

Understanding how a personalized risk prediction tool (VALUE-PERSARC) supports informed treatment decisions of soft-tissue sarcomas patients in daily clinical practice – A mixed methods study

VALUE-PERSARC research group

DOI

[10.1016/j.ejca.2024.114269](https://doi.org/10.1016/j.ejca.2024.114269)

Publication date

2024

Document Version

Final published version

Published in

European Journal of Cancer

Citation (APA)

VALUE-PERSARC research group (2024). Understanding how a personalized risk prediction tool (VALUE-PERSARC) supports informed treatment decisions of soft-tissue sarcomas patients in daily clinical practice – A mixed methods study. *European Journal of Cancer*, 210, Article 114269.
<https://doi.org/10.1016/j.ejca.2024.114269>

Important note

To cite this publication, please use the final published version (if applicable).
Please check the document version above.

Copyright

Other than for strictly personal use, it is not permitted to download, forward or distribute the text or part of it, without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license such as Creative Commons.

Takedown policy

Please contact us and provide details if you believe this document breaches copyrights.
We will remove access to the work immediately and investigate your claim.



Original research

Understanding how a personalized risk prediction tool (VALUE-PERSARC) supports informed treatment decisions of soft-tissue sarcomas patients in daily clinical practice – A mixed methods study

Anouk A. Kruiswijk^{a,b,*}, Ellen G. Engelhardt^c, Lisa A.E. Vlug^a, Robert J.P. van de Wal^b, Yvonne M. Schrage^d, Rick L. Haas^{e,f}, Michiel A.J. van de Sande^b, Perla J. Marang-van de Mheen^g, Leti van Bodegom-Vos^a, VALUE-PERSARC research group

^a Department of Biomedical Data Sciences, Medical Decision Making, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, the Netherlands

^b Orthopedic Surgery, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, the Netherlands

^c Division of Psychosocial Research and Epidemiology, The Netherlands Cancer Institute, P.O. Box 90203, 1006 BE Amsterdam, the Netherlands

^d Department of Surgical Oncology, The Netherlands Cancer Institute, 1066 CX Amsterdam, the Netherlands

^e Department of Radiotherapy, The Netherlands Cancer Institute, 1066 CX Amsterdam, the Netherlands

^f Department of Radiotherapy, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, the Netherlands

^g Safety & Security Science, Faculty of Technology, Policy & Management, Delft University of Technology, Jaffalaan 5, 2628 BX Delft, the Netherlands

ARTICLE INFO

Keywords:

Risk-prediction models
(Informed) decision-making
Clinical consultation
Soft-tissue sarcoma

ABSTRACT

Introduction: Risk prediction models (RPM) can help soft-tissue sarcoma(STS) patients and clinicians make informed treatment decisions by providing them with estimates of (disease-free) survival for different treatment options. However, it is unknown how RPMs are used in the clinical encounter to support decision-making. This study aimed to understand how a PERSONALISED SARcoma Care (PERSARC) RPM is used to support treatment decisions and which barriers and facilitators influence its use in daily clinical practice.

Methods: A convergent mixed-methods design is used to understand how PERSARC is integrated in the clinical encounter in three Dutch sarcoma centers. Data were collected using qualitative interviews with STS patients (n = 15) and clinicians (n = 8), quantitative surveys (n = 50) and audiotaped consultations (n = 30). Qualitative data were analyzed using thematic analysis and integrated with quantitative data through merging guided by the SEIPS model.

Results: PERSARC was generally used to support clinicians' proposed treatment plan and not to help patients weigh available treatment options. Use of PERSARC in decision-making was hampered by clinician's doubts about whether there were multiple viable treatment options, the accuracy of risk estimates, and time constraints. On the other hand, use of PERSARC facilitated clinicians to estimate and communicate the expected benefit of adjuvant therapy to patients.

Conclusion: PERSARC was not used to support informed treatment decision-making in STS patients. Integrating RPMs into clinical consultations requires acknowledgement of their benefits in facilitating clinicians' estimation of the expected benefit of adjuvant therapies and information provision to patients, while also considering concerns regarding RPM quality and treatment options' viability.

1. Introduction

Soft-tissue sarcomas (STS) are a rare and heterogeneous group of malignant neoplasms, with more than 100 histological subtypes [1]. They arise from mesenchymal cells and account for 1 % of all adult

malignancies [2]. STS may occur at every age and almost any anatomical site, but predominantly manifest in the extremities and trunk wall [3]. Treatment for aggressive and infiltrating (high-grade) extremity STS typically involves a combination of surgery and/or (neo)adjuvant radiotherapy. Each treatment modality has distinct advantages and

* Corresponding author at: Department of Biomedical Data Sciences, Medical Decision Making, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, the Netherlands.

E-mail address: a.a.kruiswijk@lumc.nl (A.A. Kruiswijk).

<https://doi.org/10.1016/j.ejca.2024.114269>

Received 24 May 2024; Received in revised form 29 July 2024; Accepted 2 August 2024

Available online 9 August 2024

0959-8049/© 2024 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY-NC license (<http://creativecommons.org/licenses/by-nc/4.0/>).

risks. As none of the options are clearly superior from a medical perspective, a subjective trade-off needs to be made driven by patients' informed preferences.

Recent literature underscores the complexity of treatment decision-making for individual STS patients, especially the weighing of risks and benefits, and emphasizes the pivotal role of decision-support interventions to facilitate informed decision-making and reduce decisional conflict [4–6]. Therefore, our research group developed and validated a personalized risk prediction tool (Personalised Sarcoma Care: PERSARC) [7,8]. This tool provides patients and clinicians insight into the personalised risks and benefits of each treatment option based on patient's age, tumor size, tumor depth and histology to support their decision-making process.

Risk Prediction Models (RPMs) like PERSARC seem well suited to effectively support decision-making during clinical encounters. Patients' goals and preferences for treatment vary widely, and RPMs provide individualized risks and benefits of treatment, which may help patients to weigh the treatment options and thereby engage them in the decision-making process [9,10]. Providing patients with individualised information from RPMs can thus be a first step towards informed treatment decisions that are better aligned with patients' values and goals, thereby reducing decisional conflict, if RPMs are used as intended. However, most studies have focused on the development and validation of RPMs, but the extent to which and how RPMs are used in routine clinical practice remains largely unknown, which is crucial to interpret if and how their use impacts treatment decision-making [11,12]. Therefore, the present study aims to understand how a personalized RPM (PERSARC) is used to support treatment decisions as well as to identify barriers and facilitators in clinical practice.

2. Methods

2.1. Study design

A convergent mixed-methods design was used to understand the use of PERSARC in the patient-clinician encounters and the factors influencing its use. Quantitative data assessed the extent to which PERSARC was used, while qualitative data added insights into why and how PERSARC was or was not used. This study is embedded within the VALUE-PERSARC study, a pragmatic parallel cluster randomized trial that has been described elsewhere [13]. Briefly, the VALUE-PERSARC study evaluates the (cost-)effectiveness of PERSARC implementation in

three intervention hospitals on knowledge and decisional conflict among STS patients relative to patients receiving care-as-usual in control hospitals. The VALUE-PERSARC study aims to include at least 120 patients aged ≥ 18 years with high-grade extremity STS treated between August 2021 and June 2024 in six tertiary referral centers. Clinicians in intervention hospitals use the VALUE-PERSARC app that incorporates the PERSARC RPM in patient-clinician encounters (Supplementary file 4), which could also be accessed by clinicians through a web browser. The present study, therefore, only includes patients and clinicians from the three intervention hospitals to evaluate the integration of PERSARC in clinical consultations. Figure 1 shows a description of the patient-clinician encounter where PERSARC is used to discuss treatment options.

The Medical Ethical Committee Leiden-Den Haag-Delft (METC-LDD) and five other participating Dutch sarcoma centers approved all study procedures (NL76563.058.21). The VALUE-PERSARC study was registered on 8 January 2021 in the Netherlands Trial Register (NL9160) and updated in ClinicalTrials.gov (NCT05741944).

2.2. Theoretical framework

We used the SEIPS 101 (System Engineering Initiative for Patients Safety) as the theoretical framework to understand the use of the PERSARC RPM in the patient-clinician encounters [14,15]. SEIPS 101 is a simple practice-oriented model that explores interactions between humans, the technology they use and the environment in which they work, and has been successfully applied across healthcare [16–20]. Both the qualitative and quantitative data were categorized according to the four elements of the SEIPS model to enable merging of insights derived from these data sources: 1) people (i.e., patients' and clinicians' attitudes towards and beliefs regarding the RPM), 2) environment (i.e., issues related to embedding the RPM in clinical workflows), 3) technology/tools (i.e., issues related to the software's usability or design of the app) and 4) tasks (i.e., actual use of the RPM in patient-clinician encounters).

2.3. Data collection

Quantitative data were collected to assess the extent to which PERSARC was used in clinical consultations, for which 3 data sources were used: audiotaped consultations, checklist filled in by clinicians and satisfaction surveys from both patients and clinicians (Table 1).

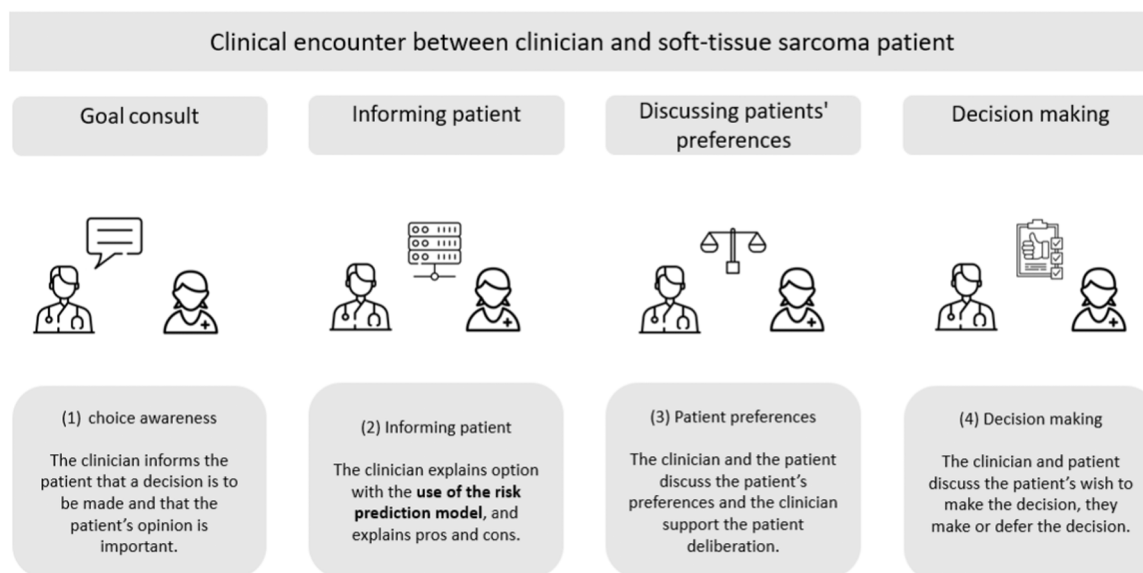


Fig. 1. Components of clinical encounters between clinicians and soft-tissue sarcoma patients with the use of the PERSARC risk prediction tool.

Table 1
Sources and data collection methods.

		Quantitative			Qualitative	
		Audiotapes of consultation	Checklist	Survey	Interviews	Field notes
People	Patients			Satisfaction with use of PERSARC	Perceived added value and usefulness PERSARC	Contextualize findings
	Clinicians			Satisfaction with use of PERSARC	Perceived added value and usefulness PERSARC	
Environmental			Use PERSARC in MTB and consultation		Barriers and facilitators for embedding PERSARC in consultation	Contextualize findings
Tool/technology					Barriers and facilitators of app / software	Contextualize findings
Task-related		Use PERSARC in consultation, Patient involvement			Use PERSARC in consultation, Patient involvement	

*People Environment Tools Tasks (PETT) scan as derived from the SEIPS 101 model.

Audiotapes. The VALUEPERSARC app can be used to audio record patient consultations. Recording of the patient consultation is not mandatory, and is requested separately when patients register in the VALUE-PERSARC app. We used transcripts of the audiotaped consultations to 1) ascertain whether PERSARC was used by clinicians to support information provision about available treatment options (including their risks and benefits) and 2) evaluate the extent to which clinicians involved patients in the decision-making process. The coding scheme (Supplementary file 1) was developed by the VALUE-PERSARC research team, and was based on a 4-step model to make informed and value congruent medical decisions described by Stiggebout and colleagues (i. e., creating choice awareness, information provision, discussing preferences, and decision-making) [21].

Checklist clinicians. After each consultation, clinicians were asked to complete a checklist to indicate whether they had used PERSARC during: a) the multidisciplinary tumor board meeting in which the patients was discussed, and b) the consultations with the patient. Clinicians received the checklist (Supplementary file 2) by email immediately after each patient consultation, with reminders sent after one week.

Satisfaction survey patients and clinicians. We evaluated satisfaction with the use of PERSARC using a self-developed questionnaire sent to all included patients and their clinicians, with reminders sent after one week. The questionnaire consists of three short questions about the usefulness of PERSARC in a consultation, its helpfulness in the decision-making process and intentions for future use (Supplementary file 3).

Qualitative data were gathered to get a more in-depth understanding of patients' and clinicians' experiences with the integration of PERSARC in clinical practice and to identify barriers and facilitators influencing its use in treatment decision-making processes, for which interviews were conducted with patients and clinicians and field notes were taken.

Interviews. Fifteen randomly selected STS patients and five clinicians treating STS patients (at least one per intervention hospital) were interviewed by two members of the research team (AK, LV) using a 16-item interview scheme. The interview scheme was developed by the research team (AK, LvB, EE) and guided by the SEIPS model [14] (Supplementary file 4).

Field notes. Field notes were made by the primary researcher (AK) during the observations of consultations. Additionally, throughout the study duration, notes were taken following contacts with clinicians (e.g., regarding patient inclusion) and patients (e.g., if assistance was needed with app installation or completion of study questionnaires). Field notes were used to contextualize quantitative and qualitative findings.

2.4. Data analysis

2.4.1. Quantitative

The audio-recordings of patient-clinician encounters were transcribed verbatim and assessed by two reviewers (AK, LV) using the Observing Patient Involvement in Decision Making 5-item (OPTION-5) scale (score range, 0–100, with 0 indicating minimal behavior and 100

indicating maximal behavior) to code clinicians behavior to involve patients in decision-making [22]. Additionally, transcripts of recordings were independently reviewed to assess the extent to which PERSARC was used during the encounter. This included identifying the treatment options discussed (surgery, pre -or post operative radiotherapy), along with their benefits and risks using a predefined coding scheme (Supplementary file 1). Discrepancies were discussed until consensus was reached.

All quantitative data (i.e., the audiotapes, checklists by clinicians and surveys from patients and clinicians) were analyzed using descriptive statistics with IBM SPSS version 29.

2.4.2. Qualitative

Interviews with patients and clinicians were audio-recorded and transcribed verbatim. Transcripts of interviews were analysed by two researchers (AK, LV) independently using a combined approach of inductive and deductive thematic analysis [23]. Discrepancies in coding were resolved through consensus. Qualitative data analyses were performed using ATLAS.ti (v24) software.

Field notes were independently reviewed (AK, LV), and utterances were assigned to themes that emerged from the data. The researchers discussed the manner in which the data fitted in the themes to reach joint consensus.

2.5. Data integration

The results of the quantitative and qualitative analysis were integrated through merging. That is, the results were compared for each of the SEIPS model elements to assess how they confirmed, expanded or contradicted each other and to draw meta-interferences about how and why PERSARC was used in daily clinical practice to support treatment decisions [24,25]. To merge the results, quantitative and qualitative themes were compared simultaneously in a back-and-forth process framed by the elements of SEIPS [26]. Joint display analysis was used to integrate the quantitative and qualitative data by constructing and reconstructing them to achieve a fuller understanding of both [27]. The final joint displays are presented in the results section and quotes from interviews and consultations will be provided for illustration.

3. Results

In total, data were collected from 50 patients and 8 clinicians in three tertiary sarcoma referral centers (Table 2). Median age of patients was 63 (IQR 51–72) years and 52 % were male. Thirty audio-recorded clinical encounters (median duration: 17(SD 6 min)) were made. Thirty-eight clinicians completed the checklist on PERSARC use after the consultations as well as the clinicians survey. Fifteen patients and five clinicians were interviewed.

For each of the elements of the SEIPS model, we describe the results from the different data sources and how they were integrated.

Table 2
Number of observed patients-, clinicians and clinical encounters using an individualized risk prediction tool (PERSARC).

	Quantitative				Qualitative	
	Audiotapes of consultation +mean duration	Checklist	Survey		Interviews	
			Clinician	Patients	Clinician	Patients
Center 1	18 19(6)	20	20	26	3	5
Center 2	12 14(5)	15	15	19	1	8
Center 3	-	3	3	5	1	2
Total	30 16(6)	38	38	50	5	15

3.1. Task-related

Observations from the audio-taped consultations showed that PERSARC was used in nearly all clinical encounters (27/30), and in most of these was used to mentioned more than one treatment option (26/30)

Table 3
Joint display of task-related factors influencing the use of PERSARC in consultation.

	Quantitative results		Qualitative results	Mixed method meta-inferences
Use of PERSARC in treatment decision processes	Audiotapes of consultation		Interviews	Δ Expansion
	Tasks clinician for informed decision-making using PERSARC (according to researchers)	Consultations (N)	▼Clinician only discussed one treatment option or did not show OS/LR graphically or explained treatment side-effects. Q: Do you also show the figures? Or do you only mention the OS/LR numbers? A: I mention the numbers. I haven't shown the figures because then I have to log in again and show everything separately. That would take too much time."(C5)	Interviews revealed that clinicians choose which treatment options to discuss and how the option(s) are presented which expanded on the results of audiotaped consultation showing that PERSARC is only partly used as intended.
	–Creating choice awareness	5/30		
	–Use of RPM during clinical encounter	27/30*		
	–No. Treatment options discussed with the use of RPM			
	–1	1/30		
	–2 or more	26/30	▼Implicit steering towards a particular treatment option	
	–Type of treatment options discussed		C: "And, of course, as a doctor, I can be quite firm, saying: "Listen, I have this option and this one, but we're going with this". You can certainly steer as a doctor. It's just a matter of how you sell that car, or which cars you choose to showcase in your showroom, so to speak." (C1)	
	–noRT	29/30		
	–pre-operative RT	30/30		
	–post-operative RT	17/30		
	–Risks graphically shown with PERSARC no. of treatment options			
	–1	14/30		
Patient involvement	–2 or more	12/30		
	–Explanation of input variables used in PERSARC	22/30		
	–Benefits and harms of treatment options discussed			
	–No	7/30		
	–Yes, implicitly	5/30		
	–Yes, explicitly	18/30		
	–Clinician elucidated patient's preferences	4/30	Interviews	▽ Contradiction
	–Treatment decision made by:		▲ Clinicians perceived patients as more engaged in the decision-making process. "I find that discussion important and it is supported by PERSARC. And I think it's good to discuss those numbers with the patient. Strangely enough, sometimes the patient makes a different decision than I would expect. But that's the beauty of it, at least you can indicate a number to some extent, and that leads to different conclusions from different people." (C5)	The low OPTION-5 scores accompanied by treatment decisions primarily made by clinicians are contradicted with the qualitative finding that clinicians perceived patients as more involved in decision-making process.
	–Patient	3/30		
	–Patient and Clinician (Shared decision)	0/30		
	–Clinician	27/30		
	–Treatment decision determined prior to consultation	15/30		
	–Patient involvement (OPTION-5) mean±SD	17±14		

▼ Barrier ▲ Facilitator *In three cases, only one LR/OS estimate was mentioned and not visually shown, without further explanation, which was considered inappropriate use of PERSARC

(Table 3). However, the risks associated with treatment were not always graphically shown for more than one treatment option (12/30) or only one of the outcomes was discussed (i.e., the overall survival or local recurrence rates). The interviews expanded on these findings, showing how clinicians regularly implicitly steered towards a particular treatment option by emphasizing the side effects of the treatment option that they felt was not preferred (C: "And, of course, as a doctor, I can be quite firm, saying: "Listen, I have this option and this one, but we're going with this". You can certainly steer as a doctor. It's just a matter of how you sell that car, or which cars you choose to showcase in your showroom, so to speak" (C1)). Clinicians' effort to involve patients in the clinical encounter, measured with the OPTION-5, achieved a median score of 15 (5–21) out of 100. Patients' preferences were elicited in 4 out of 30 encounters. In most cases the treatment decision was unilaterally made by the clinician (21/30), and seldom in consultation with the patient (6/30). This contradicts the results from the interviews in which clinicians stated that they perceived patients were more engaged in the decision-making process when using PERSARC.

3.2. Environmental

Clinicians stated in the interviews that they found it difficult to incorporate PERSARC into their consultations as that would mean

Table 4
Joint display of environmental factor influencing the use of PERSARC in consultation.

	Quantitative results		Qualitative results	Mixed methods meta-inferences
Use of PERSARC in MTB	<u>Checklist (use of PERSARC)</u>		<u>Interviews</u>	<u>Δ Expansion</u>
	PERSARC discussed during MTB (according to clinician)	Consultations (N)	▼Clinicians experienced difficulties to deviate from the treatment plan discussed during MTB "You get a prescription from the MTB and you are going to discuss that with the patient (C4)"	The quantitative findings, indicating that in almost half of the patients, only one option is discussed in MTB when using PERSARC, expand on clinicians' difficulties in deviating from this during consultation with the patient
	-No	5/38	<u>Field notes</u>	
	-Yes, 1 option	16/38	Difficulties to embed the results of PERSARC in consultation. Sometimes treatment already started or the treatment decision was already made in MTB prior to patient-clinician encounter.	
	-Yes, 2 or more options	17/38		
Embedding in consultation	<u>Checklist (use of PERSARC)</u>		<u>Interviews</u>	<u>Δ Expansion</u>
	PERSARC discussed with the patient during consultation (according to clinician)	Consultations (N)	▼Time constraints "Yes, filling in the RPM consumes a lot more time. I: Is it a reason to not use it? C: Yes, certainly, that is a very solid reason not to do something (C4)" "Did you find it appropriate during consultation?" P: "In hindsight, yes. Initially, I thought it would be a very short conversation, we are in healthcare and people are busy. I have a long list of questions and we have to rush through it in 10 min, and it's a matter of life or death, so we are not going to waste our time on an app now (P13)"	Although the quantitative results show that more than two treatment options are often discussed, the qualitative results indicate that clinicians struggle to integrate the use of RPM into consultations due to time constraints and availability of variables.
	-No	1/38	<u>Field notes</u>	
	-Yes, 1 option	4/38	Difficulties to use the app (log in), unavailability of variables needed to fill in PERSARC at the time of consultation.	
	-Yes, 2 or more options	33/38		

▼ Barrier ▲ Facilitator

presenting treatment options to patients that had not been discussed during the multidisciplinary tumor board (MTB) meeting. Moreover, the clinician checklists showed that during MTB meetings generally only the option deemed most suitable was discussed, even though multiple treatment options were mentioned during the majority of consultations with the use of PERSARC (Table 4). Another environmental barrier to PERSARC use was not having all tumor characteristics (e.g., tumor grade) needed by PERSARC to calculate prognostic estimates at the time of the patient-clinician encounter. This required the clinician to make an educated guess to be able to use PERSARC. Moreover, field notes from observed consultations and audio-taped consultation, showed that treatment decisions had already been made or initiated prior to the patient-clinician encounter, thus limiting the usefulness of PERSARC for treatment decision-making (Table 3). This was often due to time constraints, as patients had undergone extensive diagnostic procedures before being referred to a tertiary center for treatment, and therefore is an important barrier. Furthermore, both patients and clinicians expressed concerns in interviews about the time-consuming nature of filling in patient and tumor characteristics during consultations, which is in line with observations documented in field notes.

3.3. Patient-related factors

Nine patients (out of 50) reported in the satisfaction survey that PERSARC aided in clinical decision-making (Table 5). Qualitative results expand on this finding, as patients did not always feel that there was a choice in treatment. However, most patients also reported in the survey that they perceived PERSARC as embedded in the VALUE-PERSARC app as useful (48/50) and the majority (39/50) would use the app again. Reasons for patients to promote VALUE-PERSARC, mentioned in the interviews, were that it helped them in understanding the impact of different treatment options and provided insights into personalized prognostic estimates. The app was perceived as too complicated by some older (>65y) patients. For example, these patients experienced difficulties installing the app or completing the study questionnaires on their

mobile phones, as observed by the primary researcher (AK).

3.4. Clinician-related factors

Clinicians indicated in the survey that they perceived PERSARC to be useful during consultations with the patient (33/38). Interviews revealed that they did so because it enhances their understanding of individual patients' prognosis, making treatment decisions feel more tailor-made than if they had been informed by general statistics from the literature (Table 6). Simultaneously, all interviewed clinicians also expressed doubts about the retrospective data on which PERSARC is based ("I: What is the reason that you don't use PERSARC outside the framework of this research? C: Well, I think it's because PERSARC is a predictive model that was ultimately developed based on retrospective data. That inherently makes it less informative (C4)". Two-thirds of the clinicians indicated in the survey that PERSARC was helpful in drafting the treatment plan. This is contradicted by the results of the interviews in which clinicians were uncertain whether patients truly had multiple viable treatment options, as they often considered one treatment option to be superior. Clinicians' doubts about the RPM were strengthened when its prognostic estimates were not in line with their perception of the superior treatment option.

3.5. Tool/technology related

Technology-related factors that hampered the use of PERSARC, mentioned by patients and clinicians during the interviews, included software problems leading to slow responses, the need to click through multiple pages, and system freezing. Additionally, some patients forgot their account password in the app. Both issues were frustrating as they consumed valuable time during patient-clinician encounters, leading to patients receiving insufficient information in a hurried manner as observed by the primary researcher (AK). Yet, interviews revealed that patients appreciated the access to comprehensive information within the app that could be shared with relatives and consulted at home.

Table 5
Joint display of patient-related factors influencing the use of PERSARC in consultation.

	Quantitative results		Qualitative results	Mixed methods meta-inferences
Added value decision-making	<u>Satisfaction survey patients</u> PERSARC assisted in making the treatment decision	<i>Patients (N)</i> 9 /50	<u>Interviews</u> ▼Patient did not feel there was a choice in treatment “She [clinician] said it seems logical for you to do that [proposed treatment] and indeed that seemed very logical to me as well. So it was sort of if you don’t do it [proposed treatment], then you have less of a chance [survival probabilities]. What do you want” (P12)	Δ <i>Expansion</i> The qualitative results expand on the quantitative finding that PERSARC did not help in making the treatment decision, because patients did not feel that there was a choice in treatment.
Usefulness of PERSARC	<u>Satisfaction survey patients</u> PERSARC as embedded in the VALUE-PERSARC app useful What was the added value of VALUE-PERSARC for you? “Good/reliable source of information” “Provides insight into personal chances” “Could be shared with relatives”	48/50	<u>Interviews</u> ▲Patients prefer to have insight into prognostic estimates “And what I really liked is that the results of the RPM showed me why we are doing this [the proposed treatment], and not the alternative [treatment]. So, why not first choose surgery or why not opt for radiation therapy instead?” (P13)	Δ <i>Expansion</i> The qualitative results expand on the quantitative finding that the majority of patients found PERSARC useful, because it provided insight into prognostic estimates.
VALUE-PERSARC app	<u>Satisfaction survey patients</u> Prefers to use VALUE-PERSARC again What is the reason why you would not use VALUE-PERSARC again? “I want the clinician to make the decision”	39/50	<u>Interviews</u> ▼Some (older) patients prefer to have the clinician make the treatment decision as they perceive the app as too complicated “Yes, as a layperson, you naturally follow the advice of the experts, right? That’s just what you do. We might be from a different generation. I think the generation after us might handle it [PERSARC] differently” (P10) <u>Field notes:</u> The app was perceived as too complicated by some older (>65) e.g., these patients experienced difficulties to install or log into the app on their mobile phone	Δ <i>Expansion</i> The qualitative results expand on the quantitative finding that some (older) patients would not use the VALUE-PERSARC app again, as they perceived the app as too complicated.

▼ Barrier ▲ Facilitator

Table 6
Joint display of clinicians-related factors influencing the use of PERSARC in consultation.

	Quantitative results		Qualitative results	Mixed methods meta-inferences
Usefulness of PERSARC	<u>Satisfaction survey clinician after each consultation</u>	<u>Consultations (N)</u>	<u>Interviews</u> ▲PERSARC enhances clinicians' understanding of individual risk estimates "It [PERSARC] helps to correctly weigh up the added value of adjuvant therapy" (C1)	Δ <i>Expansion</i> Qualitative results expand on quantitative finding that clinicians' found PERSARC useful during consultation as it provides insights in the added value of adjuvant therapy.
	PERSARC useful during the consultation with the patient Why did you find it useful? "Provides insight into the value of adjuvant therapy"	33/38	<u>Interviews</u> ▼Doubts about the accuracy of the risk estimates provided by the model "Q: What is the reason that you don't use PERSARC outside the framework of this research? A: Well, I think it's because PERSARC is a predictive model that was ultimately developed based on retrospective data. That inherently makes it less informative. (C4)"	▽ <i>Contradiction</i> Clinicians indicated PERSARC as useful in the majority of consultations, which is contradicted with the qualitative finding that they also expressed doubts about the accuracy of risk estimates.
Added value in decision-making	<u>Satisfaction survey clinician after each consultation</u>	<u>Consultations (N)</u>	<u>Interviews</u> ▼Doubts about viability multiple treatment options, i.e., clinician often thinks one option is superior "Yes, and then there are simply good reasons to do so [treatment]. And then, well, it doesn't really matter much what that app thinks about it (C3)"	▽ <i>Contradiction</i> Clinicians indicating PERSARC as helpful in drafting the treatment plan is contradicted with the qualitative finding that clinicians often consider their opinion superior.
	PERSARC of added value in drafting the treatment plan for the patient Why did you find it not useful? "Treatment plan was already determined" "Based on retrospective data"	25/38		

▼ Barrier ▲ Facilitator

4. Discussion

PERSARC was not utilized to present all medically viable treatment options. Instead, it was frequently used to support the treatment plan developed during the MTB meeting that the clinician intended to propose to the patient. Barriers for using PERSARC to inform patients about treatment options include clinicians' doubts about whether patients truly have multiple viable treatment options and about the accuracy of the risk estimates from PERSARC, and time constraints. Conversely, facilitators for the use of the RPM include its efficacy in helping clinicians thoroughly assess the added value of adjuvant treatment and effectively communicate this information during clinical encounters, which is also perceived as beneficial by patients. Moreover, most patients would use the VALUE-PERSARC app again, as it gives them access to comprehensive information that can be shared with relatives and consulted at home.

4.1. Results in context

The implementation of RPMs into clinical practice is known to be challenging [28], which is again found in the present study. Despite their potential to help clinicians and patients adequately weigh prognostic estimates with or without treatment, and thus support informed decision-making, these challenges persist. Our results indicate that clinicians experienced several difficulties when integrating PERSARC into clinical encounters.

Firstly, clinicians did not use the RPM to support patient-clinician decision-making as intended. Instead, they primarily used the prognostic estimates provided by PERSARC to guide patients towards the treatment option deemed superior by the MTB, rather than to inform patients and elicit their preferences. Clinicians' mention multiple treatment options in almost all clinical encounters, which gave them the feeling that patients had been engaged more. However, patients did not perceive having a choice, which is probably due to the implicit steering by clinicians towards their preferred treatment option. This steering

seemed to stem from clinicians' concerns about the clinical equipoise of various treatment options for these STS patients. When prognostic estimates from the RPM did not align with clinicians' own assessments of treatment benefit, they questioned the data underlying the model. Overall, clinicians found it challenging to accept patient choices that differed from what they perceived as the best option and struggled to deviate from the MTB's recommendations, which often focused solely on the option with the greatest potential improvement in prognosis. These findings are consistent with previous studies showing that clinicians, despite using a decision aid, fail to first elicit patients' values and preferences to guide treatment decisions [12,29,30]. Furthermore, clinicians' longstanding commitment to doing what they perceive as best for their patients presents a significant barrier. To address this, a change in attitude is necessary. Although well-intentioned, this approach often overlooks the importance of patients' values, opinions, and preferences, which may differ from those of the clinicians [31]. This is particularly evident in their tendency to prioritize maximizing survival or reducing recurrence risk without fully considering the importance of quality of life for some patients.

Second, required time investment proved to be an important barrier for RPM use in the clinical encounter, which is consistent with previous studies on implementation of decision aids [32]. Given that filling in and explaining the RPM takes valuable time in the consultation, particularly when the app/software encountered technical problems, it led to a negative interaction between the patient and clinician. Patients received insufficient information and it was often done in a hurried manner, causing additional stress. The literature provides no conclusive evidence regarding the required length of consultation when using an RPM; some studies report prolonged sessions, while others do not, which might be explained by the complexity of the decision and the care setting [33,34]. Nonetheless, despite the additional time required for filling in data for the RPM, its use may also contribute to more efficiency as the RPM proved valuable in explaining prognosis and consequences of treatment, which might take more time without the individualized data on risks and benefit. Further research should include possible logistical

problems, such as the time to log in to the app or web browser and fill in the RPM, to determine its impact on the content and duration of the consultation.

4.2. Strengths and limitations

Studies on the integration of RPMs into clinical consultations are rare; to our knowledge our study is the first trying to understand how and why RPM are used and to highlight barriers and facilitators for its use in daily clinical practice. A key strength is that we utilized multiple data sources, both qualitative and quantitative, including perspectives of both patients and clinicians, supported by audiotapes and observations of actual consultations over the duration of the study.

Some limitations should be noted. First, our study excluded patients that were (indicated to be) treated with chemotherapy. As a result, our findings do not address the potential role of chemotherapy in patient outcomes, an area that warrants further investigation in future studies. Additionally, the context of conducting this study alongside a clinical trial may have contributed to overestimating RPM utilization and its potential to support decision-making. Clinicians may have enrolled a selection of patients into the clinical trial rather than all patients they see in daily practice. Moreover, knowledge of being observed might have influenced clinicians to consciously or unconsciously modify their behavior (Hawthorne effect) during audiotaped or observed consultations [35]. Finally, after the study had started, a change in the sarcoma patient care pathway occurred due to COVID-19. Instead of two separate consultations for initial diagnosis and treatment, both consultations were merged into one diagnosis-treatment consultation, significantly impacting the available time for discussion of personalised risk generated by the RPM during the consultation. However, since this was not reversed after the COVID-19 pandemic, this has become the usual care setting for future patients, and thereby makes it likely that our results highlighting time constraints to use PERSARC still apply.

4.3. Implications

The potential success of using RPMs to support decision-making in the clinical encounter is dependent on several interacting elements, described by the SEIPS model. Continuous efforts are needed to improve technology- and environmental factors (i.e., design and usability of the RPM). Integrating the RPM into electronic health records (EHR) might overcome technology-related problems and time constraints, particularly since RPMs are often developed based on routinely collected data retrieved from EHR [28]. This will reduce the time needed for accessing an app or web browser and entering patient and tumor characteristics, thereby streamlining the process, and enhancing efficiency in the clinical encounter. In addition, opportunities to improve task-related factors rely on better and continuing training for clinicians on how to use RPMs and, moreover, how to incorporate them in accordance with the principles of patient-centered care [29]. It is also imperative that clinicians' attitudes and beliefs towards the RPM improve, partly by educating them about modeling and when necessary updating and extending the RPM. Finally, most patients in our study indicated that they found the RPM useful, and we think that given the shift towards using personalized outcome information to support medical decisions, in time clinicians and patients will become more accustomed to using RPM during clinical encounters.

5. Conclusion

Our findings show that PERSARC was generally used to support clinicians' proposed treatment plan and not to help patients weigh available treatment options. Still, both patients and clinicians perceived the use of the RPM during the clinical consultation as valuable in explaining prognosis and potential consequences of treatment. These results provide some guidance for improvements to fully realize the

potential of RPMs to support clinical decision-making. To maximize RPMs effectiveness, it is imperative to promote multidisciplinary research that considers the various facets of the specific clinical context, implementation science and statistical modeling.

Funding

The VALUE-PERSARC is supported by a grant from the Dutch Cancer Society (DCS)— KWF kankerbestrijding (grant number 12642). This funding source did not influence the study in anyway, nor the writing of the manuscript.

CRediT authorship contribution statement

Anouk A Kruiswijk: Writing – review & editing, Writing – original draft, Visualization, Investigation, Formal analysis, Data curation. **Ellen G. Engelhardt:** Writing – review & editing. **Lisa A.E. Vlug:** Writing – review & editing, Formal analysis, Data curation. **Robert J.P. van de Wal:** Writing – review & editing. **Yvonne M. Schrage:** Writing – review & editing. **Rick L Haas:** Writing – review & editing. **Michiel A.J. van de Sande:** Writing – review & editing. **Perla J. Marang van de Mheen:** Writing – review & editing, Methodology. **Leti van Bodegom-Vos:** Writing – review & editing, Supervision, Conceptualization.

Declaration of Competing Interest

The authors declare no conflicts of interest.

Acknowledgments

VALUE-PERSARC group: Cornelis Verhoef, Dirk J Grunhagen, Arjen J Witkamp, Robert-Jan van Ginkel, Marc H.A. Bemelmans, Johannes J Bonenkamp, Winan van Houdt, Ingrid van der Geest, Jos van der Hage, Ibteissam Acem, Roos F Bleckman, Stefanie N. Hakkesteege, Marloes van Duijvenbode, Nicolette Leijerzapf.

Institutional review board statement

The VALUE-PERSARC study was approved by the Medical Ethical Committee Leiden-Den Haag-Delft (METC-LDD) (NL76563.058.21).

Informed consent statement

Written informed consent was obtained from all participating patients.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ejca.2024.114269.

References

- [1] WHO Classification of Tumours Editorial Board: Soft Tissue and Bone Tumours. 5th ed. 2020, Lyon, France: International Agency for Research on Cancer.
- [2] Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2021. *Ca-a Cancer J Clin* 2021;71(1):7–33.
- [3] Stiller CA, Trama A, Serraino D, Rossi S, Navarro C, Chirlaque MD, et al. Descriptive epidemiology of sarcomas in Europe: report from the RARECARE project. *Eur J Cancer* 2013;49(3):684–95.
- [4] Pablos JL, Jover JA, Roman-Ivorra JA, Inciarte-Mundo J, Dilla T, Sacristan JA, et al. Patient decision aid (PDA) for patients with rheumatoid arthritis reduces decisional conflict and improves readiness for treatment decision making. *Patient-Patient Cent Outcomes Res* 2020;13(1):57–69.
- [5] LeBlanc A, Kenny DA, O'Connor AM, Legare F. Decisional conflict in patients and their physicians: a dyadic approach to shared decision making. *Med Decis Mak* 2009;29(1):61–8.
- [6] O'Connor AM. validation of the decisional conflict scale. *Med Decis Mak* 1995;15: 25–30.

- [7] van Praag VM, Rueten-Budde AJ, Jeys LM, Laitinen MK, Pollock R, Aston W, et al. A prediction model for treatment decisions in high-grade extremity soft-tissue sarcomas: Personalised sarcoma care (PERSARC). *Eur J Cancer* 2017;83:313–23.
- [8] Willeumier JJ, Rueten-Budde AJ, Jeys LM, Laitinen M, Pollock R, Aston W, et al. Individualised risk assessment for local recurrence and distant metastases in a retrospective transatlantic cohort of 687 patients with high-grade soft tissue sarcomas of the extremities: a multistate model. *BMJ Open* 2017;7(2):e012930.
- [9] Engelhardt EG, Garvelink MM, de Haes JCJM, van der Hoeven JJM, Smets EMA, Pieterse AH, et al. Predicting and communicating the risk of recurrence and death in women with early-stage breast cancer: a systematic review of risk prediction models. *J Clin Oncol* 2014;32(3):238.
- [10] Zikmund-Fisher BJ, Fagerlin A, Ubel PA. Improving understanding of adjuvant therapy options by using simpler risk graphics. *Cancer* 2008;113(12):3382–90.
- [11] Hueting TA. Developing, validating, and evaluating clinical prediction models in breast and prostate cancer. *Univ Twente: Enschede* 2022:169.
- [12] Branda ME, LeBlanc A, Shah ND, Tiedje K, Ruud K, Van Houten H, et al. Shared decision making for patients with type 2 diabetes: a randomized trial in primary care. *BMC Health Serv Res* 2013;13:301.
- [13] Kruiswijk AA, van de Sande MAJ, Haas RL, van den Akker-van Marle EM, Engelhardt EG, Marang-van de Mheen P, et al. Cost-effectiveness of an individualised risk prediction tool (PERSARC) on patient's knowledge and decisional conflict among soft-tissue sarcomas patients: protocol for a parallel cluster randomised trial (the VALUE-PERSARC study). *BMJ Open* 2023;13(11):e074853.
- [14] Holden RJ, Carayon P. SEIPS 101 and seven simple SEIPS tools. *Bmj Qual Saf* 2021;30(11):901–10.
- [15] Carayon P, Wetterneck TB, Rivera-Rodriguez AJ, Hundt AS, Hoonakker P, Holden R, et al. Human factors systems approach to healthcare quality and patient safety. *Appl Ergon* 2014;45(1):14–25.
- [16] Acher AW, LeCaire TJ, Hundt AS, Greenberg CC, Carayon P, Kind AJ, et al. Using human factors and systems engineering to evaluate readmission after complex surgery. *J Am Coll Surg* 2015;221(4):810–20.
- [17] Holden RJ, Carayon P. SEIPS 101 and seven simple SEIPS tools. *BMJ Qual Saf* 2021;30(11):901–10.
- [18] Hoonakker PLT, Carayon P, McGuire K, Khunlertkit A, Wiegmann DA, Alyousef B, et al. Motivation and job satisfaction of Tele-ICU nurses. *J Crit Care* 2013;28(3).
- [19] Carayon P, Li YQ, Kelly MM, DuBenske LL, Xie AP, McCabe B, et al. Stimulated recall methodology for assessing work system barriers and facilitators in family-centered rounds in a pediatric hospital. *Appl Ergon* 2014;45(6):1540–6.
- [20] Mulac A, Mathiesen L, Taxis K, Gerd Granas A. Barcode medication administration technology use in hospital practice: a mixed-methods observational study of policy deviations. *BMJ Qual Saf* 2021;30(12):1021–30.
- [21] Stiggelbout AM, Pieterse AH, De Haes JCJM. Shared decision making: concepts, evidence, and practice. *Patient Educ Couns* 2015;98(10):1172–9.
- [22] Barr PJ, O'Malley AJ, Tsulukidze M, Gionfriddo MR, Montori V, Elwyn G. The psychometric properties of Observer OPTION(5), an observer measure of shared decision making. *Patient Educ Couns* 2015;98(8):970–6.
- [23] Nowell LS, Norris JM, White DE, Moules NJ. Thematic analysis: striving to meet the trustworthiness criteria. *Int J Qual Methods* 2017;16(1). p. 1609406917733847.
- [24] Creswell J, Clark PV. Designing and conducting mixed methods research. Thousand Oaks. CA: Sage Publications; 2007. p. 274.
- [25] Guetterman TC, Manojlovich M. Grand rounds in methodology: designing for integration in mixed methods research. *BMJ Qual Saf* 2024.
- [26] Moseholm E, Fetters MD. Conceptual models to guide integration during analysis in convergent mixed methods studies. *Methodol Innov* 2017;10(2). p. 2059799117703118.
- [27] Guetterman TC, Fetters MD, Creswell JW. Integrating quantitative and qualitative results in health science mixed methods research through joint displays. *Ann Fam Med* 2015;13(6):554–61.
- [28] Sharma V, Ali I, van der Veer S, Martin G, Ainsworth J, Augustine T. Adoption of clinical risk prediction tools is limited by a lack of integration with electronic health records. *BMJ Health Care Inf* 2021;28(1).
- [29] Wyatt KD, Branda ME, Anderson RT, Pencille LJ, Montori VM, Hess EP, et al. Peering into the black box: a meta-analysis of how clinicians use decision aids during clinical encounters. *Implement Sci* 2014;9:26.
- [30] Ankersmid JW, Engelhardt EG, Lansink Rotgerink FK, The R, Strobbe LJA, Drossaert CHC, et al. Evaluation of the implementation of the dutch breast cancer surveillance decision aid including personalized risk estimates in the SHOUT-BC study: a mixed methods approach. *Cancers (Basel)* 2024;16(7).
- [31] Joseph-Williams N, Lloyd A, Edwards A, Stobbart L, Tomson D, Macphail S, et al. Implementing shared decision making in the NHS: lessons from the MAGIC programme. *Bmj* 2017;357:j1744.
- [32] Elwyn G, Scholl I, Tietbohl C, Mann M, Edwards AG, Clay C, et al. Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Med Inf Decis Mak* 2013;13(Suppl 2(Suppl 2):S14.
- [33] Dobler CC, Sanchez M, Gionfriddo MR, Alvarez-Villalobos NA, Singh Ospina N, Spencer-Bonilla G, et al. Impact of decision aids used during clinical encounters on clinician outcomes and consultation length: a systematic review. *BMJ Qual Saf* 2019;28(6):499–510.
- [34] Stacey D, Lewis KB, Smith M, Carley M, Volk R, Douglas EE, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2024;1(1). p. Cd001431.
- [35] McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. *J Clin Epidemiol* 2014;67(3):267–77.