What do patients and health care professionals view as important attributes in radiotherapy decisions? Input for a breast cancer patient decision aid

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ABSTRACT
Background and aim: There is increased attention for shared decision making (SDM) when deciding on radiotherapy for selected patients with Stage 0–2 breast cancer. This study aimed to explore patients’ and health care professionals’ experiences, decisional attributes and needs as input for the development of a patient decision aid to facilitate SDM.

Methods: Qualitative semi-structured interviews were held with fifteen breast cancer patients, being confronted with a radiotherapy decision one month to eight years earlier. Another fifteen interviews were held with professionals specialized in breast cancer care. Interviews were transcribed verbatim and independently coded by two researchers, who agreed upon relevant issues.

Results: Most patients made their decision by weighing the advantages of radiotherapy, i.e. comparing the decrease in recurrence risk with and without radiotherapy, and disadvantages, i.e. possible side effects. Patients and professionals agreed that recurrence risks should be communicated, but not on how to deal with uncertainty. There was wide variation in which, and how, side effects were explained by professionals. The most common side effects mentioned by both patients and professionals were skin toxicity, fatigue and breast deformity.

Conclusion: Patients and professionals appeared to agree on what type of attributes should be communicated during SDM on radiotherapy, but how this should be done is up for discussion. To ensure the patient’s voice these attributes and needs need to be incorporated in the risk communication and value elicitation part of the patient decision aid. The format in which the attributes are communicated should be critically evaluated.

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1. Introduction

Currently, there is a growing trend to de-escalate treatment for selected patients with Stage 0–2 breast cancer. Clinical trials, such as the PRIME II trial [1], the BASO II trial [2], and the EUROPA trial (NCT04134598), evaluate the omission and/or replacement of endocrine therapy with breast radiotherapy (RT) for these patients. In the Netherlands, where endocrine therapy is not offered for these very low risk invasive breast cancer, the TOP-1 trial is being conducted in which also the local breast RT is omitted after breast conserving surgery in patients above 70 years of age (NL5983) [1,3].

In such cases, de-escalating treatment from the current adjuvant standard is justified on the grounds that a small absolute benefit in terms of tumour control will not necessarily translate into a survival advantage [4]. Consequently, the decision on which treatment...
option to apply is therefore a so-called “preference sensitive decision”, meaning that the outcome of the decision depends on the individual situation and values of the patient. For example, the trade-off of the level of recurrence risk and side effects with possible consequences for their health related quality of life (HRQoL) at which patients will accept omission of RT is an individualized decision.

Shared decision making (SDM) is a process in which a clinician and patient work together to choose the best available treatment for the individual patient [5,6], and is the preferred model for preference sensitive decisions [7–10]. Patient decision aids (PtDAs) can support doctors as well as patients in implementing SDM. PtDAs lower decisional conflict among patients and increase patients’ knowledge of different treatment options and feeling of being involved in the decision-making process [11–14]. The use of PtDAs might also reduce regional practice variation [13].

To our knowledge two PtDAs have been described for breast cancer patients, exclusively for decision making on RT. Both decision aids have been developed in Canada and are only suitable for small groups of patients (one for older women and the other for node negative woman after lumpectomy); they have not been implemented in the Netherlands [15–18].

According to international guidelines, a first step in the development of a PtDA is exploration of patients’ and HPs’ informational needs based on the results of qualitative interview studies [19–21]. There is quite some literature on informational needs of breast cancer patients deciding on other aspects of their treatment [22,23]. However, only two studies investigated the informational needs of patients deciding on RT. One study focused on older patients [24]; another study included five patients only. Both studies were not designed in the light of the development of a PtDA [25]. We found no studies exploring HPs’ perspectives.

Therefore, the aim of this qualitative study was to explore patients’ and HPs’ perspectives with regard to the most relevant attributes in decision making on RT for breast cancer. The results have since been used to develop a PtDA to support the SDM process. The development of the format of the PtDA (an online tool) and its effects will be reported at a later date in separate manuscripts.

2. Methods

We performed a qualitative study with semi-structured interviews in breast cancer patients and HPs. All interviews were held by DR, a research clinician –, who received basic training in qualitative research and interview techniques from experts in the field. There was no prior relationship between the researcher and the patients. We have used the Coreq checklist for the reporting of this study [26].

2.1. Study population and recruitment

Patients: We asked female breast cancer patients to participate, who had explicitly been given the option to receive or to omit radiotherapy after surgery in the past. We aimed to develop a PtDA for four groups of patients deciding on RT:

1. Patients with low risk ductal carcinoma in situ (DCIS) after breast conserving surgery deciding on whole/partial breast RT or no RT.
2. Patients with low risk invasive ductal carcinoma after breast conserving surgery deciding on whole/partial breast RT or no RT.
3. Patients with intermediate risk breast cancer after mastectomy deciding on thoracic wall RT or no RT.
4. Patients with intermediate risk breast cancer after breast conserving surgery deciding on whole breast RT with or without an extra boost dose to the tumour bed.

Therefore, to obtain an as heterogeneous group as possible, a purposive sample was taken of patients from each of these four groups. Patients with varying educational levels and of different ages were selected. Patients were recruited from hospitals in Amsterdam and Maastricht.

We invited patients 1–3 months after their decision and a group 5 years after treatment. The first group was selected to ensure that they had passed the stage of highest emotional arousal but still remembered sufficient details of their decisional process. The second group had participated in the SUPREMO trial (ISRCTN61145589), a clinical trial where breast cancer patients with an intermediate risk were randomized between chest wall irradiation or not, following mastectomy [27]. All patients in our study group had been allocated to receive RT so that they could reflect on the impact of the late side effects of RT and their impact on HRQoL.°

Patients were informed about the current study by their physician and were asked for consent to be contacted by the researcher. The information letter was sent to them by mail and questions were answered by phone. A face-to-face interview was planned at the time and place of their preference.

Health care professionals: A purposive sample was taken by recruiting different HPs (physician assistants, nurse practitioners, breast cancer surgeons, and radiation oncologists) from eight different peripheral and academic centers in The Netherlands. They were selected to generate a heterogeneous sample with regard to working experience and past experience in development and/or using PtDAs.

HPs were contacted by e-mail via personal contacts. A face-to-face interview was planned in their working hospitals.

2.2. Semi structured interviews/data collection

Patients: Before the start of the interview patients were asked to complete a short questionnaire, consisting of ten questions on e.g. their marital status, number of children, educational level and computer and internet skills.

The interview guide (Table 1a) was constructed based on literature [15,17,25] and on questions raised by the study protocol and the research team. The interview guide contained questions on their experience with, and their opinion about the information provision, and on how they had experienced the decision-making process and what specific attributes had been important in that process. Finally, questions were asked about specific requirements for a PtDA.

Health care professionals: The interview guide was aligned to the content of the patient interview guide (Table 1b). The interview contained questions on the information provision on RT, their experience on SDM and their experiences with and ideas for a PtDA.

2.3. Data analysis

Interviews were recorded and transcribed verbatim. The transcripts were analyzed by a thematic analysis. All interviews were independently coded by two researchers (DR and JTS), who sought consensus by discussion upon relevant issues in case of discrepancies. All findings and codes were shared with the entire project team in numerous project meetings. NVIVO 11 (QSR International Pty Ltd, Victoria, Australia) was used to store the coded interviews ordered by different themes. After the first round of coding, the codes which answered our research question were selected.
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Table 1a
Interview protocol patients.

Word of welcome: Thank you for coming, let me introduce myself. Explanation about the study: Maastro-clinic and the Netherlands Cancer Institute are currently conducting a study to improve support for future patients who have the choice between whether or not to undergo radiotherapy. To do this, we want to develop a patient decision aid to facilitate the process of “shared decision making”. The first step in the process is to talk with patients who have already experienced making a choice, to learn about how they experienced the process; to explore their ideas are about “shared decision making”; what they think about a patient decision aid and its contents. I’ll come back to this later. This conversation will take about 60 min, and with your permission I will record the whole conversation so that I can use it for scientific research. After analysing the information, I will delete the recording and the information will remain anonymous. Do you give consent for this?

Could you introduce yourself? What sort of schooling or training have you followed/what is your work?

What sort of information did you receive about the radiation treatment?
- Who provided the information and when?
- Did you look for information on the internet/from friends or acquaintances/patient organisations?

What did you think of the information?
- Amount, content, difficulty, timing?
- What information did you miss/what had you rather not known beforehand and what did you consider the most valuable?
- Did your ideas about this change during the treatment period?
- What information was the most important for you in making the treatment choice?
- If you were to advise another patient about whether or not to undergo radiotherapy or not, what in your opinion should she be aware of before making the decision? And what would you advise her?

How do you look back on your decision?
- Did you feel that there was a choice to be made?
- How was the decision made? What was your role? Was the choice made after discussing it with someone?
- In your opinion, who should make the medical decisions, and to what extent do you want to be involved in your own treatment?

As I mentioned earlier, we are currently developing a patient decision aid for patients who have a choice whether or not to undergo radiotherapy. In the patient decision aid we want to provide information about the radiation treatment including the benefits as well as the side effects.

Have you previously used an existing patient decision aid?
- What do you expect from a patient decision aid/what is your experience with one?
- Would you use one, if available?
- When do you think it would have helped you the most?
- What do you think should be definitely covered in a patient decision aid?
- Which numbers/percentages should be given?
- Would you like to see pictures/videos in the patient decision aid, and if so, which?
- What do you think about an online patient decision aid?

These were all my questions. I would like to thank you for this interview. Do you have any questions now? Should you have any questions later, then please contact me at any time.

Table 1b
Interview protocol healthcare professionals (HPs).

Word of welcome: Thank you for coming, let me introduce myself. Explanation about the study: Maastro-clinic and the Netherlands Cancer Institute are currently developing a patient decision aid to support “shared decision making” for patients who have a choice between whether or not to undergo radiotherapy. As part of the development, we would like the input from clinicians: doctors, physician assistants and nurse specialists. This conversation will take about 35 min and with your permission I will record the whole conversation so that I can use it for scientific research. After analysing the information, I will delete the recording and the information will remain anonymous. Do you give consent for this?

Could you introduce yourself?

What information is given to patients in your hospital concerning the radiotherapy?
- From whom do patients get this information, at what time-point?
- Do you refer patients to websites or other sources of information?

How much information do you give to patients?
- What information is the most relevant? And what information can you burden a patient with?
- Do you adapt the information to the patient sitting in front of you, and if so, how?

Do you always discuss the possible options with the patient?
- To what extent do you think that patients can participate in deciding on their own treatment?
- How do you apply shared decision making in your own practice?
- What is needed to facilitate the application of SDM?

As I mentioned earlier, we are currently developing a patient decision aid for patients who have a choice whether or not to undergo radiotherapy. In the patient decision aid we want to provide information about the radiation treatment including the benefits as well as the side effects.

Do you already have experience with use of a patient decision aid?
- What is your experience with a patient decision aid and do you already use one in your practice? What are the reasons for using/not using one?
- Would you use one if it was available?
- At what point in the treatment would you want to use one, and how?

What do you think should be definitely covered in a patient decision aid for these breast cancer patients?
- Which numbers/percentages should be given?
- Would you like to see pictures/videos in the patient decision aid, and if so, which?
- What do you think about an online patient decision aid?

These were all my questions. I would like to thank you for this interview. Do you have any other questions? Should you have any questions later, then please contact me.
3. Results

3.1. Patients and HPs characteristics

Fifteen patients were included; mean age was 59 years. Half of these patients received RT. Most patients were married, and half had a higher educational status (Table 2a). The interviews lasted between 30 and 90 min.

All fifteen HPs who were approached agreed to participate; eight radiation oncologists, three breast cancer surgeons, two physician assistants and two nurse practitioners. Their working experience varied between 1.5 and 30 years (Table 2b). Interviews lasted between 20 and 40 min.

After the fifteen interviews saturation was reached on both patients’ as well as on HPs’ interviews, meaning that no new attributes were identified, and that further inclusion of patients would not yield new insights.

3.2. Main findings from the interviews

Patients and HPs mentioned the same sort of attributes that should be reflected on during SDM on the decision for RT, i.e. information about recurrence risks with and without RT and the side effects of RT. In the next paragraph we describe the main findings from the interviews. Quotes from the patients and HPs are cited in the appendix.

3.2.1. Information on recurrence risk

The majority of the patients remembered that an explanation was given about their recurrence risk, with and without RT, without remembering the exact risk estimates. Most patients experienced this as a useful attribute. One patient felt that these estimates could not help her making the decision since, in her view, her odds were fifty-fifty (the tumour will recur or not). While some patients weighed the recurrence risk in relation to the possible side effects to decide on RT yes or no, other patients chose for RT independent of the actual recurrence.

While most HPs thought it is important to mention the recurrence risk, there was no consensus on how this should be done. Some HPs thought that numbers are hard to understand for patients and therefore used narratives (small, large etc.) only. Uncertainty, based on outdated trial data with non-representative patient populations, was seen as an important barrier to communicate exact numbers. Therefore, most HPs thought that the uncertainty range around the risk estimates should be communicated, although most HPs acknowledged that this might be even harder to understand for patients. HPs agreed that if numbers are given, this should be communicated to patients in a visual way.

3.2.2. Information on side effects

Quite some variation was observed in the need to be informed or to inform about side effects and its impact on HRQoL, both regarding which side effects and how side effects were framed.

Patients remembered to have been told about only a few possible side effects, not making a distinction between short-term and long-term side effects. The most frequently mentioned side effect was skin reaction, whereby they characterized the reaction mostly as a burn lesion. Pain and tiredness were also commonly remembered. The fibrosis/change in shape was framed as a deformation. Patients differed in their experience of received information about side effects on heart and lungs. Some patients mentioned to remember that RT had a negative effect on the heart and lung while others were told that...
there is no negative effect since the heart is not affected (Table 3).

There was variation in the number of side effects communicated by the HPs, between only one up to fourteen possible side effects. Most HPs differentiated between short-term and long-term side effects. The most frequently mentioned short-time side effects were skin reaction and fatigue. Oedema and pain where mentioned both as short and as long-term side effects. Most attention was given to the long-term side effects of fibrosis and subsequently change of the breast shape. There was a difference in which and how the side effects of the lungs and the heart were explained. While some HPs mentioned that RT may cause heart and lung damage, other HPs only mentioned that this is rare with the modern radiation techniques. Only a minority of the HPs mentioned the risk of secondary tumours.

### 3.2.3. Information on treatment burden

Most patients were aware of the treatment burden of the RT. The treatment burden was framed as the amount of times patients have to come to the hospital (normally three-four weeks on a daily basis, in addition to a separate preparatory session), how much time the RT takes (15–30 min a day) and travel time. Only one patient mentioned this as an important attribute. Some HPs mentioned the treatment burden as an important attribute when deciding on RT. In some centers all the practical information about RT was given after the decision on the RT has been made.

### 3.2.4. Other attributes

The majority of patients were satisfied with the (amount of) information received. Only a few patients mentioned they had missed certain information, although this did not influence their feeling about their decision. One patient did not realize that RT was given on the naked upper body. Although everybody was respectful to her, she felt her breast became a “public property”.

Another patient missed information on the consequences for the post-treatment check-ups when choosing for RT or not. Another attribute mentioned by several patients, was what they considered consequences of their choice for future therapy options. Some patients mentioned that an advantage of omitting RT left the option for breast conserving therapy open in case of a recurrence, whereas immediate RT would render breast conserving therapy impossible, due to the earlier RT.

### 4. Discussion

We found that patients and HPs mentioned the same type of attributes as relevant for SDM on RT, i.e. information about recurrence risks with and without RT and the side effects of RT impacting HRQoL. However, in what way and how detailed the
information should be communicated varied between all inter-viewed persons. Although in some countries endocrine therapy is offered to patients with a very low risk of recurrence, affecting the balance on advantages and disadvantages of choosing for RT and/or endocrine therapy this is not clinical practice in the Netherlands [3] and was therefore not included in this study.

4.1. Information on recurrence risk

The majority of patients and HPs agreed that patients should be informed about the risk reduction by RT. To find the best way of communicating risks, in a way that is understandable for patients, is however a challenge. It might seem attractive to use narratives to avoid this problem but patients interpret these labels in different ways [28]. Another issue is that while patients are aware that there is a risk of recurrence, they feel that there is an uncertainty as to whether the given risk will apply in their individual case. For example, if there is 10% recurrence risk, will I fall into the 10% group? This is called an aleatory uncertainty. HPs also worried how to communicate the uncertainty/reliability of the given risk estimates, or the range (known as epistemic uncertainty). Communicating epistemic uncertainty seems to be an even bigger challenge. A recent published paper showed wide variation in how uncertainty is being communicated in PtDAs [29,30]; this is due to a lack of evidence on how this should be done [31]. Van der Bles et al. [32] recently reviewed interdisciplinary literature on communicating epistemic uncertainty. They advise to adapt the given information on the available evidence, to separate the magnitude of the effect of the treatment and the magnitude of the uncertainty around the effect, and they point out that communicating epistemic uncertainty does not undermine trust [32]. The use of natural frequencies in combination with visual pictographs with textual explanation might support risk communication [33,34].

4.2. Information on side effects

In our study there was large variation in how many and how detailed HPs communicate about side effects. This has also been found in a study by Kunneman et al. [35]. In that study consultations with radiation oncologists giving information on RT for rectal cancer were audiotaped. A range of two to thirteen side effects were mentioned. Which and how much information patients received depended on their HP. A difference was the framing of the side effects by patients compared to HPs. While the majority of HPs referred to the skin toxicity by redness, patients phrased this as burn lesions. The same applied for fibrosis/change in shape that patients phrased as breast deformation. This may indicate that side effects should be communicated in terms of symptoms and their impact on HRQoL instead of biologic aetiology. The variation in the information patients received may be a cause of the wide practice variation observed [36]. A decision aid may reduce this practice variation, since it supports the standardization of the information given.

4.3. Information on treatment burden

Whereas other studies describe distance to radiotherapy centers as a barrier for choosing for RT [37–40], this does not seem to be a problem in our study, since in our study only one patient took the treatment burden into account when deciding on RT. An explanation might be that in small countries such as The Netherlands there is easy and wide access to RT centers for all inhabitants [40,41].

4.4. Other attributes

Apart from local recurrence risks and side effects, two patients also mentioned another reason to refrain from RT. They believed that avoiding RT in the initial treatment would increase the possibility to keep their breast in case of a recurrence, since re-irradiation is often not advised. However, literature in DCIS shows that patients who do not undergo RT after lumpectomy, have an 11% higher risk of ultimately undergoing a mastectomy, compared to those immediately irradiated post operatively [42].

4.5. Strengths and limitations

A limitation of this study may be a selection bias among the patients. Participating patients may have been more actively involved in or in the decision making process or with a more positive attitude towards SDM. We have no insight in how many patients refused since clinicians only told us when patients gave permission. No patients were included from more remote areas, such as the Dutch islands. It is impossible to avoid all recall bias in such a study. However, we tried to reduce this by interviewing patients who had been faced with a RT decision in recent weeks after the decision. Strength of this study is that we addressed information exchanged from the perspective of both patients and HPs.

5. Conclusions and future plans

These interviews yielded valuable attributes for decision making which will be incorporated into a PtDA, standardizing information on side effects and treatment burden, to assist SDM in breast cancer radiotherapy. Although a PtDA can give a good visual representation of recurrence risks with and without RT, the best way to communicate epistemic uncertainty in a decision aid is still unclear [29]. This will be further explored whilst developing the decision aid.

Ethical approval

The study was approved by the Institutional Review Board of the Netherlands Cancer Institute and Maastro-clinic and was registered at clinical.trials.gov (NCT02934126). Patients gave their written informed consent and all data were anonymized by coding personal identifiers.

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Declaration of competing interest

All authors declare to have no conflict of interest.

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Appendix

This study is funded by a grant from Alpe d’HuZes KWF, Netherlands: grant number MAC2014-7024.
Information on recurrence risk
Patient: Yes, they were mentioned, but if you would ask me now I don't think I would be able to say with any certainty. What I did take home was the chances of things developing the wrong way increases per year, and because I'm still so young, yes I'm not yet 80 … But if you're 50, 60 I'll still want to reach an old age … so the percentages … really cannot say any more, but the feeling … of hopefully you’ve still got some years to go.
Patient: No, I didn’t hear anything about them, at any rate I don’t remember, that idea of percentages. But those percentages then huh, if you hear that, then you have to think by yourself like: yeah, but what’s the point knowing this, as it doesn’t actually say anything about me. It’s just all or nothing. Either it comes back or it doesn’t. Umm yeah, it’s a question of wait and see if it goes well or not.
Patient: Then I actually have a choice, like in a while, if it turns out that, if I do the radiation and I’ve just got 1% or 2% yeah, more would help, like now I can consider it, yes I still think it’s worth the risk, with possible complications, I think it’s still worth doing the radiation. And if it’s more percent, like, then yes, I can say, yes guys, I just have to do it, you know?
Patient: Yeah, the radiation and everything around it, by your ribs maybe or um the tiredness. I was already extremely tired. I hear a lot of women talk about tiredness with radiotherapy. And umm, that your breast gets harder, and gets deformed. I’ve also got prosthesis in and I just know, radiation and prostheses don’t really go together. So umm, and umm, wounds that heals poorly. I don’t want to be bothered with all that. To be honest. If it really,uh, if the percentages had been higher, then of course I would have done it, but 3%? Then I reckon, you know, leave it at that, it’s all right.
Patient: But at the moment I had to make the decision, I found it actually all less important than the idea of: so, all that works. HP: That we expect some benefit, but because the risk that she gets a recurrence is already very low, and then is the benefit also relatively low and that in any case they are kept in follow-up. HP: Recently there have been a lot of changes in the values for the rates, hum, that’s all very difficult to estimate. So by giving detailed information umm, yes, that’s tricky. You can also make mistakes of course. That umm, if you keep it vague, umm then I think that, well that’s not much use to anyone.
HP: I always give a rough estimate as there is also uncertainty of course, because you’re sitting opposite an individual and you can’t really… So you give a general impression, of the statistics, but you can’t, I wouldn’t say like: you’ve got, 8% chance. You can’t do that. Or can’t manage to do it. You shouldn’t do it, because you don’t know.
HP: So it should be made visual to be able to introduce it.

Information on treatment burden
Patient: So the consideration of the tiredness and that daily trips to the hospital what I really wasn’t looking forward to, like, let that be clear, because I really don’t like hospitals. I find it all horrible. But I had the feeling of: if it must, it must. So if that helps, then I just do it. So that’s no longer a consideration.

Other attributes
Patient: Intimacy. And the feeling of, umm, at any rate my chest is rather public property during that trajectory and really respectful and kind and so on umm, fantastic at the radiotherapy, no bad word about it, but every day with your wherewithal open and naked I had like, I had lost it a bit and it was no longer ours, as it were.
Patient: Umm looking back me, umm, would have liked umm more information about what would happen if you don’t go for the radiation, in my case then huh, what would be the consequences?
Patient: Yeah, that umm, like they did say, at least, that was how I heard it, that if later on something is there, then they did say they what would happen? Yes, then we would have to proceed to a mastectomy.
Patient: An important argument for me was what if I do the radiation now and I get it back, then I would have to, if I got it back, I would have to have an immediate mastectomy. So that could not be done in the same procedure, while if I don’t do the radiation now, the next time I could be treated the same way. That went so quickly and well in my case that was a month of madness, but just one month.

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