

Accentuating patient values in shared decision-making: A mixed methods development of an online value clarification tool and communication training in the context of early phase clinical cancer trials

Jelle L.P. van Gorp^{a,*}, Liza G.G. van Lent^{b,2,3}, Nicole Stoel^c, Carin C.D. van der Rijt^{b,4}, Julia C.M. van Weert^{d,5}, Jeroen Hasselaar^{c,6}

^a Department of IQ Healthcare, Radboud University Medical Centre, Nijmegen, the Netherlands

^b Department of Medical Oncology, Erasmus MC Cancer Institute, Erasmus University Medical Centre, Rotterdam, the Netherlands

^c Department of Pain, Anesthesiology and Palliative Care, Radboud University Medical Centre, Nijmegen, the Netherlands

^d Department of Communication Science, Amsterdam School of Communication Research/ASCoR, University of Amsterdam, Amsterdam, the Netherlands

ARTICLE INFO

Keywords:

Early phase clinical trials
Shared decision making
Patient preference
Value of life
Value clarification
Decision tool

ABSTRACT

Objective: In the shared decision-making (SDM) process for potential early phase clinical cancer trial participation, value clarification is highly recommended. However, exploration and discussion of patient values between patients and oncologists remains limited. This study aims to develop an SDM-supportive intervention, consisting of a preparatory online value clarification tool (OnVaCT) and a communication training.

Methods: The OnVaCT intervention was developed and pilot-tested by combining theoretical notions on value clarification, with interview studies with patients and oncologists, focus groups with patient representatives and oncologists, and think aloud sessions with patients, following the Medical Research Council (MRC) framework for complex interventions. These human-centered methodologies enabled a user-centered approach at every step of the development process of the intervention.

Results: This study shows relevant patient values and oncologists' perspectives on value exploration and discussion in daily practice. This has been combined with theoretical considerations into the creation of characters based on real-life experiences of patients in the OnVaCT, and how the tool is combined with a communication training for oncologists to improve SDM.

1. Introduction

In recent decades, online decision aids have been developed to support shared decision-making (SDM) through adding to patients' knowledge, providing input for doctor—patient communication, and to make the SDM process more convenient [1]. The International Patient Decision Aid Standards (IPDAS) strongly recommends the inclusion of value clarification in these decision aids. Values are defined as persons' "concepts or beliefs that refer to desirable end states or behaviors" [2]. Values usually "transcend specific situations, can be ordered by relative

importance, and [therefore] can guide selection or evaluation of behavior and events" [2]. The IPDAS has put forward that when patients are exposed to a decision aid that features explicit value clarification, a higher proportion of patients choose an option that is congruent with their values [3,4]. It remains to be seen, however, whether this claim is also valid in particular medical contexts associated with complex and high-risk decisions, such as in the context of experimental cancer treatment and the accompanying palliative care options [5].

Early phase clinical trials are experimental treatments for advanced cancer patients that test the safety and tolerability (i.e., not yet the

* Correspondence to: Kapittelweg 54, Nijmegen 6525 EP, the Netherlands.

E-mail address: Jelle.vanGorp@radboudumc.nl (J.L.P. van Gorp).

¹ ORCID: 0000-0002-9904-2571

² Both authors contributed equally

³ ORCID: 0000-0002-4979-3051

⁴ ORCID: 0000-0001-5996-1242

⁵ ORCID: 0000-0002-2259-5864

⁶ ORCID: 0000-0002-8880-2029

efficacy or benefit) of new cancer therapies. The process of referral, decision-making, and the following course of care is explained in Fig. 1.

Patients with cancer are known to have difficulty communicating important values to their oncologists, who may be unwilling and/or incapable to do so themselves [6–8]. This aligns well with moral education and value theories which state that life can be bewildering and overwhelming, e.g., due to the diagnosis of cancer [9]. As a result, people may lack a clear perspective on their values during these episodes, and they may be unaware of how to prioritize those values or resolve possible value conflicts [10]. In the context of decisions regarding early phase clinical cancer trial participation and/or palliative care, these values could, for instance, be related to the hope for survival and/or the desire to maintain as much quality of life as possible. However, consultations on potential early phase clinical trial participation tend to focus only on medical-technical information [6,11]. In this particular medical context, with complex and high-risk life or death decisions, a value clarification tool could thus be a valuable extra asset to be used in SDM.

The goal of this study is to describe the systematic development and piloting of an intervention consisting of an online value clarification tool (OnVaCT) for patients with advanced cancer and an accompanying communication training for oncologists. Eventually, this intervention aims to help both patients and oncologists to address possible value conflicts surrounding decisions about early phase clinical trial participation.

2. Methods

2.1. Design

This study focuses on the realization of the first two phases of the Medical Research Council (MRC) framework for complex interventions, i.e., the development and piloting phase of the intervention (2018–2021) [12]. The project protocol was published previously [13] and was registered in the Netherlands Trial Registry (NL7335) [14]. The Medical Ethics Committee of the Erasmus MC, Rotterdam (the Netherlands) assessed the entire study protocol (MEC-2018–151), and research governance approval was received from the participating hospitals, i.e., the Erasmus MC Cancer Institute, the Netherlands Cancer Institute (Amsterdam) and UMC Utrecht.

2.2. Development team

In anticipation of the start of the OnVaCT project, a consortium agreement was established among the Radboudumc (Nijmegen), the Erasmus MC Cancer Institute, and the University of Amsterdam – Amsterdam School of Communication Research (ASCoR). The development team consisted of experts in early phase clinical trials, health communication, medical ethics, oncology, palliative care, and shared decision-making. This team collaborated with IT professionals from IJsfontein (Amsterdam), a company specialized in serious gaming that has expertise in a variety of health care contexts.

2.3. Development phase

Please look at Fig. 2, that visualizes the four steps of the development and piloting of the intervention. Both the steps and the piloting are described in further detail in the following paragraphs.

2.3.1. Step 1: Identifying existing theoretical and empirical evidence

Notwithstanding the inclusion of value clarification modules in previous decision aids for other medical contexts [15], it remains unclear from the available literature what *value clarification* exactly should be like, what it aims for and how it should be scripted into (an online) design [16]. The value clarification paradigm has been discussed in length within the context of moral education (Raths et al. in 10) [17,18]. Drawing heavily on value theory and theories on moral education, we came up with four questions that are relevant in the development of the OnVaCT intervention:

Can a value clarification tool be unbiased, thereby giving patients the freedom to choose values that they deem important [17]? Or does designer bias always affect the design, and thereby the patient's autonomy?

Is value clarification alone sufficient, or should a critical evaluation be included as well [9, 17, 19]? In other words, should patients only be encouraged to share their personal selection of values, or should important medical decisions be considered more profoundly with the possibility of even criticizing some of the patient's values?

Who should then discuss values with patients? Should physicians be critical friends, or must they try to remain neutral as described in the

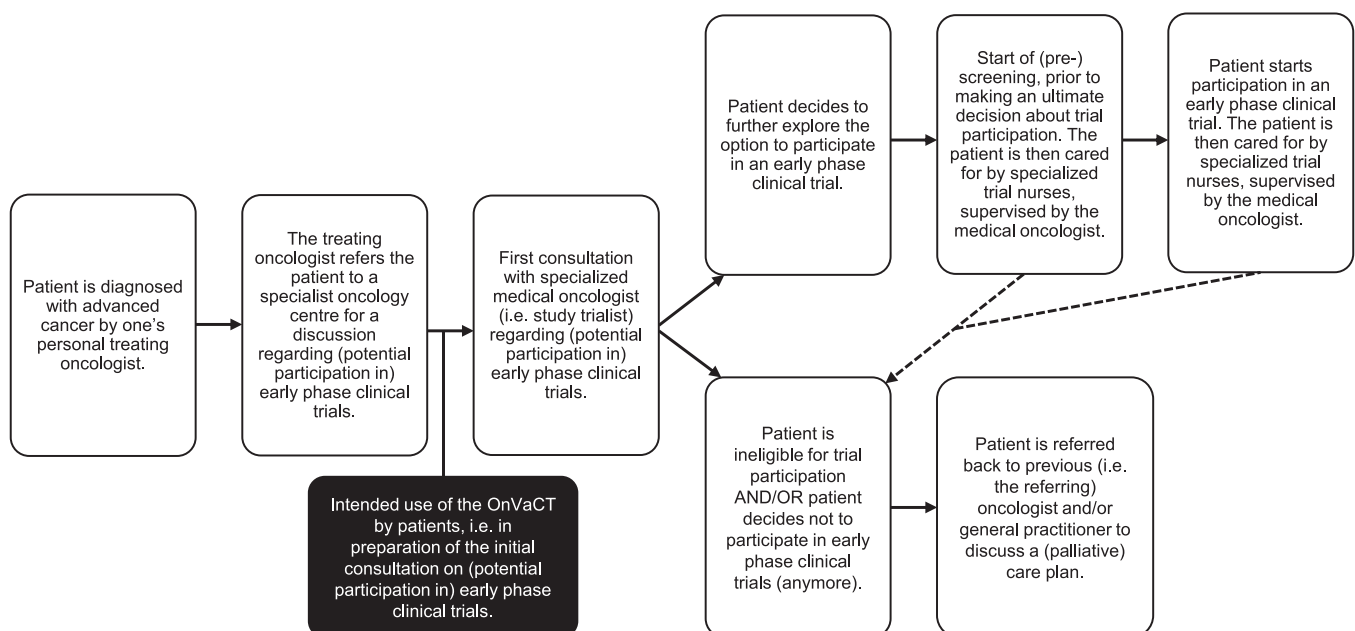


Fig. 1. The process patients go through when referred to a specialist oncology centre for a discussion regarding participation in early phase clinical trials.

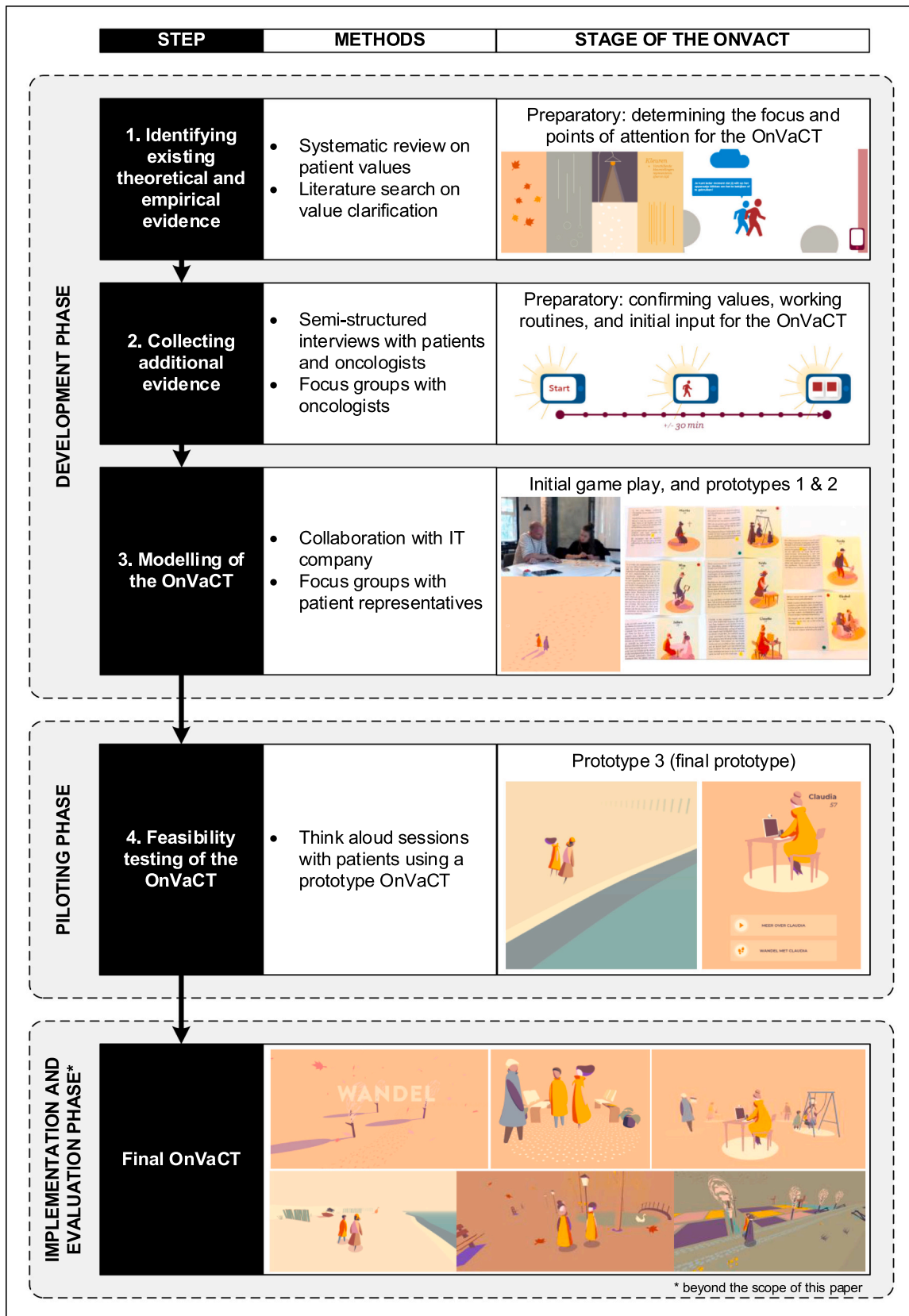


Fig. 2. Schematic overview of the steps that were taken to develop and pilot-test the OnVaCT.

original value clarification paradigm [17]? Can physicians fall back on more objective criteria when discussing values and preferences with patients? Can they also go beyond the clinical space and discuss how patients' values relate to their lives outside the hospital [19]? How can a tool take into account that the value clarification process is probably continuous, similar to patients' disease and treatment trajectory?

Our goal was to produce an OnVaCT and communication training suitable for resolving the specific value conflicts surrounding decisions about early phase clinical cancer trial participation. Therefore, the study team conducted a systematic review to identify an initial set of relevant patient values relevant in the particular context, which is reported elsewhere [20].

2.3.2. Step 2: Collecting additional evidence

To check the systematic review's overview of patient values for completeness and for cultural bias, *serial* semi-structured interviews were conducted with patients right before and after their initial appointment regarding participation in an early phase clinical. The analysis of these interviews is reported on elsewhere [21]. In addition, semi-structured interviews were conducted with medical oncologists from the participating hospitals (see Supplemental file 1 for the interview guide) to gain more insight into patient–physician interactions from the perspective of oncologists. There was special focus on oncologists' attitudes toward discussing values during their consultations and, in the future, obtaining support for those discussions using the OnVaCT. These qualitative interviews were analyzed using CAQDAS Atlas.ti software, following a thematic analysis approach. Open coding [22,23] was performed independently by two researchers, followed by discussions aimed at reaching a consensus regarding the coding. Then axial coding was applied to, in a process of constant comparison, form categories and describe any possible underlying relations and patterns among these categories [23]. Three focus groups (i.e., one per participating hospital) were conducted with medical oncologists (see Supplemental file 2 for the topic guide). The goal of these focus groups was twofold: the focus groups could function as a member check regarding the results of the interviews with oncologists, and they offered an opportunity for oncologists to provide feedback to a first outline of the OnVaCT. All focus groups were facilitated jointly by two researchers of the development team alongside the project manager and software developer of the IT company. The focus groups were transcribed verbatim and analyzed qualitatively by two researchers following the same procedure as used in the interview study [21].

2.3.3. Step 3: Modeling the OnVaCT intervention

The IT company was responsible for the design and gameplay, the development team for writing the content of the OnVaCT. The following steps could be discerned for the OnVaCT:

- An initial meeting between the professionals from the IT company and the development team provided a rough outline of the goal, content, and challenging context for this OnVaCT.
- The IT company then came up with a look-and-feel of the OnVaCT, quickly followed by a first prototype based on the input of the design team that contained draft stories based on the values that came up in the interviews and systematic review. These early versions were also presented to and discussed with healthy volunteers having some life experience with cancer.
- The development team wrote several drafts of the OnVaCT's content, which was discussed and optimized by the entire project team.
- With the full content added to prototype 1, this prototype was then presented in a group feedback session with an advisory council including patients and relatives of the Consortium on Palliative Care Southwest Netherlands and in the focus groups with oncologists. These sessions focused on the comprehensibility, attractiveness, and

appropriateness of the prototype OnVaCT. All relevant feedback was incorporated into prototype 2, which was used for further piloting.

In addition, the project team developed the communication training, which is embedded in SDM theories (e.g. 24, 25–27). The training was based on existing trainings that had been successfully used in previous projects (e.g. [26,28]). It applied the principles of Miller's learning pyramid [29], which distinguishes four levels of competence: 1: knowing (knowledge), 2: knowing how (to use knowledge), 3: showing how (acting in a simulated environment) and 4: doing (acting in everyday practice). The principles of SDM were incorporated into all parts of the training and were based on the 'Three-talk model for shared decision making' [30] and the 'Dynamic model for shared decision making in frail older patients' [31,32]. As additional inspiration for the content of the training, insights were used from the previous steps during the development phase as additional inspiration for the content of the training. The hired trainer, a psychologist with expertise in teaching communication skills to medical students and specialists, also provided ideas and feedback.

2.4. Piloting phase

2.4.1. Step 4: Feasibility testing

To assess patients' ability to navigate prototype 2 and patients' ideas regarding the layout, comprehensibility, presentation and applicability of the content of the OnVaCT, individual think aloud sessions with patients were conducted [33]. These sessions were conducted in person in a semi-structured manner by one member of the development team working alongside a professional from the IT company. Halfway through the piloting phase, feedback from patients was incorporated into prototype 3, which was presented to other patients. After concluding the piloting phase, prototype 3 was adjusted one last time to develop the final OnVaCT.

3. Results

Supplemental Table 1 shows all the decisions and their rationale that were made in accordance with the study procedures during each step.

3.1. Development phase

3.1.1. Step 1.1: Identifying existing theoretical and empirical evidence

In our systematic review, we extracted ten values that can contribute to patients' decision regarding whether to participate in early phase clinical trials [20]. We found that patients who seek to participate in such trials identified hope, trust, quantity of life, altruism, perseverance, faith and/or risk tolerance as important values, whereas quality of life and humanity (i.e., being treated as a human being rather than, e.g., a research object) were the main values reported by patients who refused participation. Social adherence and autonomy were reported by both trial seekers and refusers depending on the manner in which they were expressed by a patient.






3.1.2. Step 1.2: Collecting additional evidence

Based on serial semi-structured interviews [21] with thirteen patients, two additional values could be added to those identified in our systematic review, i.e., reconciliation with one's fate and bodily preservation. Furthermore, the interview study showed that patients' values could result in intrapersonal value conflicts, as these values can coexist within a single individual while appearing to be incompatible [21].

In total, eight oncologists specialized in early phase clinical trials (3 M/5 F), working for one of the participating tertiary hospitals Erasmus MC [3], Netherlands Cancer Institute [2] or UMC Utrecht [3], participated in a semi-structured interview (see Supplemental Table 2). These oncologists hoped that patients would be aware of the patients' personal views on life and presented themselves as critical listeners to

Table 1

The characters included in the OnVaCT and the values (subthemes) on which their narratives focused either by mentioning that a certain value or subtheme was important or by noting that it was not (or was no longer) important. The subthemes shown in the table are based on the actual topics that patients discussed during the interviews.

Values and subthemes	Claudia	Hubert	Jordy	Wim	Yalda
Characteristics					
Gender	Female	Male	Male	Male	Female
Age	57	67	35	71	48
Living situation	Divorced; has children in school	Living with partner (F); has children and grandchildren	Living alone	Living with partner (M)	Living with partner (M) and children
					
Hope	Hope for improved quality of life		Hope for a new possibility to recover/heal; Being optimistic	Hope for personal benefit; Hope for 'good' days	
Perseverance			Not wanting to give up; Wanting to have tried everything (new possibilities)	Not wanting to give up yet	
Quality or quantity of life	Experiencing a decreased quality of life; Wanting to improve quality of life	Enjoying (certain aspects of) life	Willing to make sacrifices to ensure wellbeing; Striving to prolong life; Doing things on a 'bucket list'; Not feeling ill; Enjoying life	No longer being able to do everything you want; Enjoying (certain aspects of) life	What to do with remaining time; Wanting to strive for quality of life
Risk tolerance	Uncertain whether trial participation will lead to improvements	Not wanting to risk excessively severe side effects	Being afraid of the situation		Worrying about the future of her family
Trust in the health care system or health care professionals	Wanting to discuss certain topics with the oncologist		Wanting to ask the oncologist certain questions		
Autonomy	Experiencing loneliness; Wanting to make her own decisions; Feeling dependent on others		Wanting to do things for himself	Wanting to be independent (of help and tools)	
Social adherence	Decrease in the quality of social life; the importance of connecting with your children	How to interact with others during illness; What to expect from others		Decisions affect loved ones; Being able to ask others for help	
Altruism		Wanting to participate in a trial to help (future) others			
Corporeality		Trying to stay in good condition; Enjoying unhealthy behaviors (i.e., smoking, consuming alcohol)	Doing everything possible to keep the body healthy; Changed (unhealthy) habits; Healthy lifestyle		
Accepting one's fate				Accepting limitations (e.g. decreased mobility)	Continuing to live; Spirituality; Life after death; Not being able to change things
Humanity		Wanting others to show interest in him	Wanting not to feel like a patient	Wanting the oncologist to make him feel human	

their patients, although they tended to allow one value, i.e., honesty, to prevail as their primary professional criterion. Oncologists focused on providing information to set a realistic stage; e.g., “[It depends], of course, how positive or negative I present the options, because I think that people should be realistic in their expectations” (MO 3) and then nudged patients regarding whether they should participate. In particular, if patients already experienced so many backlashes from their illness and treatment that they would be ineligible for participation, oncologists tried to nudge them to decide for themselves not to participate. Moreover, if patients hoped to ensure their survival through early phase clinical trial participation, oncologists would remark that the chance of such an occurrence was very small but hoping for such benefits was acceptable to the oncologists when the information was shared. This study’s oncologists said they tend to serve as rather formal counsellors to patients, mainly focusing on mitigating expectations – a role

that they could play more easily because they had not seen and cared for the patient before and were not (yet) the healthcare professional who was primarily responsible in the care process (i.e. also see Fig. 1).

In three small focus groups including a total of eleven medical oncologists (5 M/6 F; 4 Erasmus MC; 4 Netherlands Cancer Institute; 3 UMC Utrecht; see Supplemental Table 2), the results of the interviews were further refined. The oncologists admitted that they, in general, omit to talk about dying and death and the opportunity for palliative care. The task of discussing palliative care was considered to be difficult because a) most patients do not want to hear about nonparticipation and b) patients can immediately suffer from misconceptions, for instance, that palliative care may imply that health care professionals refrain from taking any action and completely cease treatment of the patient; that palliative care may imply that the cancer is left unchecked; and that the patient is unworthy of treatment/participation in research. A tool, they

suggested, could help to also inform patients on these matters and to prepare for the situation that a medical oncologist decides that a patient is ineligible for participation (e.g., in cases in which the patient had many or severe complaints from the cancer or previous treatments) or that no trials are available. We also decided to explicitly include and discuss palliative care as part of the communication training.

3.1.3. Step 1.3: Modeling the OnVaCT intervention

The development team decided that to make the online process of clarification, deliberation, and conflict solving feel natural, users should be able to encounter outspoken but recognizable digital characters who share their own considerations and conflicts and ask questions. In subsequent project team sessions, the patients' values and personal stories that arose during the interviews and the systematic review were transformed into eight provisional character narratives following the diversity of the actual patient population.

Based on the feedback provided during the feedback session with thirteen patient representatives (see [Supplemental Table 2](#) for background characteristics), in prototype 2, some changes were made with regard to a) gameplay (e.g., shortening and simplifying the introduction and written texts, more opportunities for interaction, professionalizing voice-overs) and b) the patient stories that were united into five final, trustworthy characters ([Table 1](#)).

The communication training for medical oncologists was based on existing trainings, using (theoretical) knowledge of learning principles and SDM as described in the methods section. In addition, the input from the previous steps was used in the development of the communication training. The aim of this communication training was to inform oncologists about what to expect from patients using the OnVaCT (e.g. in terms of values), and to support them in better integrating patient values into the SDM process during their consultation. The communication training existed of three consecutive parts [[29](#)]:

Knowledge: a web lecture focusing on SDM for potential participation in early phase clinical trial (in general) and the role of patient values in this context.

Knowing how: in an individual feedback session oncologists received feedback from the trainer on a recorded personal consultation using the SDM framework offered in the web lecture and with particular attention to the discussion of patient values

Showing how and doing: a final group training session with role play to stimulate a dialogue about patients' personal values and to highlight the specifics of the OnVaCT and how its results could be implemented in patient-physician consultations. After the training, an individual follow-up session was held to discuss the oncologists' experiences in practice.

After the research team agreed with this design, two researchers made a more elaborate proposal for the content of the communication training (Amsterdam Center for Health Communication | Communicatietraining; in Dutch). Results from previous steps of the development process, like the overview of patient values and the actual working processes described by medical oncologists, informed the content of the intervention.

3.2. Piloting phase

3.2.1. Step 2.1: Feasibility testing

In total, ten patients from the Erasmus MC participated in think-aloud sessions; all of these patients had already decided to participate in an early-phase clinical trial. We also approached several patients who decided not to participate in early phase clinical trials, but they did not consent to participate in a think aloud session. When prototype 2 of the OnVaCT was used (n = 5), some patients indicated that the tool did not help them think about what was important to them, although it was intended to do so. In prototype 3, we thus decided to add a questions

during the short narratives to actively make the patient consider the topic at hand (e.g., 'How is this for you?' or 'What is important to you?'). These questions worked, but only if the tool provided enough time for reflection between the different elements in the story, and the invitation for participants to write along was reiterated. Besides some minor bugs (e.g., incorrectly functioning buttons, distracting questions, or the unclear role of the coach), no new issues came up during the sessions with prototype 3 (n = 5). Please see [Fig. 3](#) and the accompanying [Box 1](#) for an outline of the final OnVaCT.

Based on input from the other team members and the psychologist/trainer, the content of the communication training was improved one last time. For example, the text of the web lecture was adapted to better reflect the background knowledge and jargon of oncologists, and the scoring manual that the researchers used to analyze the consultations was simplified/shortened to make it easier for oncologists to use.

4. Discussion and Conclusion

4.1. Discussion and design practice implications

In this study, we describe the structured, theory- and practice-driven development and piloting of an intervention to help patients and oncologists explore and discuss patient values and attitudes towards participation in early phase clinical trials and/or palliative care [[34](#)]. In both the OnVaCT tool and the communication training, value clarification is key. In recent literature on SDM, there has been increasing awareness of the need for goal setting in SDM [[26,27](#)]. The current study adds to this by describing how the systematic exploration of values that patients with advanced cancer hold can be incorporated into an online values clarification tool. Moreover, it shows that to resolve value conflicts surrounding decisions about participation in early phase clinical trials, a quality discussion of these values by patient and oncologist is still a prerequisite.

The impact of the intervention (i.e. the OnVaCT together with the communication training) is researched in a next part of the project (not part of this article), but our thorough and innovative development process of the OnVaCT intervention first showed that by being explicitly transparent about designer biases (see Methods), value clarification tools can actually support good SDM [[24, 35, 36](#)]. Therefore, a tool should inform the patient about the fundamental assumptions of SDM and present a well-considered, broad range of patient stories that contain important values found in interview studies and reviews. The choice for personas, i.e., "user archetypes", that summarize a representative person from the target group [[34](#)] seems to help patients relate, realize that they have a choice and elicit their preferences [[37](#)]. With the assumptions being transparent, we believe that patients gain the freedom to choose the values they consider important and discard those which seem irrelevant. However, in order to not only confirm personal preferences but also support critical reflection at home and during consultations, users are actively invited to participate in a dialogue or critical deliberation [[9, 17–19](#)] through open questions that are incorporated into the OnVaCT. In our view, exploring options for participation in early phase clinical trials needs to go hand in hand with thinking more broadly about palliative care and quality of (the last phase of) life [[38](#)]. Second, it is important to stimulate critical evaluation of patients' values, and not only clarification (see Methods). The intervention is expected to encourage patients to share their personal choice of values, but also to be actively invited to reflect on this through other people's stories, which is known to stimulate moral imagination [[39](#)]. As the OnVaCT is offered in conjunction with a consultation with an oncologist trained to include and discuss values during the SDM process this provides an opportunity to discuss and sometimes even challenge some of the patient's values. The interviews and focus groups revealed that medical oncologists were indeed willing to play the role of critical counsellors [[17,19](#)], in addition to the OnVaCT. Third, in line with previous studies [[6,11](#)], the empirical studies described in this study

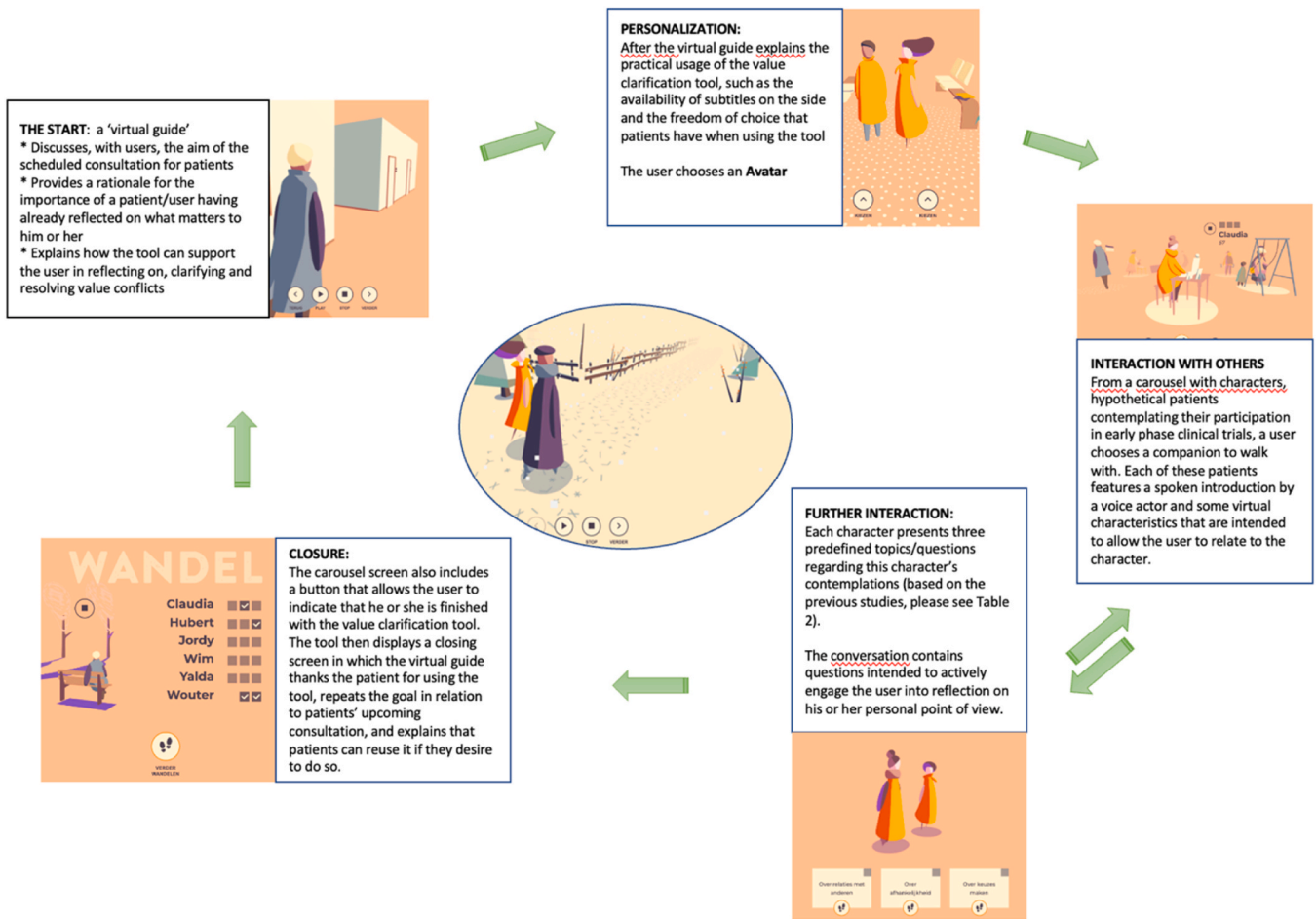


Fig. 3. Five basic steps in the final OnVaCT.

Box 1 (accompanying Fig. 3): the OnVaCT is a carefully designed serious game, which can be reached using the Internet (on any device; Amsterdam Center for Health Communication | Category | Producten). ‘Players’, i.e., patients and caregivers, are invited to join on a virtual walk with a guide that starts in an abstract hospital setting and ends in a kind of park where the five characters are introduced. During the walk in the abstract hospital setting, the users are given information about the aims of the tool, how to use it, and what to expect. Before going outside, the user chooses an avatar and then joins one of the five characters on a walk in a different environment. Each character has its own environment. With this environment, designers tried to combine being enticing to use and being as neutral as possible in relation to the emotional connotations of the conversation topics (e.g., a walk at the beach). A virtual walk with a character takes approximately 5 min, with three different, short story lines. During these stories, users are actively invited to form their own thoughts. Users can pause the story in order to think, discuss a topic with others, or perhaps write something down. No text can be added to the game: users are asked to collect their own thoughts on paper, which they can bring to the next meeting with their oncologist. The game ends with a closure screen where the user can see with which character (s) he has been walking and who is left, receives an invitation to return in the nearby future when necessary, and is given information about what can be done with the outcomes of the interaction with the tool.

confirmed that oncologists were mainly inclined to provide patients with information about early phase clinical trials, rather than to discuss patient values or even the option to ‘do nothing’. The OnVaCT intervention, with its specific focus on value clarification, was specifically designed to address this practical challenge. The current study indicates that medical oncologists are willing to discuss values with their patients if they feel supported in doing so. It is, however, important that the process of value clarification is designed to fit health care professionals practices as best as possible. The accompanying training is essential to a implementation. Fourth, we consider it important to also include patients’ relative weighing of their values and potential shifts over time (see Methods). The tool itself still runs the risk of providing only a single snapshot of the situation, while the process of valuing life is likely to be

ongoing. For this reason, the developers have added the suggestion that patients could (and perhaps should) use the OnVaCT more than once, preferably together with those who are close to them. However, as the tool was developed for patients with advanced cancer, and the decision to participate in a phase 1 clinical trial is a one-off decision, it is recommended that the intervention is tested in other contexts where the treatment pathway is longer.

A strength of this study is that it embraced and highlighted the importance of applying a patient- and user-inclusive design [40,41], which aligns well with recommendations from IPDAS program theories [42]. A limitation was that we were unable to include patients who decided not to participate in early phase clinical trials in the think aloud sessions. Still, their perspectives were included in the patient interviews

which enabled us to include their considerations into the intervention. Besides, the patient representatives from the feedback session could take a more distant position since they were not part of a clinical trial process concerning cancer.

4.2. Conclusion

Decision aids have previously been shown to be capable of improving patients' knowledge and doctor–patient communication, to decrease decisional conflict [1], and – if the aid includes value clarification – to help patients make a decision that is in line with their values [4]. The current study provides both a theoretical foundation for and a step-by-step approach to the task of designing value clarification tools that contribute to future SDM in the context of health care. We believe that, within the complex and high-risk context of contemplating early phase clinical trial participation, the OnVaCT intervention could lead to a better integration of patient values, which could, in turn, improve the SDM process and related patient outcomes.

CRedit authorship contribution statement

van Weert Julia: Writing – review & editing, Validation, Supervision, Methodology, Formal analysis, Conceptualization. **van der Rijt Carin:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Haselaar Jeroen:** Writing – review & editing, Validation, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization. **van Lent Liza:** Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Conceptualization. **van Gurp Jelle:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Stoel Nicole:** Writing – review & editing, Formal analysis, Data curation.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Carin van de Rijt reports financial support was provided by Dutch Cancer Society.

Acknowledgments

This project received external funding from the Dutch Cancer Society (KWF11086, project leader: Van der Rijt). We would like to thank all the patients and medical oncologists who were included in the study for their invaluable feedback, psychologist Dr. Adriaan van 't Spijker for his contributions to the communication training, and our collaborators from the IT company IJsfontein (Amsterdam, the Netherlands) for their hard work on the OnVaCT. In particular, we also wish to thank Anko Elzes, Theo van Wijk and Rogier Koppejan. Finally, we would like to thank Mirte van Ham for all of her work 'behind the scenes'.

Authors' contributions

JvG and LvL were responsible for the analyses of the oncologist interviews, focus groups and think aloud sessions and for writing the manuscript. NS conducted the oncologist interviews as well as the individual think aloud sessions; she also conducted parts of the analysis of the think aloud sessions. JvG and JH conducted the focus groups, and LvL was involved with the group feedback session. All authors were part of the development team, under supervision of JH and JvG, that collaborated with the IT company design team to build the tool. LvL, CvdR, and JvW were responsible for the development of the communication training. All authors reviewed the final manuscript.

Conclusion and practice implication

Based on our reflections on design biases, this mixed-method development process offers a scientific basis for future online decision support technologies and/or independent value clarification tools.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.pec.2023.108075](https://doi.org/10.1016/j.pec.2023.108075).

References

- [1] Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;(4).
- [2] Schwartz SH. Universals in the content and structure of values: theoretical advances and empirical tests in 20 countries. *Advances in Experimental Social Psychology*, 25. Elsevier; 1992. p. 1–65.
- [3] Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *Bmj* 2006;333(7565):417.
- [4] Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Libr* 2014.
- [5] Peate M, Watts K, Wakefield CE. The 'value' of values clarification in cancer-related decision aids. *Patient Educ Couns* 2013;90(2):281–3.
- [6] Thorne S, Hislop TG, Kim-Sing C, Oglov V, Oliffe JL, Stajduhar KI. Changing communication needs and preferences across the cancer care trajectory: insights from the patient perspective. *Support Care Cancer* 2014;22(4):1009–15.
- [7] Kunneman M, Marijnen CAM, Baas-Thijssen MCM, van der Linden YM, Rozema T, Muller K, et al. Considering patient values and treatment preferences enhances patient involvement in rectal cancer treatment decision making. *Radiother Oncol* 2015;117(2):338–42.
- [8] Thomas TH, Jackson VA, Carlson H, Rinaldi S, Sousa A, Hansen A, et al. Communication differences between oncologists and palliative care clinicians: a qualitative analysis of early, integrated palliative care in patients with advanced cancer. *J Palliat Med* 2019;22(1):41–9.
- [9] Boyd D, Bogdan D. Something 'clarified, nothing of 'value': a rhetorical critique of values clarification. *Educ Theory* 1984;34(3):287–300.
- [10] Kinnier RT. A reconceptualization of values clarification: values conflict resolution. *J Couns Dev* 1995;74(1):18–24.
- [11] Trice ED, Prigerson HG. Communication in end-stage cancer: review of the literature and future research. *J Health Commun* 2009;14(S1):95–108.
- [12] Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new medical research council guidance. *Bmj* 2008;337:a1655.
- [13] van Lent LGG, Stoel NK, van Weert JCM, van Gurp J, de Jonge MJA, Lolkema MP, et al. Realizing better doctor-patient dialogue about choices in palliative care and early phase clinical trial participation: towards an online value clarification tool (OnVaCT). *BMC Palliat Care* 2019;18(1):106.
- [14] Netherlands Trial Register (NTR): Cochrane Netherlands, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht; [Available from: (<https://www.trialregister.nl/>)].
- [15] Witteman HO, Scherer LD, Gavaruzzi T, Pieterse AH, Fuhrel-Forbis A, Chipenda Dansokho S, et al. Design features of explicit values clarification methods: a systematic review. *Med Decis Mak* 2016;36(4):453–71.
- [16] Pieterse AH, de Vries M, Kunneman M, Stiggelbout AM, Feldman-Stewart D. Theory-informed design of values clarification methods: a cognitive psychological perspective on patient health-related decision making. *Soc Sci Med* 2013;77:156–63.
- [17] Harrison JL. Values clarification: an appraisal. *J Moral Educ* 1976;6(1):22–31.
- [18] Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. *JAMA* 1992;267(16):2221–6.
- [19] Garrett JR. The poverty of value clarification: using ethical theory to critique and transcend the "givens" of clinical ethics consultation. *Am J Bioeth* 2016;16(9):48–51.
- [20] van Lent LGG, Jabbarian LJ, van Gurp J, Haselaar J, Lolkema MP, van Weert JCM, et al. Identifying patient values impacting the decision whether to participate in early phase clinical cancer trials: a systematic review. *Cancer Treat Rev* 2021;98.
- [21] van Gurp JLP, van Lent LGG, Stoel NK, van der Rijt CCD, de Jonge MJA, Pulleman SM, et al. Core values of patients with advanced cancer considering participation in an early-phase clinical cancer trial: a qualitative study. *Support Care Cancer* 2022.
- [22] Braun V, Clarke V, Hayfield N, Terry G. Thematic analysis. In: Liampittong P, editor. *Handbook of Research Methods in Health Social Sciences*. Singapore: Springer Singapore; 2019. p. 843–60.
- [23] Corbin JM, Strauss AL. *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded theory*. Los Angeles: SAGE Publications; 2008.
- [24] Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27(10):1361–7.

- [25] Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *Bmj* 2010;341:c5146.
- [26] Pel-Littel RE, Buurman BM, van de Pol MH, Yilmaz NG, Tulner LR, Minkman MM, et al. Measuring triadic decision making in older patients with multiple chronic conditions: observer OPTIONMCC. *Patient Educ Couns* 2019;102(11):1969–76.
- [27] Pel-Littel RE, van Weert JCM, Minkman MM, Scholte Op Reimer WJM, van de Pol MH, Buurman BM. The development of the evidence-based SDM(MCC) intervention to improve shared decision making in geriatric outpatients: the DICO study. *BMC Med Inf Decis Mak* 2020;20(1):35.
- [28] van Weert JC, Jansen J, Spreuwenberg PM, van Dulmen S, Bensing JM. Effects of communication skills training and a Question Prompt Sheet to improve communication with older cancer patients: a randomized controlled trial. *Crit Rev Oncol Hematol* 2011;80(1):145–59.
- [29] Miller GE. The assessment of clinical skills/competence/performance. *Acad Med* 1990;65(9 Suppl):S63–7.
- [30] Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision making: multistage consultation process. *BMJ* 2017;359:j4891.
- [31] van de Pol MH, Fluit CR, Lagro J, Slaats YH, Olde Rikkert MG, Lagro-Janssen AL. Expert and patient consensus on a dynamic model for shared decision-making in frail older patients. *Patient Educ Couns* 2016;99(6):1069–77.
- [32] van de Pol MHJ, Fluit C, Lagro J, Slaats Y, Olde Rikkert MGM, Lagro-Janssen ALM. Shared decision making with frail older patients: Proposed teaching framework and practice recommendations. *Gerontol Geriatr Educ* 2017;38(4):482–95.
- [33] Bolle S, Romijn G, Smets EMA, Loos EF, Kunneman M, van Weert JCM. Older cancer patients' user experiences with web-based health information tools: a think-aloud study. *J Med Internet Res* 2016;18(7).
- [34] Kip H, Keizer J, da Silva MC, Beerlage-de Jong N, Köhle N, Kelders SM. Methods for human-centered eHealth development: narrative scoping review. *J Med Internet Res* 2022;24(1):e31858.
- [35] Fagerlin A, Pignone M, Abhyankar P, Col N, Feldman-Stewart D, Gavaruzzi T, et al. Clarifying values: an updated review. *BMC Med Inform Decis Mak* 2013;13(2):S8.
- [36] Stiggelbout AM, Pieterse AH, De Haes J. Shared decision making: concepts, evidence, and practice. *Patient Educ Couns* 2015;98(10):1172–9.
- [37] Vosbergen S, Mulder-Wiggers JMR, Lacroix JP, Kemps HMC, Kraaijenhagen RA, Jaspers MWM, et al. Using personas to tailor educational messages to the preferences of coronary heart disease patients. *J Biomed Inform* 2015;53:100–12.
- [38] Brom L, De Snoo-Trimp JC, Onwuteaka-Philipsen BD, Widdershoven GA, Stiggelbout AM, Pasman HR. Challenges in shared decision making in advanced cancer care: a qualitative longitudinal observational and interview study. *Health Expect* 2017;20(1):69–84.
- [39] Scott PA. Imagination in practice. *J Med Ethics* 1997;23(1):45–50.
- [40] Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. *BMC Med Inform Decis Mak* 2013;13(2):S2.
- [41] Witteman HO, Maki KG, Vaissou G, Finderup J, Lewis KB, Dahl Steffensen K, et al. Systematic development of patient decision aids: an update from the IPDAS collaboration. *Med Decis Mak* 2021;41(7):736–54.
- [42] Joseph-Williams N, Abhyankar P, Boland L, Bravo P, Brenner AT, Brodney S, et al. What works in implementing patient decision aids in routine clinical settings? A rapid realist review and update from the international patient decision aid standards collaboration. *Med Decis Mak* 2021;41(7):907–37.