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Development, implementation and evaluation of patient decision aids supporting shared decision making in women with recurrent ovarian cancer

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ABSTRACT

Objective: Shared decision making (SDM) and use of patient decision aids (PtDAs) are key components in patient-centered care in relapsed ovarian cancer. This paper describes the development and implementation process of PtDAs into a clinical routine in three departments.
Methods: Two PtDAs were developed in collaboration between patients and clinicians. Acceptability and usability of the PtDAs were tested on clinicians and patients using items from the internationally validated questionnaire "Preparation for Decision Making Scale".
Results: Ten patients and 15 clinicians participated in the study. Most patients indicated that PtDAs would be helpful as preparation for the decision-making process with the clinicians. Ten (75%) of the clinicians responded that the PtDAs helped the patients to understand the benefits and disadvantages of each treatment option. Generally, the clinicians indicated that they would use SDM if they had a PtDA tailored to the clinical situation.
Conclusions: Two PtDAs were systematically developed, tested, and implemented thereby supporting an SDM intervention. The PtDAs are still in use at the participating departments.
Innovation: This study was successful in reusing a generic template for a patient decision aid (PtDA) developed at one institution and implemented in two other institutions. This was guided by a well-described systematic development process for PtDAs.

1. Introduction

Epithelial ovarian cancer (EOC) is the leading cause of death in women with gynecological cancer, and the seventh most common cancer among women worldwide. In 2018, 4.4% of the entire cancer-related mortality among women was attributed to ovarian cancer [1]. Patients with recurrent EOC (ROC) face a future with considerably morbidity and mortality [1]. Despite intensive primary treatment with a combination of extensive surgery and platinum-based chemotherapy epithelial ovarian cancer is associated with a high relapse rate within a few years after diagnosis, and different treatment options need to be discussed with the patients including refraining from further palliative treatment for disease recurrence. [2]. The life circumstances, values and preferences of patients and their relatives should be carefully explored to understand trade-offs in decision making and in sharing own goals and preferences with the clinicians. Thus, optimal decision making implies close cooperation between the clinician and the patient.

Shared decision making (SDM) is a key component of patient-centered care supporting the patient's active involvement in medical decision

Abbreviations: CFFB, Center for Shared Decision Making, Vejle University Hospital of Southern Denmark. (In Danish: Center for Fælles Beslutningstagning); DGCG, Danish Gynecological Cancer Group; IPDAS, International Patient Decision Aid Standards; KB, The Danish Cancer Society (In Danish: Kræftens Bekæmpelse); KIU, Danish patient organization for women diagnosed with gynecological cancer (In Danish: Kvinder med kræft i underlivet); NIH, Not Invented Here syndrome; NHS, National Health Service, publicly funded healthcare system in England; PDSA cycles, Plan-Do-Study-Act cycles; PtDA, Patient Decision Aid; ROC, Recurrent epithelial ovarian cancer; SDM, Shared Decision Making.

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making [3]. It is a collaborative process where patients and clinicians work together taking into account the scientific evidence as well as patients' values and preferences [4]. The goal is to improve the quality of decisions, i.e. the extent to which patients are informed and receive health care that matches their preferences [5].

Clinical guidelines offer support to clinicians in the decision-making process by providing the latest scientific evidence. To obtain SDM in clinical practice a tool is needed to provide the patient with similar information in a plain, comprehensible language, for example in the form of a Patient Decision Aid (PtDA). PtDAs are designed to help the patient understand information about treatment options as well as to identify and communicate the patient's preferences when making treatment decisions. PtDAs contain information on the pros and cons of the various treatment options to help the patient make informed and deliberate treatment choices [6].

The Center for Shared Decision Making (CFFB) was launched in 2014 at Lillebaelt Hospital in Denmark with the main purpose of implementing SDM through different initiatives, including developing, testing and evaluating PtDAs. One key task was the development of a generic PtDA platform to be used in the development of specific PtDAs for all types of health care decisions [7]. The PtDA template platform adheres to international quality guidelines and complies with the parameters set forth in the International Patient Decision Aid Standards (IPDAS). A key element is that patients, clinicians and other relevant experts are involved in all phases of the development process of the PtDAs. By addressing user-perceived barriers to delivering or using the PtDAs, they can facilitate a successful implementation [8,9].

The overall purpose of this study was to facilitate implementation of SDM with a systematic development, evaluation and implementation of a PtDA for women with recurrent ovarian cancer (ROC) by using the generic PtDA platform. The study group wanted to explore whether a general template for development of a PtDA can be used to design a specific PtDA to be implemented in three different oncological departments at a wider setting outside the original institution that developed the generic PtDA template. The systematic and transparent PtDA development process is described in this paper.

2. Methods

The project was conducted in collaboration between the national Danish Gynecological Cancer Group (DGCG), CFFB, the Danish patient organization for women diagnosed with gynecological cancer (KIU), The Danish Cancer Society (KB), and the departments of oncology at Aarhus University Hospital, Odense University Hospital, and Lillebaelt Hospital, University Hospital of Southern Denmark. In the following, these departments will be named X, Y and Z in random order.

In the first iteration of the International Patient Decision Aid Standards (IPDAS criteria) specific developmental steps in developing a PtDA are described. In short it is recommended that PtDAs are carefully developed, user tested and open to scrutiny, and that the development process is systematically applied and well documented [8]. An extended model of systematic development of PtDAs has been published by Coulter et al. The article identifies key features common to development of all PtDAs. Scoping and design, developing of a prototype, “alpha” testing with patients and clinicians in a iterative process, “beta” testing in “real life” conditions, and production of a final version for use and/or further evaluation are described as being main elements of a systematic development process [10]. The development process of the PtDAs in this study will be described according to this model, and includes the following elements:

- Scoping (Pareto analysis)
- Establishment of a steering group
- Design and prototyping
- Alpha testing (comprehensibility and usability)
- Beta testing in “real world setting” (feasibility)

2.1. Scoping

Initially, a Pareto analysis [11] was performed to identify opinions of and concerns towards SDM among clinicians to be considered in the development and implementation process of the PtDAs. Pareto analysis helps to identify the top portion of causes that need to be addressed to resolve the majority of problems. A survey was used to sample data for the analysis. All clinicians received an electronic questionnaire with a list of evidence-based barriers and were asked to choose the three main barriers to practicing SDM in their department (Fig. 1).

2.2. Steering

During the project planning, an advisory board and a steering committee were established. Patient representatives played an important part of the steering committee and were invited on equal terms to participate in the project. Regular steering committee meetings were held to discuss the progress of the project and plan future steps. Early in the process, it became clear that there is a significant difference in treatment options for patients relapsing from so-called platinum-sensitive and platinum-resistant disease, respectively. Therefore, the steering committee decided to develop two PtDAs, one for each of the two scenarios.

During and in-between the steering group meetings, several Plan-Do-Study-Act cycles (PDSA cycles) were used to test small measures for nudging and visibility of the project and for adjustments along the PtDA development process. A PDSA cycle is an iterative systematic process for gaining valuable learning and knowledge for the continual improvement of e.g. an implementation process. A PDSA cycle provides feedback about what works and what doesn't [12].

2.3. Design

The study was carried out as a quality improvement project divided into two main phases; “Development and test phase” and “Implementation phase”. This paper describes the development and test phase of PtDAs for patients with ROC.

2.4. Prototyping

The clinical evidence-based content of the PtDAs was reviewed in collaboration between clinicians and patients. They were based on international guidelines and the development process focused on patient involvement as well as systematic literature review with discussion of evidence. The generic PtDA template used for prototyping and designing the PtDAs has previously been described in detail. Briefly, the development complied with the IPDAS criteria and included mutual dynamic and iterative processes in very close collaboration with Kolding Design School, international researchers, patients, relatives, and the CFFB. It is an online PtDA “development” platform from where clinicians can log in and create a PtDA for a specific clinical situation from a generic PtDA template comparable to using a Power Point template from Microsoft Office. Based on demonstration projects CFFB developed criteria that future PtDAs should meet: Present the choice and the options; structure the conversation; collect patient preference, encourage dialogue on what matters most to patients; offer balanced information including relevant statistics on pros and cons of specific options; include patient stories; and guide a shared decision in the end [13-18]. The generic PtDA template consists of fixed text and optional sections in which text can be altered or chosen from different generic text possibilities. The fixed text ensures that the framework for SDM and the vital original design are maintained, and that the PtDAs comply with the IPDAS criteria. The optional sections can be adapted to the specific clinical decision-making situation in which the PtDAs are to be applied.

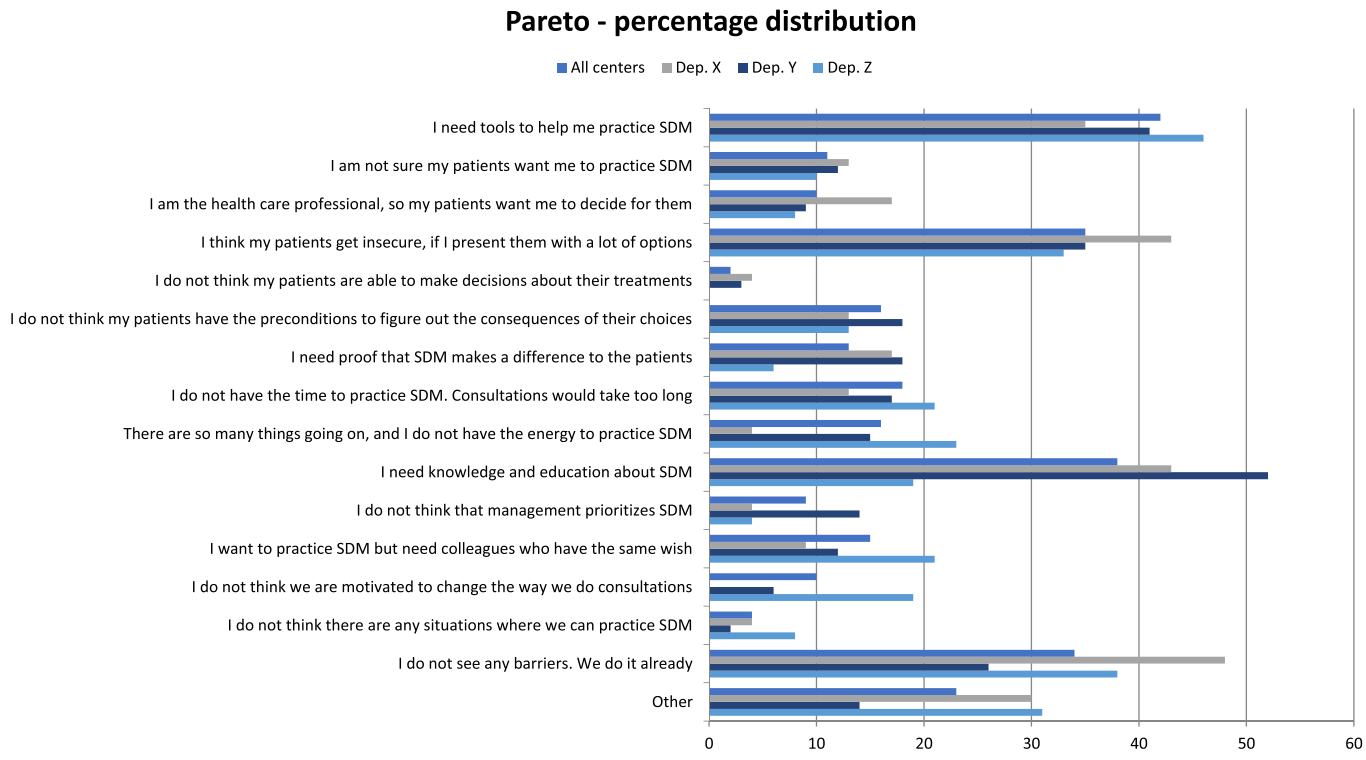

Fig. 1. Pareto chart. The figure illustrates the percentage of participating clinicians agreeing to each statement in each center (department X,Y,Z) and in total.

2.5. Testing

In accordance with the model described by Coulter et al. for a systematic development process for PtDAs, a newly developed PtDA should be alpha tested for acceptability and usability and beta tested to assess feasibility [10]. Acceptability is defined as the participants' perception of the amount and balance of information, the understandability of words and pictograms, and the willingness to use the PtDA measured by questions regarding these aspects. Usability is defined as the participants' perception of the usefulness of the PtDA in preparing and supporting decision making. This paper focuses on the alpha testing. Since we have used a generic platform for PtDAs where length, font, icons and space for data entry have previously been acceptability tested [19] and since these elements cannot be changed in the generic template, we have not repeated acceptability but focused on test for usability of the developed PtDAs by using the Preparation for Decision Making Scale [20].

The alpha testing consisted of one-to-one interviews with patients and clinicians. The interviews included the items of the internationally validated questionnaire “Preparation for Decision Making Scale” for patients and clinicians, respectively. The Preparation for Decision Making Scale for patients contains 10 questions that assesses a patient's perception of how useful a PtDA is in preparing the patient to communicate with the clinician and make a health decision. The version for clinicians contains 11 questions that measures clinicians' view on the usefulness of the PtDA [21].

In addition to the 11 items for clinicians, the interviews with clinicians included an ad hoc question about willingness to use a PtDA in future clinical practice and three questions from the patient version. The scores on the preparation for the decision-making scale was converted to a 0–100 scale. Higher scores indicate higher perceived level of preparation for decision making [21].

The patient version already existed in Danish based on a forward-backward translation process in accordance with WHO guidelines [20]. Since the items of the patient and clinician versions are similar, we agreed to base this study on a one-way translation process of the clinician version.

Interviews took place in all three departments and included residents and specialists in oncology. Study nurses at each department performed the one-to-one interviews taking outset in the scale items. The participants were guided through the PtDA as in a real-life consultation and quantitative data were retrieved by ticking off the scale.

The feasibility of the intervention was tested in two-phase beta tests. Beta test 1 and 2, respectively, included consultations before and after implementation of the PtDAs using the same assessment methods. Both test periods included observer perceived levels of SDM in addition to the levels perceived by patients and clinicians. Details and results of the beta testing will be published elsewhere (submitted).

All participants gave written and orally informed consent. The study was approved by The Region of Southern Denmark (18/30213).

3. Results

3.1. Scoping

The Pareto analysis included 141 clinicians (121 females and 20 males, 46 doctors and 95 nurses) with a mean age of 46.8 years. The mean experience in cancer care was 13.7 years. The three departments recruited 23, 52 and 66 participants, respectively. The main “barrier” statements were “I need tools to help me do SDM”, “I think my patients get insecure if I present them with a lot of options”, “I need knowledge and education in SDM” and “I do not see any barriers we do it already”(Fig. 1). These statements were discussed within the steering committee to focus on strategies of overcoming the barriers before the PtDA implementation process.

3.2. Steering

The project was organizationally anchored in CFFB in close cooperation with the participating hospitals. A study nurse was allocated to the project at each department. The steering committee consisted of a project manager from CFFB, seven clinicians from the participating hospitals, one clinical

specialist with many years of experience in SDM and a representative from KB. Additionally, two patient representatives from KIU and one patient representative previously treated for ovarian cancer were part of the steering committee and were on equal terms as the clinicians and experts involved in all the decisions regarding development and implementation of the PtDAs.

The advisory board consisted of three board members from the national Danish Gynecological Cancer Group (DGCG) thus proving national anchoring and advice for the project. Due to their strong clinical affiliation and contacts with the management of the local hospitals the steering committee and the advisory board played a major role in terms of creating the basis for implementation of the project and helped creating clinically ownership and prioritization at the individual local hospitals. CFFB provided knowledge and experience in SDM and project management. During the project there were 12 meetings in the steering committee. For all meetings the project manager sent out an agenda in advance as well as minutes and prepared the meetings in order to secure continuous progress of the project according to the milestone plan, updating and expanding the content of the PtDAs, and planning and evaluation of the PtDA development and implementation process.

3.3. Design

At the first steering committee meeting, future workshops aiming to develop the first PtDA were planned and patients and clinicians were given the opportunity to exchange opinions and experience. As described earlier a main finding of the initial workshop was the need to develop two PtDAs due to different treatment options and prognoses in the two settings.

During the development process it became clear that the patient may benefit from some kind of preparation for the decision-making situation before the consultation. A preparation letter to accompany the PtDAs was designed outlining the nature of the decision and encouraging the patient to consider preferences and information needs in relation to the consultation.

3.4. Prototype

The PtDA consists of a folding frame and a number of option cards to be placed within it. (Fig. 2). Each card describes a specific treatment option enabling the patient to compare benefits and disadvantages of the available options side by side. By means of pictograms with a short accompanying text, each option card presents the pros and cons of the individual treatment option. Other cards in the folder presented authentic patient narratives and statistics in order to support and involve the patient in the decision-making process.

The initial draft versions of the PtDAs were printed for evaluation and testing. The study nurses at each department provided their comments, and the patient representatives tested the option cards (Fig. 2C and D). The generic platform included a narrative element, and patient statements were added here (Fig. 2E and F). The initial PtDA versions were revised following this process and feedback. The revision mainly included change of icons or text on the pros and cons cards. Following multiple iterative processes and PDSA cycles, the final versions were agreed on. These versions were in line with the format from the generic platform.

3.5. Alpha-testing

Structured interviews constituting the alpha test took place from October 2018 to February 2019 with the participation of 10 patients and 15 clinicians. The majority of patients agreed that the PtDAs were helpful in the decision-making process during the conversation with the doctor (Table 1). The item scores ranged from 62.5 to 95 with a mean score of 80.5 points (Fig. 3).

The clinicians responded positively to whether the PtDAs would be helpful for the patient in the decision-making process (Table 2). Ten (66.7%) clinicians gave the highest score to the statement that the PtDAs would help patients to understand the benefits and disadvantages of each treatment option. Most clinicians indicated that they would use a PtDA, if they had a version tailored to the clinical situation. Seven (46.6%) answered “quite a bit” and seven (46.6%) answered “a great deal”. The item scores ranged from 63.3 to 98.3 with a mean score of 81.0 (Fig. 4).

3.6. Implementation

The implementation of SDM and PtDAs call for pragmatic real-life solutions to implement successfully in today's health care, and this project took outset in existing theory of SDM and SDM implementation. As described by others there are significant gaps between SDM theory and real-world implementation [22]. There is already extensive research on, for example, which positive outcomes the use of patient decision aids has on a number of patient, health care provider, and system benefits [23] On the other hand, information on in which situations, how, why, and for whom does the concept of SDM contribute to improved decision making is less well described. Uptake of SDM into clinical practice requires that clinicians support the underlying rationale and moreover that push back from clinicians and challenges from the patient side i.e. low health literacy or cultural background that lack a tradition of individuals making autonomous decisions are delt with during implementation [24]. It necessitated a change in the participating departments clinical routines and ways of communicating with patients and in this study we used the model for improvement to structure the implementation process [25,26]. The model for improvement helped the steering committee to define the aims of what should be accomplished, establishing measures to determine success, selecting changes that would benefit a successful implementation process and finally testing the changes in real world settings using the PDSA cycle [12].

The implementation and use of the final version of the PtDAs were thoroughly discussed in the steering committee with focus on practical and logistic issues. Practical topics included development of postcards, small introductory films to be shown in the patient waiting area, and introductory workshops for relevant staff. The project had also developed power-point material with brief information about SDM for use in lectures and a laminated quick guide to SDM to make it easy and accessible to introduce new staff to SDM in general and to the use of the PtDAs in particular.

Upon initiation of the study a meeting was held at each participating center with participation from CFFB, the project manager of the study, the local board oncologist, and the chief oncologist to ensure prioritization of the implementation by the clinicians as well as the management.

In line with the IPDAS criteria, and for evidence and implementation reasons, it was important upon the end of the study to secure continuous update of the PtDAs to always reflect the newest treatment results.

The steering group argued that implementation of the PtDAs into clinical guidelines would improve their trustworthiness and increase their use. At the end of the project the PtDAs were therefore implemented in the Danish national ovarian cancer guidelines with a link to the CFFB website, http://www.cffb.dk.

4. Discussion and conclusion

4.1. Discussion

4.1.1. Main findings

In this study, two PtDAs were developed to be used in consultations with ROC patients. The PtDAs were developed in a study group counting clinicians and patient representatives.

The main results were 1) the decision to develop two PtDAs instead of one to be able to target the information and decision making to the individual patient, 2) the IPDAS criteria and PtDA development model explained by Coulter et al. was a useful framework for the process, 3) the generic platform for the development of PtDAs was useful and helped structuring the work, and 4) it was pivotal for the implementation into national clinical guidelines that the development process was based on collaborative work

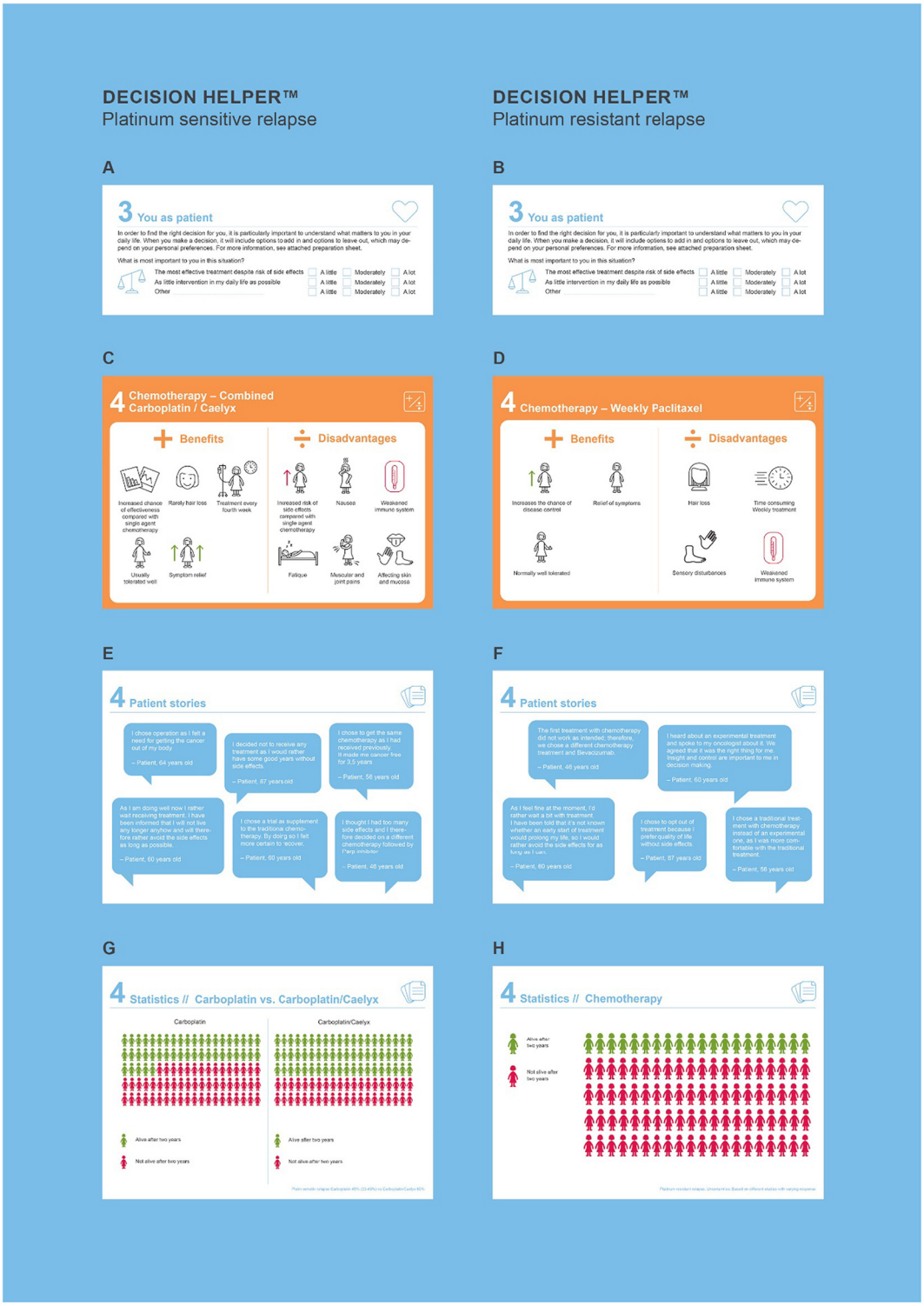

Fig. 2. Illustration of selected parts of the Patient Decision Aid used for platinum-sensitive and platinum-resistant ROC. PtDA folding frame, item 3, identification of patient preferences (Fig. 2A and B), example of insert-cards explaining pros and cons of each option (Fig. 2C and D), insert-cards with patient narratives (Fig. 2E and F), and example of insert-cards illustrating statistics (Fig. 2G and H).

among SDM specialists, the Danish Gynecological Cancer Group, clinicians, and patient representatives.

4.1.2. Development of the patient decision aids

The purpose of using a PtDA is to directly help the patient make a decision (so-called informed decision-making) or indirectly by preparing the patient for participation in a conversation with clinicians about treatment options.

There are two main types of PtDAs, i.e. "over-the-counter (or pre-encounter) PtDAs" which are accessible on the Internet, and "consult PtDAs" which are used by patients and clinicians during the consultation [27]. An over-the-counter PtDA enables the patient to prepare for the consultation and it can be sent to the patient or is accessible online. A consult PtDA is designed to encourage and support shared decision making in the conversation between patient and health professional during the consultation [28]. Experience from the implementation of SDM in the NHS suggests

Table 1
Patients ratings of the decision aid as preparation for decision making (n = 10).

		Not at all	A little	Some	Quite a bit	A great deal
1	Help you recognize that a decision needs to be made?	0	0	0	4	6
2	Prepare you to make a better decision?	0	1	3	2	4
3	Help you think about the pros and cons of each option?	0	0	1	4	5
4	Help you think about which pros and cons are most important?	0	0	0	5	5
5	Help you know that the decision depends on what matters most to you?	0	0	1	5	4
6	Help you organize your own thoughts about the decision?	0	0	2	4	4
7	Help you think about how involved you want to be in this decision?	0	0	1	3	6
8	Help you identify questions you want to ask your doctor?	1	0	4	0	5
9	Prepare you to talk to your doctor about what matters most to you?	1	0	0	5	4
10	Prepare you for a consultation with your doctor?	1	0	2	3	4

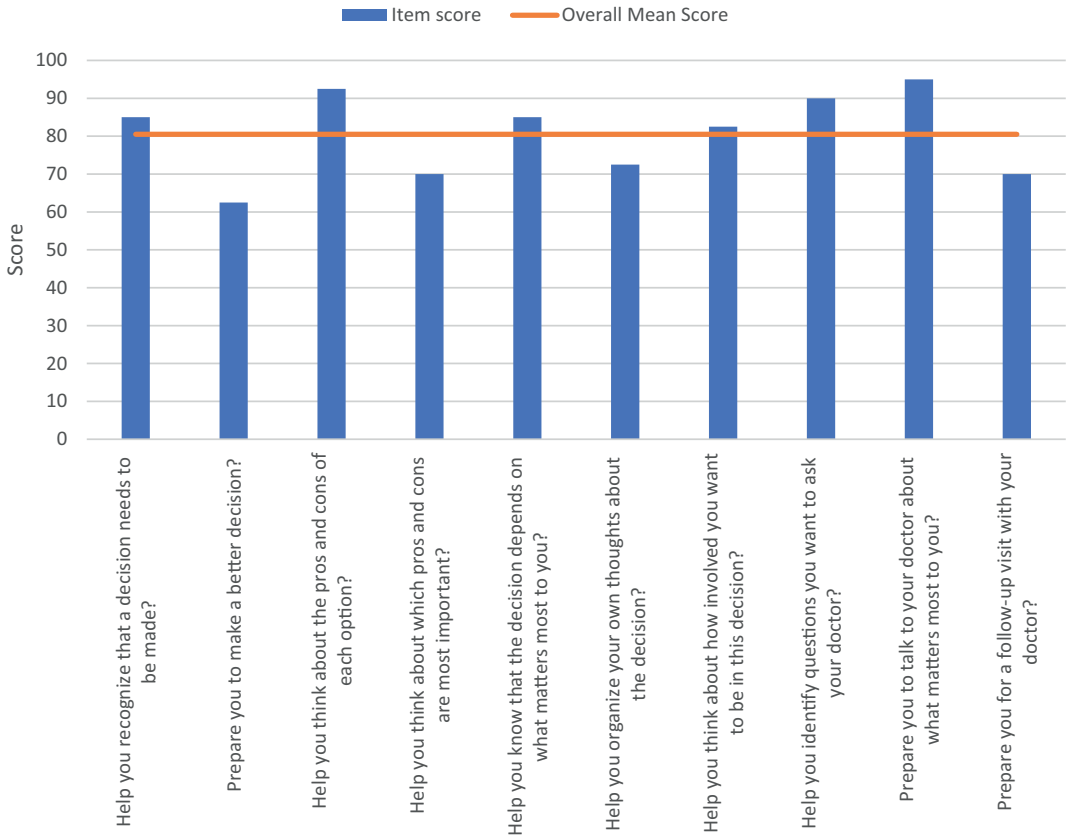

Fig. 3. Patient-perceived preparation for decision making. Scores from the alpha-test using the 'Patient Preparation for Decision Making Scale' (n = 10).

that PtDAs used in the consultation room are often superior in facilitating a discussion between patient and clinicians compared to PtDAs used outside the consultation room. Over-the-counter PtDAs on the other hand enable patients to prepare questions for clinicians before the consultation and thereby facilitate a discussion about patient preferences and life values, which is a core element of SDM [10,29].

Since in the present study all patients were in follow-up and came to the consultation to learn about results of imaging or blood tests in relation to screen or diagnose a recurrence, a consult PtDA was used. Patients were not aware of the disease recurrence before the consultation, which limits the possibility to facilitate their reflections regarding treatment options in advance and an in-consult PtDAs was therefore regarded the best choice for our study.

Detailed information on the development process of PtDAs is generally lacking in trials as reports fails to provide clear information about how the PtDAs is developed [8,10]. This means, that learning from one initiative cannot be adopted by other researchers and clinicians. Second, when the development processes are not transparent to others, quality assessments are hindered, which may result in harm instead of SDM supported by evidence. Third, clues for future implementation processes may be wasted. As poor quality PtDAs may reduce the possibility to practice evidence based SDM, it is important that future users of PtDAs are assured that the development process is carried out according to quality standards. In our study, it was important for every step in the development process to be transparent, described in detail and follow the model published by Coulter et al. [10]. We believe that we succeeded with these process goals.

4.1.3. Pareto analysis

The Pareto analysis gave useful information about the main obstacles and barriers to SDM among clinicians. Many of them endorsed the statements that performing SDM required a tool and that a PtDA in itself was sufficient to enable SDM. In a paper evaluating the implementation of SDM in the NHS a key learning point was described as "skills trump tools, and attitude trumps skills", meaning that use of a PtDA in the conversation between doctor and patient can support the decision-making process but cannot

Table 2
Clinicians ratings of the decision aid as preparation for decision making (n = 15).

		Not at all	A little	Some	Quite a bit	A great deal
1	Helps patients recognize that a decision needs to be made?	0	0	0	6	9
2	Prepares patients for talking about what matters the most to them?	0	0	1	5	9
3	Helps patients organize their thoughts about the decision?	0	1	0	8	6
4	Helps patients to fully understand the risks and benefits of each option?	0	0	1	4	10
5	Helps patients identify the importance they place on the risks and benefits of each option?	0	1	4	4	6
6	Helps patients to make a more informed decision?	0	0	0	7	8
7	Helps patients to be as involved in the decision-making process as they desire?	1	0	0	8	6
8	Prepares patients for the next visit at the hospital?	0	2	8	2	3
9	Help you to more fully understand the issues that are most important to the patient?	0	0	1	8	6
10	Help you tailor the consultation to the patients preference for decision participation?	0	0	1	7	7
11	Facilitates the consultation?	0	0	1	7	7
12	Affects the patient-clinician relationship?	1	0	6	4	4
13	Improve the way time is spent during the consultation?	0	1	4	5	5
14	Improves the quality of the consultation?	0	1	1	6	7
15	Would you use the PtDA, if you had a version tailored your clinical situation?	0	0	1	7	7

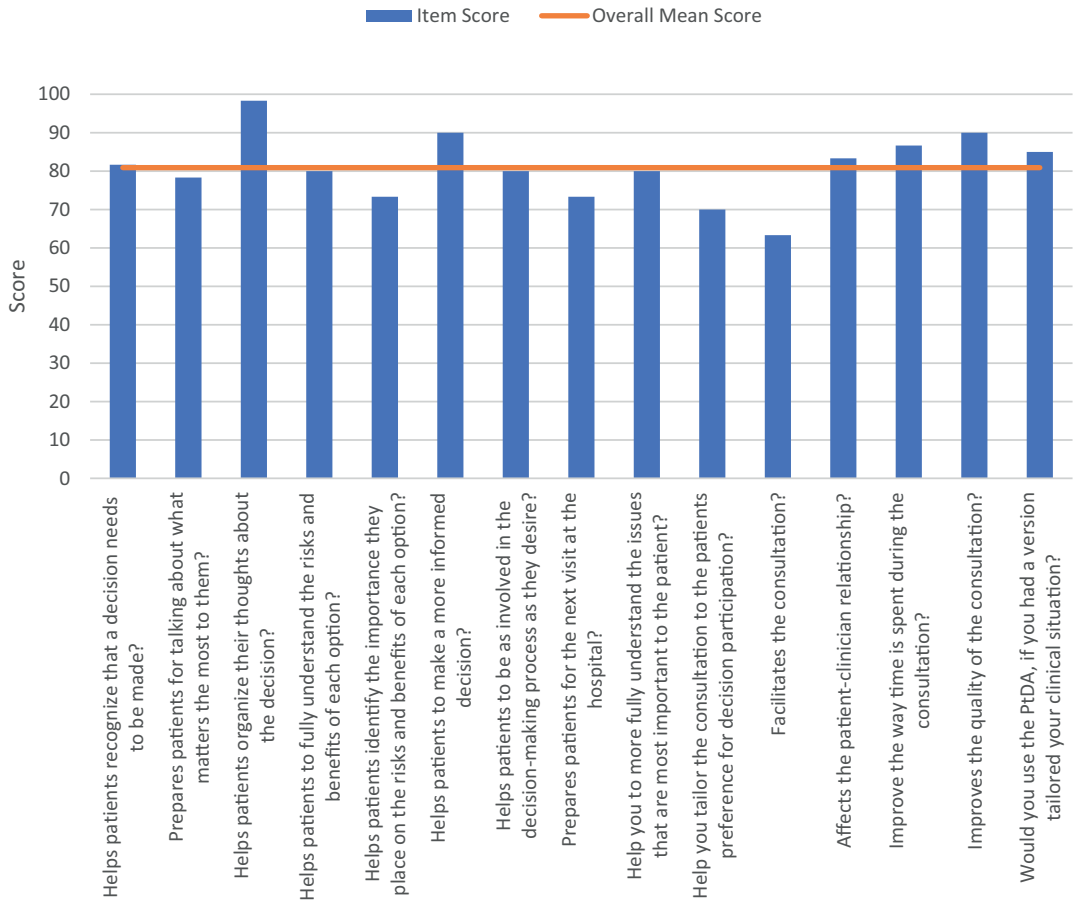

Fig. 4. Clinician-perceived preparation for decision making. Scores from the alpha-test using the 'Patient Preparation for Decision Making Scale' (n = 15).

replace communication skills and pre-existing perceptions for or against SDM [30].

We found a common misconception among health professionals that conversations with patients about treatment options including 'informed consent' was similar to SDM. When asked about opinions and concerns towards SDM in our study, one of the main statements were "I do not see any barriers we do it already" indicating a misconception to the definition of SDM. Informed consent is described as a process in which patients are given important information, including possible risks and benefits, about a medical procedure or treatment, to help them decide if they want to be treated, and therefore not similar to the definition of SDM where patients and clinicians work together, supporting patients' active involvement in medical decision making. Additionally, studies have shown that some patients feel unable rather than unwilling to make health-related decisions. The reason may be that some patients are unaware of the invitation to participate in the decision-making process or have a desire to be a "good" patient by following the doctor's recommendation. Some patients may even have a longstanding expectation of a paternalistic doctor, who may get annoyed if the patient expresses an opinion about a suggested treatment option [31,32]. In a consultation room, this can be mistaken for insecurity or

even a lack of interest in engaging in SDM and maybe an explanation to why the clinicians in our study stated that the patients got insecure if they were presented with a lot of options.

4.1.4. Alfa testing

Patients as well as clinicians found the PtDAs acceptable as tools to prepare patients for treatment-related decisions and to facilitate SDM during the consultation. A study by Olling et al. describing the development and alfa testing of the generic platform showed similar results when both patients and clinicians evaluated the feasibility of the PtDA in preparing the patient for SDM [19]. Even though the design of the two studies is not directly comparable, one could argue that the quality of the PtDAs we developed for three hospitals was comparable to that of the alpha-tested generic PtDA template developed for a single institution.

4.1.5. Implementation

Despite numerous evidence-based benefits of using PtDAs there is generally a lack of studies describing the process of implementing PtDAs into clinical practice. By additionally making the implementation of the developed PtDAs into a clinical setting a preplanned element of our study, we wanted to contribute with knowledge on the implementation and in particular what makes the process successful.

In a review from 2020, Joseph-Williams N. et al. recommended key strategies to support successful implementation of PtDAs into clinical settings. This work stated that in order to implement PtDAs successfully it must be clear that SDM is an organizational priority and accountable leadership should take ownership of the PtDA implementation. The strategies must also be co-produced with end-users, the entire team must be engaged and informed about the purpose and intended use of the PtDA, and the significance every team member plays in the PtDA implementation must be recognized and tasks distributed appropriately. Moreover, adequate SDM skills training for future users of the PtDAs must be provided. Finally, a simpler tool that integrates into clinical workflow and prepares patients to engage in the SDM process is described as raising the odds for a successful implementation process [29].

Our findings are very much in line with these recommendations. We succeeded in having meetings with the leadership group and other relevant members of the hospital staff at all three participating centers before initiation of the study. During the meetings, the concept of SDM and the aim of the study were accepted with great enthusiasm as an organizational priority. The local board oncologist from each center and three patient representatives having participated in the steering committee throughout the study contributed substantially to the success in having accountable leadership taking ownership of the implementation process as well as co-producing the process with end-users (patients and clinicians).

Clinicians often find themselves in outpatient clinics with a high patient flow and time pressure. Nevertheless, clinicians in our study reported that continuous use of the PtDAs in conversations with relevant patients was manageable in the daily clinic.

The PtDAs developed in our study were introduced and are still routinely used in clinical practice in all three participating departments. This may be attributed to the fact that the clinicians involved in developing the PtDAs are still working in the respective clinics. Participation in and ownership of the implementation process is a very important issue for successful introduction of PtDAs, which has also been described by Berry et al. They found that even if a designated lead is appointed, the absence of a clinical lead physically present and seeing patients in daily clinical practice acted as a barrier for PtDA uptake [33].

Implementing a PtDA, however, is not a tick box exercise reflecting SDM implementation, and more work is needed at each participating department before a paradigm shift can be achieved and for SDM to become standard of care for all Danish patients with ROC. We succeeded in getting our PtDAs adopted in the Danish national guideline for ovarian cancer SDM, and the use of PtDAs has now been implemented in a national strategic plan for future work in the Danish multidisciplinary cancer groups [34].

Highly specialized clinicians have a tendency to believe they possesses a monopoly of knowledge in their field, which leads to a rejection of new methods or ways of communication with their patients. The phenomenon is known as the Not-invented-here syndrome (NIH) and can be defined by a tendency for people and organizations to avoid initiatives that they didn't create themselves [35].

The aim of this study was to explore whether a general template for development of a PtDA could be used to design a specific PtDA to be implemented in a setting outside the original institution that developed the generic PtDA template. By numerous testing and revisions of the prototype among future users and by performing a Pareto analysis and identifying opinions and concerns from the future users, we succeeded in implementing the PtDAs outside the original institution that developed the PtDA template and overcoming the NIH phenomenon.

4.1.6. Strengths and limitations

The PtDAs were generated from an existing template developed at the CFFB [19,36,37], which supported a systematic procedure and minimized the risk of ending up with inferior PtDAs. The model had been previously tested and proven successful, which increased the chance of our PtDAs being useful in the clinical setting [15,16,38]. The development, testing, and implementation of the PtDAs taking place at three Danish oncology centers ensured a broad test environment. It was also a strength that the specific content and wording of the PtDAs was agreed on in a multidisciplinary setting by study board members including patient representatives and furthermore pilot-tested and revised before implementation.

No formal training of clinicians in SDM skills was provided but instead managed by the local oncologist. The steering committee had prepared teaching material available to each center. Evaluation of whether the local training was adequate to ensure proper use of the PtDAs was not analyzed.

The revision and update of the PtDAs will continue under the auspices of the national Danish Gynecological Cancer Group. This increases the chance of continued implementation and secures regular update.

4.2. Innovation

There is a growing focus on SDM and patient involvement in the development of PtDAs, which is highlighted in several political healthcare agendas in many countries [39]. By use of key features described by Coulter et al. [10] in a systematic process we developed two PtDAs ready for implementation in clinical practice. We hope our description of the entire process of developing two PtDAs from a generic template will help others achieve a structured, less resourceful development of high quality PtDAs without having to invent the wheel from scratch. At present time the PtDAs developed in this study are an important part of performing SDM in conversations with patients with ROC and we hope that the experience described in our study can facilitate successful implementation of PtDAs with increased chance of sustainability.

Future initiatives focusing on SDM implementation should be aware that development and implementation of a PtDA alone cannot lead the change of culture and attitude that is essential for successful implementation of SDM into clinical practice. Projects should also include formal, mandatory training of clinicians in SDM and the use of PtDAs as well as focus on ensuring that accountable leadership takes ownership of the implementation process.

We hope that our results are applicable internationally in the development of PtDAs. Our PtDA template and accompanying manual have recently been translated into English for inspiration and use by non-Danish speaking patients and settings.

5. Conclusion

Two PtDAs were systematically developed, tested, and implemented at three Danish departments of oncology supporting SDM in consultations. The PtDAs are still in use in the participating clinics after completion of the study. To sustain practice changes into daily routine future studies are needed in order to test the sustainability of the PtDAs.

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CRediT authorship contribution statement

Mette Hæe: Investigation, Project administration, Formal analysis, Writing – original draft. **Christian Nielsen Wulff:** Investigation, Project administration, Writing – review & editing. **Lars Fokdal:** Investigation, Project administration, Writing – review & editing. **Karina Olling:** Project administration, Supervision, Investigation, Writing – review & editing. **Karina Mølgaard Jensen:** Supervision, Writing – review & editing. **Dorte Gilså Hansen:** Writing – review & editing. **Anja Ør Knudsen:** Investigation, Project administration, Writing – review & editing. **Birthe Lemley:** Writing - review & editing. **Dorte Blou:** Writing - review & editing. **Hanne Büchmann:** Writing - review & editing. **Karina Dahl Steffensen:** Conceptualization, Investigation, Funding acquisition, Writing – review & editing.

Declaration of Competing Interest

The authors declare that there is no conflict of interest.

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