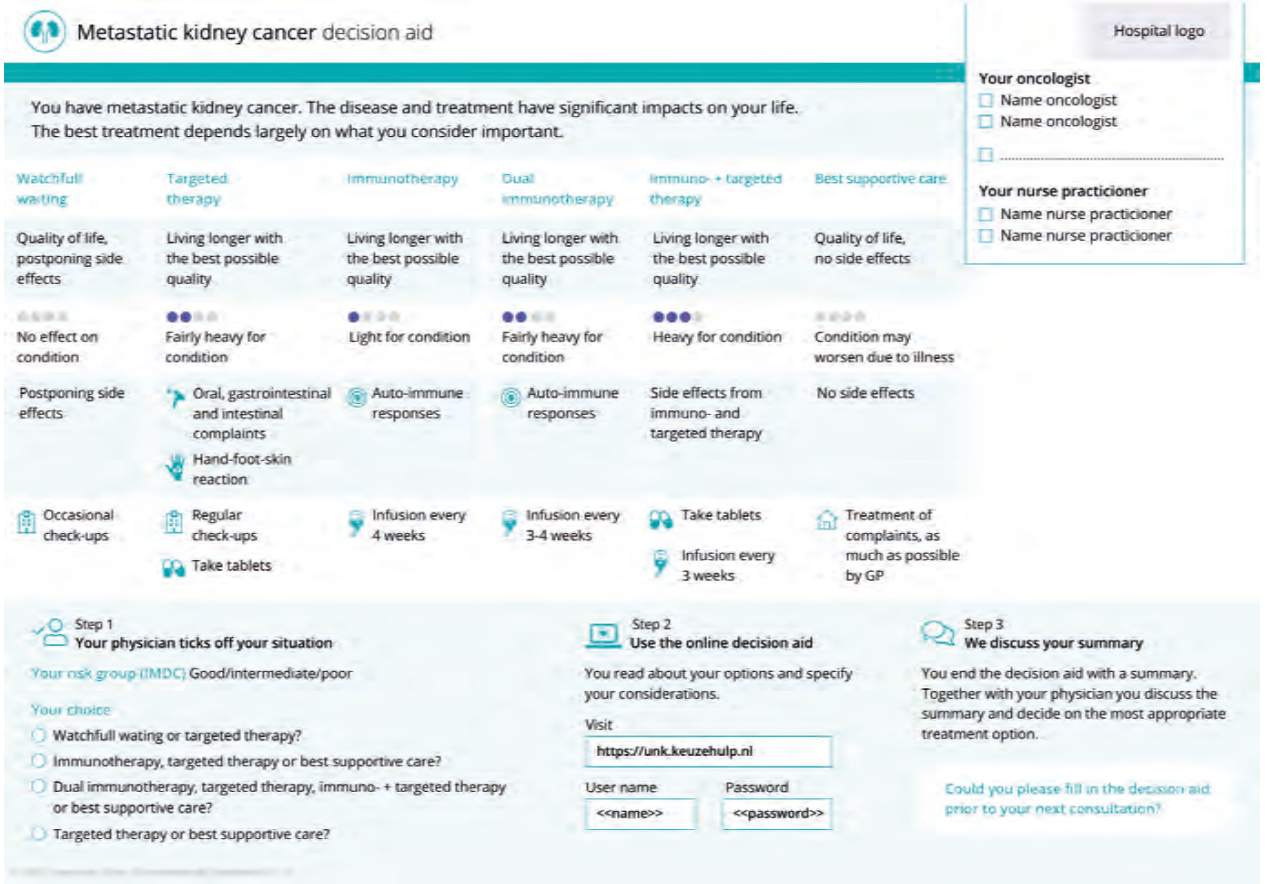

Figure 4. Decision aid handout for metastatic clear cell renal cell carcinoma
*Note: this is a translation from Dutch to English

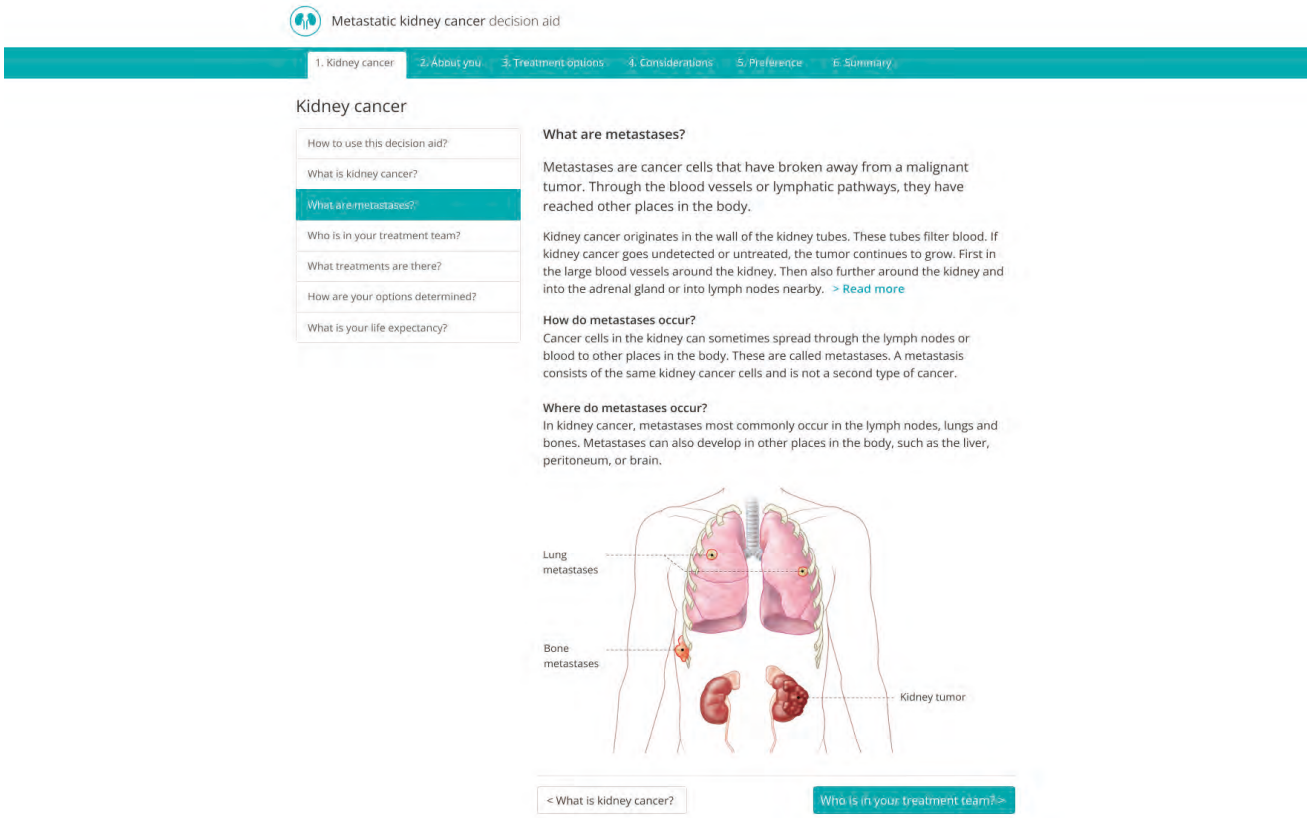

Figure 5. Online patient decision aid for metastatic clear cell renal cell carcinoma – screenshot
*Note: this is a translation from Dutch to English

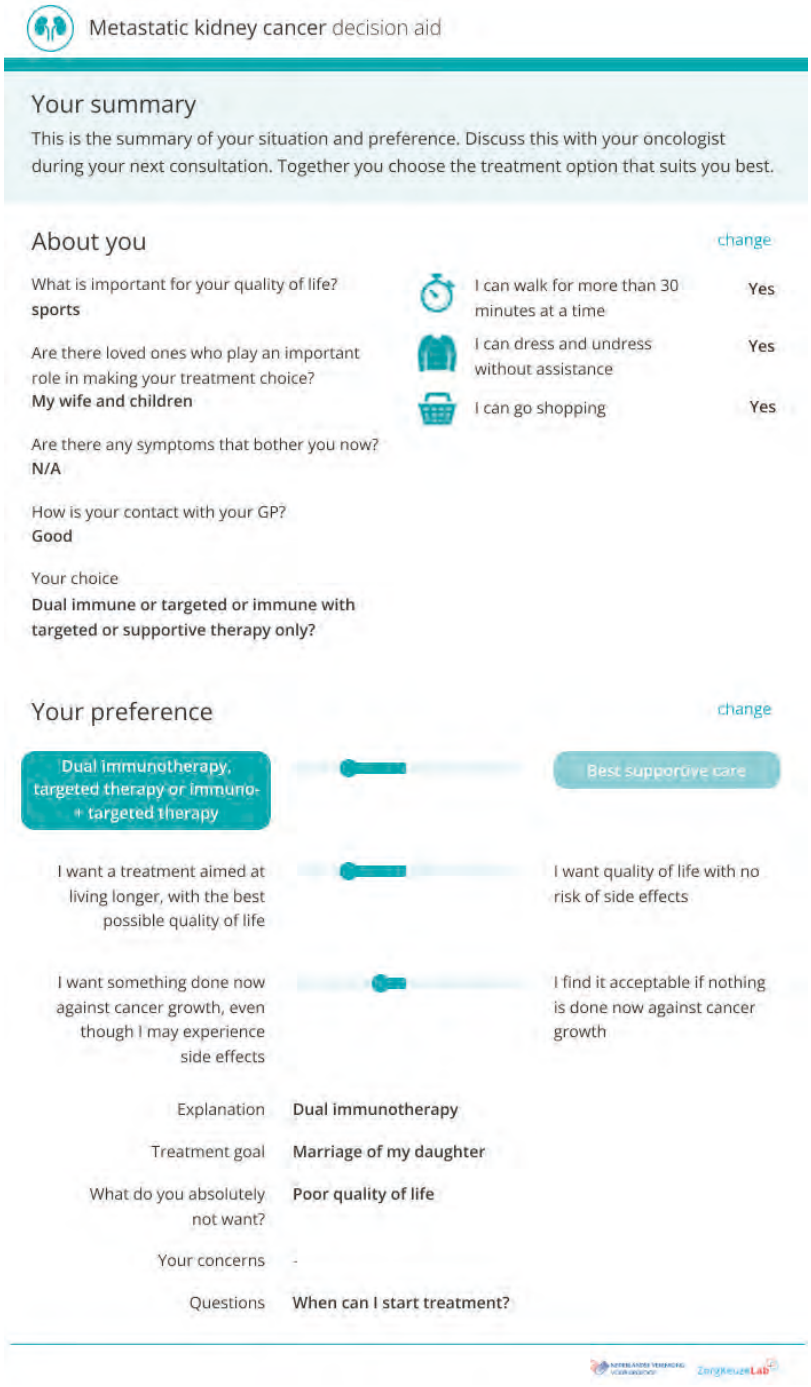

Figure 6. Decision aid summary for metastatic clear cell renal cell carcinoma
*Note: this is a translation from Dutch to English

Appendix II: Supplementary Table S1

Supplementary Table S1. The OPTION-5 instrument

Item	Behavior description
1	For the health issue being discussed, the clinician **draws attention to or confirms** that alternate treatment or management options exist or that the need for a decision exists. If the patient rather than the clinician draws attention to the availability of options, the clinician responds by agreeing that the options need deliberation.
2	The clinician reassures the patient or re-affirms that the clinician **will support the patient to become informed or deliberate** about the options. If the patient states that they have sought or obtained information prior to the encounter, the clinician supports such a deliberation process.
3	The clinician **gives information or checks understanding about the options** that are considered reasonable (this can include taking no action), to support the patient in comparing alternatives. If the patient requests clarification, the clinician supports the process.
4	The clinician makes an effort to **elicit the patient's preferences** in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive.
5	The clinician makes an **effort to integrate the patient's elicited preferences** as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician makes an effort to do so.

Scoring: 0 = no effort, 1 = minimal effort, 2 = moderate effort, 3 = skilled effort, 4 = exemplary effort

Appendix III: Supplementary Table S2

Supplementary Table S2. Overview of outcome measures

Outcome	Measure instrument	Perspective	Number of items	Example item	Answering options	Minimum-maximum score	Cronbach's alpha (in this study)
Observed level of SDM	OPTION-5[19]	Observer	5	*"The clinician makes an effort to elicit the patient's preferences in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive."*	5-point Likert scale ranging from "No effort" to "Exemplary effort"	0-100	0.72
Decisional conflict	Decisional Conflict Scale (DCS)[21]	Patient	16	*"I know which options are available to me"*	5-point Likert scale ranging from "Strongly agree" to "Strongly disagree"	0-100	t1: 0.87 t2: 0.88
Preparation for decision-making	Prep-DM[22]	Patient	10	*"Did this educational material prepare you to make a better decision?"*	5-point Likert scale ranging from "Not at all" to "A great deal"	0-100	0.932
	Control Preference Scale (CPS) – preferred & actual[23]	Patient	2	N/A	5 response options ranging from the patient making the treatment decision independently to the HCP making the decision	N/A	N/A
Patient reported SDM	SDM-Q-9[20]	Patient	9	*"My doctor made clear that a decision needs to be made."*	6-point Likert scale ranging from "Completely agree" to "Completely disagree"	0-100	0.88
HCP reported SDM	SDM-Q-9-Doc[20]	Healthcare professional	9	*"I made clear to my patient that a decision needs to be made."*	6-point Likert scale ranging from "Completely agree" to "Completely disagree"	0-100	0.82

Supplementary Table S2 *Continued*

Outcome	Measure instrument	Perspective	Number of items	Example item	Answering options	Minimum-maximum score	Cronbach's alpha (in this study)
Patient knowledge	Knowledge questionnaire	Patient	10	*"The types of side effects and the likelihood of them occurring vary depending on the treatment."*	3-point scale: "True", "False", "I don't know"	0-10	Localized RCC: 0.60 Metastatic ccRCC: 0.59
Outcome information in consultations	ACEPP subscale 1A[24]	Observer	10	*"Did the clinician describe the benefit(s) of the option(s) to the patient (including how likely the benefit is)?"*	3-point scale: "No", "Basic", "Extended"	0-10	0.64
Quality of life	EORTC QLQ-C30[25]	Patient	30	*"Do you have any trouble taking a long walk?"*	4-point Likert scale ranging from "Not at all" to "Very Much"	0-100	t0: 0.86 t2: 0.88
	Hospital Anxiety and Depression Scale (HADS)[26]	Patient	14	*"I still enjoy the things I used to enjoy"*	4-point Likert scale ranging from "Not at all" to "Very Much"	0-21	t0: 0.90 t2: 0.91

Appendix IV: Supplementary Table S3

Supplementary Table S3. OPTION-5 item level scores across hospitals

Hospital	OPTION-5 item 1	OPTION-5 item 2	OPTION-5 item 3	OPTION-5 item 4	OPTION-5 item 5	OPTION-5 total score
Hospital A (n=68)	Pre: 2.03 ± 1.30 Post: 2.65 ± 1.08	Pre: 0.92 ± 1.21 Post: 2.00 ± 1.51	Pre: 2.22 ± 0.85 Post: 2.13 ± 0.81	Pre: 1.27 ± 0.87 Post: 2.10 ± 0.75	Pre: 1.46 ± 1.37 Post: 2.77 ± 0.76	Pre: 39.46 ± 19.92 Post: 58.23 ± 16.15
Hospital B (n=23)	Pre: 2.60 ± 1.06 Post: 3.38 ± 0.92	Pre: 1.73 ± 1.58 Post: 3.00 ± 1.46	Pre: 2.33 ± 0.82 Post: 3.00 ± 0.76	Pre: 1.33 ± 0.72 Post: 2.25 ± 1.04	Pre: 2.00 ± 1.51 Post: 2.63 ± 0.52	Pre: 50.00 ± 19.27 Post: 71.88 ± 19.45
Hospital C (n=45)	Pre: 3.00 ± 0.98 Post: 3.05 ± 1.07	Pre: 2.58 ± 1.38 Post: 2.48 ± 1.47	Pre: 2.50 ± 0.51 Post: 2.48 ± 0.51	Pre: 1.71 ± 0.69 Post: 2.00 ± 0.45	Pre: 3.04 ± 1.00 Post: 2.81 ± 0.68	Pre: 64.17 ± 15.30 Post: 64.05 ± 11.58
Hospital D (n=33)	Pre: 2.07 ± 0.70 Post: 2.33 ± 0.59	Pre: 0.73 ± 0.96 Post: 1.83 ± 1.38	Pre: 2.20 ± 0.56 Post: 2.33 ± 0.49	Pre: 1.33 ± 0.62 Post: 2.22 ± 0.65	Pre: 1.27 ± 0.88 Post: 2.44 ± 0.71	Pre: 38.00 ± 13.73 Post: 55.83 ± 9.89
Hospital E (n=26)	Pre: 2.36 ± 1.21 Post: 2.40 ± 0.83	Pre: 1.82 ± 1.17 Post: 1.87 ± 1.13	Pre: 2.27 ± 0.47 Post: 2.33 ± 0.49	Pre: 1.18 ± 0.75 Post: 2.47 ± 0.74	Pre: 1.36 ± 1.21 Post: 2.67 ± 0.62	Pre: 45.00 ± 18.30 Post: 58.67 ± 13.82
Hospital F (n=11)	Pre: 2.67 ± 0.87 Post: 2.00 ± 0.00	Pre: 0.78 ± 1.56 Post: 1.50 ± 0.71	Pre: 2.11 ± 0.33 Post: 1.50 ± 0.71	Pre: 1.89 ± 0.78 Post: 1.50 ± 0.71	Pre: 2.00 ± 1.23 Post: 2.50 ± 0.71	Pre: 47.22 ± 12.53 Post: 45.00 ± 7.07
All hospitals (n=206)	Pre: 2.41 ± 1.14 Post: 2.68 ± 0.98	Pre: 1.44 ± 1.46 Post: 2.14 ± 1.44	Pre: 2.29 ± 0.68 Post: 2.34 ± 0.68	Pre: 1.42 ± 0.78 Post: 2.16 ± 0.70	Pre: 1.88 ± 1.37 Post: 2.68 ± 0.69	Pre: 47.21 ± 19.70 Post: 60.00 ± 14.55

Appendix V: Supplementary Table S4

Supplementary Table S4. Multilevel analyses for continuous secondary and exploratory outcomes by group

	Pretest		Posttest		Mean			Variance/	Variance/	
	N	Mean ± SE	N	Mean ± SE	difference (β)	95% CI	P-value	σ^2 (hospital)	σ^2 (residual)	ICC
SDM-Q-9 (0-100)	103	80.05 ± 2.49	80	82.69 ± 2.72	+2.64	[-3.19-8.47]	p=0.37	12.67	388.20	0.03
SDM-Q-Doc (0-100)	108	71.76 ± 2.03	76	78.73 ± 2.17	+6.97	[4.06-9.88]	**p<.001**	18.70	93.75	0.17
Outcome information in consultations (ACEPP subscale 1A)										
Description problem/mechanism (1st option)[a]*	111	0.91 ± 0.02	95	0.95 ± 0.02	+0.05	[0.00-0.10]	p=0.07	0.00	0.03	0.00
Description problem/mechanism (2nd option)*	98	0.80 ±0.03	92	0.88 ± 0.03	+0.08	[0.00-0.16]	**p=0.05**	0.00	0.07	0.02
How many options are given	111	2.70 ± 0.12	95	2.95 ± 0.12	+0.25	[0.03-0.47]	**p=0.03**	0.04	0.65	0.06
How many harms (1st option)	111	1.61 ± 0.13	95	2.11 ± 0.14	+0.49	[0.18-0.81]	**p=0.00**	0.03	1.30	0.02
How many benefits (1st option)[a]	111	2.05 ± 0.11	95	2.39 ± 0.11	+0.34	[0.04-0.65]	**p=0.03**	0.00	1.24	0.00
Description of benefit/harm in terms of patient outcomes (1st option)*	111	0.77 ± 0.03	95	0.97 ± 0.03	+0.20	[0.13-0.27]	**p<.001**	0.00	0.06	0.04
Description of benefit/harm in terms of patient outcomes (2nd option)*	99	0.70 ± 0.04	92	0.90 ± 0.04	+0.20	[0.12-0.28]	**p<.001**	0.00	0.08	0.04
Probability/likelihood of benefit or harm (1st option)*	111	0.41 ± 0.05	95	0.47 ± 0.05	+0.06	[-0.04-0.15]	p=0.23	0.01	0.11	0.05
Probability/likelihood of benefit or harm (2nd option)*	111	0.21 ± 0.04	95	0.28 ± 0.05	+0.07	[-0.01-0.15]	p=0.09	0.01	0.09	0.06
Individualized information tailored to patient (1st option)*	111	0.76 ± 0.04	95	0.93 ± 0.04	+0.17	[0.01-0.24]	**p<.001**	0.01	0.06	0.08
Individualized information tailored to patient (2nd option)*	99	0.61 ± 0.04	92	0.84 ± 0.05	+ 0.23	[0.14-0.32]	**p<.001**	0.01	0.10	0.05
Source of evidence mentioned, yes (1st option)[b]*	111	18 (16)	95	8 (8.4)	N/A	N/A	p=0.09	N/A	N/A	N/A
Source of evidence mentioned, yes (2nd option)[b]*	99	8 (7.2)	92	4 (4.2)	N/A	N/A	p=0.29	N/A	N/A	N/A
Total score	111	5.22 ± 0.24	95	6.30 ± 0.25	+1.09	[0.65-1.52]	**p<.001**	0.20	2.40	0.08

	Pretest		Posttest		Mean difference (β)	95% CI	P-value	Variance/ σ^2 (hospital)	Variance/ σ^2 (residual)	ICC
	N	Mean ± SE	N	Mean ± SE						
Decisional conflict - t1										
Informed decision[a]	103	15.37 ± 1.91	80	19.90 ± 2.17	+4.52	[-1.18-10.23]	p=0.12	0.00	376.19	0.00
Values clarity[a]	103	20.47 ± 1.96	80	23.13 ± 2.23	+2.66	[-3.21-8.52]	p=0.37	0.00	397.29	0.00
Support	103	14.77 ± 1.92	80	14.40 ± 2.15	-0.37	[-5.67-4.93]	p=0.89	2.66	323.85	0.01
Uncertainty[a]	103	20.47 ± 2.34	79	27.95 ± 2.67	+7.48	[0.47-14.50]	**p=0.04**	0.00	564.67	0.00
Effective decision[a]	104	12.74 ± 1.97	80	7.50 ± 2.24	-5.24	[-11.13-0.65]	p=0.08	0.00	402.35	0.00
Total score[a]	103	16.57 ± 1.50	79	17.82 ± 1.71	+1.26	[-3.23-5.74]	p=0.55	0.00	231.33	0.00
Decisional conflict – t2										
Informed decision[a]	92	15.40 ± 2.24	72	20.37 ± 2.53	+4.97	[-1.69-11.63]	p=0.14	0.00	459.38	0.00
Values clarity[a]	91	19.05 ± 2.04	72	24.31 ± 2.29	+5.26	[-0.80-11.32]	p=0.09	0.00	378.74	0.00
Support	93	11.38 ± 2.04	72	14.57 ± 2.28	+3.20	[-2.31-8.70]	p=0.25	3.80	313.36	0.01
Uncertainty	93	18.83 ± 2.30	72	26.55 ± 2.59	+7.72	[1.23-14.20]	**p=0.02**	2.79	436.52	0.01
Effective decision[a]	94	10.51 ± 2.10	72	13.19 ± 2.40	+2.69	[-3.62-9.00]	p=0.40	0.00	415.76	0.00
Total score[a]	90	14.71 ± 1.65	72	19.42 ± 1.85	+4.72	[-0.18-9.62]	p=0.06	0.00	246.27	0.00
Preparation for decision-making (0-100)[a]	104	74.98 ± 2.13	80	74.97 ± 2.43	-0.01	[-6.38-6.37]	p=1.00	0.00	471.91	0.00
Patient knowledge (0-10)	104	7.62 ± 0.29	80	7.82 ± 0.31	+0.21	[-0.34-0.75]	p=0.45	0.29	3.34	0.08
EORTC QLQ-C30 – t0										
Global health status	101	68.89 ± 3.13	79	70.85 ± 3.30	+1.96	[-3.59-7.50]	p=0.49	34.66	340.27	0.09
Physical functioning	101	83.30 ± 3.03	79	83.70 ± 3.24	+0.40	[-5.87-6.67]	p=0.90	25.14	437.76	0.05
Role functioning	101	79.31 ± 4.13	79	83.34 ± 4.36	+4.03	[-3.47-11.54]	p=0.29	58.35	624.79	0.09
Emotional functioning	101	76.31 ± 2.03	79	75.00 ± 2.29	-1.32	[-7.32-4.69]	p=0.67	0.28	410.00	0.00
Cognitive functioning[a]	101	89.93 ± 1.69	79	88.40 ± 1.91	-1.54	[-6.57-3.50]	p=0.55	0.00	288.49	0.00
Social functioning	101	84.39± 2.32	79	86.52 ± 2.55	+2.13	[-3.89-8.15]	p=0.68	6.33	408.85	0.02
Fatigue	101	28.19 ± 3.40	79	25.95 ± 3.66	-2.23	[-9.81-5.34]	p=0.56	26.44	641.36	0.04
Nausea and vomiting	101	5.93 ± 2.00	79	5.02 ± 2.14	-0.91	[-5.08-3.26]	p=0.67	10.78	193.72	0.05
Pain[a]	101	21.95 ± 2.61	79	17.51 ± 2.95	-4.44	[-12.22-3.35]	p=0.26	0.00	689.23	0.00

Supplementary Table S4 *Continued*

	Pretest		Posttest		Mean			Variance/	Variance/	
	N	Mean ± SE	N	Mean ± SE	difference (β)	95% CI	P-value	σ^2 (hospital)	σ^2 (residual)	ICC
Dyspnoea[a]	101	12.54 ± 2.19	79	16.03 ± 2.47	+3.49	[-3.02-10.01]	p=0.29	0.00	483.30	0.00
Insomnia	101	27.38 ± 3.05	79	25.16 ± 3.41	-2.22	[-10.86-6.43]	p=0.61	3.99	848.12	0.01
Appetite loss	101	14.18 ± 2.89	79	8.84 ± 3.16	-5.34	[-12.48-1.81]	p=0.14	13.22	573.28	0.02
Constipation	101	10.10 ± 3.20	79	14.19 ± 3.39	+4.09	[-1.99-10.16]	p=0.19	32.96	410.37	0.07
Diarrhoea[a]	101	6.27 ± 1.82	79	8.02 ± 2.06	+1.75	[-3.69-7.18]	p=0.52	0.00	336.18	0.00
Financial difficulties[a]	101	4.62 ± 1.16	79	2.53 ± 1.31	-2.09	[-5.53-1.35]	p=0.23	0.00	134.86	0.00
HADS – t0										
Anxiety	101	4.34 ± 0.40	79	4.73 ± 8.60	+0.39	[-0.78-1.53]	p=0.50	0.04	14.79	0.00
Depression	101	3.54 ± 0.54	79	3.66 ± 0.57	+0.12	[-0.91-1.15]	p=0.82	0.92	11.79	0.00
Total	101	7.85 ± 0.85	79	8.34 ± 0.92	+0.49	[-1.49-2.47]	p=0.63	1.40	43.97	0.03
EORTC QLQ-C30 – t2										
Global health status	94	70.07 ± 2.65	72	72.06 ± 2.89	+1.99	[-4.08-8.05]	p=0.52	15.33	379.31	0.04
Physical functioning	94	79.97 ± 2.27	72	83.41 ± 2.54	+3.48	[-2.61-9.56]	p=0.26	5.13	385.20	0.01
Role functioning	94	66.21 ± 3.27	72	73.93 ± 3.68	+7.88	[-1.30-16.76]	p=0.09	7.88	848.76	0.01
Emotional functioning	94	75.93 ± 2.59	72	79.80 ± 2.85	+3.87	[-2.38-10.13]	p=0.22	12.21	404.30	0.03
Cognitive functioning[a]	94	84.57 ± 2.01	72	87.27 ± 2.29	+2.69	[-3.32-8.71]	p=0.38	0.00	378.50	0.00
Social functioning	94	76.44 ± 3.48	72	79.10 ± 3.77	+2.66	[-4.80-10.12]	p=0.48	31.74	572.89	0.05
Fatigue	94	40.15 ± 5.20	72	35.11 ± 5.43	-5.04	[-12.77-2.69]	p=0.20	116.30	610.31	0.16
Nausea and vomiting[a]	94	11.70 ± 2.12	72	5.09 ± 2.42	-6.61	[-12.96- -0.26]	**p=0.04**	0.00	421.64	0.00
Pain	94	26.21 ± 4.06	72	22.59 ± 4.39	-3.62	[-12.14-4.90]	p=0.40	45.57	746.71	0.06
Dyspnoea[a]	94	20.57 ± 2.45	72	10.52 ± 2.80	-10.38	[-17.74- -3.03]	**p=0.01**	0.00	565.65	0.00
Insomnia[a]	94	27.31 ± 3.14	72	25.46 ± 3.59	-1.84	[-11.26-7.58]	p=0.70	0.00	927.59	0.00
Appetite loss	94	15.98 ± 2.66	72	11.49 ± 2.99	-4.49	[-11.74-2.76]	p=0.22	6.06	547.09	0.01
Constipation	94	13.51 ± 3.08	71	13.06 ± 3.38	-0.45	[-7.50-6.60]	p=0.90	21.18	508.51	0.04
Diarrhoea	94	8.62 ± 2.56	72	12.55 ± 2.86	+3.94	[-2.88-10.75]	p=0.26	6.80	482.81	0.01
Financial difficulties	94	8.59 ± 2.90	72	7.68 ± 3.12	-0.91	[-6.74-4.92]	p=0.76	25.36	349.11	0.07

	Pretest		Posttest		Mean difference (β)	95% CI	P-value	Variance/ σ^2 (hospital)	Variance/ σ^2 (residual)	ICC
	N	Mean ± SE	N	Mean ± SE						
HADS – t2										
Anxiety	94	4.10 ± 0.49	72	4.10 ± 0.53	-0.09	[-1.21-1.03]	p=0.88	0.52	12.91	0.04
Depression	94	3.62 ± 0.61	72	3.09 ± 0.65	-0.53	[-1.51-0.46]	p=0.29	1.52	9.89	0.13
Total	94	7.77 ± 1.09	72	7.16 ± 1.16	-0.62	[-2.54-1.30]	p=0.53	4.36	37.69	0.10
Number of consultations needed for decision-making	111	1.24 ± 0.06	95	2.12 ± 0.07	+0.89	[0.75-1.02]	**p<.001**	0.01	0.25	0.03
Consultation duration (MM:SS)[c]	105	24:10 ± 02:42	61	35:24 ± 2:58	+11:14	[06:49-15:38]	**p<.001**	643848.69 sec.^{2}	114349.79 sec.^{2}	0.15
Number of days from diagnosis-treatment decision	111	34.31 ± 3.41	95	42.40 ± 3.69	+8.09	[-1.82-18.00]	p=0.11	0.00	1239.27	0.00
Number of days from treatment plan-start treatment[d]	89	56.58 ± 24.87	66	47.66 ± 26.53	-8.92	[-51.77-33.93]	p=0.68	2423.62	17151.68	0.12

All data are presented as n (%) unless otherwise specified. Values are model-estimated means (± SE) from multilevel models with random intercepts for patients nested within hospitals. Mean difference = estimated fixed effect of post-pre change.

[a]Model convergence issues caused by lack of hospital-level variance.

[b]Unadjusted Fisher's exact test was performed because of low cell counts.

[c]Only patients of whom all consultations were audiorecorded, were included in this analysis.

[d]Only patients receiving active treatment were included (active surveillance, watchful waiting, and best supportive care were excluded).

*These items contribute towards the total score for ACEPP Subscale 1A.

Appendix VI: Supplementary Table S5

Supplementary Table S5. Categorical secondary and exploratory outcomes by group

Outcome	Pretest n (%)	Posttest n (%)	P-value
Control preference scale - preferred			
Active	38 (37)	29 (37)	p=0.89[b]
Shared	42 (40)	34 (43)	
Passive	24 (23)	16 (20)	
Control preference scale - actual			
Active	49 (48)	48 (60)	p=0.07[b]
Shared	29 (28)	23 (29)	
Passive	25 (24)	9 (11)	
Referral for treatment	4 (3.6)	3 (3.2)	p=1.00[a]
Chosen treatment – localized RCC			
Partial nephrectomy	31 (41)	21 (36)	p=0.09[b]
Radical nephrectomy	15 (20)	5 (8.6)	
Focal therapy	14 (19)	10 (17)	
Active surveillance	13 (17)	20 (35)	
Radiation therapy	-	1 (1.7)	
Other	2 (2.7)	1 (1.7)	
Chosen treatment – metastatic ccRCC			
Checkpoint inhibitor	-	3 (8.1)	p=0.49[b]
Tyrosine kinase inhibitor	3 (8.3)	2 (5.4)	
Dual checkpoint inhibition	22 (61)	22 (60)	
Checkpoint inhibitor + tyrosine kinase inhibitor	2 (5.6)	2 (5.4)	
Watchful waiting	9 (25)	7 (19)	
Best supportive care	-	1 (2.7)	

All data are presented as n (%) unless otherwise specified.
[a]Fisher's exact test was performed
[b]Chi-square test was performed

PART IV

Implementation of the shared decision-making intervention

Chapter 8

Insights into successful implementation of a shared decision-making (SDM) intervention for patients with renal cell carcinoma.

C.C. Bresser
H.H.E. van Melick
B.M.M. van den Berg
F.C.K. Dolk
P.B. van der Nat*
M.M. Garvelink*

*Authors contributed equally and share last authorship

Under review

Abstract

Objectives: Shared decision-making (SDM) and patient decision aids (PtDAs) can improve the quality of treatment decisions, yet their uptake in routine care often remains limited. To determine whether a SDM intervention for renal cell carcinoma (RCC) can be sustainably integrated into clinical practice, this study aimed to 1) assess implementation of a SDM intervention, 2) evaluate PtDA use by patients, and 3) explore the experiences of patients and healthcare professionals (HCPs) with the implementation process and the PtDA.

Methods: Mixed methods evaluation of the implementation of a SDM intervention, consisting of a PtDA and HCP training, in six Dutch hospitals. Implementation activities were documented, PtDA use rates were derived from log data. To assess experiences from end-users, semi-structured interviews were conducted with patients and HCPs.

Results: The SDM intervention was implemented across all six participating hospitals, with only minor adaptations to local workflows. Although the overall implementation structure was similar, there was variation in the timing of PtDA provision, the HCPs involved and patient participation rates. The majority of patients accessed and used the PtDA, completed values-clarification exercises and reported high levels of satisfaction. Both patients and HCPs viewed the PtDA as a valuable, structured tool that facilitated SDM and enhanced the quality and focus of treatment consultations in routine RCC care.

Conclusions: These findings suggest that a structured implementation strategy could successfully integrate a SDM intervention into RCC care.

Practice implications: To ensure long-term, widespread adoption of the SDM intervention in routine practice, sustained integration requires attention to key process factors, such and sufficient resources and collective team engagement.

Introduction

The use of patient decision aids (PtDAs) to support shared decision-making (SDM) has been shown to consistently improve the quality of clinical decisions, increase patient knowledge, and enhance patient involvement in care[1,2]. However, translating PtDAs from research into routine clinical practice remains challenging. Despite rigorous evaluation and demonstrated efficacy, less than half of the PtDAs studied in trials continue to be used once research funding and structured implementation efforts cease[3]. Many PtDAs fail to achieve sustained use due to limited integration in clinical workflows, insufficient institutional support and the absence of a long-term implementation plan[3,4]. These findings highlight that developing a high-quality PtDA is not enough in itself. Achieving an impact in everyday care requires deliberate, well-designed implementation strategies.

Renal cell carcinoma (RCC) is the most common type of kidney cancer, and treatment decisions often involve complex trade-offs between achieving oncological control, minimizing side effects and improving quality of life[5]. Several treatment options exist that differ in these respects, and selecting the optimal treatment is a multidisciplinary process involving various specialists to ensure comprehensive patient care. These trade-offs require careful consideration by patients and HCPs to ensure that the chosen treatment aligns with the patient's preferences and values. To facilitate this process, PtDAs for RCC have been developed to support SDM in clinical practice[6,7]. As PtDA implementation must fit the specific demands of this multidisciplinary context, we incorporated evidence-based insights on SDM implementation[4]. Multifaceted approaches that address barriers at multiple levels are particularly effective in embedding SDM in practice[8,9]; efforts initiated early in the development process improve long-term integration into routine care[4]; and HCP training has the greatest impact when it is inter-professional and delivered to the entire care team involved in the decision-making process, promoting consistency and shared ownership[10]. Guided by these principles, we implemented a SDM intervention consisting of PtDA and HCP training. This intervention combined co-production with end users, team-level training, patient activation, senior-level support and continuous evaluation for improvement.

Understanding how PtDAs can be effectively embedded within the RCC care pathway is essential to ensuring their sustained and meaningful use. Mapping implementation processes and determinants prior to large-scale introduction is therefore key to informing the development of context-sensitive, tailored implementation strategies. This study builds on the SDM-RCC study that evaluated the effectiveness of a SDM intervention for RCC consisting of PtDA implementation and HCP training[11]. This study demonstrated that using the intervention increased observed and perceived levels of SDM and the number of treatment options discussed during consultations[12]. To ensure long-term implementation and upscaling of the

PtDA, the current study aims to investigate the implementation of the SDM intervention and to determine its potential for sustainable embedding in routine care. Therefore, this study has three objectives: 1) to assess implementation of the SDM intervention in each participating hospital; 2) to evaluate PtDA use by patients; and 3) to explore the experiences of patients and HCPs with (implementation of) the SDM intervention.

Material (Patients) and Methods

Study design

This study is part of the SDM-RCC study[11], a multicenter pretest-posttest cohort study in which a SDM intervention was implemented in six Dutch hospitals, starting in November 2023 with patient inclusion and follow-up continuing through November 2025. Here, we will focus on the post-implementation phase. Ethical approval was obtained from the Medical Research Ethics Committees United (reference W22.121/NWMO22.06.013). Local feasibility was approved in each participating hospital. Written informed consent was obtained from all patients. Confidentiality was ensured through study ID use and handling of personal data complied with EU General Data Protection Regulation and any local regulations.

The SDM intervention

The SDM intervention comprised two PtDAs for cT1 renal masses and metastatic clear cell RCC (ccRCC), developed in collaboration with ZorgKeuzeLab, a company specialized in the development and implementation of PtDAs, and in co-creation with patients and HCPs[6,7]. The PtDAs consist of three components: 1) a decision aid handout providing an overview of treatment options; 2) an online PtDA offering detailed information about RCC, treatment options, and values-clarification exercises (VCEs); and 3) a decision aid summary to support decision-making during the consultation.

The PtDAs were implemented using a strategy guided by the Consolidated Framework for Implementation Research (CFIR)[13]. This strategy included a training for HCPs on SDM and PtDA use, a preparatory e-learning, and feedback on SDM based on recorded consultations from the pretest-period of the study. The implementation was tailored to the context of each specific hospital, with preparatory meetings held at all sites to align the PtDA with the existing care pathway. To encourage ongoing use, HCPs received regular feedback dashboards displaying PtDA utilization data (e.g. number of patient logins and distribution per HCP). Hospitals can usually access the PtDAs via a subscription model provided by ZorgKeuzeLab, which entails implementation and maintenance costs. However, in the context of this study, the PtDAs were made available free of charge.

Measures and procedures

For this mixed-methods study, three objectives were formulated to evaluate the implementation of the SDM intervention.

Assessing implementation of the SDM intervention in each hospital (workflow)

Implementation activities and HCP training participation were systematically documented. The researcher recorded attendance at SDM training sessions using attendance lists. In addition, the researcher observed and registered how the SDM strategy was integrated into each hospital's workflow.

Evaluating PtDA use by patients (participation rate)

Participation rates were calculated by dividing the number of patients who accessed the online PtDA by the total number of patients enrolled in the SDM-RCC study during the post-test period (i.e. after implementation of the SDM intervention). Usage data were obtained from ZorgKeuzeLab, the organization involved in the development of the PtDA. Additional log data provided information on how frequently patients accessed the PtDA and which sections of the website they visited (i.e. information on RCC, treatment information, VCEs, or treatment preference).

Assessing experiences of patients and HCPs with (implementation of) the SDM intervention

Semi-structured online interviews were conducted with patients and HCPs to investigate their experiences with the SDM intervention and its implementation in clinical practice. Eligible HCPs were invited after implementation of the SDM intervention; patients were invited after completing the last questionnaire for the study. All interviews were conducted by a trained researcher (CB) using a predefined interview guide, which covered experiences with decision-making, PtDA use and the implementation process (Appendix I/II). A minimum of 15 HCPs and 12 patients were interviewed, including at least one medical specialist and one nurse per hospital. The interviews were audio-recorded, transcribed verbatim, and analyzed in Atlas.ti using a combined inductive-deductive approach guided by the CFIR and 4SDM frameworks[13,14]. Two researchers (CB, MM or JW) coded the transcripts independently and resolved any discrepancies through consensus discussions. Recruitment continued until theoretical saturation was reached, and member checks were performed to ensure credibility. Illustrative quotes were selected to support key themes.

Results

The SDM intervention was implemented across all six participating hospitals.

Assessing implementation of the SDM intervention in each hospital (workflow)

The SDM intervention was implemented across ten teams in six hospitals. The PtDA for localized RCC was implemented in the urology teams of all six hospitals, while the PtDA for metastatic ccRCC was implemented in four oncology teams providing care for patients with metastatic ccRCC. In the remaining two hospitals, patients with metastatic ccRCC were routinely referred elsewhere for systemic treatment, and therefore the metastatic PtDA was not introduced in these settings. One medical specialist and one nurse were present at each preparatory meeting. In total, 42 of the eligible 49 HCPs were trained (22 medical specialists, eighteen nurses or nurse specialists, and two residents), with an average of five HCPs per team (range 1-7). Attendance rates at the SDM- and PtDA-training sessions varied between teams, ranging from 50% to 100% of the HCPs who were eligible for training.

Figure 1 illustrates the general use of the PtDAs in the workflow implementing the PtDAs, which was largely consistent across teams. All hospitals implemented a second consultation after providing the PtDA, even those where this was not standard practice beforehand. Only minor contextual differences existed in how the intervention was integrated into daily practice across teams. In seven teams, the PtDA was introduced before the multidisciplinary team (MDT) meeting, enabling patient preferences to inform the discussion. In the other teams, the PtDA was offered after the MDT meeting, but before the consultation to make the final treatment decision, still giving patients time to log in to the online PtDA website and prepare questions.

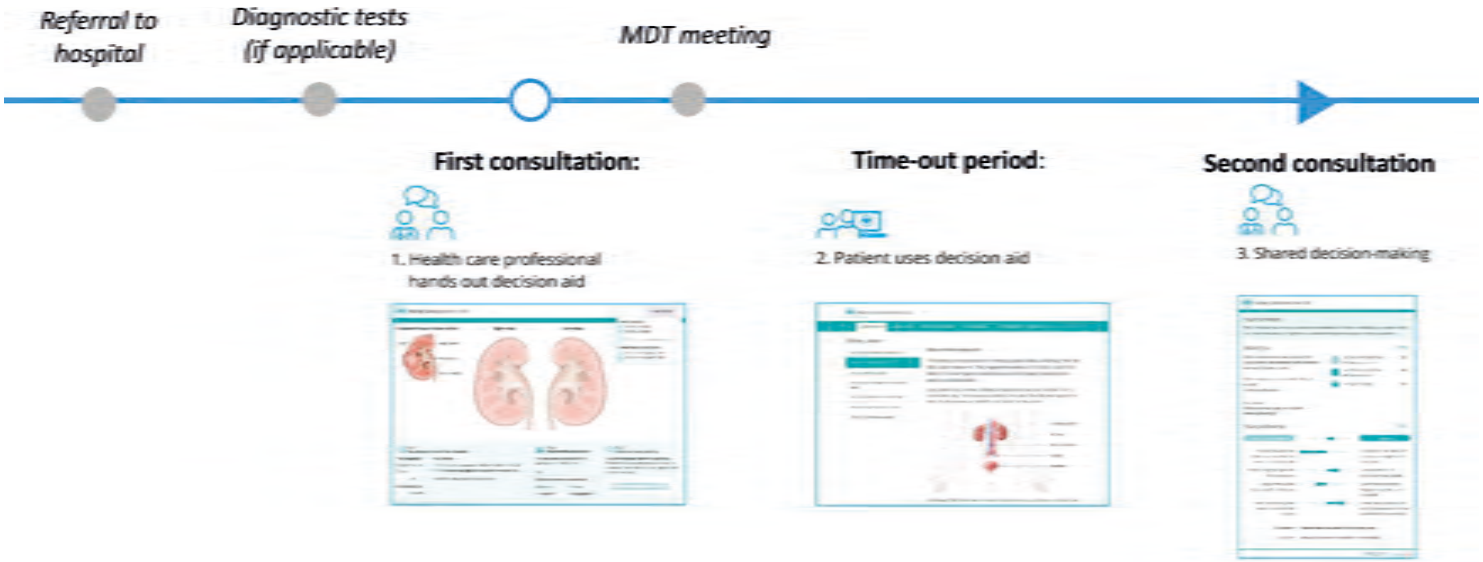

Figure 1. General use of the PtDAs in the workflow.
Abbreviations: MDT = multidisciplinary team

There were also differences in how the PtDA was distributed to patients. In most teams, a HCP provided the decision aid handout in person during the outpatient visit, whereas in two teams, the HCP occasionally sent the material by post after the initial consultation by phone. Furthermore, the type of HCP responsible for introducing and following up on the PtDA varied. In some hospitals, medical specialists distributed and discussed the PtDA themselves, whereas in others, this was primarily the role of the nurse (specialist). In a few settings, responsibilities were shared: medical specialists introduced the PtDA and nurses revisited it with the patient after the time-out period.

Assessing PtDA use by patients (participation rate)

Overall, 79% of the patients with localized RCC and 54% of the patients with metastatic ccRCC included in our study, logged into the PtDA website (Figure 2). Participation rates ranged from 50-100% across hospitals. Patients spent a median of 36 minutes on the PtDA website [IQR 19-50 min.] and on average they visited the website 1.8 times (range 1-7).

RCC information pages were accessed by 82% of localized RCC patients and metastatic ccRCC information pages by 80% of patients with metastatic disease among those who logged into the PtDA. Treatment information was read by 59% of localized RCC patients and by 84% of patients with metastatic ccRCC. 96% of patients with localized RCC completed the VCEs in the PtDA and indicated their treatment preference. Among patients with metastatic ccRCC, 95% completed the VCEs and indicated their preference. Overall, 39 patients (59%) expressed their satisfaction with the PtDA after using it. On a 5-point scale (very dissatisfied, dissatisfied, neutral, satisfied, very satisfied), the majority (n=34, 87%) were either satisfied or very satisfied with the tool. Three patients (8%) were neutral and two patients (5%) reported being not satisfied.

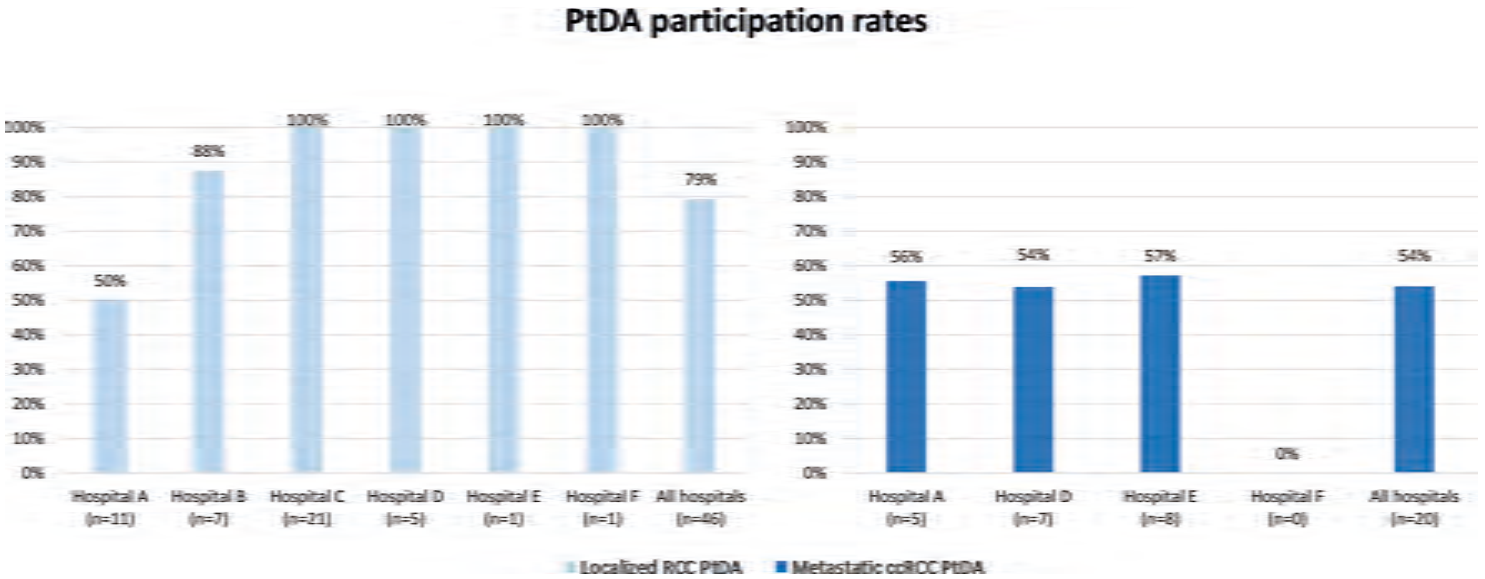

Figure 2. Participation rates of the PtDAs per hospital
Abbreviations: PtDA = patient decision aid

Assessing experiences of patients and HCPs with (implementation of) the SDM intervention

Semi-structured 30-minute interviews were held with twelve patients from five hospitals included in the post-implementation period: six patients with localized RCC and six patients with metastatic ccRCC. Mean age was 67.1 years (standard deviation (SD): 8.5), 42% were female (n=5), and 67% were highly educated (n=8). Fifteen HCPs from five hospitals were interviewed: five urologists, four medical oncologists, three nurse specialists, and three nurses. Median age was 41 years [IQR 40-58.5], thirteen were female (87%), and median experience in urology or oncology care was 14 years [IQR 9.5-22.5]. Median experience with RCC care was 6 years [IQR 4.5-10].

Interviews with patients and HCPs revealed seven main themes, describing how the intervention was experienced and sustained in clinical practice. HCPs perceived the PtDAs as valuable, structured tools that improved patient understanding and facilitated SDM. The PtDAs were considered to enhance consultation quality and stimulate patient engagement, while also prompting HCPs to reflect on their communication and decision-making styles. Similarly, patients described the PtDAs as clear, accessible and consistent with the information they received during consultations. They appreciated being able to review the material at their own pace and reported feeling better informed and more confident when discussing options. They also said that the PtDAs helped them to clarify what mattered most to them. However, some patients noted that they did not use the PtDA, either because the topic was too emotionally charged or because they had already decided on a treatment. Successful implementation depended largely on motivated HCPs, structured training and organizational support. Time constraints, limited digital literacy among patients and a lack of structural financing were reported as barriers. Sustainable use was linked to technical integration within electronic health records (EHRs), regular updates, clear team responsibilities, and institutional endorsement. The main themes and illustrative quotes are summarized in Table 1.

Table 1. Description of findings from interviews with patients and HCPs

Main theme	Illustrative quote
1. The patient decision aid (PtDA) as a valuable addition to the consultation Healthcare professionals (HCPs) described the PtDAs as a clear, transparent structured addition to consultations. They supported the transfer of information by providing accessible, visual explanations of complex treatment options. HCPs noted that patients had a better understanding of their disease and treatment options, and that the PtDAs helped information to 'stick'. Similarly, patients experienced the PtDAs as clear, concise and consistent with what was discussed during consultations. They appreciated being able to review the information at their own pace. For some patients, the PtDA mainly served to confirm a decision that had already been made, before finalizing it together with their HCP.	*"I think it [the PtDA] provides a great deal of transparency, as it lists all the available treatments. There is no hidden agenda - not that I have one - but I can see how some patients might think otherwise. I therefore always explain why patients are or are not eligible for immunotherapy. This creates a sense of openness, which I believe patients really appreciate."* - HCP about the PtDA increasing transparency during consultations
2. The SDM intervention supporting the SDM process Both patients and HCPs found that the PtDA supported multiple stages of the shared decision-making (SDM) process. HCPs noted that the PtDAs made it easier to highlight the existence of choices (step 1 SDM), presented options neutrally (step 2 SDM) and helped patients weigh the pros and cons based on their values and preferences (step 3 SDM) in order to make a well-informed decision (step 4 SDM). Patients reported feeling empowered to participate in the decision-making process, and said that the PtDA helped them to understand their options and consider what is important to them.	*"The PtDA really helped me to organize my thoughts. Of course, I made the decision myself, based on all the information I had gathered, but without the PtDA it would have been almost impossible to come to a choice. It gave structure and direction to my thinking. Without it, you are just relying on conversations and cannot really take charge yourself. As a patient, you have to put in energy; it's not like ordering something like fries. You need that support to come to a well-informed decision."*- patient about the PtDA supporting the SDM process
3. Effects on patient engagement and consultation dynamics HCPs observed that the PtDAs resulted in patients who were more conscious, better informed, and more engaged in the decision-making process. Patients often used the PtDAs as reference material, sometimes with relatives, and returned with more specific questions and clearer preferences. While this was generally considered positive, it occasionally led to confusion when patients thought a choice had already been made before using the PtDA.	*"Perhaps it [the PtDA] actually raises more questions because patients are much more actively involved. I think it does lead to more questions, but I see that as a positive thing. It shows me that the patient has engaged with the material, thought it through and is involved in their own process."* - HCP about increased patient engagement through the PtDA

Table 1 *Continued*

Main theme	Illustrative quote
4. Implementation barriers and facilitators The implementation of the PtDAs varied between hospitals. HCPs emphasized the importance of a motivated team, training and reminders (e.g. feedback reports) in helping to integrate the PtDAs into routine care. They reported that usage 'had to grow' over time, and that training and feedback were key elements of the implementation strategy. The main barriers are time pressure during consultations, limited digital skills or language barriers among patients, inconsistent team involvement and a lack of structural funding. Patients also indicated that not all of them had used the PtDA. Some found it too emotional, while others had already made a decision or preferred to start treatment without additional information.	*"We would like to use it [the PtDA], but I know from experience that it's not cheap. So, when it comes to making a business case within the hospital, the question always becomes: what does it offer compared to what it costs? If the PtDA is expensive, it becomes quite challenging to implement. You can advocate quality and all the good reasons to use it, but it's still quite difficult to implement it structurally."* - HCP about financial barriers to sustainable implementation of the PtDA
5. Organizational and structural conditions for embedding HCPs mentioned several prerequisites for the sustainable embedding of the PtDAs: linking them to the electronic health record (EHR) to facilitate the provision of the PtDA and collection of the PtDA summaries and workflow alignment of the PtDAs in multidisciplinary team (MDT) meeting reports or 'smart phrases' in the EHR. Greater involvement of nurses or case managers in PtDA use and provision was frequently reported by HCPs. Having the same HCP for consecutive consultations was seen as important for continuity, coherence, and strengthening the SDM process.	*"Sometimes, the treatment choice has already been made during the first consultation with the oncologist, after which everything is set in motion. Then I find it difficult to bring it [the PtDA] up in the second consultation and say: 'You still have the option to choose for a tyrosine kinase inhibitor'. I'm not always sure what the oncologist has discussed or emphasized, and that can easily cause confusion."* - HCP about the importance of continuity and coordination between consultations
6. Professional reflection and learning HCPs reported that the implementation of the SDM intervention made them more aware of their influence and communication style during consultations. This process encouraged reflection on presenting real choices, even when the treatment options were not fully equivalent. HCPs described this as a form of professional development that fosters a more transparent decision-making process.	*"I also became more proactive in emphasizing that there is a choice. For a long time, we questioned whether a real choice existed when treatment outcomes were not entirely equivalent. It's something I have had to come to terms with, realizing that there are actually choices to be made. So yes, I have become much more engaged with shared decision-making in my consultations."*- HCP about reflecting on professional learning and growing awareness of SDM

Main theme	Illustrative quote
7. Sustainability and future needs HCPs expressed a desire for the PtDAs to be available nationwide to promote uniform care, structural financing and regular content updates in line with new treatment guidelines. They also emphasized the importance of recognition by professional societies and the need for nurse(s) (specialists) to play a broader role in the decision-making process. According to HCPs, sustainable use depends on technical integration, organizational support, and continuity within care teams.	*"It would work better if oncology nurses were more involved. Currently, they are only minimally engaged. They often just say: "Oh yes, that form is somewhere." If they were more involved, patients could receive the PtDA in advance and be better prepared. There really needs to be more support for this within the team."* - HCP about the need for broader team involvement

Abbreviations: EHR = electronic health record, HCP = healthcare professional, MDT = multidisciplinary team, PtDA = patient decision aid, SDM = shared decision-making.

Discussion and conclusion

Discussion

This study evaluated the implementation of a SDM intervention for RCC across six Dutch hospitals, examined the use of the PtDAs by patients, and explored the experiences of both patients and HCPs. The intervention was implemented in all hospitals, with adaptations made to local workflows. While the overall implementation approach was similar, differences were observed in how and when the PtDAs were provided and which HCPs were involved. Participation rates varied between hospitals, but most patients used the PtDA and engaged with it, completing VCEs and expressing high satisfaction with the tool. Both patients and HCPs considered the PtDAs valuable and structured tools that support SDM and improve the quality of consultations. This study led us to make three main observations.

First, both patients and HCPs found the PtDAs to be clear and structured tools that improved understanding and transparency during consultations. Patients reported that it helped them organize their thoughts, weigh up their options and make well-informed decisions. These findings are in line with existing literature on the effects of PtDAs for several clinical conditions[1,15]. Our implementation adds to the existing evidence by demonstrating that these positive perceptions remained consistent across hospitals with different workflows, highlighting the robustness of the tool in routine RCC care. The RCC-specific design, developed through iterative input from patients and clinicians, was particularly well-received. Meanwhile, HCPs emphasized that the PtDA made it easier to explain complex treatment choices and increased transparency in communication. Additionally, they noted that the standardized information improved consistency between HCPs and facilitated more coherent counselling across consultation stages. Taken together, these findings demonstrate that, in addition to enhancing understanding and communication within individual consultations,

our implementation shows how a condition-specific, workflow-aligned PtDA can support SDM in RCC care.

Secondly, we observed significant variation in participation rates across hospitals, ranging from 50 to 100%. Once patients had accessed the website, the full PtDAs were well used, indicating active engagement. This suggests that the way patients are introduced to and referred to the PtDA is crucial for uptake. To improve initial engagement, it is important to ensure that patients recognize the relevance and added value of accessing the PtDA early in the decision-making process. Similar variability has been reported in other studies on PtDA implementation in breast cancer and stroke care, where participation rates ranged from 29-83% and 27-100%, respectively[16,17]. In our study, we could not assess the relation between differences in participation rates and local implementation practices, including the timing of PtDA introduction (before or after the MDT meeting) and the type of HCPs responsible for delivering and discussing it. It is notable that participation rate was lower for the metastatic PtDA than for the localized version. This may reflect the higher disease burden, greater clinical complexity, or shorter decision timelines in the metastatic setting. Our observations suggest that organizational factors, such as having a small, dedicated team or involving nurses in follow-up consultations, may contribute to higher levels of patient engagement. Additionally, although some teams had higher attendance rates at HCP training than others, HCP enthusiasm and confidence in SDM and PtDA use appeared to influence implementation more than attendance alone. These findings emphasize the importance of consistent integration of PtDAs within the care pathway, supported by clear team roles and aligned workflows, for successful implementation[4,18].

Last, while many studies have evaluated the effects of PtDAs on decision quality and patient outcomes, there is a lack on research on the effectiveness of implementation strategies[19]. Our study addresses this gap by assessing PtDA use, as well as the contextual, organizational and individual factors that influence successful implementation and sustained adoption in RCC care. In our study, several barriers for sustainable implementation of the PtDAs were identified, consistent with findings from previous studies[18,20,21]. These included time constraints, inconsistent team involvement and the absence of structural funding. HCPs stressed that long-term use requires a motivated team, structured training, and organizational support. Importantly, these elements should not be limited to the initial implementation phase; they require ongoing reinforcement to maintain engagement and usage over time. A key concern is the potential decline in PtDA use and SDM levels once study-based support ends[4]. Ensuring long-term sustainability will therefore depend on structural integration of the PtDA into workflows (e.g. linking to the EHR[22]), clear allocation of team responsibilities, ongoing feedback to HCPs, and stable financial arrangements, as well as continuity of care through involvement of the same HCP across consultations and active participation

of nurses in the decision-making process. At the patient level, HCPs reported that limited health literacy primarily hindered their ability to offer the PtDA, as some patients struggle to understand complex medical information and weighing treatment options. Similarly, Duan et al. found that low health literacy, inaccurate disease understanding, poor communication skills and emotional factors limited patients' ability to participate effectively in decision-making[23]. Although the PtDA was designed to address these barriers by providing structured, accessible information, it must still reach patients to ensure the equitable and sustainable implementation of SDM.

Strengths and limitations

This study has several strengths. Firstly, the mixed-method design, which combined quantitative data on PtDA use with qualitative interviews with end-users, provided a comprehensive understanding of PtDA adoption and use in clinical practice. Secondly, the multicenter setting, which included both localized and metastatic RCC care, increases the relevance of the findings across different organizational contexts. Thirdly, this study is part of a broader research initiative involving the development and evaluation of the PtDAs. This allows insights from multiple complementary studies to strengthen the interpretation and validity of the current findings.

However, some limitations should be noted. First, some of the interviewed HCPs were involved in developing the PtDA, which could have introduced positive bias as they were early adopters or clinical champions. Nevertheless, these HCPs demonstrated their ability to reflect critically on the implementation process and the practical application of the PtDA in clinical practice. Their involvement highlights the importance of engaging end users from the start of the development, in order to ensure clinical relevance, ownership and long-term sustainability. Secondly, most of the participating patients were highly educated, which may have influenced their level of engagement and limited the generalizability of the findings to populations with lower health literacy. Thirdly, we assessed the overall participation rate, rather than the exact implementation rate (i.e. the proportion of eligible patients who received the PtDA), since it was not possible to determine patient eligibility on an individual patient level. This restricts how precisely the consistency and extent of PtDA delivery can be evaluated and makes it challenging to monitor long-term maintenance and quality improvement. Finally, as data were collected shortly after implementation, long-term sustainability could not be assessed. Future studies should examine sustained PtDA use within hospitals, with clear criteria to measure maintenance over time, as well as strategies to support broader patient engagement and organizational embedding.

Conclusion and practice implications

This study demonstrates that a SDM intervention, combining HCP training with PtDAs for RCC, was implemented across participating hospitals with minor adaptations to local workflows (objective 1). Most patients actively used the PtDAs, which supported their understanding of, preparation for, and engagement in, the decision-making process (objective 2). Both patients and HCPs perceived the PtDAs as valuable tools that enhanced information exchange and promoted more informed, preference-congruent treatment choices. Sustainable embedding requires continued attention to process-related factors, including deliberate time-outs, sufficient resources, and collective team commitment, as well as national coordination and structural funding to ensure the long-term, system-wide integration of SDM in RCC care. Furthermore, gaining structural insight into PtDA use and implementation rates will support ongoing monitoring and quality improvement (objective 3).

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Appendix I. Interview guide semi-structured interviews - patients

- Could you introduce yourself please?

Decision-making process:

- What are your experiences with receiving the diagnosis?
- Can you tell me how you chose your treatment?
- How did you experience the decision-making process?
- Who was involved (both within the hospital and in your personal environment), and what was their role?
- How were you informed that a decision about your treatment needed to be made, and that your opinion was important in this? (SDM step 1)
- Did you receive the handout of the decision aid?
- What treatment options did you have, and what information did you receive about them? (SDM step 2)
- Did you use the online decision aid? If yes, why? If no, why not?
- What were the most important considerations for you in choosing a treatment? How were these taken into account in your decision? (SDM step 3)
- Did you use the summary of the decision aid in this process?
- What was the final decision, and how was it made? (SDM step 4)
- Do you feel you were actively involved in the decision-making process? Why?
- How did you experience the role of the various healthcare professionals?

The patient decision aid (if it was used):

- What did you think of the decision aid?
- When/where did you use it?
- How was the decision aid handed out?
- With whom did you discuss the decision aid? (healthcare professional/relatives)
- Did you find it clear how to use the decision aid?
- Did you miss any information?
- Did you understand the information?
- How was it to use the decision aid?
- What did you like about the decision aid?
- What did you like less?
- What did the decision aid offer you? What was especially helpful?
- To what extent did the decision aid influence your final decision? If it had influence: Which part/which information?
- To what extent was the decision aid discussed in the consultation with the healthcare professional?
- Would you recommend other patients to use the decision aid?

Appendix II. Interview guide semi-structured interviews - HCPs

Decision-making process:

When you think back to your most recent consultations with patients where you used the decision aid…

- To what extent do you tell patients that a decision needs to be made about their treatment and that their opinion is important in this? (SDM step 1)
- How do you present treatment options to patients? (SDM step 2)
- To what extent do you ask what is important to the patient? (SDM step 3)
- How do you incorporate this information into the decision-making process? (SDM step 4)
- To what extent did the decision aid influence this process?

The patient decision aid:

- What did you think of the decision aid?
- To what extent did you use the decision aid? Why or why not?
- When/where did you use it?
- With which patients did you use the decision aid? Why?
- Which parts of the decision aid did you use? (decision aid handout, summary)
- How is the decision aid distributed?
- What did you think of the decision aid?
- Did you find it clear how to use the decision aid?
- Did you miss any information?
- What did you like about the decision aid?
- What did you like less?
- What did the decision aid offer you? What was especially helpful?
- To what extent was the decision aid discussed during the consultation?
- To what extent is it your responsibility to use the decision aid?
- Would you recommend the decision aid to future patients? Why?
- What do your colleagues think about the decision aid? To what extent have you discussed it with them?
- Would you recommend the decision aid to colleagues in other hospitals?
- To what extent are you willing to continue using the decision aid after this study? Why?
- To what extent are you ready to start using the decision aid?
- What does the decision aid contribute to shared decision-making?
- What are the advantages of using the decision aid?
- What are the disadvantages of using the decision aid?

Implementation strategy:

- What did you think of the implementation strategy (shared decision-making training, training on how to use the decision aid, evaluations) for the decision aid? Did you miss anything? If yes, what?
- What is the role of the decision aid in the care process? Have there been any organizational changes to implement the decision aid?
- To what extent is the implementation strategy sufficient to properly embed the decision aid into the care pathway?

Chapter 9
Summary and general discussion

Summary

Part I. The current situation

In Part I, we evaluated the current state of SDM in clinical practice through a review of the existing literature. Additionally, we examined treatment variation among cT1a RCC patients. **Chapter 2** reports the findings of an (updated) systematic review on patient involvement in decision-making, as measured using Observing Patient Involvement in Decision Making (OPTION)-instruments. Following an extensive literature search, 174 studies, comprising almost 20,000 clinical consultations, were included in the review. Of these, 102 studies used OPTION-12, 64 used OPTION-5, and four studies used both instruments. A meta-analysis was conducted to provide an overall indication of the level of observed patient involvement in clinical practice. Meta-analysis of means revealed that the mean level of SDM, as per the total OPTION-score, for studies unaffected by interventions was 25 for OPTION-12 and 32 for OPTION-5. Subgroup analyses were performed to examine the association between OPTION-scores and several study variables. These analyses showed that studies incorporating SDM interventions had significantly higher OPTION scores for both instruments. Finally, meta-regression analyses were performed to explore potential moderators of OPTION-scores. For both OPTION-12 and OPTION-5, a longer consultation length was found to be significantly associated with higher OPTION-scores. Additionally, for OPTION-12, the proportion of female patients was found to be a moderator for higher scores. Overall, this review shows that over the last decade, little improvement has been observed in the extent to which HCPs involve patients in SDM, whereas studies implementing SDM interventions, including PtDAs, consistently report higher OPTION-scores. These observations highlight the importance of developing and evaluating structured interventions to support SDM in RCC care.

Chapter 3 reports on variation in the treatment of cT1a RCC across seven Dutch teaching hospitals. For SDM to function well, patients must be offered a comparable and complete set of treatment options, regardless of which hospital they visit. Therefore, it is essential to understand how treatment decisions vary across hospitals in order to interpret the context in which SDM for RCC takes place. This historical multicenter cohort study included 501 patients with 544 cT1a renal cancer tumors. In total, 65% of tumors were treated with active treatment, although the proportion varied substantially between hospitals (44-85%), with notable differences in the specific treatment modalities selected. This variation persisted after stratification by comorbidity and tumor characteristics. Multivariable analyses revealed that higher comorbidity was associated with lower odds of active treatment. In contrast, increasing tumor complexity was linked to a higher likelihood of receiving active treatment. Notably, the

hospital of diagnosis remained an independent predictor of the treatment received, even after adjusting for case mix (i.e. comorbidity, kidney function and tumor complexity). These findings demonstrate considerable unwarranted treatment variation that cannot be explained by patient- or tumor factors. The results highlight the need for more standardized care pathways, robust outcome measurement, structured SDM and inter-hospital benchmarking, to enhance the quality and consistency of RCC care.

Part II. Development of two patient decision aids for RCC

Part II focuses on the development of two PtDAs designed for different stages of RCC. Both PtDAs were tailored to the Dutch healthcare context, offering an improvement on existing international RCC PtDAs. This was achieved by ensuring compatibility with national guidelines, and by incorporating elements that had been systematically developed and user-tested, such as personalized summaries. **Chapter 4** outlines the development of a PtDA for patients with cT1 renal masses. In this setting, multiple management strategies are possible and individual preferences play a significant role[2]. Informed by contributions from patients, HCPs and a patient representative, we have co-created a PtDA that primarily aims to structure conversations around cT1 RCC treatment choices, developed in accordance with established PtDA development guidelines such as the International Patient Decision Aids Standards (IPDAS) framework[6]. The PtDA comprises a decision aid handout outlining options, an online website providing balanced information and values-clarification exercises, and a personalized summary to support the follow-up consultation. End-users consistently rated the PtDA as clear, accessible and relevant. The tool complies with all IPDAS criteria and is expected to encourage more consistent, patient-centered decision-making in the treatment of localized RCC.

Chapter 5 focuses on the development of a PtDA for metastatic clear-cell RCC (ccRCC) in a palliative setting. This context is characterized by rapidly evolving systemic therapies and a significant disease burden for patients. As with the PtDA for patients with cT1 renal masses (Chapter 4), we applied the same structured and guideline-based development process to ensure methodological consistency and relevance. The needs assessment revealed distinct challenges compared with localized RCC: patients reported uncertainty about treatment choices, a desire for transparent information on prognosis and treatment impact, and a need for guidance on psychosocial and lifestyle issues. HCPs recognized the value of a tool that could help patients navigate complex treatment decisions and prepare for discussions about goals of care. The resulting web-based PtDA was refined through iterative testing and received positive feedback regarding its clarity and relevance for metastatic disease. It meets all IPDAS criteria and addresses decisional needs specific to metastatic ccRCC.

As with the localized RCC PtDA, it is expected to facilitate patient-centered decision-making in routine RCC care.

Part III. Effects of the patient decision aids as part of an shared decision-making intervention

Chapter 6 presents the study protocol for the 'Shared Decision-Making in Renal Cell Carcinoma' (SDM-RCC) study. This study evaluated the impact of a comprehensive SDM intervention on the decision-making process and outcomes for patients with RCC across six Dutch hospitals. The intervention combined online PtDAs (**Chapter 4** and **5**) with training for HCPs in SDM principles and the effective use of the PtDAs. The study used a multicenter, prospective pretest-posttest design. Patients with either localized (cT1) or metastatic RCC were included. In **Chapter 7**, the effects of the SDM-RCC study are reported. A total of 206 patients from six hospitals were included, with 111 in the pretest group and 95 in the posttest group. The primary outcome was the quality of the decision-making process, as assessed through OPTION-5 scores. Secondary outcomes included patients' and HCPs' perceptions of decision-making quality, overall decision quality and the extent to which the intervention was implemented in clinical practice. This was evaluated using user statistics and semi-structured interviews with both patients and HCPs. Quantitative questionnaire data were analyzed alongside qualitative interview data, allowing for methodological triangulation. Our results showed a significant increase in the observed level of SDM after implementation of the SDM intervention. Furthermore, SDM levels reported by HCPs, and the use of outcome information during consultations increased after implementation of the SDM intervention. There was no significant difference in patient-reported SDM levels between pre- and posttest groups. Additional findings included an increase in the number and duration of consultations, as well as higher decisional conflict scale (DCS) uncertainty scores after implementation of the intervention. However, patients' decision-making roles remained unchanged, as most patients already reported a shared or active role.

Part IV. Implementation of the SDM intervention

In **Chapter 8**, the implementation of the SDM intervention in routine RCC care was evaluated. A mixed-methods approach was used across six Dutch hospitals to evaluate the integration of the intervention into clinical practice, the extent to which the PtDAs were used by patients, and the experiences of patients and HCPs. The intervention was implemented in all participating hospitals, with only minor required adjustments to existing workflows. While the overall implementation structure was consistent across sites, variations were

observed in the timing of PtDA provision, the HCPs involved, and patient participation rates. A significant number of patients accessed and used the PtDA throughout the two disease stages, frequently completing the values-clarification exercises and expressing high levels of satisfaction. Both patients and HCPs considered the PtDAs to be helpful, structured tools that supported SDM and improved the quality of consultations. These results suggest that our structured implementation strategy effectively incorporated the SDM intervention into RCC care. However, long-term adoption will depend on sustained attention to processes, resources, and team engagement. For this, we outline specific recommendations in this chapter.

General discussion

The overarching aim of this thesis was to improve SDM for treatment decision-making in RCC. Together, the studies in this thesis demonstrate the current implementation of SDM in routine care, the variation in treatment decisions, particularly for small renal masses, and the requirements of patients and HCPs to engage meaningfully in SDM consultations. Throughout this thesis, we found that both patients and HCPs recognized the relevance of SDM, but each group encountered different challenges. Patients emphasized the need for clear, structured information to enable them to participate meaningfully, whereas HCPs encountered practical and contextual constraints that limited the consistent application of SDM in practice (**Chapter 4 and 5**). This work also shows how a structured, evidence-based SDM intervention can support the SDM process, leading to higher observed SDM levels and positive uptake of the PtDAs across clinical settings (**Chapter 7 and 8**). While these findings highlight encouraging progress in SDM, they also reveal persistent structural and conceptual challenges that continue to influence how SDM is understood, measured and implemented in clinical practice. These insights extend beyond the individual findings and raise broader questions.

In this discussion, I reflect on four overarching themes that emerged throughout the studies: **the role of patient empowerment in meaningful participation in SDM**, **expectations of disease-specific SDM research**, **fragmentation of SDM measurement**, and **the increasing importance of artificial intelligence (AI) in the practice and evaluation of SDM**.

The first theme is **the role of patient empowerment in meaningful participation in SDM**, concerning the role of the patient and the timing of their involvement. Traditional SDM models describe a sequence of consultation-based steps: creating choice awareness (step 1), explaining options (step 2), discussing preferences (step 3), and making the decision (step

4)[7]. However, SDM often depends on processes that begin well before the consultation itself. Recent research shows that patients' readiness for SDM, including their understanding of the need for their own input, their perceived autonomy, and their expectations about decision-making, develops prior to the clinical encounter and substantially influences the effectiveness of SDM[8–10]. Patients' expectations, sense of autonomy and assumptions about their role in decision-making vary enormously. Many patients (unconsciously) expect a paternalistic model of care, in which the HCP selects the optimal treatment. Others do not realize that modern health decisions frequently involve trade-offs that reflect their personal values. Although this readiness also applies to HCPs, they are increasingly being trained in the principles of SDM[11], meaning they typically enter the consultation well prepared. If patients enter a consultation unaware of the fact that their input is essential, the perceived power imbalance in the HCP-patient relationship may make them hesitant to express preferences or ask questions, which could limit the SDM process from the start. This raises the question at which point SDM actually begins. Much of the literature implicitly assumes that SDM begins when the HCP informs the patient that they have a choice (i.e. step 1 of the SDM process)[12]. In practice, however, the foundation of SDM can be established earlier, when patients realize that their perspective is important and that their values matter, and that decisions are not just a matter of medical correctness, but also of personal preference[13]. While these insights can be introduced during the consultation, they may also emerge beforehand, shaping how engaged patients participate in the conversation. Without this preparatory mindset, tools such as PtDAs may be underused or misunderstood. Patients who do not recognize the importance of reflecting on their own values may view such tools as obligations rather than support. Consequently, even well-designed interventions may fail to achieve their intended effect, when they are not properly introduced[9]. Recognizing this emphasizes that SDM is not only a communication method, but also an approach to care. This process depends on cognitive and emotional readiness, which is not automatically present in all patients or HCPs for that matter. For SDM to be performed in the right way, patients must recognize that they are partners in decision-making, not passive recipients. This means that SDM does not begin with presenting information or options, but with empowerment of patients in helping them to understand that their role matters and that their participation is a precondition for well-aligned decisions. This insight, I believe, broadens the conceptual boundaries of SDM beyond the consultation, calling for a more extensive view in which preparation, expectation setting and patient empowerment form part of the SDM continuum, rather than being additional elements.

The second theme concerns **expectations of disease-specific SDM research**. Throughout this thesis, HCPs frequently expressed the need for 'disease-specific evidence', meaning proof that the use of PtDAs is specifically effective or appropriate for RCC care. This expectation emerged despite the well-established benefits of SDM and PtDAs in broader fields such as oncology, chronic disease management, and primary care, where more than

200 PtDAs have been shown to enhance knowledge, reduce decisional conflict, and facilitate value-aligned treatment choices[5]. The call for RCC-specific evidence reflects a wider pattern in healthcare whereby novel approaches or tools are expected to demonstrate specialty-specific effectiveness before being fully embraced. Rather than rejecting the general value of SDM, HCPs often remain reluctant to implement tools to support SDM without evidence collected specifically in their own area of expertise[14], including in the care of patients with RCC. However, when we consider the fundamental needs of patients facing preference-sensitive decisions, the similarities across SDM processes far outweigh the differences. Several studies suggest that disease-centered HCP beliefs can hinder the implementation of SDM, as HCPs tend to rely on evidence that is closely related to their specific clinical context[15]. Whether a patient is facing breast cancer, inflammatory bowel disease or RCC, the core elements of meaningful decision support do not fundamentally change. Patients want clarity, guidance on weighing benefits and harms, support in dealing with uncertainty, and support to express what matters to them. From this perspective, conducting similar PtDA trials for every disease category seems both scientifically unnecessary and practically inefficient. It places an additional burden on patients and slows the wider implementation of SDM by creating the impression that new tools require disease-specific trials before they can be adopted. The findings of this thesis are consistent with the wider literature on SDM[5,16,17]: the PtDA improved observed SDM levels, was valued by patients and HCPs, and was successfully implemented across multiple hospitals (**Chapter 7 and 8**). Taken together, it becomes reasonable to question whether a disease-specific evaluation was necessary to demonstrate benefits that have already been well established across various clinical contexts. Nevertheless, it is important to note that this thesis offered highly valuable insights into how SDM interventions can be integrated in routine RCC care. It provided practical insights into implementation strategies that would not have emerged without studying this context directly. Here, a more fundamental question was raised, namely why this expectation is maintained despite the robust generic evidence. In my view, the demand for disease-specific evidence stems more from prevailing HCP norms than from scientific necessity. Traditionally, the culture of biomedical research has prioritized disease-specific testing because the physiological effect of drugs depends on the diagnosis. However, SDM is not a physiological intervention, it is an interpersonal process between patients and HCPs. Its effectiveness does not depend on tumor type, but on how information is exchanged, how uncertainty is navigated, and how patient preferences are elicited and incorporated[5]. Therefore, expecting disease-specific evidence for SDM reflects the transfer of biomedical evidence standards to a research domain in which they are not reasonably applicable[18]. In this context, rather than asking whether PtDAs are effective for a specific disease, it is more meaningful to consider how they can be integrated, normalized and sustained within the clinical context of that disease. Although disease-specific research remains relevant, there is no need to repeatedly prove the effectiveness of PtDAs. Instead, research is needed to

understand the contextual factors, workflow dynamics, and content-specific adaptations, that influence the successful integration of PtDAs into routine care and ensure their sustainability. Re-proving the core value of PtDAs for each diagnosis is neither scientifically justified nor practically useful.

The third theme is **fragmentation of SDM measurement**. Many of the outcomes that are used to evaluate SDM, such as decisional conflict, patient involvement and satisfaction, are inherently subjective and cannot be evaluated with the same methodological clarity as traditional clinical outcomes. The field therefore faces a conceptual challenge: the types of outcomes to evaluate SDM do not align with the evidence frameworks that HCPs are used to. This tendency is particularly evident in the context of VBHC, encouraging healthcare systems to prioritize outcomes that matter to patients. Over the past few decades, numerous instruments have been developed in the field to capture different steps of the SDM process (i.e. creating choice awareness, explaining options, discussing preferences, and making the decision) (**Chapter 2**, **6 and 7**)[19–21]. This diversity in measurement tools reflects the conceptual diversity of SDM, yet it also leads to fragmentation of the field. Researchers and HCPs use different tools and scoring systems, each capturing different aspects of SDM[22], and operate without clear thresholds or cut-offs for interpretation. Consequently, the same consultation may be evaluated differently depending on the chosen instrument, underscoring the need for consensus on a limited set of core instruments that allows for meaningful comparison across settings. This phenomenon is not just methodological, it also suggests that the concept of SDM is still developing. This is notable given that efforts to define and implement SDM have been ongoing for several decades. The lack of alignment has encouraged the development of an international, standardized outcome set for SDM, which is part of an international initiative aimed at harmonizing definitions, core constructs, and measurement practices across settings[23]. Throughout the work presented in this thesis, I repeatedly encountered the consequences of this fragmentation. For example, in the review (**Chapter 2**), the absence of clear cut-offs complicated the interpretation of OPTION scores, as it prevented us from determining what constituted 'good' levels of SDM. Similarly, in the effect evaluation (**Chapter 7**), the lack of uniform measurement limited comparability with other studies. This required the use of multiple instruments to capture several aspects of SDM, which introduced additional complexity by requiring subsequent decisions about which perspective and which outcomes should be prioritized. It also increased patient burden, as patients had to complete several questionnaires. Without commonly accepted cut-offs, SDM scores remain descriptive. While they indicate specific communication behaviors, such as whether options were presented or preferences were explored, they provide little guidance on whether the observed level of SDM is clinically meaningful or sufficient. Following the implementation of the intervention, observed SDM improved substantially (OPTION-5 increased from 47.2 to 60.5), with improvements observed in most hospitals and across all

OPTION items. While these findings demonstrate clear behavioral improvement, the absence of agreed cut-offs means that it is still not possible to determine whether post-intervention scores reflect a clinically meaningful level of SDM. The results show that SDM can be improved in RCC care with structured interventions. However, we lack the criteria needed to determine when improvement becomes clinically relevant. Nevertheless, the behavioral changes observed in our study suggest that the intervention was effective in supporting SDM in practice. This contrasts with other quality indicators, where benchmarking and thresholds guide interpretation. However, defining cut-offs for SDM is not straightforward (**Chapter 2**). SDM is not a fixed behavioral checklist, it is a complex process that varies according to clinical context, patient preference, and the complexity of the decision. In addition, SDM behaviors can be initiated by either the HCP or the patient, and they can take different forms while achieving a similar level of involvement. Furthermore, the four SDM steps can be completed correctly by the HCP without achieving genuine SDM, as these steps do not fully capture aspects such as active listening, responsive communication, and empathy. Therefore, defining what constitutes 'good SDM' requires conceptual reflection. Not every decision requires the same level of SDM, nor does every patient desire the same degree of involvement. In this context, SDM measurements are most valuable as a basis for reflection, feedback and raising awareness, rather than as primary endpoints aimed at repeatedly proving effectiveness. This observer-based approach focuses on ongoing learning rather than providing quality assessment. As **Chapter 7** demonstrates, even well-established measures such as OPTION-5 and patient-reported SDM scores require clarity about the specific SDM behaviors they capture and how their outcomes should be interpreted. Without agreed definitions and interpretive criteria, it is unclear how outputs of technological methods should be interpreted. Consequently, their results may simply reflect the uncertainty observed in traditional SDM assessments.

The fourth theme that emerged during my PhD thesis is **the increasing importance of AI in the practice and evaluation of SDM**. Technological tools, particularly those involving large language models (LLM) and machine learning, have recently emerged and are increasingly applied in healthcare[24]. A recent study demonstrates that LLM can effectively evaluate consultations in healthcare, highlighting their increasing relevance in clinical settings[25]. The prospect of automated consultation analysis offers the hope of greater scalability, consistency, and continuous evaluation of SDM. In addition, automated recording systems could address some of the practical challenges identified in this thesis, such as missing audio recordings. This would be achieved by ensuring that consultations are captured systematically, thereby eliminating the need for HCPs to initiate this. Beyond measurement alone, AI may also play a complementary role in supporting SDM in clinical practice. For instance, AI systems could summarize consultations in line with the four SDM steps or automatically produce recordings and summaries for patients to review at home, thereby

improving understanding and preparation. By streamlining administrative and informational tasks, AI systems can free up more time for meaningful dialogue between patients and HCPs, an aspect that is often cited as a barrier to SDM in routine care. Furthermore, AI-driven tools could assist in scanning and synthesizing emerging evidence to help maintain the relevance of PtDAs, prompting timely updates and reducing the risk of patients making decisions based on outdated information. Personalization is another opportunity. AI-enabled PtDAs can adapt the depth of information, presentation style, or values-clarification exercises to suit individual patients' needs, thereby supporting those who struggle with generic materials. However, this raises the question of which elements of SDM can be meaningfully captured by algorithms and which cannot, and what the purpose of such measurements is (e.g. formative feedback or benchmarking). While AI excels at pattern recognition, it struggles to interpret relational nuances, emotional tone, and the context of partnership. These elements are also largely lacking in current SDM instruments, such as OPTION-5 or 4SDM, and are only just beginning to be addressed in the newer observer-based methods being developed in the field[26]. If we wish to utilize AI to measure SDM, the field must first clarify which aspects of SDM are definable, code-able and measurable, and which parts are too complicated for a computer to detect. Without conceptual clarity and methodological standardization, integrating AI could worsen existing inconsistencies rather than resolve them. This tension highlights the need to refine not only the tools used to measure SDM, but also the shared understanding of how to put established SDM definitions into practice. This includes clarifying which behaviors are essential for demonstrating SDM during a consultation, and which are supplementary. While there is expert consensus on SDM definitions, their implementation remains inconsistent. This underscores the importance of focusing on observable behaviors and the underlying purpose of SDM rather than definitional statements alone.

Together, these themes emphasize the need to shift the focus of SDM research and practice. Towards activating patients earlier to enable meaningful participation, moving beyond repeatedly demonstrating the value of disease-specific PtDAs, advancing more consistent SDM measurement with agreed thresholds, and integrating AI as a new dimension of SDM practice and evaluation. Although some HCPs still have doubts about SDM, this thesis contributes to the growing body of evidence supporting its application in RCC care. The relevant questions increasingly concern how SDM can be conceptually grounded, methodologically coherent, and systemically embedded in healthcare. Although this thesis focuses on RCC, it highlights that many challenges in SDM may not be disease-specific. Rather than repeatedly demonstrating the value of PtDAs to support SDM in specific clinical areas, I think the task ahead is to strengthen the conceptual foundations that will support sustainable, equal and meaningful SDM across the healthcare system, a direction further outlined in Chapter 9.4.

Strengths and limitations

This thesis has several important strengths, as well as limitations that must be considered when interpreting the overall findings. These relate to four overarching methodological domains: methodology, representativeness and generalizability, data quality and completeness, and the evaluation and implementation of the SDM intervention.

First, the methodological basis of the studies in this thesis is a significant strength. Together, the studies cover the entire intervention cycle: development, implementation, and evaluation of effects, providing an integrated understanding of how SDM can be supported in RCC care. In the systematic review in **Chapter 2**, we synthesized a large and diverse international body of evidence covering more than a decade in time and integrating 174 studies applying OPTION-12 or OPTION-5 across various clinical settings. The review enabled subgroup and meta-regression analyses that offer a detailed understanding of SDM measurement by developing an updated and comprehensive database. Independent duplicate screening and extraction procedures enhanced the reliability of the findings, reducing the risk of bias that often affects large evidence syntheses. Across the other chapters, mixed-methods approaches were employed to generate a multifaceted perspective on decision-making in RCC care. The SDM-RCC studies in **Chapters 6, 7 and 8** combined quantitative outcomes with qualitative interviews involving perspectives of patients, HCPs and trained observers. This triangulation provided insights that could not have resulted from a single method. Furthermore, it strengthened the internal validity of the findings by enabling convergence and complementarity across the different data sources. Moreover, although randomized controlled trials are often considered the gold standard in methodology, our use of a pretest-posttest design in the implementation chapters aligns well with the current evidence in implementation science. A recent scoping review demonstrated that pretest-posttest designs are commonly used and represent the most frequently employed evaluation approach in implementation optimization studies, particularly in real-world clinical settings where randomization is often impractical[27]. This is particularly important for SDM research, since behavioral and communication interventions often cannot be strictly randomized without disrupting natural clinical workflows or contaminating usual care. By conducting the study in a routine setting and minimizing disruption, we enhanced real-world validity, an essential strength when evaluating SDM, as it is inherently context dependent. Another strength lies in the multicenter design used in **Chapters 3, 6, 7 and 8**, which included both academic and teaching hospitals and covered both localized and metastatic RCC. This ensured that the data reflected diversity of hospitals within the Netherlands. Although multicenter research introduces variability, this heterogeneity is a methodological advantage in implementation studies, as it enables the performance of the intervention to be examined across different organizational contexts. Crucially, many stakeholders, particularly HCPs, were continuously

involved from the PtDA development phase (**Chapter 4 and 5**) up to evaluation and implementation (**Chapter 7 and 8**). Their sustained engagement resulted in a motivated group, even during the implementation phase, which enhanced the feasibility and uptake of the study. This long-term commitment also helped to ensure good uptake by ensuring that the tools were aligned with clinical practice and were considered relevant[14,28].

Second, some limitations related to representativeness and generalizability of the results need to be considered. External validity was strengthened by the multicenter approach, although referral patterns and local agreements affected the composition of the study populations. For example, the dataset in **Chapter 3** originated from seven hospitals only, which could have introduced selection bias. As these hospitals typically provide a wide range of treatments, their patient population and care processes may not accurately represent those in non-teaching settings. Teaching hospitals account for a significant proportion of RCC care in the Netherlands. Santeon hospitals alone deliver around 11% of all hospital care in the country[29]. Consequently, the sample captured meaningful variation in routine practice, supporting the robustness of the main findings on treatment variation. In the PtDA development studies (**Chapter 4 and 5**), most of the patients who participated were highly educated and not sufficiently representative in terms of ethnicity, literacy, and digital skills. Consequently, the findings on acceptability and usability findings may not fully capture the needs of the wider Dutch RCC population. To minimize this limitation, diversity in literacy and accessibility was intentionally incorporated into the PtDA design itself, even if it was not fully reflected in the testing samples. This increases the likelihood that the tools will remain usable for a broader range of patients despite sampling constraints. Sample sizes in the developmental phases were small, limiting the range of patient experiences represented. In **Chapter 4 and 5**, both patients and HCPs were purposively recruited for the development of the two PtDAs. Although we deliberately sought to include critical voices to ensure a balanced range of perspectives, HCPs participating in the development phase may have held more positive views towards SDM than those not involved in this process. Patients who volunteered for needs assessments or usability testing were likely to be motivated individuals who were comfortable with reflective tasks such as think-aloud exercises. Several patients contributed to multiple phases of the development, which may have influenced their familiarity with PtDA materials and shaped their feedback. Nevertheless, the consistency of themes across patients with localized or metastatic disease and HCPs suggests that the core needs identified are not likely to be limited to the most engaged participants. In addition, in **Chapter 7** we included a large sample of patients to assess the effectiveness of the PtDAs, but there was an uneven distribution of localized versus metastatic cases, which restricted the ability to investigate the effects of the intervention at different stages of the disease. Nevertheless, improvements in observed SDM were consistent across most participating hospitals, which strengthened confidence in the intervention's overall effectiveness.

Third, challenges relating to data quality and completeness were encountered across multiple chapters. In **Chapter 3**, limitations in the NCR's registration procedures, particularly the incomplete documentation of non-histologically diagnosed tumors and conservatively managed cases, restricted the ability to evaluate treatment patterns among patients on active surveillance or watchful waiting. As hospitals differ in their diagnostic and management practices for these patients, the true extent of variation between hospitals may therefore be even greater than was observed. In **Chapter 7**, the number of consultations available for OPTION-5 scoring was reduced due to missing audio recordings. This is a methodological limitation of studies that depends on HCPs collecting data in high-pressure clinical environments. To address this, we analyzed all available audio recordings and supplemented observer-based outcomes with HCP- and patient-reported measures. This ensured triangulation despite the partial audio data. Although missing recordings may have led to an underestimation of observed SDM levels, the consistent improvement across multiple outcomes strengthens confidence in the observed effect. Similar issues arose in the systematic review (**Chapter 2**)**,** where many included studies lacked essential reporting details on rating procedures, OPTION version or language. This limited the interpretability of subgroup and methodological comparisons. To address this, we systematically coded the quality of reporting, only performing subgroup analyses when sufficient information was available, and transparently documenting all uncertainties. These issues highlight the difficulties involved in relying on data generated by other researchers, given that documentation practices vary across studies and important methodological details are not always reported consistently.

Fourth, the evaluation and implementation of the SDM intervention had its strengths and limitations. Implementing the intervention across all participating hospitals was a significant achievement. The intervention, which combines PtDAs with HCP training, reflects an integrated approach to improving SDM. End users in **Chapter 8** found the intervention valuable and feasible, and usage data showed that many patients completed the values-clarification exercises embedded in the PtDAs. Importantly, the consistent improvements observed across hospitals strengthen the confidence that these effects were not site-specific but rather reflect a broader shift in SDM behavior. However, some limitations must be noted. In **Chapter 7**, awareness of the audio recording may have influenced the behavior of HCPs, potentially narrowing the differences between the study phases. However, with previous studies, there is little evidence that audio recording significantly alters the behavior of patients or HCPs, suggesting that its impact on performance in this study was probably minimal[30]. In **Chapter 8**, it was not possible to calculate true implementation rates or assess compliance because the number of patients that would in theory be eligible to use the PtDA could not be determined from available data. This complicates the evaluation of long-term maintenance and the identification of quality improvement targets. Nevertheless,

triangulation of user statistics, interview data and observations provided a coherent overview of the early integration of the intervention into clinical workflows. Although HCPs provided valuable insights during implementation interviews, their previous involvement in the PtDA development may have introduced a positive bias. This risk was partly reduced by deliberately including critical and less enthusiastic voices in the development and evaluation processes to ensure a broader range of perspectives was represented. Furthermore, since **Chapter 8** collected data shortly after implementation, conclusions regarding sustainability remain unclear. However, we did gain a clear understanding of the initial adoption and use of the PtDAs, as well as the intentions of the HCPs to continue using them. A key facilitator of continued use was the availability of sufficient financial resources to support ongoing delivery and maintenance of the PtDAs. At the same time, the rapidly evolving treatment landscape for both localized and metastatic RCC highlights an ongoing challenge. PtDA content requires continuous updating to remain clinically accurate and relevant. Although our collaboration with ZorgKeuzeLab helps ensure timely content maintenance, this does not eliminate the complexity of integrating continuously updated PtDAs into routine practice.

Overall, the strengths and limitations of this thesis reflect the complexities involved in studying SDM in a real-world uro-oncological context. The thesis demonstrates a strong foundation across four key areas: methodology, representativeness and generalizability, data quality and completeness, and the evaluation and implementation of the SDM intervention. This thesis is strengthened by methodological triangulation across multiple data sources and perspectives, a multicenter design and extensive stakeholder involvement throughout the development and implementation process. It is supported by comprehensive quantitative and qualitative data. Although limitations relating to sampling, representativeness, heterogeneous reporting, and the inherent constraints of observational and developmental research must be considered when interpreting the findings, these limitations do not undermine the robustness of the results. Rather, they contextualize the results and clarify the boundaries within which the conclusions should be understood. Overall, the strengths of this thesis provide confidence in the validity and practical relevance of its findings, while the identified limitations highlight meaningful opportunities to further refine and optimize SDM in RCC care.

Practice implications and future perspectives

The findings of this thesis have several important implications for advancing SDM in RCC care. While we demonstrate that SDM and PtDAs can be incorporated into RCC care pathways, we also highlight structural limitations that hinder their optimal implementation. The next step is to move beyond the initial development and implementation of SDM and work towards embedding it sustainably in routine clinical practice. This will ensure that

it becomes a stable and expected component of everyday care, rather than a project-based activity. The four core recommendations that emerge from these implications are: 1) strengthening the role of the patient in SDM, 2) reconsidering disease-specific evidence in SDM implementation, 3) standardizing SDM measurement, and 4) using AI to support SDM. Together, these recommendations outline future perspectives aimed at a shift in the focus of SDM research and practice.

Recommendation 1: Strengthening the role of the patient in SDM

Shared decision-making is often conceptualized as a balanced process in which the patient and the HCP jointly explore options, preferences, and implications. In practice, however, this balance is not always achieved. Patients vary considerably in their readiness to participate, their ability to process complex medical information, and their confidence in expressing doubts or preferences[31]. While individual differences are inevitable, they can become a challenge when the healthcare system implicitly expects patients to participate in SDM without adequate preparation or support. Therefore, the future of SDM should involve a specific focus on encouraging patients to participate meaningfully in decision-making and providing them with the necessary support. Rather than viewing patients as passive recipients of information, or assuming that the presence of a PtDA automatically empowers them, the practice of SDM could shift towards actively building patients' skills and confidence. Patient empowerment or decision coaching, whether delivered by nurse specialists, digital modules, or peer support structures, could encourage individuals to identify questions, reflect on values, and engage more assertively in consultations[32,33]. This type of preparatory support can facilitate SDM understanding, and the role of the patient in this process, particularly for those who feel overwhelmed or uncertain. Research has shown that decision coaching improves patients' knowledge and understanding of their options, supporting engagement through all the four steps of the SDM process[34,35]. This supports more informed participation in SDM and may help reduce the risk of only highly educated, confident or digitally skilled patients participating fully in SDM. Strengthening the patient's role also involves acknowledging the emotional and existential aspects of (oncology) care[13]. Many decisions in RCC involve uncertainty, trade-offs, and priorities. Therefore, future SDM strategies may benefit from integrating proactive guidance, and supportive conversations that extend beyond the immediate treatment choice. When viewed in this way, SDM becomes a process that helps patients integrate medical decisions into their lives, rather than just an exchange of medical information. This requires us to view SDM as an evolving partnership that adapts to changing circumstances and preferences, rather than as a one-time event.

Recommendation 2: Reconsidering disease-specific evidence in SDM implementation

Although valuable insights into specific diseases can support local implementation, the expectation that SDM tools, such as PtDAs, must demonstrate disease-specific effectiveness before adoption remains a persistent barrier to their use in clinical practice. The core components of meaningful decision support do not differ fundamentally across diseases. Therefore, conducting repeated trials for each disease is not only scientifically unnecessary, but also slows the broader adoption and places an additional burden on patients and HCPs. Future SDM strategies would benefit from shifting attention away from establishing the generic effectiveness of PtDAs, and towards understanding how contextual factors, workflow integration and disease-specific adaptations influence their use in practice. By adjusting the expectation for disease-specific evidence, healthcare systems can accelerate implementation and foster a culture in which SDM tools are considered universally relevant, with local adoption focused on what is practical rather than what has already been proven.

Recommendation 3: Standardizing shared decision-making measurement and defining meaningful thresholds

As SDM becomes a more prominent quality indicator, the way it is measured is becoming increasingly important. Currently, the field is characterized by conceptual diversity: dozens of instruments are available, and different studies often use different tools that capture partly overlapping aspects of SDM[19–21]. While the diversity of methods can be intellectually enlightening, problems arise when the aim is to evaluate progress, monitor implementation, or compare outcomes across clinical settings. Such heterogeneity makes cross-study comparisons difficult and highlights the need for greater alignment in measurement practices. One way forward is to work towards greater standardization without sacrificing nuance. Establishing consensus on a single core instrument as the primary measure of SDM, supplemented by optional, context-specific tools where needed, would provide a more coherent foundation for both research and clinical quality improvement[23]. In addition to the challenge of achieving consistent measurement, there is also the issue of interpretation to consider: scoring approaches vary, and cut-offs for determining what constitutes a meaningful or sufficient level of SDM remain undefined. A shared instrument would also facilitate the development of normative thresholds, enabling more meaningful interpretation of scores. For example, defining what constitutes 'adequate' SDM could help HCPs understand where they stand and how they could improve. It would also enable organizations to monitor the impact of SDM initiatives over time. It is important to note that this does not imply that existing instruments are inadequate or that new measures are needed. Rather, the field would benefit from selecting one of the well-established, well-validated instruments as the primary standard and using it consistently across studies and settings. Standardization does not necessarily mean a lack of flexibility. Instead, it creates opportunities to enhance SDM

measurement with qualitative insights, patient-reported experiences, and contextual details, while providing a framework for more flexible and diverse approaches. Furthermore, a more unified measurement culture would enhance the comparability of studies, promote learning, and minimize the conceptual uncertainty that currently characterizes SDM evaluation. Ultimately, clearer and more consistent measurement will strengthen the transformation of SDM from an abstract concept into a practice that can be systematically supported, monitored, and refined.

Recommendation 4: Using artificial intelligence to support shared decision-making

Overall, the integration of AI within SDM is still in its infancy, with current developments only representing the first steps towards its application in clinical practice[36]. For example, AI systems that automatically capture and summarize consultations are emerging to support HCP workflow. Overall, both patients and HCPs are generally open to AI-assisted PtDAs. Users consistently report that such tools enhance understanding, engagement and the quality of consultations[37]. The increasing complexity of RCC treatment presents both challenges and opportunities for SDM. The evolving therapeutic landscape involving combinations of systemic therapies and prognostic considerations, the informational load for both patients and HCPs is growing. Although AI cannot replace the moral and relational dimensions of human empathy, it has the potential to support and expand certain empathic functions[38]. This is achieved by creating time and space for more meaningful interactions between patients and HCPs, thereby playing a complementary role that enhances clarity, continuity, and personalization, rather than replacing human dialogue. By streamlining administrative and informational tasks, it may also increase the time available for high-quality interactions between patients HCPs, addressing a commonly cited barrier to SDM. One promising application lies in sustaining the relevance of PtDAs. As evidence of treatments evolves, AI-driven systems could assist in scanning and synthesizing emerging data, prompting updates to PtDA content and reducing the risk of patients making decisions based on outdated information. While this would not replace expert review, it would help to maintain efficiency in rapidly changing clinical fields. Artificial intelligence may also support the analysis of clinical consultations. Natural language processing and speech recognition technologies could help to identify elements of SDM in routine practice, generating structured feedback for HCPs or supporting institutional monitoring. These tools would reduce the labor associated with manual coding and enable real-time feedback loops, making SDM improvement more dynamic. This also relates directly to the challenges outlined in the discussion, where the fragmentation of SDM measurement and the absence of shared criteria for interpretation limit the comparability of studies. If the field of SDM can reach agreement on which behaviors should be defined, coded and interpreted, AI-driven analysis could, in principle, contribute to greater consistency. Finally, AI-enabled tools offer personalization possibilities for both

patients and HCPs. This could tailor the depth of information, presentation style, and values-clarification exercises to the needs of individual patients, which could help those who struggle with generic decision support tools. If implemented thoughtfully, such tools could empower patients by making preparation more accessible and responsive without the need for someone to have this conversation with them in person. Given the rapid evolution of treatments and prognostic tools in RCC specifically, AI-supported decision tools may be especially valuable in this field. Despite these opportunities, however, AI in SDM should be guided by clear ethical principles. Transparency, and the preservation of human autonomy must remain central. The relational core of SDM, mutual trust, shared understanding, and recognition of patient values, cannot be automated. Therefore, AI should be developed as a supportive layer that enhances, rather than replaces, this interpersonal foundation.

Practical recommendations for kidney cancer care

For RCC care specifically, several practical steps could strengthen SDM and ensure consistent, equitable decision support. PtDAs should be incorporated as a standard component of RCC care pathways to ensure that all patients, whether they have localized or metastatic disease, receive the tool early enough to prepare for their consultation. Ideally, this preparation would begin prior to the initial clinical appointment, enabling patients to formulate questions, clarify their values, and gain a better understanding of the decisions ahead. Integrating PtDA delivery directly into standard workflows would reduce variation between hospitals and guarantee consistent access. PtDAs must be made available nationwide and free of charge so that every patient in the Netherlands, regardless of hospital or socioeconomic background, can benefit from equal support. Additionally, AI could enhance the personalization and clinical accuracy of PtDAs by integrating existing RCC prediction models, such as the RENAL Nephrometry score (a standardized system that quantifies tumor complexity based on anatomical characteristics)[39], prognostic survival algorithms, or toxicity-risk calculators for systemic therapies, directly into the online decision aid website. I believe that generating individualized risk estimates based on patient-specific characteristics would ensure that the information is up to date and tailored to the patient's situation, while supporting HCPs in maintaining responsibility for the relational and value-sensitive aspects of decision-making.

Conclusion

This thesis aimed to improve SDM for treatment decisions in RCC. Through subsequent studies involving the development of tailored PtDAs and the integration of mixed-methods evaluations capturing the perspectives of both patients and HCPs, we were able to develop and implement an SDM intervention that contributed to higher levels of SDM in RCC treatment decision-making consultations. The findings show that SDM is valued in RCC care and that structured support tools can enhance patients' ability to reflect on their preferences and participate more actively in treatment discussions. However, the studies also highlight that the level of SDM remains inconsistent in practice and is influenced by contextual, behavioral, and organizational factors.

Overall, this thesis provides a comprehensive basis for strengthening SDM in RCC, demonstrating where progress has been made and where further work is required. The next step is to shift the focus from development and implementation to the sustainable embedding of SDM in routine clinical practice. Long-term success will require ongoing attention to patient empowerment, consistent measurement of SDM quality, and integration of innovative technologies. The most important challenge and opportunity for the future is to ensure that SDM becomes a durable and expected component of everyday RCC care.

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Appendices

Nederlandse samenvatting

Dit proefschrift had als doel om Samen Beslissen (SB) te verbeteren bij het maken van behandelkeuzes voor patiënten met renaalcelcarcinoom (RCC). Dit is de meest voorkomende vorm van nierkanker. De keuze van een behandeling voor RCC kan lastig zijn, omdat er vaak meerdere behandelopties mogelijk zijn. Daarnaast spelen de persoonlijke voorkeuren, waarden en de individuele situatie van de patiënt een belangrijke rol bij het bepalen van de meest geschikte behandeling. Hoewel SB wordt aanbevolen in internationale urologische richtlijnen, voelen veel patiënten met RCC zich onvoldoende betrokken bij de beslissing over hun behandeling. Om op een betekenisvolle manier deel te kunnen nemen aan het besluitvormingsproces, hebben patiënten behoefte aan duidelijke, begrijpelijke en consistente informatie over alle beschikbare behandelopties en de mogelijke voor- en nadelen daarvan. Keuzehulpen kunnen dit proces ondersteunen en zijn bewezen effectief: ze vergroten de kennis van patiënten, helpen patiënten besluiten te nemen die beter aansluiten bij hun eigen waarden en voorkeuren, en zorgen ervoor dat patiënten zich beter geïnformeerd en zekerder voelen over hun voorkeuren. Voor RCC zijn echter nog maar weinig keuzehulpen beschikbaar. De keuzehulpen die in het buitenland zijn ontwikkeld, sluiten vaak onvoldoende aan bij de Nederlandse gezondheidszorg. Bovendien zijn er geen keuzehulpen voor RCC beschikbaar in de Nederlandse taal. Daarnaast is er, los van de beschikbaarheid van keuzehulpen, weinig bekend over hoe Nederlandse patiënten en zorgverleners het besluitvormingsproces ervaren. Het is met name onduidelijk welke informatie zij belangrijk vinden, welke belemmeringen zij ondervinden bij het bespreken van behandelopties en in hoeverre behandelkeuzes tussen regio's verschillen. Ook is er nog geen bewijs over de effecten van keuzehulpen binnen de Nederlandse nierkankerzorg. Deze observaties wijzen op belangrijke tekortkomingen in de Nederlandse nierkankerzorg. Deze tekortkomingen benadrukken de noodzaak om de huidige klinische praktijk en de behoeften van patiënten in kaart te brengen, keuzehulpen te ontwikkelen die passen binnen de Nederlandse gezondheidszorg en aansluiten bij deze behoeften, en vervolgens de impact en implementatie daarvan in de dagelijkse zorg te evalueren.

Voor dit proefschrift zijn de volgende doelstellingen geformuleerd:

1. Het evalueren van de geobserveerde mate van patiëntbetrokkenheid tijdens besluitvormingsprocessen door inzicht te krijgen in de huidige toepassing van SB in de klinische praktijk.
2. Het evalueren van behandelpatronen voor cT1a RCC (niertumoren ≤ 4 cm) in Nederlandse ziekenhuizen om de huidige klinische context beter te begrijpen.
3. Het ontwikkelen van twee Nederlandse nierkanker keuzehulpen om SB tijdens klinische consulten te ondersteunen.
4. Het onderzoeken van de effectiviteit van de keuzehulpen als onderdeel van een SB-interventie om de toegevoegde waarde in de klinische praktijk te bepalen.
5. Het evalueren van het gebruik van de SB-interventie en de implementatie ervan in de klinische praktijk door de ervaringen van patiënten en zorgverleners te onderzoeken.

In dit hoofdstuk wordt een samenvatting van dit proefschrift gegeven. Daarnaast wordt in de discussie een reflectie gegeven op de resultaten en inzichten van dit proefschrift en worden aanbevelingen gericht op het verder versterken van SB gedaan. Tot slot worden de algemene conclusies van dit proefschrift gepresenteerd.

Deel I. De huidige situatie

In deel I is de huidige stand van zaken met betrekking tot SB in de klinische praktijk geëvalueerd aan de hand van een overzicht van de bestaande literatuur. Daarnaast is de praktijkvariatie in de behandeling van cT1a nierkanker tumoren onderzocht. In **Hoofdstuk 2** worden de bevindingen van een (geüpdatete) systematische review naar de betrokkenheid van patiënten bij het besluitvormingsproces beschreven, gemeten met behulp van het 'Observing Patient Involvement in Decision Making' (OPTION)-instrument. In een uitgebreide literatuurstudie zijn 174 studies opgenomen, waarin bijna 20.000 klinische consulten werden geanalyseerd. Hiervan maakten 102 studies gebruik van OPTION-12, 64 van OPTION-5 en vier studies van beide instrumenten. Er is een meta-analyse uitgevoerd om een algemeen beeld te krijgen van de mate van patiëntbetrokkenheid in de klinische praktijk. Deze analyse toonde aan dat het gemiddelde niveau van SB, uitgedrukt in OPTION totaalscore (0-100), voor studies zonder SB-interventies een gemiddelde score van 25 bedroeg voor OPTION-12 en een gemiddelde score van 32 voor OPTION-5. Uit subgroep analyses bleek dat studies waarin SB-interventies waren opgenomen, significant hogere OPTION-scores rapporteerden voor beide instrumenten. Ten slotte werden meta-regressieanalyses uitgevoerd om mogelijke moderatoren van OPTION-scores te onderzoeken. Voor zowel OPTION-12 als OPTION-5 bleek een langere consultduur significant geassocieerd te zijn met hogere OPTION-scores. Bovendien bleek voor OPTION-12 dat een hoger aandeel vrouwelijke patiënten geassocieerd was met hogere scores. Over het algemeen blijkt uit deze studie dat er in studies zonder SB-

interventies in het afgelopen decennium weinig verbetering is opgetreden in OPTION-scores. In studies waarin SB-interventies werden toegepast, werden daarentegen hogere OPTION-scores gerapporteerd. Deze observaties benadrukken het belang van het ontwikkelen en evalueren van gestructureerde interventies ter ondersteuning van SB in de nierkankerzorg.

In **Hoofdstuk 3** wordt de variatie in de behandeling van cT1a niertumoren in zeven perifere Nederlandse ziekenhuizen onderzocht. Om SB goed te laten plaatsvinden, moeten patiënten in principe alle relevante behandelopties aangeboden krijgen, ongeacht het ziekenhuis dat ze bezoeken. Daarom is het essentieel om inzicht te krijgen in verschillen in behandelbeslissingen tussen ziekenhuizen, om zo de context waarin SB voor RCC plaatsvindt beter te kunnen interpreteren. In dit historische multicenter cohortonderzoek werden 501 patiënten met 544 cT1a niertumoren meegenomen. In totaal werd 65% van de tumoren actief behandeld, hoewel dit percentage aanzienlijk varieerde tussen ziekenhuizen (44-85%). Daarbij werden opvallende verschillen gezien in de gekozen behandelingen (zoals partiële nefrectomie, actief afwachten, focale therapie, etc.). Deze variatie bleef bestaan na stratificatie op basis van comorbiditeit en tumorkenmerken. Uit multivariate analyses bleek dat een hogere comorbiditeit geassocieerd was met een lagere kans op actieve behandeling. Daarentegen was een hogere tumorcomplexiteit geassocieerd met een hogere kans op actieve behandeling. Opvallend was dat het ziekenhuis waar de diagnose werd gesteld een onafhankelijke voorspeller bleef van de behandeling, zelfs na correctie voor case mix (d.w.z. comorbiditeit, nierfunctie en tumorcomplexiteit). Deze bevindingen laten zien dat er aanzienlijke, ongewenste praktijkvariatie in de behandeling van cT1a niertumoren bestaat, die niet verklaard kan worden door patiënt- of tumorkarakteristieken. Deze resultaten benadrukken de noodzaak van meer gestandaardiseerde zorgtrajecten, robuuste uitkomstmetingen, gestructureerde toepassing van SB en benchmarking tussen ziekenhuizen om de kwaliteit en consistentie van de Nederlandse nierkankerzorg te verbeteren.

Deel II. Ontwikkeling van twee keuzehulpen voor patiënten met renaalcelcarcinoom

Deel II richt zich op de ontwikkeling van twee keuzehulpen die zijn ontworpen voor verschillende stadia van RCC. Beide keuzehulpen zijn afgestemd op de Nederlandse context en de inhoud is gebaseerd op nationale nierkanker richtlijnen. De keuzehulpen zijn ontwikkeld in overeenstemming met internationaal erkende richtlijnen voor de ontwikkeling van keuzehulpen (International Patient Decision Aids Standards (IPDAS)). De keuzehulpen bestaan uit een uitreikvel met een overzicht van de behandelopties, een website met evenwichtige informatie en oefeningen ter verduidelijking van persoonlijke waarden en voorkeuren, en een gepersonaliseerde samenvatting ter ondersteuning van het vervolgconsult. **Hoofdstuk 4** geeft

een overzicht van de ontwikkeling van een keuzehulp voor patiënten met cT1 niertumoren. In deze setting zijn meerdere behandelopties mogelijk en spelen individuele voorkeuren een belangrijke rol. Op basis van input van patiënten, zorgverleners en een patiëntvertegenwoordiger is gezamenlijk een keuzehulp ontwikkeld die bedoeld is om gesprekken over behandelkeuzes bij cT1 RCC te ondersteunen. Eindgebruikers beoordeelden de keuzehulp als duidelijk, toegankelijk en relevant. De keuzehulp voldoet aan alle IPDAS-criteria en zal naar verwachting bijdragen aan meer consistente en patiëntgerichte besluitvorming bij de behandeling van gelokaliseerd RCC.

In **Hoofdstuk 5** wordt de ontwikkeling beschreven van een keuzehulp voor gemetastaseerd heldercellig RCC. Deze palliatieve context wordt gekenmerkt door snel evoluerende systemische behandelopties en een aanzienlijke ziektelast voor patiënten. Net als bij de keuzehulp voor patiënten met cT1 niertumoren (**Hoofdstuk 4**) is hetzelfde gestructureerde en op richtlijnen gebaseerde ontwikkelingsproces toegepast, om methodologische consistentie en relevantie te waarborgen. Uit het behoeftenonderzoek kwamen duidelijke behoeften naar voren. Patiënten gaven aan onzeker te zijn over behandelkeuzes, behoefte te hebben aan transparante informatie over de prognose en de impact van behandeling, en behoefte te hebben aan begeleiding bij psychosociale en lifestyle gerelateerde hulpvragen. Zorgverleners erkenden de toegevoegde waarde van een keuzehulp die patiënten kan ondersteunen bij het maken van complexe behandelbeslissingen en bij de voorbereiding op consulten. De resulterende online keuzehulp werd verfijnd door middel van gebruikersonderzoeken onder patiënten en ontving positieve feedback van zorgverleners over de duidelijkheid en relevantie voor gemetastaseerde ziekte. De keuzehulp voldoet aan alle IPDAS-criteria en sluit aan bij de specifieke besluitvormingsbehoeften van patiënten met gemetastaseerd heldercellig RCC. Net als bij de keuzehulp voor gelokaliseerd RCC wordt verwacht dat deze tool zal bijdragen aan meer patiëntgerichte besluitvorming binnen de Nederlandse nierkankerzorg.

Deel III. Effecten van de keuzehulpen voor patiënten als onderdeel van een interventie voor Samen Beslissen

Hoofdstuk 6 omvat het onderzoeksprotocol voor de ‘Shared Decision-Making in Renal Cell Carcinoma’ (SDM-RCC) studie. Dit onderzoek had als doel om de impact van een SB-interventie op het besluitvormingsproces bij patiënten met RCC te evalueren in zes Nederlandse ziekenhuizen. De interventie bestond uit online keuzehulpen voor patiënten (**Hoofdstuk 4 en 5**) en een training voor zorgverleners gericht op SB-principes en het effectief gebruik van de keuzehulpen. Dit onderzoek maakte gebruik van een multicenter, prospectief pretest-posttest design. Patiënten met gelokaliseerd (cT1) of gemetastaseerd heldercellig RCC werden geïncludeerd. In **Hoofdstuk 7** worden de effecten van de SDM-RCC studie gepresenteerd. In totaal werden 206 patiënten uit zes ziekenhuizen geïncludeerd, waarvan

111 in de pretestgroep en 95 in de posttestgroep. De primaire uitkomstmaat was de kwaliteit van het besluitvormingsproces, beoordeeld aan de hand van OPTION-5 scores. Secundaire uitkomsten waren onder meer de door patiënten en zorgverleners ervaren kwaliteit van het besluitvormingsproces en het aantal en de duur van de consulten. Onze resultaten toonden een significante toename van het geobserveerde niveau van SB na implementatie van de SB-interventie. Daarnaast namen de door zorgverleners gerapporteerde SB-niveaus en het gebruik van uitkomstinformatie tijdens consulten toe. Er was geen significant verschil in de door patiënten gerapporteerde SB-niveaus tussen de pre- en posttestgroepen. Aanvullende bevindingen waren een toename van zowel het aantal als de duur van de consulten, evenals hogere scores op de 'decisional conflict scale' (DCS) na de implementatie van de interventie. De besluitvormingsrol van de patiënten bleef ongewijzigd, aangezien de meeste patiënten in de voormeting van de studie al aangaven een gedeelde of actieve rol te hebben in het besluitvormingsproces.

Deel IV. Implementatie van de Samen Beslissen-interventie

In **Hoofdstuk 8** werd de implementatie van de SB-interventie in de Nierkankerzorg geëvalueerd. In zes Nederlandse ziekenhuizen werd een mixed-methods studie uitgevoerd om de implementatie van de interventie in de klinische praktijk te onderzoeken. Ook werden het gebruik van de keuzehulpen door patiënten (participatiegraad) en de ervaringen van patiënten en zorgverleners geëvalueerd aan de hand van gebruikersstatistieken en semigestructureerde interviews met zowel patiënten als zorgverleners. Kwantitatieve vragenlijstgegevens (**Hoofdstuk 7**) werden samen met kwalitatieve interviewgegevens geanalyseerd, waardoor methodologische triangulatie mogelijk was. De interventie werd in alle deelnemende ziekenhuizen geïmplementeerd, waarbij slechts kleine aanpassingen van bestaande werkprocessen nodig waren. Hoewel de algemene implementatiestructuur in alle ziekenhuizen gelijk was, werden er verschillen waargenomen in het moment waarop de keuzehulpen werden uitgereikt, de betrokken zorgverleners en de participatiegraad van patiënten. Een aanzienlijk deel van de patiënten (79% van de patiënten met gelokaliseerd RCC en 54% van de patiënten met gemetastaseerd heldercellig RCC) heeft de online keuzehulpen gebruikt. Daarbij werden de oefeningen voor het verduidelijken van waarden en voorkeuren vrijwel altijd voltooid, en gaven patiënten een hoge mate van tevredenheid aan over (het gebruik van) de keuzehulpen. Zowel patiënten als zorgverleners beschouwden de keuzehulpen als bruikbare en gestructureerde hulpmiddelen die SB ondersteunden en bijdroegen aan een hogere kwaliteit van de consulten. Deze resultaten suggereren dat de gekozen implementatiestrategie heeft geleid tot een effectieve integratie van de SB-interventie in de Nederlandse nierkankerzorg. De borging op lange termijn zal echter afhangen van aanhoudende aandacht voor werkprocessen, beschikbare middelen en de betrokkenheid van het team.

Discussie en conclusie

In dit proefschrift hebben we onderzocht hoe SB bij de behandeling van RCC kan worden versterkt. De resultaten laten zien dat zowel patiënten als zorgverleners de waarde van SB erkennen, maar dat zij in de dagelijkse praktijk tegen verschillende barrières aanlopen. Patiënten gaven aan behoefte te hebben aan duidelijke, gestructureerde informatie en ondersteuning om hun eigen rol in het besluitvormingsproces beter te kunnen vervullen. Zorgverleners noemden vooral tijdsdruk, organisatorische beperkingen en onzekerheid over het moment en de wijze waarop SB optimaal kan worden toegepast. Onze studies tonen aan dat een gestructureerde interventie, bestaande uit online keuzehulpen, training en een implementatiestrategie, leidt tot een toename van de geobserveerde mate van SB en tot een positieve waardering door zowel patiënten als zorgverleners. Tegelijkertijd maken de bevindingen duidelijk dat structurele en conceptuele uitdagingen het duurzaam inbedden van SB in de klinische praktijk bemoeilijken.

Op basis van de resultaten en reflecties in dit proefschrift zijn vier centrale discussiepunten naar voren gekomen: het belang van het actief betrekken van patiënten voorafgaand aan het consult, de verwachting dat keuzehulpen voor elke aandoening afzonderlijk bewezen moeten worden, de fragmentatie in de manier waarop SB wordt gemeten, en de toenemende rol van kunstmatige intelligentie in de praktijk en evaluatie van SB. Deze discussiepunten vormen de basis voor vier aanbevelingen die gericht zijn op het verder versterken en duurzaam verankeren van SB in de klinische praktijk. Ten eerste is het essentieel om de rol van de patiënt binnen SB verder te versterken. Niet elke patiënt voelt zich automatisch voorbereid of bevoegd om actief deel te nemen aan het besluitvormingsproces. Vroegtijdige voorbereiding, bijvoorbeeld door ondersteuning bij het formuleren van waarden en voorkeuren, kan dit proces aanzienlijk verbeteren en ongelijkheid in patiëntparticipatie verminderen. Ten tweede is het belangrijk om de noodzaak van ziekte-specifiek bewijs voor keuzehulpen te heroverwegen. Omdat de kernprincipes van goede besluitvormingsondersteuning niet afhankelijk zijn van de specifieke onderliggende aandoening, kunnen herhaalde effectiviteitsstudies per ziektegebied de implementatie onnodig vertragen. Een sterke focus op context, inbedding in het zorgpad en praktische toepasbaarheid kan de implementatie van keuzehulpen juist versnellen. Ten derde is standaardisatie van SB-metingen noodzakelijk. De veelheid aan instrumenten en het ontbreken van duidelijke interpretatiekaders maken het moeilijk om resultaten te vergelijken of te bepalen wat als ‘voldoende’ SB kan worden beschouwd. Een internationaal afgestemde set van meetinstrumenten met betekenisvolle drempelwaarden zou de evaluatie van SB aanzienlijk kunnen verbeteren. Ten vierde biedt kunstmatige intelligentie kansen om SB te ondersteunen, bijvoorbeeld door keuzehulpen actueel te houden, consulten te analyseren of informatie te personaliseren. Tegelijk vraagt dit om zorgvuldige ethische waarborging en een heldere afbakening van welke aspecten van SB meetbaar zijn en welke niet.

Dit proefschrift biedt een inhoudelijk en methodologisch fundament voor het verder versterken van SB binnen de Nederlandse nierkankerzorg. Een volgende stap is het verleggen van de focus van ontwikkeling en implementatie naar duurzame verankering van SB in de dagelijkse klinische praktijk. Borging op de lange termijn vraagt om blijvende aandacht voor het actief betrekken van patiënten, het kritisch heroverwegen van de noodzaak van ziekte-specifiek bewijs voor keuzehulpen, consistente meting van de kwaliteit van SB en de zorgvuldige integratie van innovatieve technologieën. De belangrijkste uitdaging en de grootste kans voor de toekomst is om SB te laten uitgroeien tot een vanzelfsprekend en duurzaam onderdeel van de dagelijkse nierkankerzorg.

Research Data Management paragraph

1. Ethics and privacy

This thesis is based on the results of research involving human participants and existing data from published papers, which were conducted in accordance with relevant national and international legislation and regulations, guidelines, codes of conduct and Radboudumc policy. A statement that the study was not subject to the Dutch Medical Research Involving Human Subjects Act (WMO), was obtained from the recognized Medical research Ethics Committees United (MEC-U) for Chapter 3-5 and 7-8 (Chapter 3: W24.115, Chapter 4 & 5: AW23.027/W22.125, Chapter 6-8: AW24.049/W22.121). Chapter 2 is a literature review and Chapter 6 is a protocol paper and therefore did not require an ethics review.

According to Dutch legislation, data collection from electronic patient files was performed by personnel with a treatment relationship with the patient and by the researcher(s) upon consent by the study participant. The privacy of the participants in these studies was warranted by the use of pseudonymization (Chapter 3, 7 and 8) and anonymization (Chapter 4 & 5). The pseudonymization key was stored on a secured network drive that was only accessible to members of the project who needed access to it because of their role within the project. The pseudonymization key was stored separately from the research data.

Informed consent was obtained from participants to collect and process their data for this research project (Chapter 4, 5, 7 and 8). The sensitivity and confidentiality of the raw qualitative data (i.e. semi-structured interviews) and quantitative data (i.e. questionnaires, audio recordings) of Chapter 4, 5, 7 and 8 makes sharing of the data without compromising confidentiality and privacy impossible, therefore consent for sharing of the raw data was not asked from the participants.

2. Data collection and storage

Data from Chapter 2 was obtained through literature research. Data for Chapter 3 was extracted from electronic health records. Data for Chapter 4 and 5 was obtained through interviews and online questionnaires. Data from Chapter 7 and 8 was obtained through electronic health records, audio recordings, and (online) questionnaires. REDCap was used for secured online data collection of the questionnaires. Excel was used for data collection for the literature review. Data were converged from (electronic) health records or Castor EDC to SPSS (SPSS Inc., Chicago, Illinois, USA) or STATA. Data from all chapters were stored and analyzed on the department server or in REDCap and are only accessible by project members working at the St. Antonius Hospital. Hardcopy informed consent forms and questionnaires are stored in locked cabinets on the department. These secure storage options safeguard the availability, integrity, and confidentiality of the data.

3. Data sharing according to the FAIR principles

All studies are or will be published open access. The St. Antonius Hospital is owner of all data. All data, including descriptive files of the data, will be archived for 15 years on the department server of the St. Antonius Hospital or in REDCap.

Chapter 2 was based on existing data (literature review). Chapter 6 is a study protocol. The aggregated data underlying the published Chapters 3, 4, 5, 7 and 8 are available from the corresponding author from the St Antonius hospital.

Portfolio

Department: **IQ Health**

PhD period: **01/05/2022 – 31/12/2025**

PhD Supervisor: **Prof. P.B. van der Nat**

PhD Co-supervisor(s): **Dr M.M. Garvelink and Dr H.H.E. van Melick**

Training activities	Hours
Courses	
- MWO/Good Clinical Practice training (2022)	10.00
- Radboudumc - eBROK course (for Radboudumc researchers working with human subjects) (2022)	26.00
- Introductiecursus Kwalitatief Onderzoek in de gezondheidszorg (2022)	18.00
- Workshop datavisualisatie (2022)	6.00
- Radboudumc - Introduction Day (2022)	6.00
- RIHS - Introduction course for PhD candidates (2022)	15.00
- Getting Things Done (2022)	12.00
- Train-the-trainer Samen Beslissen (2023)	9.00
- Workshop zoeken in Pubmed voor CAT of systematic review (2023)	3.50
- Introduction to practical biostatistics (e-learning) (2023)	20.00
- Workshop ‘Betere flow door waardestroomanalyse’ (2023)	3.00
- Radboudumc - Scientific integrity (2023)	10.00
- Cursus Actieonderzoek (2024)	6.00
Seminars	
- Workshop Waardegedreven Zorg (2022)	2.00
- Samen Beslissen nascholing (2025)	5.50
Conferences	
- Wetenschapsavond St. Antonius Ziekenhuis (2022): poster presentation	4.00
- Najaarsvergadering Nederlandse Vereniging voor Urologie (2022)	7.00
- European Multidisciplinary Congress on Urological Cancers 2022 (2022)	24.00
- Symposium keuzehulpen voor kwetsbare groepen 2022 (2022)	5.00
- DRCG multidisciplinair Jaarsymposium niercelcarcinoom (2023)	7.00
- CaRe days 2023 (2023)	12.00
- Symposium ‘How to use PROMs for Shared Decision Making’ (2023)	6.00
- Voorjaarsvergadering Nederlandse Vereniging voor Urologie 2023 (2023): oral presentation	18.00
- Symposium ‘Waardegedreven zorg - de praktijk en de wetenschap’ (2023)	3.00
- Symposium ‘Op weg naar gelijkheid in de zorg’ (2023)	3.00
- Symposium ‘Samen Beslissen met kwetsbare ouderen’ (2023)	5.00
- V&VN Urologie symposium (2023): oral presentation	7.00
- ICHOM conference 2023 (2023): poster presentation	24.00

Training activities	Hours
- European Multidisciplinary Congress on Urological Cancers 2023 (2023): poster presentation	24.00
- Wetenschapsavond 2024 - St. Antonius Ziekenhuis (2024): oral presentation	4.00
- DRCG Multidisciplinair Jaarsymposium Niercelcarcinoom 2024 (2024): oral presentation	7.00
- CaRe Days 2024 (2024)	
- Voorjaarsvergadering Nederlandse Vereniging voor Urologie 2024 (2024)	8.00
- Network Event Research Program Value Based Networked Care (2024): oral presentation	18.00
- 12th International Shared Decision Making Conference (2024): oral presentation and poster presentation	3.00
- European Multidisciplinary Congress on Urological Cancers 2024 (2024): poster presentation	22.00
- Nierkanker VS/verpleegkundigen symposium (2024): oral presentation	24.00
- EAU(N) 2025 (2025): oral presentation	4.00
- Voorjaarsvergadering Nederlandse Vereniging voor Urologie 2025 (2025): oral presentations	18.00
- Wetenschapsavond St. Antonius Ziekenhuis (2025): oral presentation	16.00
- Symposium collectieve patiëntenparticipatie in zorgpaden (2025)	4.00
Teaching activities	4.00
Supervision	
- Supervision internship Health Sciences (bachelor) (2022)	
- Supervision internship Health Sciences (master) (2024)	
- Supervision internship Medicine (bachelor) (2025)	
- Supervision internship Medicine (master) (2025)	
Total	**433.00**

List of publications

Publications included in this thesis:

- C.C. Bresser, A. Duarte-Díaz, H. González-Pacheco, A. Rivero-Santana, Y. Ramallo-Fariña, H.J. Westerink, L.M. Dijksman, H.H.E. van Melick, P.B. van der Nat, F. Légaré, G. Elwyn, M.M. Garvelink, and L. Perestelo-Pérez. Assessing shared decision-making in clinical practice: A systematic review and meta-analysis of studies using OPTION-12 and OPTION-5. *Accepted for publication in BMJ Evidence-Based Medicine.*
- C.C. Bresser, P.B. van der Nat, H. Yildirim, B.J.P. Kersten, H.J.J. Leenarts, K.K.H. Aben, P.J. Zondervan, L.M. Dijksman, P.D. Polm, M.M. Garvelink, and H.H.E. van Melick for the Santeon RCC Working Group. Hospital variation in the treatment of cT1a renal cancer. *Accepted for publication in BJUI Compass.*
- C.C. Bresser, H.H.E. van Melick, R. The, P. B. van der Nat, and M.M. Garvelink. Development of a patient decision aid for T1 renal cell carcinoma: A user-centered mixed methods study. *Urology Practice* 2025 Sep;12(5):568-577. doi: 10.1097/UPJ.0000000000000830. Epub 2025 May 15. PMID: 40372309; PMCID: PMC12382743.
- C.C. Bresser, H.H.E. van Melick, R. The, P. B. van der Nat, and M.M. Garvelink. Improving value of care for renal cell carcinoma patients; development of a decision aid for metastatic clear-cell renal cell carcinoma. *Patient Education and Counseling* 2025 Aug; 137:108800. doi: 10.1016/j.pec.2025.108800. Epub 2025 Apr 29. PMID: 40315706.
- C.C. Bresser, M.M. Garvelink, B.M.M. van den Berg, F.C.K. Dolk, P.B. van der Nat, and H.H.E. van Melick. Evaluating the impact of a shared decision-making intervention for patients with renal cell carcinoma: The SDM-RCC study protocol. *European Urology Oncology* 2025 Apr;8(2):245-248. doi: 10.1016/j.euo.2024.09.003. Epub 2024 Sep 20. PMID: 39304394.
- C.C. Bresser, M.M. Garvelink, T. van Dijk, N. van der Linde, B.M.M. van den Berg, F.C.K. Dolk, P.B. van der Nat, and H.H.E. van Melick for the SDM-RCC Study Group. Improved shared decision-making for patients with renal cell carcinoma: results of the SDM-RCC study. *Accepted for publication in European Urology Oncology.*
- C.C. Bresser, M.M. Garvelink, B.M.M. van den Berg, F.C.K. Dolk, P.B. van der Nat, and H.H.E. van Melick. Insights into successful implementation of a shared decision-making (SDM)-intervention for patients with renal cellcarcinoma. *Under review.*

Other (co-authored) publications:

- H.J. Westerink, C.C. Bresser, M.M. Garvelink, C.F. van Uden-Kraan, O. Zouitni, H.A.J. Bart, P. van der Wees, P.B. van der Nat and the Santeon Patient Participation Study Group. The use of outcome data in patient consultations from the healthcare professionals' and patients' perspectives: A mixed methods study. *Patient Education and Counseling* 2024 Jan;118:108043. doi: 10.1016/j.pec.2023.108043. Epub 2023 Oct 31. PMID: 37925975.
- J.E. Wiersema, C.C. Bresser, and P.B. van der Nat. Organizing Care Around Conditions: An Expanded Model of Value-Based Health Care. *NEJM Catalyst* 4 (2023) 1–15. doi: 10.1056/cat.23.0180.
- C.C. Bresser, H.H.E. van Melick, R.The, P. B. van der Nat, and M.M. Garvelink. Reply by authors. *Urology Practice* 2025 Sep;12(5):577. doi: 10.1097/UPJ.0000000000000849. Epub 2025 Aug 22. PMID: 40844165.
- L.V. Schewe, F. Scheibler, L. Fischer, A. Baghus, P. van Bostraeten, C.C. Bresser, J.S. Burgers, D. Conijn, D. Dreesens, G. Elwyn, R.C. Forcino, J. Franco, M.M. Garvelink, A. Giguere, M.R. Gionfriddo, S. Gupta, T. Hoffmann, A. van Leeuwen, M. Maes-Carballo, Z. Munn, M. Peleg, L. Perestelo-Perez, D. Schubbe, D. Sprengers, D. Stacey, A. Stiggelbout, M.M. Trujillo-Martín, G. van der Weele, I.D. Florez, A. Hutchinson, S. Li, L. Puljak, T. Karge, T. Langer, C. Orduhan, C. Schaefer, and D. Pieper. Criteria to Prioritize Clinical Practice Guideline Recommendations for Patient Decision Aid Development: Results from a Modified Delphi Consensus Study. *Accepted for publication in Journal of Clinical Epidemiology.*

Curriculum Vitae

Cato Caroline Bresser was born in Amsterdam, The Netherlands, on the 4th of June 1996. She grew up together with her two younger brothers, Gijs and Bram. Cato attended the Barlaeus Gymnasium in Amsterdam, before starting medical school at the University of Groningen in 2014. She enjoyed student life to the full during her studies, joining several committees and working various part-time jobs.

It was during her internships that she developed a growing interest in urology. In 2021, she began working as a resident not in training (ANIOS) in the urology department at the Spaarne Gasthuis in Hoofddorp and Haarlem. The following year, she began her PhD research focused on shared decision-making in renal cell carcinoma at the St. Antonius Hospital and Radboudumc, supervised by Prof. Dr Paul van der Nat, Dr Mirjam Garvelink and Dr Harm van Melick.

Throughout her PhD, she has coordinated several studies in various Dutch hospitals, all of which aimed to improve shared decision-making and kidney cancer care. She also participated in several committees in the St. Antonius Hospital and had the opportunity to present her research at national and international congresses.

Outside of work, Cato enjoys sports, cooking, and long dinner evenings. She also volunteered with the Stichting Thuisgekookt, preparing a home-cooked meal each week for a neighbor. Cato lives in Amsterdam with her boyfriend, Max. From March 2026, she started training to become a general practitioner.

Foto door Kaagvrouw

Dankwoord

Het zit erop! Na 3,5 jaar is mijn proefschrift af. Bij deze wil ik graag iedereen bedanken die een bijdrage heeft geleverd aan de totstandkoming van dit proefschrift. Ik kijk terug op een leerzame, gezellige en waardevolle periode, waarin ik met heel veel plezier heb samengewerkt met veel verschillende mensen en een andere kant van de zorg heb ontdekt. Graag wil ik een aantal mensen in het bijzonder bedanken.

Allereerst natuurlijk alle **patiënten en zorgverleners** die hebben deelgenomen aan de studies die zijn opgenomen in dit proefschrift. Dit proefschrift had niet tot stand kunnen komen zonder jullie hulp. Het is niet makkelijk om na een nierkanker diagnose open te staan voor onderzoek. Toch waren jullie bereid om te helpen en mocht ik meeluisteren met audio-opnames van gesprekken in de spreekkamer, waarvoor enorm veel dank.

Prof. Dr. Paul van der Nat, beste Paul, dankjewel voor de fijne begeleiding als mijn promotor de afgelopen jaren. Jij hebt mij kennis laten maken met het concept 'Waardegedreven Zorg' en geleerd in te zien waarom dit zo belangrijk is. Je overtuigde mij zelfs aan het begin van mijn promotietraject om mijn eerste artikel te schrijven over archetypes binnen de zorg, iets wat voor mij echt een ver-van-mijn-bed show was. Toen jij mij daarna vroeg of ik samen met Jet wilde helpen om jouw oratie én bijbehorend symposium te organiseren, voelde ik mij enorm vereerd. Wat was dat een bijzondere dag! De afgelopen jaren heb ik je steeds beter leren kennen, soms zelfs onder het genot van een biertje. Tijdens de afronding van mijn proefschrift heb ik ook nog veel van je geleerd, vooral tijdens het schrijven van mijn Introductie en Discussie, soms met ietwat frustratie, maar het is er echt veel beter van geworden. Het was een genoegen om met je samen te werken, dankjewel!

Dr. Mirjam Garvelink, beste Mirjam, wat ben ik blij met jou als copromotor! Tijdens mijn sollicitatie vertelde ik enthousiast dat ik wel van keuzehulpen 'knutselen' hield, maar stiekem wist ik toen nog niet zo goed waar ik aan begon. Met jouw ervaring binnen het vakgebied van Samen Beslissen en het ontwikkelen van keuzehulpen, heb je mij enorm goed op weg geholpen. Jouw begeleiding was heel fijn, ik kon altijd bij je langslopen met vragen en je durfde mij ook kritische feedback te geven op manuscripten. We hebben het ook heel gezellig gehad tijdens onze tripjes naar het ICHOM congres in Barcelona en het ISDM congres in Lausanne. Na een lange dag luisteren naar praatjes genoten we 's avonds van een lekker diner en natuurlijk een potje Punto. Jij hebt ervoor gezorgd dat ik een echte Samen Beslissen 'believer' ben geworden. Ik hoop dat we in de toekomst nog contact blijven houden en misschien ook wel kunnen blijven samenwerken met Samen Beslissen binnen de Huisartsgeneeskunde.

Dr. Harm van Melick, beste Harm, wat was het fijn om jou als copromotor te hebben. Ik weet nog goed dat jij mij vertelde over dit promotietraject, wat op dat moment nog niet helemaal rond was. We hielden contact en toen ik op gesprek mocht komen, viel alles op zijn plek. Op de afdeling urologie werd ik hartelijk ontvangen en heb ik mij als een vis in het water gevoeld. Als dokters onder elkaar konden wij goed met elkaar sparren over de medische inhoud van het onderzoek. Toen ik jou vertelde dat ik toch een ander pad koos voor mijn toekomstige carrière, heb jij mij, na een eerste geschrokken reactie ('Je maakt je PhD toch wel af?'), heel fijn opgevangen. Dank daarvoor! Tijdens onze overleggen zorgde jij ervoor dat er ook tijd was om in te checken hoe het met iedereen ging, iets dat ik nog wel eens vergat als ik begon aan mijn (lange lijst met) agendapunten. Dankjewel voor deze gezellige tijd bomvol leuke herinneringen en zelfs drie keer een EMUC!

Geachte leden van de manuscriptcommissie, **Prof. Dr. Peter Mulders**, **Prof. Dr. Willem-Jan Bos** en **Dr. Arwen Pieterse**, hartelijk dank voor het lezen en beoordelen van mijn proefschrift. Ik kijk uit naar de verdediging waar we van gedachten kunnen wisselen over de inhoud hiervan.

Aan alle betrokkenen vanuit de **Patiëntenvereniging blaas- of nierkanker**, de **Nederlandse Vereniging voor Urologie** en andere betrokken **beroepsverenigingen**, dank voor jullie hulp bij de ontwikkeling van de Nierkanker keuzehulpen en het onderzoek daaromheen. Dank ook aan **ZorgKeuzeLab** voor jullie inzet en hulp bij de ontwikkeling en implementatie van de keuzehulpen, ik heb heel veel van jullie geleerd. **Birgit** en **Christiaan** en alle andere betrokkenen vanuit **Merck Sharp & Dohme**, dank voor de samenwerking de afgelopen jaren. Ook dank aan de andere sponsoren van de ontwikkeling en implementatie van de keuzehulpen: **Ipsen, Pfizer** en **Bristol Myers Squibb**.

Collega's van de Waardegedreven Zorg, dank jullie wel voor de gezellige tijd! Waar we eerst verstopt zaten in een verlaten gang boven de OK, hebben we nu een echte onderzoekskamer bemachtigd op de R-vleugel met zelfs een gezellige barista koffiebar. **Kirsten, Anna Roos, Lian, Tom, Bo** en **Lilian**, dank voor het warme onthaal op de afdeling. **Femke, Sara, Dorine** en **Linda**, wat leuk dat jullie ons team zijn komen versterken. Lieve **Jet**, wat was het fijn om tegelijk met jou onze beide promotietrajecten uit te voeren. Als kers op de taart was daar natuurlijk jouw promotie afgelopen december. Ik ken weinig mensen die zo goed georganiseerd zijn en waar je het ook nog eens zó gezellig mee kan hebben. Lieve WGZ-onderzoekers, ik ga jullie missen!

En dan de collega's van de urologie: **urologen, arts-assistenten, onderzoekers, verpleegkundig specialisten, verpleegkundigen**. Dank voor jullie hulp de afgelopen jaren en voor de gezellige lunches en koffietjes op de H1. Specifiek dank aan **Aswin, Pepijn, Gwenda, Esmee, Susanne** en **Ilse** uit het Nierkanker verbeterteam, waar altijd even werd stilgestaan bij het nierkanker onderzoek. Dank **Jacqueline** en **Heleen** voor jullie hulp bij alle praktische zaken vanuit de urologie. **Lieke** en **Joris**, als echte pioniers zijn jullie gestart op onze onderzoeksafdeling en kijk met hoeveel we nu zijn! **Rosemarijn, Alexandra, Vera** en **Sophie**, heel gezellig dat jullie ons team zijn komen versterken de afgelopen jaren. Lieve **Leonor** en **Anne**, wat heb ik onwijs genoten om tegelijkertijd met jullie onderzoek te doen. Wat als carpoolers begon, heeft zich ontwikkeld tot een echte vriendschap en daar ben ik heel blij mee! Dank ook aan de studenten die ik tijdens mijn promotietraject heb mogen begeleiden: **Nienke, Tessa, Rozemarijn, Mylan** en **Bart**.

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Lieve **Suus**, wat begon met een potje 30 Seconds in de steeg bij Max' huis in Groningen, is uitgemond in een hele waardevolle vriendschap. Ik heb nog niet vaak iemand ontmoet waarmee ik zó goed klik en waarmee ik zulke fijne en goede gesprekken kan voeren. Jouw aanstekelijke passie voor het verbeteren van de zorg en runnen van een eigen bedrijf zijn bewonderingswaardig. De afgelopen jaren hebben we samen, maar ook met Marnix en Kaag, ontelbare dinertjes georganiseerd, inclusief door ons zelf gepresenteerde quizzen, die soms zelfs eindigden met een karaoke sessie springend op de bank. Ik vind het heel bijzonder om van dichtbij mee te maken dat Marie in jullie leven is gekomen en waardeer het enorm dat wij hier zo bij worden betrokken. Ik hoop dat onze vriendschap forever zo blijft en dat we samen nog veel mooie momenten mogen meemaken.

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