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MARLEEN KUNNEMAN

SHARED  
DECISION  
MAKING IN  
ADJUVANT  
CANCER  
TREATMENT



# Shared decision making in adjuvant cancer treatment

Marleen Kunneman

Shared decision making in adjuvant cancer treatment

PhD Thesis, Leiden University Medical Center, the Netherlands

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# Shared decision making in adjuvant cancer treatment

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*'Dum vivimus vivamus'* (While we live, let us live)



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# Chapter 1

General introduction





## Background

For many years, the clinician-patient relationship has focused on two extremes: clinicians' paternalism and patients' autonomy.<sup>1</sup> The first extreme can be seen as a parental or priestly model, in which the doctor knows best and uses his/her knowledge and skills to determine which strategy is most likely to restore the patient's health.<sup>1;2</sup> The second extreme represents more of a consumer model, in which the patient gathers all relevant information and selects the strategy he or she prefers.<sup>1;2</sup> In their seminal 1956 paper, Szaz and Hollender added a third model where they defined a partnership between the clinician and the (chronically ill) patient.<sup>3</sup>

In 1972, Veatch first used the term 'sharing of decision making' in the scientific literature.<sup>2</sup> Yet, it was not until the mid-1990's, Charles and colleagues' landmark paper,<sup>4</sup> that shared decision making gained momentum.<sup>5;6</sup> Prominent medical journals published articles "heralding a 'paradigm shift' in which the concept of shared decision making was said to be replacing the old notion that 'doctor knows best'".<sup>7</sup> Nowadays, shared decision making is increasingly advocated as the preferred approach to making healthcare decisions when more than one reasonable strategy is available.<sup>4;6;8</sup> Several arguments support this change to shared decision making, both from an ethical and a clinical point of view. Shared decision making respects and facilitates patient autonomy,<sup>1</sup> and reduces unwarranted practice variation.<sup>9</sup> By avoiding the provision of unwanted interventions, it may reduce health care costs and waste.<sup>10</sup> Moreover, shared decision making is associated with improved patient satisfaction with the treatment decision and care, as well as lower anxiety and decisional conflict.<sup>11;12</sup> Appropriate and timely information is a minimal and necessary condition for shared decision making, and these elements can help better manage treatment harms, and thereby reduce physical side-effects.<sup>13;14</sup> However, some have questioned whether this strategy is the 'ideal' clinician-patient partnership because it fails to acknowledge the inherent imbalance in knowledge and power.<sup>1;15</sup> Others claim that time constraints, patients' incapability or the particular clinical situation may make shared decision making inapplicable.<sup>16;17</sup> Indeed, in daily clinical practice, following the principles of shared decision making seems challenging.<sup>18;19</sup>

## *Effective versus preference-sensitive decisions*

For medical decision making, two distinct types of decisions exist: effective and preference-sensitive.<sup>20:21</sup> Effective decisions have an optimal strategy available, as there is sufficient evidence on the effectiveness of the strategy, and possible benefits outweigh harms. In contrast, preference-sensitive decisions have no such “best strategy”. There may be insufficient evidence on the effectiveness, or weighing of benefits and harms strongly depends on individual (patient) values. While ensuring that the patient’s voice is heard is important in all healthcare decisions, this aspect is particularly critical for preference-sensitive decisions. Preference-sensitive decisions may occur within oncology, particularly relating to the use of (neo-)adjuvant cancer treatment. Examples include preoperative radiotherapy in rectal cancer, adjuvant systemic therapy in early-stage breast cancer, or vaginal brachytherapy in endometrial cancer. Foregoing these treatments is often a clinically viable option,<sup>22-24</sup> making the involvement of patients in selecting the best treatment strategy crucial. Each of these clinical scenarios are reviewed below

In rectal cancer, primary treatment consists of a total mesorectal resection. The effect of short-course (5x5 Gray) preoperative radiotherapy (PRT) on local control in patients with localised disease has been clearly demonstrated.<sup>25:26</sup> Nevertheless, due to good local control achieved with surgery alone, the number needed to treat to prevent one local recurrence is high.<sup>25:26</sup> Furthermore, PRT has not been shown to yield a survival benefit.<sup>25:27</sup> PRT has also been associated with adverse outcomes, such as higher probabilities of faecal incontinence and sexual dysfunction than surgery alone.<sup>26:28</sup> It is unclear which patients are likely to benefit most from PRT. Research has shown large variation in individual patients’ treatment preferences and their valuation of the possible benefits and harms of treatment.<sup>29</sup> Therefore, the Dutch medical community has recently acknowledged the need to involve patients in the decision making process in their revised guidelines on colorectal cancer treatment.<sup>22</sup>

Current (inter-)national clinical guidelines apply relatively broad eligibility criteria for adjuvant chemotherapy and/or endocrine therapy in early-stage breast cancer.<sup>23</sup> Due to these broad criteria, up to 60% of early-stage breast cancer patients may experience harms of treatment and loss of quality of life, without a survival benefit.<sup>30</sup> In general, most breast cancer patients require only

a small beneficial effect of adjuvant treatment to consider it worthwhile, but again, large variation exists in individual preferences.<sup>31</sup> This makes it essential to involve patients in choosing a treatment that best fits their values and preferences.

Primary treatment of high-intermediate risk endometrial cancer consists of total hysterectomy and salpingo-oophorectomy. Postoperative vaginal brachytherapy (VBT) provides a significant reduction in the risk of vaginal cancer recurrence, but does not confer a survival benefit and is associated with adverse effects such as mucosal atrophy.<sup>32:33</sup> Watchful waiting is an alternative to postoperative VBT, where patients are only treated with radiotherapy if they develop a vaginal relapse.<sup>34</sup> However, the possible side-effects of this salvage radiotherapy are more severe. The five-year local control, including treatment for relapse, is estimated to be similar for both treatment strategies.<sup>24</sup> Based on other research on cancer patients' preferences, it may be expected that individual patients with endometrial cancer might value these treatment strategies and outcomes differently, though no studies have yet been done in this particular context.

We investigated the above cases in this thesis, as they all concern preference-sensitive decisions and allowed us to investigate a broad spectrum of (neo-) adjuvant cancer treatment decisions in terms of patient population, treating oncologist, and tumour type. These three cases are highly suitable for involving patients in the decision making process, and therefore, for applying the principles of shared decision making.<sup>35:36</sup>

### *Shared decision making: Definition and steps to be taken*

No widely supported or clear definition of shared decision making exists, but most acknowledge that clinicians and patients should work together in making decisions, using the best available evidence.<sup>4-6;37,38</sup> Key words in proposed definitions and in the concept of shared decision making are 'patient values', 'patient preferences', 'options', 'partnership', 'patient participation' and 'deliberation'.<sup>5</sup> There are various theoretical models for the implementation of shared decision making in daily clinical practice.<sup>6;39:40</sup> Although these models



differ to some extent, they all distinguish three key steps relevant to the adjuvant treatment decision:

*Step 1: Creating choice awareness.*

The clinician defines and/or explains the problem and acknowledges that a decision needs to be made. Both parties should be aware that more than one reasonable option is available and that there is no 'best choice'. If doing nothing (e.g., foregoing adjuvant treatment) is a clinically viable or relevant option, it should be presented as such.

*Step 2: Discussing treatment options in detail.*

The clinician and patient discuss the possible options in more detail. All relevant benefits and harms of the presented options should be addressed, as well as their respective probabilities. Communicating probabilities is complex, but in most instances essential, as probabilities may help weigh benefits and harms.

*Step 3: Discussing patients' values and preferences and deciding what is best.*

Patients' ideas, concerns, and expectations should be discussed and considered. At this stage, the patient's preferred role in the decision making process might also be explored.<sup>6,41</sup> Both parties should then decide what is best and agree on the course of action. This could also include postponing the final decision, if the patient does not feel ready to decide or would like to talk to a third party (such as a significant other or another clinician) before reaching a decision.

## Aim and outline of this thesis

Taking the above key steps in shared decision making as the starting point, our overall aim is to assess to what extent these key steps of shared decision making are currently followed in preference-sensitive decisions on (neo-)adjuvant cancer treatment in routine clinical practice.

### *Part I. Step 1: Creating choice awareness.*

In the first part of this thesis, we study the first and pivotal step in shared decision making – creating choice awareness. In **Chapter 2**, we assessed whether oncologists explicitly state that a treatment decision needs to be made in pre-treatment consultations for (neo-)adjuvant cancer treatment. We analysed pre-treatment consultations between radiation oncologists and rectal cancer patients regarding PRT, and between medical oncologists and breast cancer patients regarding chemotherapy and/or endocrine therapy.

### *Part II. Step 2: Discussing treatment options in detail.*

The second part of this thesis focuses on the detailed discussion of treatment options in the context of preoperative radiotherapy in rectal cancer. **Chapter 3** describes what information radiation oncologists provide about possible benefits and harms of preoperative radiotherapy during the pre-treatment consultations with rectal cancer patients. We used these results for a follow-up study described in **Chapter 4**, where we aimed to reach consensus among radiation oncologists and treated patients on which benefits and harms should be addressed during this pre-treatment consultation. We composed a core list of topics that, according to our expert panels, should always be discussed. We then assessed congruence of our core list with routine clinical practice. **Chapter 5** focuses on communication of (neo-)adjuvant treatment risks. We examined if and how oncologists provide probabilistic information during the consultation, and how patients estimated probabilities of major treatment outcomes after this

consultation. In **Chapter 6**, we offered verbal labels (non-numerical statements) to convey probabilities during consultations to a representative sample of Dutch adults (proxies for newly-diagnosed cancer patients) to assess how individuals interpret these labels.

*Part III. Step 3: Discussing patients' values and preferences and deciding what is best.*

The third part of this thesis concentrates on the final step of shared decision making. **Chapter 7** describes the extent to which rectal cancer patients' values concerning health-related benefits and harms of preoperative radiotherapy and patients' treatment preferences are voiced and explicitly considered when deciding about treatment. In **Chapter 8** we assessed the preferences of patients with endometrial cancer and treating clinicians regarding postoperative vaginal brachytherapy and a postoperative watchful waiting policy, and evaluated their preferred and perceived involvement in treatment decision making.

Finally, in **Chapter 9** the main research findings are summarized and discussed in the light of the broader empirical literature. We further discuss the implications of our findings and provide perspectives for future research.

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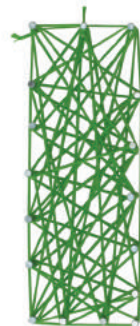
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# Part I

Step 1: Creating choice awareness





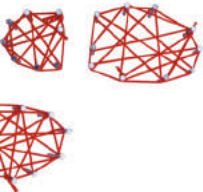


# Chapter 2

## Deciding about (neo-)adjuvant rectal and breast cancer treatment: Missed opportunities for shared decision making

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## Abstract

**Background:** The first step in shared decision making (SDM) is creating choice awareness. This is particularly relevant in consultations concerning preference-sensitive treatment decisions, e.g., those addressing (neo-)adjuvant therapy. Awareness can be achieved by explicitly stating, as the 'reason for encounter', that a treatment decision needs to be made. It is unknown whether oncologists express such reason for encounter. This study aims to establish 1) if 'making a treatment decision' is stated as a reason for the encounter and if not, what other reason for encounter is provided, and 2) whether mentioning that a treatment decision needs to be made is associated with enhanced patient involvement in decision making.

**Material and Methods:** Consecutive first consultations with 1) radiation oncologists and rectal cancer patients, or 2) medical oncologists and breast cancer patients, facing a preference-sensitive treatment decision, were audiotaped. The tapes were transcribed and coded using an instrument developed for the study. Oncologists' involvement of patients in decision making was coded using the OPTION-scale.

**Results:** Oncologists (N=33) gave a reason for encounter in 70/100 consultations, usually (N=52/70, 74%) at the start of the consultation. The reason for encounter stated was 'making a treatment decision' in 3/100 consultations, and 'explaining treatment details' in 44/100 consultations. The option of foregoing adjuvant treatment was not explicitly presented in any consultation. Oncologist' involvement of patients in decision making was below baseline (Md OPTION-score=10). Given the small number of consultations in which the need to make a treatment decision was stated, we could not investigate the impact thereof on patient involvement.

**Conclusion:** This study suggests that oncologists rarely express that a treatment decision needs to be made in consultations concerning preference-sensitive treatment decisions. Therefore, patients might not realize that foregoing (neo-) adjuvant treatment is a viable choice. Oncologists miss a crucial opportunity to facilitate SDM.

## Introduction

Shared decision making with patients (SDM) is particularly relevant when treatment decisions are preference-sensitive, i.e., in the absence of a clinically 'best choice', or when individual patients' valuations of the benefits and harms may strongly vary.<sup>1</sup> Decisions about short-course preoperative radiotherapy (PRT) in rectal cancer and about adjuvant chemotherapy and/or endocrine therapy in early-stage breast cancer are often indeed preference-sensitive.<sup>2;3</sup> In rectal cancer, PRT decreases the 5-year local recurrence risk from 11% to 6%, but increases the probability of adverse outcomes such as faecal incontinence and sexual dysfunction.<sup>4;5</sup> There is a high number needed to treat to prevent one local recurrence, without a clearly demonstrated additional overall survival benefit.<sup>4</sup> For early-stage breast cancer, adjuvant systemic treatment is recommended for patients who have a 10-year recurrence risk of 25% or more, and when treatment would at least yield an absolute recurrence benefit of 10%.<sup>3</sup> It has been argued that up to 60% of breast cancer patients only experience harms of adjuvant systemic treatment and loss of quality of life, with little or no survival benefit.<sup>6</sup> In both the rectal and breast cancer context, the effect of (neo-)adjuvant treatment has been demonstrated,<sup>4;7</sup> but difficulties arise in selecting those patients who will benefit from treatment. Foregoing these (neo-)adjuvant treatments is a clinically viable option,<sup>2;3</sup> and given that individual patients may weigh benefits and harms of treatment differently,<sup>8;9</sup> involving patients in treatment decision making is essential.

In most SDM models, three key steps are distinguished: 1) explaining to the patient that a decision has to be made; 2) discussing all relevant treatment options and their associated benefits and harms; and 3) eliciting patients' ideas, concerns and expectations and supporting patients in the process of deliberation, before reaching a decision.<sup>1;10;11</sup> Although the first step is pivotal for SDM,<sup>1</sup> it received relatively little attention in the literature so far.<sup>12</sup> Patients facing a decision with marked trade-offs between benefits and harms often report that they were not aware that a treatment decision had to be made.<sup>13</sup> Yet, most patients, including those with cancer, indicate they want an active role in deciding about treatment.<sup>14;15</sup> Oncologists can create 'choice awareness' by explicitly stating that making a treatment decision is a 'reason for the

encounter'. To date, there is little evidence on which reason for encounter oncologists express during consultations with cancer patients facing a preference-sensitive treatment decision.

The aims of this study were to establish 1) if 'making a treatment decision' is stated as a reason for the encounter in decision-related consultations on (neo-) adjuvant cancer treatment, and if not, what other reason for encounter is provided, and 2) whether explicitly stating that a treatment decision needs to be made is associated with enhanced patient involvement in decision making.

## **Materials and methods**

### *Design*

A secondary analysis was conducted of data collected in two large ongoing multicentre descriptive studies on (risk) communication during first consultations concerning (neo-) adjuvant therapy.<sup>16;17</sup> We chose the two contexts of (neo-)adjuvant rectal and breast cancer treatment as they both concern preference-sensitive decisions and allowed us to investigate a broader spectrum of adjuvant treatment consultations between oncologists and cancer patients.

Consecutive first consultations - usually the only consultation prior to the start of the adjuvant treatment - between 1) radiation oncologists and rectal cancer patients, and 2) medical oncologists and breast cancer patients, were audiotaped. The Medical Ethics Committee of the Leiden University Medical Center approved both studies. Eligible patients signed an informed consent form prior to the consultation and completed a questionnaire to assess socio-demographic details, either before (rectal cancer study) or after (breast cancer study) the consultation.

### *Study population*

Participants were recruited in six radiation and four medical oncology outpatient clinics of general teaching and non-teaching hospitals, and university medical centers in the Netherlands. Eligible patients were 1) primary rectal cancer patients eligible for short-course (5x5 Gy) preoperative radiotherapy (clinical stage I-III), or 2) early-stage breast cancer patients eligible for adjuvant chemotherapy and/or endocrine therapy (pathological stage I-III). They were to have a good comprehension of the Dutch language.

All radiation oncologists treating rectal cancer patients and medical oncologists treating breast cancer patients from the participating departments were invited to participate.

### *Procedure*

We aimed to select a sample of 50 consultations each from both study databases using the random sampling function of IBM SPSS Statistics (version 20). In the rectal cancer study, we balanced for gender and included all participating female patients in the present analyses (N=26). An equal number of male rectal cancer patients was then selected at random. Fifty female patients were randomly selected from the breast cancer study. Two patients were excluded from the analyses because of incomplete audiotaping. The 100 patient selected eventually were treated between November 2010 and October 2013.

### *Measures*

Audiotapes of consultations were transcribed verbatim. The coding instrument was self-developed. One coder drafted a first version of the items and categories to code the reason for encounter based on four consultations. These codes were developed inductively, i.e., based on the data. The draft of the coding instrument was then complemented and refined based on 22 subsequent consultations. These were coded again using the final version of the coding scheme. Each

version of the coding scheme was discussed among the authors (MK, EE, FH, AP).

We coded whether 'making a treatment decision' was stated as a reason for encounter (yes/no), and if not, what other reason for encounter was provided (i.e., referral by other clinician, mentioning treatment, explaining treatment details, explaining treatment process; see Table 1, column 1). We further coded when the reason for encounter was stated and how the patient responded to the oncologist's stated reason for encounter (see Table 1, column 1). Utterances of patients' accompanying significant others were coded as the patients', unless the patient contradicted such statements. Finally, we coded whether foregoing adjuvant treatment was explicitly presented as a treatment option (yes/no), and whether a treatment decision was made during the consultation (yes, no, explicitly postponed).

Two raters independently coded the same ten audiotapes (10%) using the final version of the coding scheme. Inter-rater reliability was high (mean Cohen's  $K = 0.84$ . Range; 0.71-1). One of the raters coded the remaining tapes. Intra-rater reliability, based on ten tapes (10%) coded twice with a time difference of two months, was also high (mean Cohen's  $K = 0.94$ . Range; 0.65-1).

Next, the OPTION (Observing PaTient InvOlvement) scale was used to quantify the extent to which oncologists involve patients in the decision making process.<sup>18</sup> The OPTION scale measures 12 patient-involving behaviours of clinicians on a 0-4 scale. Inter-rater reliability of two independent raters, based on 10 audiotapes (10%), was substantial (Cohen's  $K = 0.66$ ). The remaining tapes were coded by one of the raters (Intra-rater agreement: Cohen's  $K = 0.72$  and 0.93). The overall mean OPTION-scores were converted to a 0-100 scale, with 0 indicating no behaviour of the oncologist to involve the patient in deciding about treatment, to 100 indicating maximum behaviour.<sup>12</sup> A score of 50 is considered to represent baseline skill level.<sup>12</sup>

## *Statistical analyses*

Descriptive statistics were used to establish patients' and oncologists' characteristics, and the statements concerning the stated reasons for the encounter. As OPTION-scores were not normally distributed, medians are presented and compared by reason for encounter mentioned with Mann-Whitney U-tests. Testing was done two-sided at  $\alpha=0.05$ .

## **Results**

### *Participants*

Twenty radiation oncologists and thirteen medical oncologists audiotaped a median of three consultations (range, 1-7). Patients were on average 61.8 years old (range, 37-87).

### *Reasons for encounter provided*

A reason for encounter was provided in 70/100 consultations (70%). The oncologists explicitly stated, as a reason for encounter, that a treatment decision needed to be made in 3/100 consultations (3%, Table 1). In these cases the oncologist invited patients to participate in deciding about adjuvant treatment by using the phrases "whether you want this adjuvant treatment", "you can decide whether or not you want to do it" or "if you agree with the proposed treatment". Across contexts, most often (N=44/100, 44%), the oncologists indicated the reason for encounter to be 'explaining the treatment details'. In 17/100 consultations (17%), oncologists stated that the patient was there 'for the treatment' (e.g., radiotherapy or chemotherapy, and/or endocrine therapy), without specifying what they would discuss. In 30/100 consultations, the oncologists provided no reason for encounter.



**Table 1.** Reasons for encounter (frequencies) stated

	<b>Total</b> N (%)	<b>Rectal cancer</b> N (%)	<b>Breast cancer</b> N (%)
<b>All consultations</b>	<b>N=100</b>	<b>N=51</b>	<b>N=49</b>
What was the oncologist’s stated reason for encounter?			
Making a treatment decision Example: “ <i>Well, the idea is that we just... give you the treatment as we normally do, but in light of this consultation, you can decide whether or not you... want to do it.</i> ”	3/100	2/51 (4)	1/49 (2)
Explaining treatment details Example: “ <i>Well, the purpose of this consultation is for me to talk to you about radiotherapy, why, what you can expect, and what the side effects are.</i> ” or “ <i>You are here to talk about adjuvant treatment. You might benefit from chemotherapy and endocrine therapy</i> ”	44/100	20/51 (39)	24/49 (49)
Mentioning treatment Example: “ <i>So mrs. P, you have come today for the first consultation about the radiotherapy... of the rectum.</i> ”	17/100	14/51 (27)	3/49 (6)
Referral by other clinician Example: “ <i>Okay, you have come... you were referred... for radiotherapy</i> ”	5/100	3/51 (6)	2/49 (4)
Explaining treatment process Example: “ <i>What we are going to do. We... we are going to explain the whole course of treatment with radiotherapy and the surgery. And... then we are going to sort it all out for you.</i> ”	1/100	1/51 (2)	0
No reason for encounter stated	30/100	11/51 (22)	19/49 (39)
<b>All reasons for encounter</b>	<b>N=70</b>	<b>N=40</b>	<b>N=30</b>
When was the reason for encounter stated?			
At the start of the consultation	52/70 (74)	33/40 (83)	19/30 (63)
At the start, but after a summary of the disease/treatment process so far	10/70 (14)	3/40 (7)	7/30 (23)
After history taking	6/70 (9)	2/40 (5)	4/30 (13)
After (part of) information provision on treatment	2/70 (3)	2/40 (5)	0
How did the patient respond?			
No reaction or minimal response Example: “ <i>Yeah</i> ”, “ <i>Okay</i> ” or “ <i>Hmm</i> ”	55/70 (79)	32/40 (80)	23/30 (77)
Agreement Example: “ <i>Yes, that’s right</i> ”	12/70 (17)	6/40 (15)	6/30 (20)
Surprise Example: “ <i>Oh, is that why I’m here?</i> ”	3/70 (4)	2/40 (5)	1/30 (3)

If the oncologist stated a reason for encounter, this was usually (N=52/70, 74%) done at the start of the consultation (Table 1). Patients mostly (N=55/70, 79%) reacted minimally or not at all to the oncologist's reason for encounter (Table 1). Patients sometimes (N=12/70, 17%) responded by stating that their understanding of the reason for encounter was similar to that of the oncologist, and in a few instances (N=3/70, 4%) by stating that the oncologist's reason for encounter surprised them.

### *Treatment decision making*

In none of the consultations, including those in which the oncologist stated that a treatment decision needed to be made, the option of foregoing (neo-)adjuvant treatment was explicitly presented as a possible strategy.

A treatment decision was made in 56/100 consultations. The decision was explicitly postponed in 9/100 consultations, of which two concerned rectal, and seven breast cancer patients. In all other cases (N=35/100), the treatment decision seemed to have been made before the start of the consultation ("You are here because of your bowel cancer, basically, we will give you a short series of radiotherapy followed by surgery.").

### *Patient involvement in treatment decision making*

Patient involvement in decision making amounted to a median score of 10 (range, 2-60) on a 0-100 scale. Given that only in three consultations decision making was mentioned as a reason for encounter, we could not investigate the association with patient involvement, but in these three consultations, the oncologists showed more behaviour to involve patients than the average (13,17 and 38).

## Discussion

Involving patients in treatment decision making is related with improved satisfaction of patients with care and with the decision, and less anxiety and decisional conflict in patients.<sup>19</sup> SDM is especially important when treatment decisions are preference-sensitive.<sup>1</sup> Yet, even then patients often are not aware that a treatment decision needs to be made.<sup>13</sup> Oncologists can create choice awareness in patients and facilitate SDM by explicitly stating, as a reason for encounter, that a treatment decision needs to be made. To the best of our knowledge, the current study is the first to assess whether choice awareness is created in preference-sensitive decision consultations.

In this study, we examined the reasons for encounter given during first consultations of oncologists and cancer patients facing a preference-sensitive decision concerning (neo-)adjuvant cancer treatment. In only 3% of the consultations the need to make a treatment decision was found to be made explicit. Rather, the oncologists indicated that the reason for encounter was for them to explain the treatment details. Interestingly, in none of the 100 consultations, including those in which the need to make a treatment decision was expressed, the option of foregoing (neo-)adjuvant treatment was explicitly addressed. This is not in line with informed consent norms. Moreover, choosing between two possible treatment strategies might feel less burdensome to patients than declining the one treatment the oncologist has on offer.<sup>20</sup> Only if patients are offered a balanced view of possible treatment strategies, they will be prevented from consenting to treatments that go against their informed values and preferences.<sup>21-23</sup>

In this study, we also aimed to assess whether explicitly mentioning that a treatment decision needs to be made is associated with enhanced patient involvement in decision making. Unfortunately, we were unable to do so because oncologists expressed this need to make a treatment decision in almost none of the consultations.

Patient involvement in the decision making process was quite low. This is reflected by the OPTION-scores as compared to other studies in oncology using this scale and to the norm for baseline skills.<sup>12</sup> A possible explanation for the low level of patient involvement is that in roughly one-third of the consultations a treatment decision seemed to have been made before the start of the consultation. This most probably had been done during the multidisciplinary team (MDT) meeting. Oncologists might then consider the treatment recommendation from the MDT as the one best treatment, thus leaving less room for patients' values and preferences to be incorporated in the final decision. In previous research, we also showed that oncologists' behaviour to involve patients in treatment decision making was limited, but that at the same time, oncologists do believe they apply the principles of SDM in daily practice.<sup>24</sup> Our findings reflect the limited skills of the oncologists in SDM and points to the need for thorough training to support the implementation of SDM in clinical practice.

A strength of our study is that we were able to observe actual communication in a broad spectrum of consultations between oncologists and cancer patients and that we did not depend on oncologists' or patients' recall or interpretation on whether 'making a treatment decision' was addressed. A possible limitation of our study is that although the Dutch national rectal and breast cancer treatment guidelines provide room to opt for different treatment strategies,<sup>2,3</sup> we do not have information on the extent to which oncologists perceived a treatment choice. Future research should therefore focus on assessing oncologists' perceptions of the viability of declining adjuvant treatment, and especially on oncologists' reasoning behind these perceptions. Given that patients' valuations of treatment and of benefits and harms of treatment vary,<sup>8,9</sup> and given that the treatment guidelines already consider these treatment decisions to be preference-sensitive,<sup>2,3</sup> choice awareness might have to be created in oncologists as well.

In conclusion, creating awareness of treatment choice is considered to be pivotal for SDM, but it has received little attention in the literature so far. Our results show that during preference-sensitive decision consultations on adjuvant

cancer treatment, oncologists rarely express that a treatment decision needs to be made. Thus, they miss a crucial opportunity to create choice awareness in patients and engage patients in an SDM process. Instead, oncologists seem to use the consultation to explain the one treatment strategy they recommend. We expect that creating awareness in patients of treatment choice, thus taking the first step of SDM, will provide more opportunities for oncologists and patients to collaborate in selecting the best possible course of action and thus improve patient outcomes. Indeed, adequately creating choice awareness among patients might be a simple, cheap, yet effective step in empowering patients to participate in treatment decision making and helping them to receive the treatment that is in accordance with their values and preferences.

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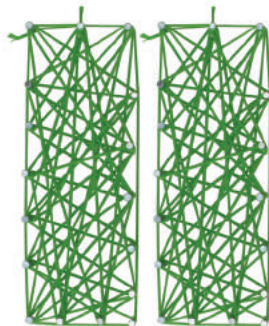
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# Part II

Step 2: Discussing treatment options in detail





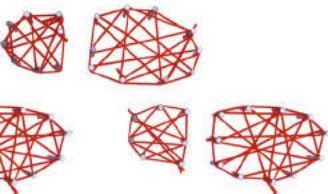


# Chapter 3

## Decision consultations on preoperative radiotherapy for rectal cancer: Large variation in benefits and harms that are addressed

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## Abstract

**Background:** For shared decision making to be successful, patients should receive sufficient information on possible benefits and harms of treatment options. The aim of this study was to evaluate what information radiation oncologists provide during the decision consultation about preoperative radiotherapy with rectal cancer patients.

**Methods:** Decision consultations of 17 radiation oncologists with 81 consecutive primary rectal cancer patients, eligible for short-course radiotherapy followed by a low anterior resection, were audiotaped. Tapes were transcribed and analyzed using the ACEPP (Assessing Communication about Evidence and Patient Preferences) coding scheme.

**Results:** A median of seven benefits/harms were addressed per consultation (range, 2-13). This number ranged within and between oncologists and was not clearly associated with the patient's characteristics. A total of 30 different treatment outcomes was addressed. The effect of radiotherapy on local control was addressed in all consultations, the effect on survival in 16%. The most important adverse effects are bowel and sexual dysfunction. These were addressed in respectively 82% and 85% of consultations; the latter significantly less often in female than in male patients. Four out of five patients did not initiate discussion on any benefits/harms.

**Conclusion:** Our results showed considerable inconsistency between and within oncologists in information provision, which could not be explained by patient characteristics. This variation indicates a lack of clarity on which benefits/harms of radiotherapy should be discussed with newly-diagnosed patients. This suboptimal patient information hampers the process of shared decision making, in which the decision is based on each individual patients' weighing of benefits and harms.

## Introduction

In 2012, about 380 000 new cases of rectal cancer were diagnosed worldwide, and this number is increasing annually.<sup>1</sup> Primary treatment consists of total mesorectal excision (TME). The effect of short-course (5x5 Gy) preoperative radiotherapy (PRT) on local control in patients with localized disease has been clearly demonstrated.<sup>2</sup> However, difficulties arise in selecting those patients who benefit most from PRT, with a high number needed to treat to prevent one local recurrence.<sup>2;3</sup> Furthermore, PRT is associated with adverse effects, the most important of which are bowel problems and sexual dysfunction.<sup>3;4</sup>

Large differences exist between individual rectal cancer patients' treatment preferences and their valuation of possible benefits and harms of treatment.<sup>5</sup> These preferences cannot be predicted based on socio-demographic factors or disease characteristics.<sup>6</sup> This situation, in which individual patients weigh possible benefits and harms of treatment differently, is highly suitable for shared decision making.<sup>7;8</sup>

In general, rectal cancer treatment guidelines make little or no recommendations on which benefits and harms to communicate to patients. The Dutch guidelines on colorectal cancer state that clinicians should "discuss the possible benefits and harms of radiotherapy with the patient", without specifying which benefits and harms.<sup>9</sup> Informing patients about possible treatment options and associated outcomes is a minimal and necessary condition for eliciting and considering patient preferences and for involving them in treatment decision making. Moreover, it helps to meet cancer patients' information needs.<sup>10</sup> Patients who are well-informed and have a clear understanding of their preferences regarding treatment outcomes, experience less anxiety.<sup>11</sup> In addition, appropriate and timely information can help provide better management of cancer treatment side effects, and thereby reduce physical side effects.<sup>12;13</sup> The majority of treated cancer patients, however, indicate that they are not or not sufficiently informed about possible harms of the treatment they underwent.<sup>14</sup>

This study aimed to evaluate the information provision during the first consultation between radiation oncologists and rectal cancer patients, in which the decision about PRT is usually made. Research questions to be answered were: (1) Which benefits and harms of PRT are addressed in the consultation? (2) Are benefits and harms addressed on the initiative of the radiation oncologist, the patient or a companion? and (3) If variation in the benefits and harms addressed or in the initiation of these is seen, is this variation associated with patient characteristics?

## **Materials and methods**

### *Study population*

This study was conducted in four of the 18 radiotherapy centers in the Netherlands. All primary rectal cancer patients eligible for short-course (5x5 Gy) preoperative radiotherapy followed by a low anterior resection, with a good comprehension of the Dutch language, were eligible for inclusion. All radiation oncologists treating rectal cancer patients were asked to participate.

### *Procedure*

Inclusion of patients started in one radiation center and was gradually extended to the other centers. Decision consultations of participating radiation oncologists with all consecutive eligible primary rectal cancer patients scheduled to undergo a low anterior resection were audio taped. The Medical Ethics Committee of Leiden University Medical Center approved the study. Eligible patients signed an informed consent form and completed a self-report questionnaire to assess socio-demographic details before the consultation started. Radiation oncologists were asked to fill in a questionnaire assessing their socio-demographic and work-related details at the start of the study.

## *Measures*

Audio tapes of consultations were transcribed verbatim and analyzed using the ACEPP (Assessing Communication about Evidence and Patient Preferences) coding scheme.<sup>15</sup> By using this scheme, all health related benefits and harms of PRT that were discussed in the consultation were identified. Benefits and harms related to inconvenience or costs, such as travel time or expenses, were not included. Two raters independently coded the same 10 (12% of total number) audiotapes. Inter-rater reliability was high (Cohen's K = 0.83).<sup>16</sup> The remaining tapes were coded individually (intra-rater agreement based on eight (10%) tapes per rater coded twice with a time difference of 19 months, Cohen's K= 0.78-0.85).

## *Statistical analyses*

Descriptive statistics were used to report patients' and radiation oncologists' characteristics, and information provision on benefits and harms of PRT. The number of benefits and harms addressed per consultation was not normally distributed, so medians are presented and compared with Mann-Whitney U tests. Spearman correlations were used to measure linear dependence between number of benefits/harms addressed and consultation time. A logistic regression analysis was conducted to predict the discussion of benefits/harms, using age as a predictor. Using  $\chi^2$  tests, initiative of patients and clinicians to discuss benefits and harms was compared. Significance testing was done two-sided at  $\alpha = 0.05$ .

## Results

### Participants

In total, 112 eligible patients, diagnosed between November 2010 and March 2013, were asked to participate. Of them, 84 agreed (response rate 75%). Three patients were excluded from the analyses because their consultation had not (completely) been recorded. All 17 radiation oncologists treating patients with rectal cancer agreed to participate and audio taped a median of five consultations with new rectal cancer patients (range, 1-11). In Table 1 patient and clinician characteristics are listed.

**Table 1.** Participant characteristics.

	N (%)
<b>Patients (N=81)</b>	
Mean age, years $\pm$ s.d. (range)	65 $\pm$ 10.4 (40-87)
Male	57 (70)
Partner (yes) <sup>a</sup>	51 (76)
Educational level <sup>a, b</sup>	
Low	20 (30)
Intermediate	30 (45)
High	16 (24)
Companion in consultation	73 (90)
<b>Clinicians (N=17)</b>	
Mean age, years $\pm$ s.d. (range)	39 $\pm$ 6.3 (27-50)
Male	5 (29)*
Median time since specialization, years (range)	4 (0-20)
Median number of rectal cancer patients per month (range)	3 (1-8)

<sup>a</sup> Fourteen patients did not complete the self-report questionnaire.

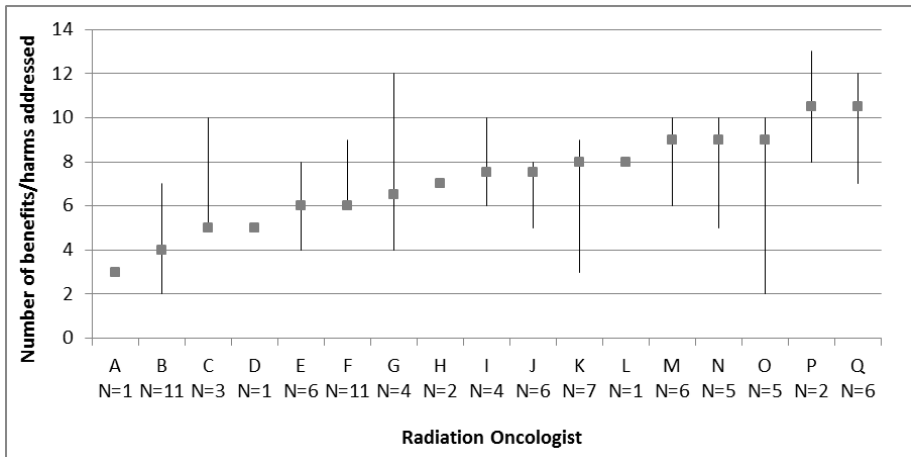
<sup>b</sup> Educational levels included low = completed no/primary school; intermediate = completed lower general secondary education/vocational training; or high = completed pre-university education/high vocational training/university. One patient did not respond to this question.

\* Male radiation oncologists audio taped a total of 20 (25%) consultations.

### Benefits and harms addressed per consultation

Figure 1 shows the variation in the number of benefits and harms addressed per consultation both between and within radiation oncologists. Overall, a median of seven benefits and harms were addressed per consultation (range, 2-13). There was no significant association between the number of benefits and harms addressed and patient gender, age, or educational level.

Overall, consultations lasted significantly longer when more benefits and harms were addressed (median=33 minutes for  $\leq 6$  benefits/harms vs 40 minutes for  $7 \geq$  benefits/harms,  $\rho = .23$ ,  $p < 0.05$ ).

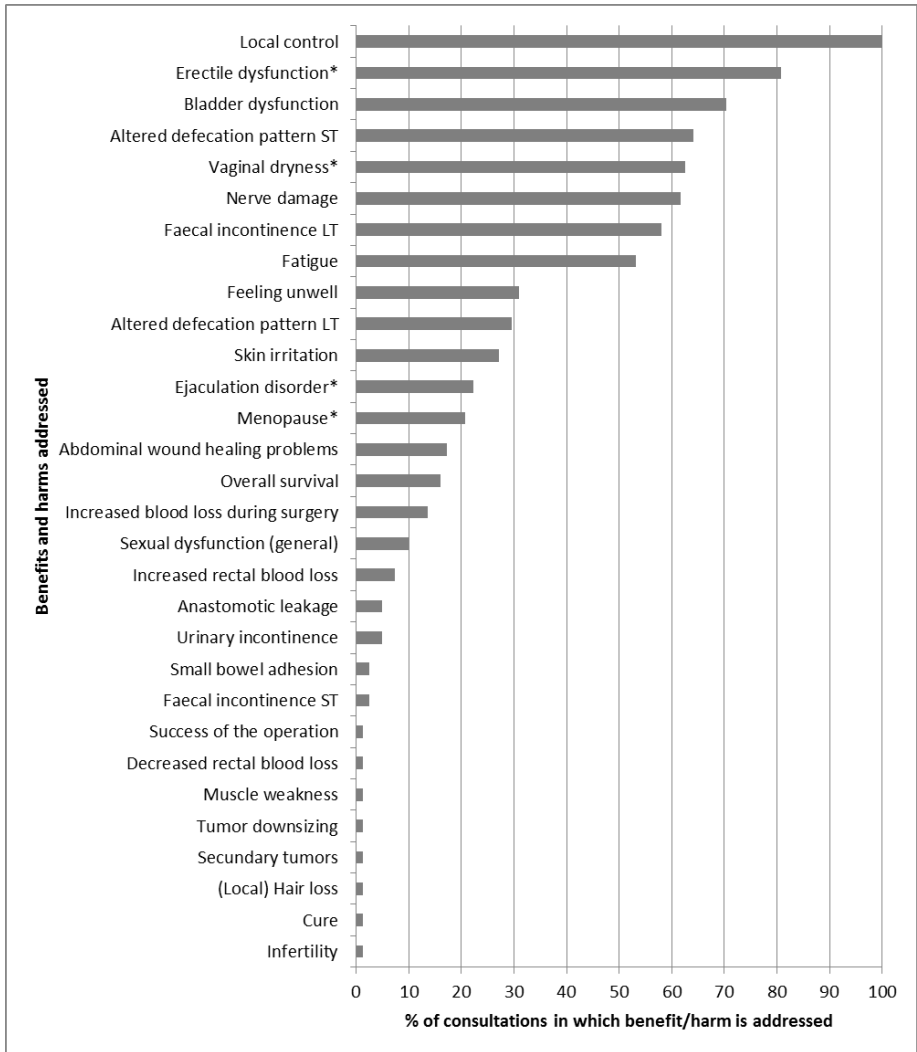


**Figure 1.** Number (median and range) of benefits and harms addressed in consultations per radiation oncologist, sorted by median.

Abbreviation: N = number of consultations taped per radiation oncologist.

In the 81 audio taped consultations, a total of 30 different benefits and harms of PRT in rectal cancer were addressed (see Figure 2). The beneficial effect of PRT on local control of the cancer was addressed in all consultations. The effect of PRT on overall survival was addressed in 13 (16%) consultations, conducted by five (29%) different radiation oncologists.





**Figure 2.** Benefits and harms of PRT addressed in decision consultations.  
 Abbreviations: ST = on the short term; LT = on the long term. \*As a percentage of consultations with patients from relevant patient group (male/female patients).

The most important adverse effects of PRT described in the literature are bowel problems and sexual dysfunction. Bowel problems, such as altered defecation pattern, fecal incontinence or rectal blood loss, were addressed in 66 (82%) consultations, conducted by 15 (88%) different radiation oncologists. In 53 (65%) consultations short-term bowel problems during treatment were discussed, and in 57 (70%) consultations long-term bowel problems were discussed, with a high within-patient overlap. There was no significant association between discussing bowel problems and patient gender, age, or educational level.

Long-term sexual dysfunction, such as erectile or ejaculation disorders (male patients), vaginal dryness (female patients), or sexual problems in general (without further specification) was addressed in 69 (85%) consultations, conducted by 16 (94%) different radiation oncologists, and significantly less often in female than in male patients (N=16, 67% vs N=53, 93% respectively;  $\chi^2= 7.56$ ,  $p<0.01$ ). Although not statistically significant, the older the patients were, the less often sexual dysfunction was discussed during the consultation ( $p=0.07$ ). There was no association between discussing sexual dysfunction and patient's educational level or marital status.

#### *Initiative to address benefits and harms*

Across consultations, radiation oncologists initiated 89% of the discussions about benefits and harms. The other discussions were initiated by the patients (9% of benefits/harms) or the patients' companions (2% of benefits/harms), for example by asking a question or addressing a new topic. In total, there were 16 patients (20%) who showed initiative during their consultation to discuss at most two harms (e.g., skin irritation, feeling unwell, bladder dysfunction, long term fecal incontinence, fatigue, nerve damage, secondary tumors, muscle weakness and abdominal wound healing problems). Topics that companions additionally raised were anastomotic leakage, overall survival and sexual dysfunction.

In consultations in which the patient initiated the discussion of a harm, a median of two more benefits/harms were addressed compared to consultations with more passive patients (Md=8 vs 6,  $p<0.05$ ). There was no significant association between whether or not a patient took the initiative to raise a topic

and patient's gender, age or education level, or being accompanied during the consultation.

## Discussion

This study aimed to examine what information is provided about possible benefits and harms of PRT in the first consultation between newly-diagnosed rectal cancer patients and their radiation oncologist, in which a decision about PRT is usually made.

Our study showed considerable variation, both in the number and in the type of benefits and harms that were discussed. This variation was present between as well as within radiation oncologists and could not consistently be explained by patients' characteristics. The variation found implies that some patients receive limited information, while other patients are informed extensively. It is a necessary condition for informed consent and shared decision making alike, that all patients receive sufficient information on possible benefits and harms of treatment options.<sup>17</sup> At the same time, the more information is given, the less patients usually remember.<sup>18</sup> Depending on the total amount of information given, it is expected that about 40-80% of this information is forgotten immediately after the consultation,<sup>19</sup> though this percentage should decrease when clinicians tailor their information to patients' frame of reference.<sup>20;21</sup> Another potential drawback of extending information-giving to patients, is that placebo research in other settings have shown that patients tend to report experiencing side effects they have been warned about.<sup>21</sup> These caveats do not imply that information should not be provided, but rather highlight the importance of consensus about which benefits and harms should be presented to newly-diagnosed rectal cancer patients.

The beneficial effect of PRT on local control was addressed in all consultations. In contrast, the effect on overall survival was discussed in a small portion of consultations only. This finding might not come as a surprise given that PRT does not improve overall survival in this patient group.<sup>2</sup> However, if the absence of a survival benefit is not made explicit in the consultation, many

patients might wrongly assume that increased local control will result in increased overall survival. Discussing both topics prevents patients from interpreting information wrongly, and will help them develop realistic expectations on the possible benefit of treatment.

PRT is associated with several adverse effects, such as bowel and sexual dysfunction.<sup>4</sup> Both topics were addressed in the majority of consultations, but over one in four patients did not receive information on the effect of PRT on long term bowel dysfunction, whilst half of irradiated rectal cancer patients will experience some form of fecal incontinence. Sexual dysfunction was addressed in a large majority, however more often with male than with female patients. Because of the high prevalence of in particular long term bowel and sexual dysfunction in patients treated with PRT, and the lack of gain in overall survival, our findings show that there is still much room for improvement in information provision. Furthermore, if these topics are not discussed during the consultation, the trade-off between possible benefits and harms as the basis for the treatment recommendation might not be clear to the patient.

It is noteworthy that radiation oncologists occasionally addressed benefits or harms which have not been described in the literature (e.g., increased or decreased rectal blood loss) or which do not hold for short-course (5x5 Gy) preoperative radiotherapy (e.g., tumor downsizing). This highlights the need for a core list of topics to be addressed or not during the consultation with newly-diagnosed rectal cancer patients. In a follow-up study, we intend to seek consensus between rectal cancer patients and radiation oncologists on which benefits and harms of PRT should be addressed with all newly-diagnosed rectal cancer patients during the decision consultation. This follow-up study will result in a core list of topics that need to be addressed. As the national treatment guidelines are a reference for clinicians, the core list will be included in the revised national guidelines on colorectal cancer. Further implementation strategies, such as the use of communication checklists or leaflets in addition to the oral communication, need to be considered in the future.

Radiation oncologists initiated the discussion of most of the benefits and harms addressed. About four out of five patients did not initiate discussion on any benefits/harms. It has been shown that cancer patients are often unsure about what they should ask their clinician,<sup>22:23</sup> but the lack of patients' initiative

could also imply that they perceive their radiation oncologists to be comprehensive. When patients actually take the initiative to discuss outcomes of treatment, significantly more benefits and harms were discussed in the consultation. This implies that outcomes that the patient brings forward add to the outcomes that the clinician already addresses.

A limitation of this study is that we present quantitative data. Conclusions cannot be drawn about the quality of information provision on benefits and harms of PRT, nor about the consistency of quality between and within radiation oncologists. Furthermore, because of relatively small numbers of patients included per radiation oncologist, we were unable to assess associations between the variation in benefits and harms discussed and oncologists' characteristics. Finally, it is noteworthy that we only have data on information provision during patient's consultations with the radiation oncologist, and not during earlier consultations with other clinicians, such as the surgeon or the gastroenterologist. Future research should focus on establishing whether information provision is consistent and sufficient across specialties.

In conclusion, our results showed considerable variation in information provision during the decision consultation on PRT regarding possible benefits and harms of PRT in rectal cancer. This variation indicates a lack of clarity on which benefits and harms of PRT should be discussed with a newly-diagnosed patient. Radiation oncologists should be aware of this between and within-clinician variation. Standardizing information provision and making sure that all relevant benefits and harms are discussed with each individual patient would not only help to meet patients' information needs, it would also promote a process of shared decision making about radiotherapy, in which treatment decisions are a function of individual patients' weighing of benefits and harms.

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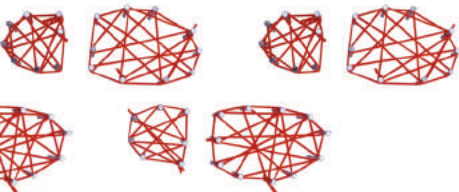


# Chapter 4

Which benefits and harms of preoperative radiotherapy should be addressed? A Delphi consensus study among rectal cancer patients and radiation oncologists

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## Abstract

**Background and Purpose:** We previously found considerable variation in information provision on preoperative radiotherapy (PRT) in rectal cancer. Our aims were to reach consensus among patients and oncologists on which benefits/harms of PRT should be addressed during the consultation, and to assess congruence with daily clinical practice.

**Materials and Methods:** A four-round Delphi-study was conducted with two expert panels: 1) 31 treated rectal cancer patients and 2) 35 radiation oncologists. Thirty-seven possible benefits/harms were shown. Participants indicated whether addressing the benefit/harm was 1) essential, 2) desired, 3) not necessary, or 4) to be avoided. Consensus was assumed when  $\geq 80\%$  of the panel agreed. Results were compared to 81 audio-taped consultations.

**Results:** The panels reached consensus that six topics should be addressed in all patients (local control, survival, long term altered defecation pattern and faecal incontinence, perineal wound healing problems, advice to avoid pregnancy), three in male patients (erectile dysfunction, ejaculation disorder, infertility), and four in female patients (vaginal dryness, pain during intercourse, menopause, infertility). On average, less than half of these topics were addressed in daily clinical practice.

**Conclusions:** This study showed substantial overlap between benefits/harms that patients and oncologists consider important to address during the consultation, and at the same time poor congruence with daily clinical practice.

## Introduction

Preoperative radiotherapy (PRT) improves local control of rectal cancer. Although not demonstrated in randomised controlled trials, there might be a small survival benefit at the population level.<sup>1:2</sup> Due to the good local control with surgery alone, there is a high number needed to treat to prevent one local recurrence.<sup>2:3</sup> In addition, PRT is associated with adverse outcomes, such as higher chances of bowel and sexual dysfunction than with surgery alone.<sup>3:4</sup> When deciding about treatment, the possible benefit in terms of local control should therefore be balanced against the possible harms, taking into account patient preferences. Patients need to be informed about the most relevant benefits and harms of treatment in order to develop a preference. Informing patients also prevents them from overestimating the impact of treatment on cure.<sup>5</sup> Moreover, patients who are well-informed experience better health-related quality of life and may cope better with treatment side effects.<sup>6:7</sup>

In earlier research, we found considerable variation in information provision regarding benefits and harms of PRT during the decision consultation between rectal cancer patients and their radiation oncologist.<sup>8</sup> This variation indicates a lack of clarity on which benefits and harms of PRT should be discussed with newly-diagnosed patients. In general, treatment guidelines provide little or no recommendation on which benefits and harms to communicate to patients. The Dutch guidelines for the treatment of rectal cancer for example state that clinicians need to 'discuss the possible benefits and harms of radiotherapy with the patient', without further specification.<sup>9</sup>

The aims of this study were to 1) reach consensus among rectal cancer patients and radiation oncologists and compose a core list of benefits and harms of PRT that should minimally be addressed during the decision consultation, and 2) assess congruence with daily clinical practice.

## Materials and methods

### *Participants*

A Delphi study was performed in two panels: treated rectal cancer patients and radiation oncologists. One of the most critical requirements in the Delphi method is the selection of experts, rich in information and experience.<sup>10</sup> Eligible patients had received radiotherapy and had finished their oncologic treatment at least four months ago. Patients treated at the Leiden University Medical Center who participated in an earlier study were approached via mail. Furthermore, members of the Dutch colorectal cancer patient organization were approached through the monthly newsletter of their association. Members of the Gastrointestinal-subsection of the Dutch Society for Radiation Oncology were approached for participation. All 45 radiation oncologists who were member of this platform were considered to be clinical experts.

We aimed to include at least half of the radiation oncologists from the platform, and an equal number of rectal cancer patients.

### *Design*

In order to reach consensus, we used the Delphi technique. This is a structured process that uses a series of questionnaires or 'rounds' to gather information until consensus in the panels is reached.<sup>11</sup> As we expected differences in opinions between patients and radiation oncologists, we aimed to reach consensus in each panel separately.<sup>12</sup> Based on previous Delphi studies, we intended a maximum of three online rounds in which participants could indicate which benefits and harms should always be addressed during the decision consultation.<sup>11</sup> Since there was only consensus on a limited number of benefits/harms after three rounds, we organized additional and separate consensus meetings with a fourth and final voting round. Between January and September 2013, the participants completed an iterative series of four questionnaires with feedback reports. In the first online questionnaire, socio-

demographic and treatment- (patients) or work- (radiation oncologists) related details were obtained.

To assess congruence between the results of this Delphi-study and daily clinical practice, we compared the core list that was obtained to results of a previous study on information provision regarding benefits and harms of PRT.<sup>8</sup> In that study, we audiotaped and analyzed 81 decision consultations between radiation oncologists and rectal cancer patients.

### *Questionnaire rounds*

The first questionnaire consisted of 37 benefits and harms, ordered by subject matter (see Table 1). These were obtained from all benefits/harms that had been discussed in any of the first 45 of 81 previously audio taped decision consultations between radiation oncologists and rectal cancer patients.<sup>8</sup> Benefits/harms related to inconvenience or costs were excluded. We complemented the list with outcomes described in the literature.<sup>2;3;13-18</sup> This led to a total of 30 outcomes on which PRT could have an effect for all patients, three for male patients only, and four for female patients only. In both panels, the same brief description of the items was given to help minimize interpretation differences. Information on probable prevalence was given in words and ranges (rare: 0-5%; sometimes: 5-25%; often: 25-75%; (almost) always: 75-100%).

Participants were asked to indicate whether they thought that addressing the outcome during the first consultation was 1) essential, 2) desired, 3) not necessary, or 4) to be avoided. Participants were asked to respond to all outcomes. For example, all participants (including female patients) were asked to indicate the importance of addressing 'erectile dysfunction' during consultations with male patients. After each subject matter, participants could comment on the item descriptions or suggest additional outcomes. The first questionnaire was pilot-tested in eight radiation oncologists and eight lay people. The final version of the first questionnaire was adjusted according to their feedback.

**Table 1.** Benefits and harms of preoperative radiotherapy presented in the first Delphi-round.

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1. Local control
2. Overall survival
3. Secondary tumours

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4. Altered defecation pattern (short term)
5. Altered defecation pattern (long term)
6. Faecal incontinence (short term)
7. Faecal incontinence (long term)
8. Soiling
9. Increased rectal blood loss
10. Decreased rectal blood loss
11. Small bowel adhesions

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12. Bladder dysfunction
13. Urinary incontinence

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14. Infertility (women)
15. Infertility (men)
16. Avoidance of pregnancy
17. Erectile dysfunction (men)
18. Ejaculation disorder (men)
19. Vaginal dryness (women)
20. Pain during intercourse (women)
21. Menopause (women)

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22. Anastomotic leakage
23. Increased blood loss during surgery
24. Abdominal wound healing problems
25. Perineal wound healing problems
26. Increased readmission rate

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27. Nerve damage (short term)
28. Nerve damage (long term)
29. Muscle weakness

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30. Skin irritation
31. (Local) Hair loss

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32. Fatigue
33. Longer recovery
34. Feeling unwell
35. Less appetite
36. Cardiovascular problems
37. Fistula

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Based on literature, we defined consensus as at least 80% of the participants in one panel ticking the same answer category (e.g., 1 'essential') and no more than 15% an answer category two or three categories away (e.g., 3 'not necessary' or 4 'avoid').<sup>11</sup> Outcomes on which consensus was reached were removed from the subsequent questionnaire(s). The other items were included in the subsequent questionnaire, together with feedback on the responses of the panel and the participant's own responses. Radiation oncologists also received feedback on patients' responses. Feedback on participants' responses in each of the categories was shown as a percentage and a column bar. In the second and third questionnaire, participants were asked to reconsider their previously given responses in light of the opinion of other panel members.

### *Consensus meetings*

After the three online questionnaires, we organized a separate in-person consensus meeting for each panel, with the aim to discuss the importance of addressing benefits/harms for which no consensus had been reached in the online rounds. All participants who had completed the third round were invited. The meetings started with a brief presentation on the background of the study, followed by the results up to then. After a group discussion on the importance of addressing the benefits and harms, participants' final opinions were assessed anonymously.

At the consensus meeting, several participants indicated that the response categories 1 (essential) and 2 (desired) were only marginally different. We therefore decided to merge these categories in the analysis of the responses in this final round.

### *Statistical analyses*

Responses of patients and radiation oncologists were analyzed separately. Descriptive statistics were used to report patients' and radiation oncologists' characteristics, their views on which benefits and harms should be addressed and congruence between the results of this study and daily clinical practice.



Using Chi-square tests and Mann-Whitney U tests, characteristics and responses of participants who did versus did not complete the study were compared. A two-sided p-value of  $\leq 0.05$  was considered statistically significant.

## Results

Of the 38 eligible patients approached, 23 (61%) completed the first questionnaire. An additional eight were included through the patient organization. Of these 31 patients, 28 patients completed the second and third questionnaire (90% of those who started). Ten patients attended the consensus meeting and completed the final voting round (36% of those who completed the third questionnaire).

Of the 45 radiation oncologists who are member of the platform, 35 (78%) completed the first questionnaire. The second and third questionnaire were completed by 32 and 29 oncologists, respectively (91 and 83% of started, 71 and 64% of total). All 29 oncologists who completed the third round also completed the final voting round.

In Table 2 participant demographic and treatment- (patients) or work- (oncologists) related characteristics are listed. Radiation oncologists working at a non-teaching center compared to an academic or non-academic teaching center significantly more often declined further participation in the study ( $N=4$ , 44% vs  $N=1$ , 8% vs  $N=1$ , 7%;  $\chi^2=6.36$ ,  $p<0.05$ ). Otherwise, no significant differences were found between characteristics of participants who did versus did not complete the study. To assess bias caused by the 36% response rate of the consensus meeting, we compared the scores in round 3 of attenders and non-attenders. We found that patients who attended the consensus meeting rated 'bladder dysfunction' as significantly more important than patients who did not attend the consensus meeting ( $\chi^2=10.04$ ,  $p<0.01$ ). After receiving feedback on the answers given in round 3 and a discussion during the consensus meeting, patients eventually reached consensus that this outcome need not necessarily be discussed. Otherwise, no significant differences were found

between the answers of those who did versus those who did not attend the consensus meeting.

**Table 2.** Participant characteristics in round 1.

	<b>N (%)</b>
<b>Patients (N=31)</b>	
Member of patient association	10 (32)
Mean age, years $\pm$ s.d. (range)	64 $\pm$ 10.7 (32-85)
Mean time since diagnosis, years $\pm$ s.d. (range)	2 $\pm$ 2.2 (0.3-9)
Male	18 (58)
Educational level <sup>a</sup>	
Low	2 (7)
Intermediate	16 (55)
High	11 (38)
Neo-adjuvant treatment	
PRT (5x5 Gy)	19 (61)
Chemoradiation	12 (39)
Stoma	
No stoma	12 (34)
Temporary	11 (36)
Permanent	8 (26)
<b>Radiation oncologists (N=35)</b>	
Mean age, years $\pm$ s.d. (range)	47 $\pm$ 8.1 (35-66)
Mean time since specialization, years $\pm$ s.d. (range)	12 $\pm$ 9.0 ( 2-39)
Mean number of new rectal cancer patients per month $\pm$ s.d. (range)	5 $\pm$ 2.3 ( 1-10)
Male	12 (34)
Current institution	
Academic teaching center	14 (40)
Non-academic teaching center	12 (34)
Non-teaching center	9 (26)

<sup>a</sup> Educational levels included low = completed no/primary school, intermediate = completed lower general secondary education/vocational training; or high = completed pre-university education/high vocational training/university. Two patients did not respond to this question.

Patients and radiation oncologists reached consensus on, respectively, 29 and 30 of the 37 benefits/harms. Both panels agreed that six benefits/harms should be addressed with all newly-diagnosed rectal cancer patients, together with three benefits/harms for male patients only and four for female patients only. They also agreed that 11 benefits/harms need not always be addressed. According to the panels, none of the benefits/harms should be avoided during the first consultation. The final core list of benefits/harms that should be addressed and items that need not necessarily be addressed can be found in Table 3a and 3b.

**Table 3a.** Benefits and harms of PRT that should be addressed with newly-diagnosed rectal cancer patients, and number of rounds needed by expert panel before reaching consensus

<b>Consensus on benefits/harms that should be addressed:</b>	<b>Patients reached consensus in round:</b>	<b>Oncologists reached consensus in round:</b>
1. Local control	4	4
2. Survival	4	3
3. Altered defecation pattern (long term)	3	4
4. Faecal incontinence (long term)	4	4
5. Perineal wound healing problems	4	4
6. Advice to avoid pregnancy <sup>a</sup>	1	3
7. Erectile dysfunction	1	3
8. Ejaculation disorder	1	4
9. Infertility	1	4
10. Vaginal dryness	4	4
11. Pain during intercourse	3	4
12. Menopause <sup>b</sup>	2	1
13. Infertility <sup>b</sup>	2	1
<b>Consensus in patients only:</b>		
- Increased readmission rate	4	-
<b>Consensus in clinicians only:</b>		
- Altered defecation pattern (short term)	-	4
- Nerve damage (short term)	-	4

<sup>a</sup> Men and premenopausal women only

<sup>b</sup> Premenopausal women only

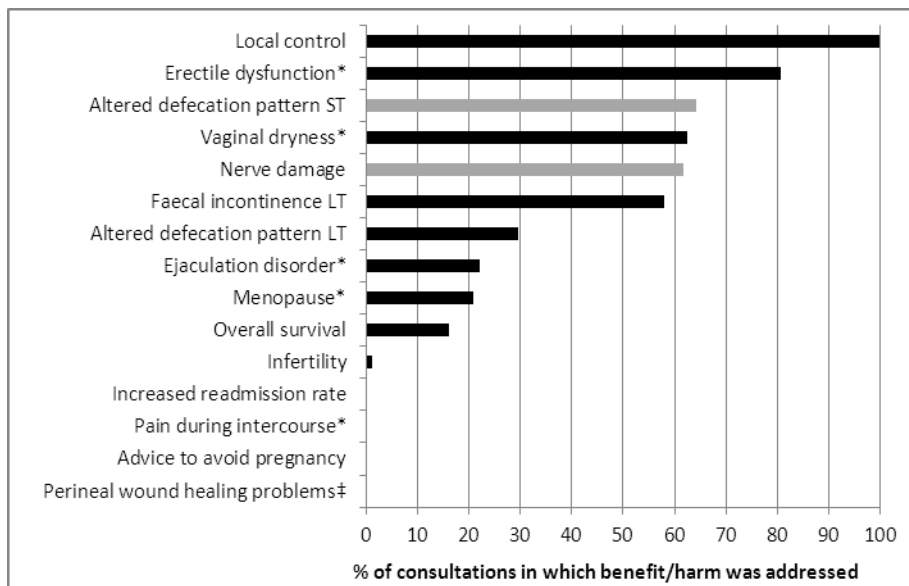
Light grey shades refer to benefits/side effects concerning male patients only, dark grey shades refer to benefits/side effects concerning female patients only.

**Table 3b.** Benefits and harms of PRT that need not be addressed with newly-diagnosed rectal cancer patients, and number of rounds needed by expert panel before reaching consensus

<b>Consensus on benefits/harms that need not necessarily be addressed:</b>	<b>Patients reached consensus in round:</b>	<b>Oncologists reached consensus in round:</b>
1. Faecal incontinence (short term)	4	3
2. Increased rectal blood loss	4	3
3. Decreased rectal blood loss	4	3
4. Increased blood loss during surgery	4	3
5. Nerve damage (long term)	4	2
6. Skin problems	4	4
7. (Local) Hair loss	4	3
8. Feeling unwell	4	3
9. Less appetite	4	1
10. Cardiovascular problems	4	4
11. Fistula	4	4
<b>Consensus in patients only:</b>		
- Bladder dysfunction	4	-
- Abdominal wound healing problems	4	-
- Muscle weakness	4	-
- Fatigue	4	-
<b>Consensus in clinicians only:</b>		
- Secondary tumours	-	2
- Small bowel adhesions	-	3
- Urinary incontinence	-	4
- Anastomotic leakage	-	2

In total, there were 11 topics on which one panel reached consensus, and the other panel did not. On two topics, patients’ and oncologists’ opinions were almost contrary. Patients agreed that ‘increased readmission rate’ should be addressed, while oncologists approached consensus that this is not necessary (72% agreement). Also, oncologists agreed that ‘short-term altered defecation pattern’ should be addressed, while patients tended to rate this as ‘not necessary’ (60% agreement).

To assess congruence between the results from the Delphi-study and daily clinical practice, we compared the core list to results on information provision regarding benefits and harms of PRT, based on 81 audiotaped decision consultations.<sup>8</sup> We found that in daily clinical practice, male patients received information on 3.3 (37%) of the nine topics from the core list (range, 1-6) on average. Female patients on average received information on 3.2 (32-46%) of the seven topics from the core list for postmenopausal women or 10 topics for premenopausal women (range, 1-6). In none of the 81 audiotaped consultations, all benefits/harms as defined in the core list were addressed. As can be seen in Figure 1, only the effect of PRT on local control was addressed in all consultations. There were seven (9%) consultations in which local control was the only topic from the core list that was addressed.



**Figure 1.** Topics which should be addressed and the percentage of consultations in which the benefit/harm was addressed.

Abbreviations: ST = on the short term; LT = on the long term. \* as a percentage of consultations with patients from relevant patient group (male/female patients). ‡ Only relevant for patients undergoing abdominoperineal resection, all patients in our sample underwent a low anterior resection. Black bars = consensus in both panels, Grey bars = consensus in radiation oncologist panel only.

Several topics which are not on the core list are frequently addressed in consultations. Both panels reached consensus that 'skin problems' and 'feeling unwell' are not necessary to address in the first consultation. In daily clinical practice, these topics were addressed in 27 and 31% of the consultations, respectively. In addition, the patient panel agreed that 'fatigue' and 'bladder dysfunction' need not necessarily be addressed. In respectively 53 and 70% of consultations, patients received information on these harms of treatment.

## **Discussion**

The first aim of this study was to reach consensus among rectal cancer patients and radiation oncologists on which benefits and harms of PRT should minimally be addressed in the decision consultation. The patient and oncologist panels agreed that six benefits/harms should be addressed with all newly-diagnosed rectal cancer patients, together with three benefits/harms for male patients only and four for female patients only. It is noteworthy that all topics in the final core list are long-term benefits/harms. Indeed, during the consensus meeting, patients indicated to be less interested in temporary short-term effects. The long-term benefits/harms include the effect of PRT on local control, survival, defecation and sexual functioning, and these effects are well-established and described in the literature.<sup>1-3</sup>

Of particular interest are the topics on which panels had different opinions. Firstly, oncologists reached consensus that 'short-term altered defecation pattern' should be addressed during the consultation, but patients' opinion differed. This might be due to the fact that most patients already experience an altered defecation pattern at the time of the consultation. Secondly, oncologists agreed that 'short-term nerve damage' should be addressed, while patients' opinions were divided. Because of the very low prevalence of short term nerve damage and patients' bias towards their own experiences, it might be difficult for patients to understand the consequences of this harm, despite the description we provided. This lack of consensus highlights that oncologists should be aware that patients' information needs might differ from what they themselves consider important to address.

The second aim of the study was to assess congruence between the core list and daily clinical practice. We found that patients received information on a limited number of topics from the core list. On average, less than half of the topics from the list were addressed during the consultation. Even more importantly, almost one in ten patients received no information on any of the adverse effects that should have been addressed, according to both patients and radiation oncologists. The need for implementing this list in daily clinical practice is therefore clearly demonstrated.

Panels agreed that several topics not necessarily need to be addressed with newly-diagnosed patients. Some of these topics are nevertheless discussed in a large part of the audiotaped consultations. Possible reasons to address these topics may have to do with patient characteristics or patient's question asking behaviour. In previous research we found that four out of five patients did not initiate discussion on any benefits/harms by asking questions or raising new topics. Furthermore, no clear association between benefits/harms mentioned and patient's characteristics such as gender, age or educational level was seen. However, factors like co-morbidity and medical history of individual patients might give a reason to discuss certain additional topics.

Our study has some limitations. Firstly, although we pilot-tested our questionnaire and panellists were given the opportunity to comment on the questionnaire in each round, participants only indicated during the consensus meeting that the meaning of the answer categories 'essential' and 'desired' was only marginally different. We decided to merge these categories in the analysis of the responses on the final round. Had we started the Delphi study with three categories, consensus on some topics might have been reached earlier. Secondly, of the 28 patients who completed the third questionnaire, only 10 patients attended the consensus meeting and completed the final questionnaire. However, the characteristics of patients who attended compared to those who declined further participation did not differ significantly. Although there was a significant difference in how attending and non-attending patients valued the discussion of 'Bladder irritation', the attenders converged to the opinion of the larger group of non-attenders on this topic. . Finally, we have no information on which adverse effects of PRT the members of our patient panel

experienced during or after their treatment. Therefore, we cannot make any statements on the influence of patients' own experience on their views about whether or not to address the benefits/harms offered in our questionnaire.

Delphi-methods have been used before in order to develop core lists. However, so far no studies have been published on core lists of benefits and harms of treatment to be communicated to patients during the consultation. Even though previous research has shown that cancer patients have a strong need for information about side effects of treatment,<sup>19;20</sup> our study showed that treated patients are capable of prioritizing those benefits/harms they think are necessary to address during the consultation. Therefore, patients' perspectives are valuable when creating core lists. The method we used thus seems feasible for creating core lists for other treatments and other cancer types. As can be seen from a number of recent publications, the interest in the sequelae of rectal cancer treatment, and other cancer treatments as well, is rising.<sup>21;22</sup> Our study is thus timely in showing a feasible method to determine which such sequelae should be communicated with patients during the consultation.

In conclusion, our results showed substantial overlap between which benefits and side effects of PRT patients and radiation oncologists consider important to address in the first consultation. These topics were poorly addressed in daily clinical practice. Our core list can be supplemented with outcomes of relevance to the individual patient. Addressing information on these major outcomes of PRT will better enable individual rectal cancer patients to balance possible side effects against the possible benefit in local control when deciding about PRT.



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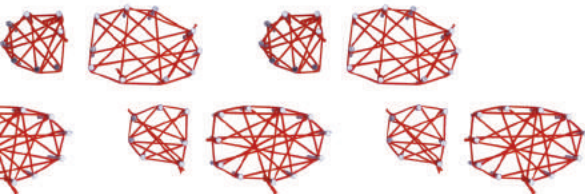


# Chapter 5

## Probabilities of benefit and harms of preoperative radiotherapy for rectal cancer: What do radiation oncologists tell and what to patients understand?

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## Abstract

**Objective:** Probabilities of benefits and harms of treatment may help patients when making a treatment decision. This study aimed to examine 1) whether and how radiation oncologists convey probabilities to rectal cancer patients, and 2) patients' estimates of probabilities of major outcomes of rectal cancer treatment.

**Methods:** First consultations of oncologists and patients eligible for preoperative radiotherapy (PRT) (N=90) were audiotaped. Tapes were transcribed verbatim and coded to identify probabilistic information presented. Patients (N=56) filled in a post-consultation questionnaire on their estimates of probabilities.

**Results:** Probabilities were mentioned in 99% (local recurrence), 75% (incontinence), 72% and 40% (sexual dysfunction in males and females, respectively) of cases. Most patients (89%) correctly estimated that PRT decreases the probability of local recurrence, and 10% and 38%/54% that it increases the probability of incontinence and sexual dysfunction in males/females, respectively. Patients tended to underestimate the probabilities of harms of treatment.

**Conclusion:** Our results show that oncologists almost always mention probabilities of benefit of PRT. In contrast, probabilities of harms often go unmentioned. The effect of PRT on adverse events is often underestimated.

**Practice implications:** Oncologists should stay alert to patients' possible misunderstanding of probabilistic information and should check patients' perceptions of probabilities.

## Introduction

Determining the best choice when facing a treatment decision can be difficult for both clinicians and patients. Over the past decades, patients have become more actively involved as partners in the decision making process.<sup>1</sup> In particular for 'preference-sensitive' decisions, i.e., decisions for which there is insufficient evidence or in which individuals might value benefits and harms of treatment markedly differently, shared decision making (SDM) has become increasingly important.<sup>2</sup> One such preference-sensitive decision is the decision on neo-adjuvant short-course preoperative radiotherapy (PRT) in the treatment of localized rectal cancer.<sup>3</sup> The beneficial effect of PRT on local control in patients with localized rectal cancer has been clearly demonstrated.<sup>4</sup> However, PRT has not been shown to convey an additional survival advantage<sup>4</sup> and is associated with a higher risk of adverse effects, most importantly faecal incontinence and sexual dysfunction.<sup>5-7</sup> Difficulties arise in selecting those patients who benefit most from PRT, which makes it even more relevant to enable individual patients to weigh the benefits and harms of treatment for themselves.

In the process of SDM, the clinical consultation is an opportunity for patients to learn about their treatment options, including no adjuvant treatment, the benefits and harms of each option, and to be supported in making decisions.<sup>8</sup> Communicating probabilities that are relevant to the treatment decision is complex but essential, as probabilities often are the foundation of clinicians' treatment recommendation and help determine the importance of potential benefits and harms. Research has shown that the format (i.e., words, numbers) in which probabilistic information is presented can have significant effects on patients' interpretation of probability and their readiness to undergo treatments.<sup>9-11</sup> If probabilistic information is presented in words rather than in numbers, patients tend to have a less accurate interpretation of probabilities and overestimate the probability of an adverse event occurring.<sup>11-14</sup> Furthermore, presenting patients with relative risks appears more persuasive in making health care decisions than presenting the corresponding absolute risks.<sup>9</sup>

To date, research on effective methods for risk communication has primarily focused on written communication and the textual or visual representation of probabilities, including the application of these methods in decision aids.<sup>15-17</sup> To our knowledge, research on oral risk communication during clinical consultations in which treatment decisions are made has received no attention.

This study had a dual objective. The first aim of the study was to examine whether and how radiation oncologists provide probabilistic information, specifically in what proportion of risk statements they convey a probability using words, numbers, or both, and whether these proportions or the overall number of probabilities mentioned is associated with patients' age, gender and educational level. The second aim was to examine patients' estimates of probabilities of major outcomes of rectal cancer treatment (local control, faecal incontinence, sexual dysfunction), namely, if patients' estimates are correct and whether correct estimates is associated with the format used to communicate probabilities and with patients' age, gender and educational level.

## **Methods**

### *Study population*

The study was conducted at six of the 18 radiation centres in the Netherlands in the context of a large ongoing multicentre study on communication and treatment decision making during first consultations on PRT. All rectal cancer patients eligible for short-course PRT followed by a low anterior resection (sphincter-saving operation, with a possible risk of faecal incontinence), were eligible for inclusion. All radiation oncologists treating patients with rectal cancer were asked to participate.

## *Procedure*

First consultations, in which the decision about PRT is usually made, of radiation oncologists with consecutive primary rectal cancer patients were audio taped. Participating patients signed an informed consent form and completed a questionnaire to assess socio-demographic details prior to the consultation. Patients were also asked to fill in a questionnaire within one week of the consultation, to assess their estimates of probabilities of major outcomes of rectal cancer treatment. Patients who filled in the post-consultation questionnaire more than 14 days after the consultation were excluded from the analyses (N=3). Radiation oncologists were asked to fill in a questionnaire assessing their socio-demographic and work-related details at the start of the study.

The Medical Ethics Committee of Leiden University Medical Centre approved the study.

## *Measures*

Audio tapes of consultations were transcribed verbatim and coded using the ACEPP (Assessing Communication about Evidence and Patient Preferences) coding scheme.<sup>18</sup> By using this scheme, presented evidence relating to treatment outcomes was identified. Utterances conveying a probability of a patient experiencing benefit and/or harms of treatment were coded as a word ('verbal label'), a number, or both, as applicable. If a verbal label was used, we coded whether the label conveyed a direction of the *effect* of PRT ('yes', e.g., *smaller* chance; or 'no', e.g., *small* chance). If a number was used, we coded whether a percentage, a natural frequency (e.g., "5 out of 100"), or both were used. Also, we coded whether the number represented an absolute risk (e.g., "5 out of 100" or "35%"), an absolute risk reduction (e.g., "5% less chance" or "60% of patients with treatment, but 20% of patients fewer without treatment"), a relative risk (e.g., "twice as likely" or "will halve your risk"), or a range around risk (e.g., "about 30-40 patients"). If multiple formats were used to express numerical probabilities on one benefit/harm, all formats used were coded and therefore, categories of numbers mentioned do not add up to 100%.



Two independent raters coded the same ten (11%) audiotapes. Inter-rater reliability was high (Cohen's  $K = 0.80$ ). The remaining tapes were each coded by one rater only; intra-rater reliability based on eight (9%) tapes per rater coded twice with a time difference of 19 months was substantial (Cohen's  $K = 0.67-0.92$ ).

The major benefit of PRT described in the literature is local control, and major harms are faecal incontinence and sexual dysfunction. In the post-consultation questionnaire, patients were asked to indicate side-by-side the absolute probability ranges of each of these three outcomes occurring as a result of one of two treatment strategies: surgery only and PRT followed by surgery (multiple-choice questions, see Figure 1). The question on local control was framed in terms of 'local recurrence', as we expected this framing to be used in communicating probabilities in daily clinical practice. The question on sexual dysfunction was matched to the patient's gender. For each outcome, we considered patients' answers to be correct if they could reproduce the numerical probabilities that their oncologist had mentioned (i.e., risk recall). If no numerical probability was mentioned, we considered patients' answers to be correct if they ticked the probability ranges for the group averages, as reported in key publications and in the Dutch treatment guidelines (i.e., risk interpretation).<sup>3;7;19;20</sup> From this point forward, recall and interpretation will be referred to as 'estimate'. If patients' responses indicated that with PRT followed by surgery, compared to surgery only, the probability of a local recurrence is lower, or that the probability of faecal incontinence or sexual dysfunction is higher, we considered the response to reflect the correct effect of PRT.

Of 100 people who have been treated for a tumour in the rectum, **in how many will the disease recur within 5 years** after treatment with ...

a)... radiotherapy followed by surgery?	b)... surgery only?
<input type="checkbox"/> no one	<input type="checkbox"/> no one
<input type="checkbox"/> 1 to 5	<input type="checkbox"/> 1 to 5
<input checked="" type="checkbox"/> 6 to 10	<input type="checkbox"/> 6 to 10
<input type="checkbox"/> 11 to 15	<input checked="" type="checkbox"/> 11 to 15
<input type="checkbox"/> 16 to 20	<input type="checkbox"/> 16 to 20
<input type="checkbox"/> more than 20	<input type="checkbox"/> more than 20

Of 100 people who have been treated for a tumour in the rectum, **how many will experience leakage of stools in the years** after treatment with ...

a)... radiotherapy followed by surgery?	b)... surgery only?
<input type="checkbox"/> no one	<input type="checkbox"/> no one
<input type="checkbox"/> less than 30	<input type="checkbox"/> less than 30
<input type="checkbox"/> 30 to 50	<input checked="" type="checkbox"/> 30 to 50
<input checked="" type="checkbox"/> 51 to 70	<input type="checkbox"/> 51 to 70
<input type="checkbox"/> more than 70	<input type="checkbox"/> more than 70

**Only for MEN:**

Of 100 men who have been treated for a tumour in the rectum, **how many will be confronted with sexual problems** (erection problems and/or ejaculation problems) in the years after treatment with ...

a)... radiotherapy followed by surgery?	b)... surgery only?
<input type="checkbox"/> no one	<input type="checkbox"/> no one
<input type="checkbox"/> less than 40	<input type="checkbox"/> less than 40
<input type="checkbox"/> 40 to 60	<input checked="" type="checkbox"/> 40 to 60
<input checked="" type="checkbox"/> 61 to 80	<input type="checkbox"/> 61 to 80
<input type="checkbox"/> more than 80	<input type="checkbox"/> more than 80

**Only for WOMEN:**

Of 100 women who have been treated for a tumour in the rectum, **how many will be confronted with sexual problems** (vaginal dryness and/or pain during intercourse) in the years after treatment with ...

a)... radiotherapy followed by surgery?	b)... surgery only?
<input type="checkbox"/> no one	<input type="checkbox"/> no one
<input type="checkbox"/> less than 10	<input type="checkbox"/> less than 10
<input type="checkbox"/> 10 to 20	<input checked="" type="checkbox"/> 10 to 20
<input checked="" type="checkbox"/> 21 to 30	<input type="checkbox"/> 21 to 30
<input type="checkbox"/> 31 to 40	<input type="checkbox"/> 31 to 40
<input type="checkbox"/> more than 40	<input type="checkbox"/> more than 40

**Figure 1.** Multiple-choice questions on the interpretation of risks of major outcomes of PRT. Correct answer boxes per outcome and treatment strategy are ticked and were based on key publications and on the Dutch treatment guidelines.

## *Statistical analyses*

Descriptive statistics were used to report patients' and radiation oncologists' characteristics, and information provision on the probability of patients experiencing benefits and/or harms of treatment. The overall number of probabilities mentioned and the number of verbal labels, numbers, or both used per consultation were not normally distributed, so medians are presented and were compared by patients' gender and patients' interpretation with Mann-Whitney U-tests. Spearman correlations were used to measure linear dependence between overall number of probabilities addressed and number of verbal labels, numbers or both used, and patients' age. Logistic regression analysis was conducted to assess the association between the discussion of probabilities (yes/no) and patients' age. Using  $\chi^2$  tests, patients' correct estimate of probabilities (yes/no) and patients' correct estimate of the effect of PRT (yes/no) were compared by oncologists' use of verbal labels only and by patients' gender and education. Significance testing was done two-sided at  $\alpha = 0.05$ .

## **Results**

### *Participants*

We approached 128 eligible patients, all diagnosed between November 2010 and April 2014. Twelve patients (9%) could not be reached and twenty-one (17%) refused to participate. Ninety-five patients (74%) agreed to have their consultation audio taped. Five of them were excluded from the analyses because their consultation had not been audio taped completely. Of the remaining 90 patients, 56 (62%) completed the post-consultation questionnaire, a median of five days after the consultation (range, 0-13). Patients were on average 64 years old (range, 40-87), and the majority (73%) were male (Table 1). No significant differences were found for patients' age, gender or educational level between those who did versus did not complete the post-consultation questionnaire. All 21 radiation oncologists approached for the study agreed to participate and audiotaped a median of four consultations (range, 1-11).

**Table 1.** Participants' characteristics

	N
<b>Patients (N=90)</b>	
Mean age, years $\pm$ s.d. (range)	64 $\pm$ 10.1 (40-87)
Male	66 (73%)
Educational level <sup>a</sup>	
Low	17 (33%)
Intermediate	32 (44%)
High	26 (22%)
<b>Radiation oncologists (N=21)</b>	
Mean age, years $\pm$ s.d. (range)	40 $\pm$ 6.5 (27-52)
Male	6 (29%) <sup>b</sup>
Median time since specialization, years (range)	6 (0-20)
Median number of rectal cancer patients per month (range)	3 (1-8)

<sup>a</sup> Educational levels included low = completed no/primary school; intermediate = completed lower general secondary education/vocational training; or high = completed pre-university education/high vocational training/university. Eighteen patients did not respond to this question.

<sup>b</sup> Male radiation oncologists audio taped a total of 19 consultations (21%).

### *Oncologists' overall provision of probabilistic information on benefits/harms*

In the 90 consultations, 611 benefits and harms of PRT were mentioned (Md=7 per consultation; range, 2-12) (Table 2). The oncologists mentioned the probability of their occurrence for 358 benefits and harms (59%, Md=4 per consultation; range, 0-8). The oncologists mentioned significantly fewer probabilities in consultations with less compared to more educated patients (Md 'Low education'=3, 'Intermediate education'=4, 'High education'=5 probabilities per consultation,  $F(2,69)=7.52$ ,  $p=0.001$ ). There was no significant association between the number of probabilities the oncologists mentioned and patients' age or gender.

**Table 2.** Communication of probabilities of treatment outcomes of PRT followed by surgery and frequency of formats used in N=90 consultations

	LR	F. Inc	Sex M	Sex F	Total major outcomes	All outcomes (incl major)
Frequency	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
<b>All consultations</b>	<b>N=90</b>	<b>N=90</b>	<b>N=66</b>	<b>N=24</b>	<b>N=90</b>	<b>N=90</b>
Outcome addressed in consultation	89 (99)	51 (57)	61 (91)	15 (63)	216	611
<b>When outcome is addressed</b>	<b>N=89</b>	<b>N=51</b>	<b>N=61</b>	<b>N=15</b>	<b>N=216</b>	<b>N=611</b>
Probability mentioned	88 (99)	38 (75)	44 (72)	6 (40)	176 (81)	358 (59)
<b>When a probability is mentioned</b>	<b>N=88</b>	<b>N=38</b>	<b>N=44</b>	<b>N=6</b>	<b>N=176</b>	<b>N=358</b>
Verbal label only	12 (14)	19 (37)	24 (39)	3 (50)	58 (33)	220 (61)
Number only	24 (27)	9 (18)	11 (18)	2 (33)	46 (26)	57 (16)
Verbal label and number	52 (58)	10 (20)	9 (15)	1 (17)	72 (41)	81 (23)
<b>When a verbal label is mentioned</b>	<b>N=64</b>	<b>N=29</b>	<b>N=33</b>	<b>N=4</b>	<b>N=131</b>	
Direction of PRT-effect mentioned	57 (89)	20 (69)	20 (61)	3 (75)	100 (77)	
<b>When a number is mentioned*</b>	<b>N=76</b>	<b>N=19</b>	<b>N=20</b>	<b>N=3</b>	<b>N=118</b>	
Percentage	52 (68)	18 (94)	17 (81)	2 (67)	89 (75)	
Natural	12 (16)	1 (5)	0	0	13 (11)	
Frequency						
Absolute risk	18 (24)	11 (58)	11 (55)	1 (33)	41 (35)	
Absolute risk reduction	49 (64)	13 (68)	9 (45)	1 (33)	72 (61)	
Relative risk	52 (68)	2 (26)	2 (10)	0	54 (46)	
Range around	16 (21)	7 (37)	2 (10)	1 (33)	26 (22)	

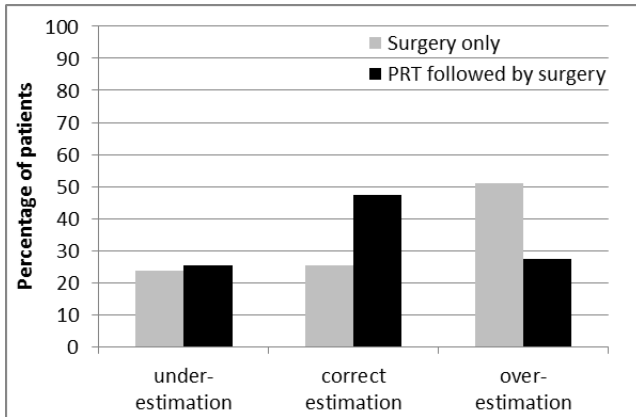
Abbreviations: PRT = Preoperative radiotherapy; LR = Local recurrence; F. Inc = Faecal Incontinence; Sex M = Sexual dysfunction males; Sex F = Sexual dysfunction females. \* Categories of numbers mentioned do not add up to 100%, because multiple categories can apply to a probability statement.

### *Patients' estimates of probabilities*

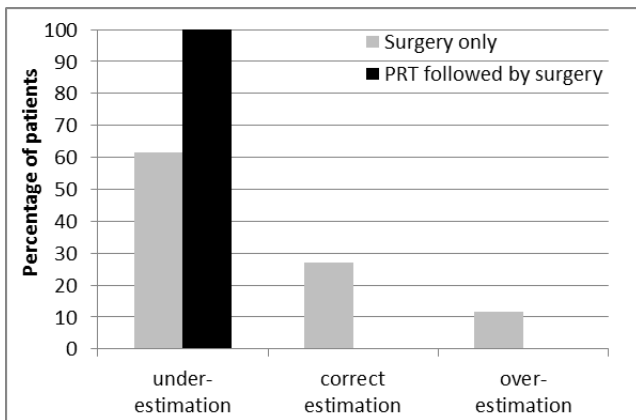
The patients selected the correct absolute probability ranges of both surgery only and PRT followed by surgery, in 12/56 cases (21%) for local recurrence, 0/52 cases (0%) for faecal incontinence, 3/39 cases (8%) for sexual dysfunction in males, and 4/14 cases (29%) for sexual dysfunction in females.

Patients had a slight tendency to *overestimate* the probability of a local recurrence for treatment with surgery only (Figure 2a). For PRT followed by surgery, patients' estimates of a local recurrence were spread across categories. All patients *underestimated* the probability of faecal incontinence for PRT followed by surgery, and the majority (61%) of patients also *underestimated* the probability for surgery only (Figure 2b). For both treatment strategies, male patients tended to *underestimate* the probability of sexual dysfunction (Figure 2c). Female patients' estimates of the probability of sexual dysfunction were spread across categories, with a slight tendency to *overestimate* the probability for surgery only and to *underestimate* the probability for PRT followed by surgery (Figure 2d).

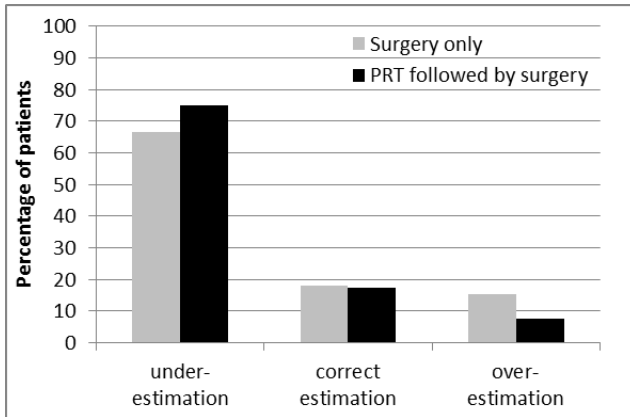
Table 3 shows the percentage of patients who correctly interpreted the *effect* of PRT, compared to surgery only, on the major treatment outcomes. Most patients (89%) correctly interpreted that PRT decreases the probability of a local recurrence. Regarding faecal incontinence and sexual dysfunction in males and females, the patients correctly interpreted that PRT increases the probability in 10%, 38% and 54%, respectively. Of note, over one-third (38%) of patients believed that PRT decreases the probability of faecal incontinence. There were four patients (7%) who correctly interpreted the effect of PRT on all three major outcomes.



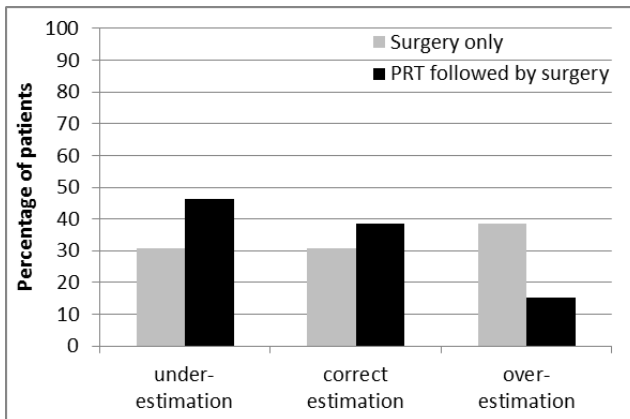
**Figure 2a.** Patients' estimates of probabilities of local recurrence  
Abbreviation: PRT = Preoperative radiotherapy.



**Figure 2b.** Patients' estimates of probabilities of faecal incontinence  
Abbreviation: PRT = Preoperative radiotherapy.



**Figure 2c.** Patients' estimates of probabilities of sexual dysfunction (males)  
Abbreviation: PRT = Preoperative radiotherapy.



**Figure 2d.** Patients' estimates of probabilities of sexual dysfunction (females)  
Abbreviation: PRT = Preoperative radiotherapy.



**Table 3.** Patients' interpretation of the effect of PRT followed by surgery on major treatment outcomes compared to surgery only

	Local recurrence N=56	Faecal incontinence N=52 <sup>a</sup>	Sexual dysfunction males N=39 <sup>b</sup>	Sexual dysfunction females N=13 <sup>b</sup>
<b>PRT decreases probability</b>	89%	38%	13%	15%
<b>PRT does not influence probability</b>	9%	52%	49%	31%
<b>PRT increases probability</b>	2%	10%	38%	54%

Abbreviation: PRT = Preoperative radiotherapy. Grey boxes represent the correct effect of PRT followed by surgery, compared to surgery alone. <sup>a</sup> Four patients did not respond to this question.

<sup>b</sup> Two patients did not respond to this question.

There was no significant association between the oncologists' use of either verbal labels only or numbers (with or without verbal labels) or the number of probabilities the oncologists mentioned during the consultation and whether patients correctly estimated the absolute probabilities or the direction of the PRT-effect on the treatment outcomes. Also, there was no significant association between whether the oncologists conveyed a direction of the effect of PRT (either by verbal labels or numbers) and patients' correct estimate of the effect of PRT. Further, there was no significant association between patients' age, gender or educational level and whether patients correctly estimated the absolute probabilities or the direction of the PRT-effect on the treatment outcomes.

## Discussion and conclusion

### *Discussion*

The first aim of this study was to describe the oncologists' provision of probabilistic information, and specifically in what proportion of cases when the oncologists mention a benefit/harm of treatment, they also convey a probability. Almost two-third of the times that a benefit or harm was discussed, the

oncologists also mentioned the probability of its occurrence, albeit significantly less frequently to patients with lower education. The major benefit of PRT described in the literature is local control, and major harms are faecal incontinence and sexual dysfunction. Earlier, we showed that oncologists as well as patients consider these topics important to address during the first consultation.<sup>21</sup> The current study showed that the (decreased) probability of local recurrence, the benefit of PRT, is virtually always mentioned during the consultation. In contrast, probabilities of major harms of PRT often go unmentioned. An explanation of the discrepancy may lie in two factors. The first may be that oncologists simply do not know the probabilities of the major harms as well as they know the probability of local recurrence. Another explanation may lie in the fact that oncologists think that PRT is the best option for the patient, and they either implicitly or explicitly use the persuasive strategy of selectively presenting the benefits of treatment.<sup>22</sup> Further, it is noteworthy that oncologists do not only discuss sexual dysfunction significantly more often with male than with female patients, as has been shown in previous research,<sup>23</sup> but they also mention its probability substantially more often to male patients. Not mentioning the probabilities of possible harms has been shown to be associated with less understanding of these harms and an increased acceptance of interventions that might do harm.<sup>24</sup>

When presenting probabilities of local recurrence, oncologists tended to present a relative risk, stating that PRT will cut by half its probability of occurrence. In a majority of these cases, the oncologists also gave information on the baseline absolute risk or the absolute risk reduction. Adding this information should be helpful to patients' understanding. Indeed, it has been shown that when relative risks are not accompanied by an absolute risk, they can steer patients towards accepting a treatment or intervention, since particularly with low baseline risks a relative risk reduction seems larger than an absolute risk reduction and the effect of treatment thus seems larger.<sup>17</sup>

The second aim of this study was to examine patients' estimates of probabilistic information on major treatment outcomes, and specifically if patients' estimates were correct. This was true for few patients. We were unable to find significant associations between formats used to convey probabilities and the correctness of patient's estimates, which might have been due to the limited number of patients returning the questionnaire.

In the majority the cases in which a probability of a major outcome was mentioned, the oncologists used a number, with or without the accompaniment of a verbal label. In one-third of the cases, only verbal labels were used. The latter should be discouraged as previous research has shown that the accuracy of patients' interpretation and patients' satisfaction are lower when only verbal labels are used, compared to when numbers are mentioned.<sup>11:12</sup> We found that patients tend to overestimate the probability of getting a local recurrence if adjuvant treatment with radiotherapy is foregone (e.g., treatment with surgery alone). Also, we found that patients tend to underestimate the probability of harms occurring after radiotherapy treatment. The findings of an overestimation of the small probability of local recurrence and an underestimation of the large probabilities of incontinence and sexual dysfunction are in line with prospect theory.<sup>25</sup> Since our crude way of assessing over- and underestimation is unlike the general way of assessment in prospect theory research, however, we are not sure whether it truly reflects the concept of probability distortion specified by this theory. This deserves further research.

We did not find an effect of the use of verbal labels only on patients' estimates of probabilities, possibly due to the small sample size of patients. In a systematic review on risk communication, Zipkin and colleagues recommended to improve patients' understanding by avoiding the use of verbal labels only, a recommendation which is widely supported.<sup>15-17:26</sup> Also, literature suggests that the use of illustrations or icon arrays might aid patients' understanding.<sup>26</sup>

Most, though not all, patients interpreted the effect of PRT on local recurrence correctly. In contrast, the effect of PRT on faecal incontinence and sexual dysfunction was most often estimated incorrectly. For example, over one-third of patients believed that PRT followed by surgery, compared to surgery only, decreases the probability of faecal incontinence, while in fact, PRT increases the risk from about 40 to 60%.<sup>27</sup> This suggests that many patients believe that there is no harm in undergoing PRT. There may be several explanations for patients' misinterpretations. Firstly, patients might not consider these harms important given the potential gain, and especially at this point in time when they are primarily focused on becoming disease-free. In earlier research, however, we found that rectal cancer patients consider both faecal incontinence and sexual dysfunction important topics to be discussed with the radiation oncologist at the time of decision making, and that they take these

harms in consideration when forming a treatment preference.<sup>21:28</sup> Secondly, patients might ignore these probabilities, as they believe that the treatment decision has already been made. In most of these first consultations, oncologists do not tell the patient that a treatment decision needs to be made.<sup>29</sup> This might lead to post hoc justification, that is, to patients having the desire to justify the prior decision as being the correct one, and one which will do them no harm.<sup>30</sup>

A strength of our study is that by audio taping the consultations, we were able to observe the actual communication between radiation oncologists and rectal cancer patients and therefore, we did not depend on oncologists' or patients' recall on which probabilities were mentioned. Our study also has potential limitations. The first is that because of relatively small numbers of patients included per oncologist, we were unable to assess associations between probabilities mentioned and oncologists' characteristics. Further, the range in the number of recorded consultations per oncologist might have led to somewhat skewed results. The second limitation is that only 57 of the 90 patients included in the study filled in the post-consultation questionnaire (within 14 days). Most (22/33, 67%) of the patients who did not complete the questionnaire only gave consent for audiotaping their consultation. Other patients returned the questionnaire without filling in the questions on risk interpretation, possibly because they did not know the answers or were uncomfortable with the questions. If this is the case, then the rates of correct estimates of probability ranges that we established, most probably are overestimations of actual understanding. Finally, patients might have received or searched for additional (probabilistic) information prior to the consultation or after the consultation and before completing the questionnaire. Again, this would imply that our results overestimate the number of patients who correctly estimate the probabilities of treatment outcomes based on the information given during the consultation.

## Conclusion

Our results show that the probability of the additional benefit of PRT on local control is virtually always mentioned during the first and pre-treatment consultation. In contrast, probabilities of adverse events are often left unspoken. Most patients interpret the beneficial effect of PRT on local control correctly, but the effect of PRT on adverse events is most often underestimated.

## Practice implications

In order for patients to understand and weigh the pros and cons of treatment, and in order for them to be involved in deciding about treatment, they need to be aware of the relevant probabilities of major outcomes. This is a challenge for oncologists who should be careful to mention both the probabilities of benefit and harms whenever possible and stay alert to patients' potential misunderstanding. It is recommended that oncologists regularly check patients' perceptions of probabilities during the consultation.

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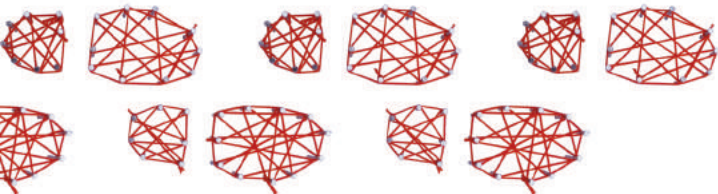


# Chapter 6

## Do oncologists convey what they intend? Lay interpretation of verbal risk labels used in decision consultations

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Submitted for publication



## Abstract

**Background:** Probabilities of benefits and harms of treatment may help patients making a treatment decision. Oncologists frequently use verbal labels only (non-numeric statements) to convey a probability. This study aimed to assess the numerical probability that patients associate with verbal labels and the influence of medical outcome, age, gender, educational level, health literacy and numeracy.

**Materials and methods:** Frequently-used verbal labels (N=11) were extracted from N=90 audiotaped decision consultations. A sample of the adult Dutch population (N=300), as proxies for newly-diagnosed cancer patients, assigned numerical probabilities to the labels and filled in a questionnaire on their socio-demographic characteristics, health literacy and numeracy.

**Results:** Considerable variation was seen in how individuals interpreted the verbal labels. Participants' probability estimates of verbal labels was lower in the context of cancer recurrence compared to nausea. Low numerate participants tended to differentiate less between the labels. The same tendency was found for educational level and health literacy, but not statistically significant. There was no association between participants' estimates and age or gender.

**Discussion:** Our results showed considerable variation in how individuals interpret verbal labels frequently-used, with medical outcome and numeracy as possible determinants. It is recommended to avoid the use of verbal labels only, to minimize misunderstandings.

## Introduction

In medical consultations, oncologists frequently use verbal labels (non-numeric probability statements) to convey a probability of an event occurring.<sup>1</sup> Primary reasons to use verbal labels is lack of availability of numerical information, and uncertainty about the actual numerical probability for a specific patient.<sup>2</sup> Also, compared to numbers, verbal labels are easy and natural to use, and may better capture a person's emotions, intuitions, and directionality.<sup>2-4</sup> On the other hand, using verbal labels has the potential weakness of a high degree of variability in interpretation.<sup>3</sup> That is, the magnitude of the probability that an oncologist aims to convey using a verbal label may not be interpreted as such by a patient. This variability could especially be problematic when oncologists communicate probabilities that are relevant to treatment decision making. Probabilities often are the foundation of oncologists' treatment recommendations and they better enable patients to weigh the benefits and harms of different treatment strategies. We recently showed that in medical consultations with newly-diagnosed rectal cancer patients facing a treatment decision, in one-third of the cases, radiation oncologists only use verbal labels to convey a probability, in spite of the potential pitfall of variability in interpretation. Of note, in this clinical case numerical probabilities are available and known to most oncologists.<sup>1</sup>

The way in which probabilities are presented can have a significant effect on patients' interpretation and their readiness to undergo treatment.<sup>5</sup> More than with numerical probabilities, the interpretation of verbal labels can be influenced by the assumed frequency of an event occurring and by its severity, with people assigning higher numerical probabilities to verbal labels concerning high frequent or less severe events.<sup>6-8</sup> The influence of other determinants such as age, gender, educational level, health literacy and numeracy has been investigated to some extent, but is still equivocal.<sup>2:9-11</sup> To the best of our knowledge, no research has been conducted on the simultaneous influence of these determinants, nor on the interpretation of verbal labels that are frequently used in medical consultations with newly-diagnosed cancer patients facing a treatment decision.

This study aimed to assess the numerical probability that individuals associate with verbal labels used to convey probabilities of outcomes in cancer treatment decision consultations, and the association with type of treatment outcome and individuals' characteristics. Research questions to be answered were: 1) How do individuals from the general adult population (as proxies for newly-diagnosed cancer patients facing a treatment decision) interpret frequently-used verbal labels, in the context of two outcomes of cancer treatment? and 2) Is there an association between individuals' interpretation of verbal labels and the type of outcome, individuals' age, gender, educational level, health literacy, or numeracy?

## **Materials and methods**

### *Design*

An online questionnaire was offered to a sample representative for the adult Dutch population, in which participants were asked to rate verbal labels, regarding one of two outcomes of rectal cancer treatment. Verbal labels were offered in writing, excluding the influence of non-verbal factors as emphasis or stress.

### *Study population*

The sample consisted of 300 adult Dutch participants, stratified to mirror the adult census population in terms of age, gender and educational level. For taking part in this study, participants received credits from a research agency, which they can exchange for gifts.

## *Procedure and measures*

In preparation of the online questionnaire, we extracted utterances conveying a probability of a patient experiencing a treatment benefit or harm by use of a verbal label.<sup>1,12</sup> To this end, we used data collected during a large multicenter study on (risk) communication regarding short-course preoperative radiotherapy.<sup>1</sup> Consecutive consultations (N=90) between radiation oncologists and newly-diagnosed rectal cancer patients facing a treatment decision were audiotaped and coded. Verbal labels were selected for the current study from those most frequently used that covered a wide range in 1) wording of the labels and 2) probabilities conveyed with the verbal labels. Only verbal labels expressing an absolute risk were selected. Expressions containing a negation (e.g., not often) were excluded. This resulted in a list of 11 frequently-used verbal labels, which covered 71% of all verbal labels used during the 90 consultations.

The research agency invited members of their panel to participate by sending them a link to the questionnaire. Participants were given a short introduction stating that “to convey a probability that someone experiences for example a side-effect of treatment, clinicians may use probability words, such as often or sometimes”. Next, they were asked to complete socio-demographic details. They were then either directed to the questionnaire or redirected back to the website of the research agency if the maximum number of participants with their characteristics had been reached. Participants directed to the questionnaire were randomized to one of two outcomes of rectal cancer treatment: 1) ‘A patient will be treated with radiotherapy because of rectal cancer. A disadvantage of radiotherapy is that people can get nauseous’; or 2) ‘A patient will undergo surgery because of rectal cancer. In spite of this surgery, the cancer could come back.’ The situations were chosen such that they presented realistic outcomes of the treatment and that they differed in seriousness. To increase comparability and to best mimic current clinical practice, both were framed negatively. Characteristics of participants were comparable across the two groups (data not shown). Participants were offered the 11 verbal labels each as part of a short sentence (i.e., “sometimes people become nauseous”) and in random order. They were asked to indicate how many people in their view will experience this outcome, by filling in a natural frequency (both the numerator and the denominator: “approximately ... out of ... people”).

After rating the verbal labels, participants filled in a short questionnaire on health literacy and numeracy.<sup>13;14</sup>

### *Statistical analyses*

Descriptive statistics were used to report the participants' characteristics and numerical estimate of each verbal label. Frequencies were converted to percentages. An overall numeracy score was calculated by averaging the ratings across all numeracy items. The classification of participants' health literacy and numeracy levels (inadequate/adequate and lower/higher, respectively) was based on recommendations of the questionnaire developers.<sup>15;16</sup>

We tested differences in the numerical probabilities that individuals associated with the verbal labels (within-subject levels) by medical outcome, age, and gender (between-subject factors) using repeated measure general linear models, adjusted using the Greenhouse-Geisser method. As we expected that individuals with a lower educational level, inadequate health literacy, or lower numeracy discriminate less between high and low probabilities and thus, assign lower probabilities to labels conveying a higher chance and higher probabilities to those conveying a lower chance,<sup>10;17</sup> we also tested whether there was a difference in the numerical probabilities individuals associated with the 'low' versus 'high' verbal labels depending on educational level, health literacy, and numeracy (between-subject factors).

## **Results**

### *Participants*

In total, 4902 people were invited to participate, and 994 (20%) began the survey. After filling in their socio-demographic details, 499/944 people were redirected from the questionnaire, because the maximum of participants with their characteristics had already been reached. All other participants (N=495) were directed to the questionnaire. Thirteen of them were excluded from the

analyses, because they filled in the same numbers for all verbal labels. A total of 300/482 (62%) participants completed the questionnaire, in a median time of 4.9 minutes (Table 1).

**Table 1.** Participants' characteristics (N=300)

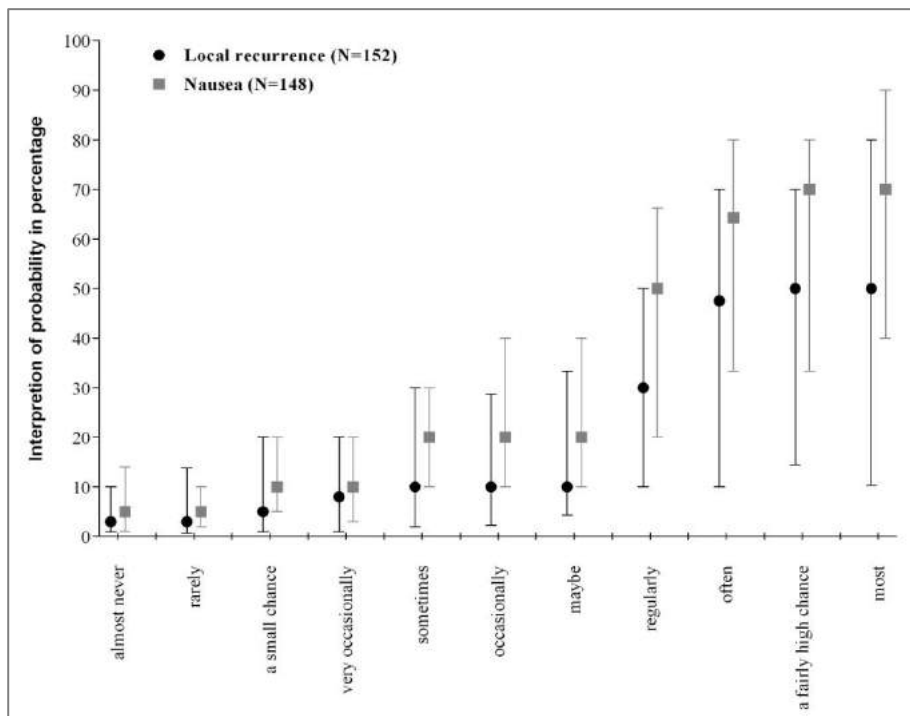
	N (%)
Age	
20-39 years	99 (33)
40-64 years	145 (48)
65-80 years	56 (19)
Male gender	151 (50)
Educational level <sup>a</sup>	
Low	47 (16)
Intermediate	168 (56)
High	84 (28)
Health literacy	
Inadequate	110 (37)
Adequate	190 (63)
Subjective numeracy	
Low, median score on 1-6 scale (range)	3.3 (1-4)
High, median score on 1-6 scale (range)	5.1 (4.3-6)

<sup>a</sup> Educational levels included low = completed no/primary school; intermediate = completed lower general secondary education/vocational training; or high = completed pre-university education/high vocational training/university. One participant (0.3%) filled in 'other', without specifying level of education.

### *Interpretation of verbal labels*

Figure 1 shows how verbal labels were interpreted for the two medical outcomes. There was a significant effect of outcome on the estimated numerical probabilities of verbal labels, that is, participants' estimates of verbal labels were lower for cancer recurrence compared to nausea ( $F(3.4, 1025.5)=5.21$ ,  $p=0.001$ ). On average, participants' estimates of verbal labels were an absolute 11% lower for cancer recurrence compared to nausea (range, 2-20).





**Figure 1.** Interpretation in percentages of each verbal label (median (1st and 3rd quartile))

Based on our data, we identified those labels that the participants considered to reflect a low versus high probability (N=7 vs N=3, respectively; see Figure 1). The verbal label ‘regularly’ was excluded as it represented an intermediate probability. Low numerate participants tended to estimate higher probabilities than high numerate participants for verbal labels indicating a low probability, and significantly lower probabilities for verbal labels indicating a high probability ( $F(1.9, 590.6)=7.34, p=0.001$ ). Thus, lower numerate participants discriminated less between verbal labels than higher numerate participants. The same tendency was seen for educational level and health literacy, but the results were not statistically significant (data not shown). There was no significant association between participants’ estimates and participants’ age or gender.

## Discussion

Our study showed considerable variation in how individuals interpret verbal labels that are frequently-used in cancer consultations in which a treatment decision needs to be made. Communicating probabilities that are relevant to the treatment decision is complex but essential, as probabilities help to weigh the potential benefits and harms of treatment. Most people prefer to receive probabilistic information numerically, but to use verbal labels to convey a probability,<sup>18;19</sup> despite recommendations from the literature to avoid the use of verbal labels only.<sup>20;21</sup> Indeed, in daily clinical practice, radiation oncologists frequently use verbal labels only to convey probabilities to patients facing a treatment decision.<sup>1</sup> Patients' satisfaction has been shown to be lower when receiving probabilistic information verbally, and their interpretation to be less accurate.<sup>5;22</sup> That is, the magnitude of the probability that an oncologist aims to present using a verbal label may not be interpreted as such by the patient. Probabilities of common side-effects might be known to clinicians, but clinicians should not assume that patients interpret probabilities for different outcomes in the same way clinicians do. In fact, in earlier research, we found that patient tend to underestimate the probability of a side effect occurring.<sup>1</sup>

In line with previous research, we found that the interpretation of verbal labels was influenced by the medical outcome, which is likely due to the perceived severity and/or the assumed frequency of occurrence of the outcomes.<sup>6-8</sup> We cannot disentangle the individual effect of perceived severity and assumed frequency of occurrence as the outcomes we presented differed on both, as is usually the case in actual clinical cases. We further found that less numerate individuals estimated numerical probabilities of verbal labels closer to 50% than more numerate individuals, that is, less numerate individuals tended to differentiate less between the verbal labels. This finding is consistent with research outside of the medical field,<sup>10</sup> and might reflect an "I don't know" response. However, since we do not have a 'golden standard' for the interpretation of verbal labels, we cannot make any statements on whether the high versus low numerate group has more accurate estimates of verbal labels. We found a similar effect in differentiation between labels for individuals' educational level and health literacy, although not statistically significant.

A strength of our study is that we offered participants a list of verbal labels that are most frequently used during cancer decision consultations. This enabled us to gain insight in how they interpret non-numerical probability statements used in daily clinical practice. Furthermore, we were able to assess the influence of multiple determinants in a large sample of the adult census population, as proxies for newly-diagnosed patients facing a treatment decision. A possible limitation is that our participants did not experience the emotions that patients do when they are diagnosed with cancer and face treatment. In general, patients seem to underestimate the probability of an adverse effect occurring (1). We expect that the variation in interpretation will be similar for newly-diagnosed cancer patients and the general adult population.

In conclusion, our results show considerable variation in how individuals interpret frequently-used verbal labels, with medical outcome and individuals' numeracy as possible determinants. By using verbal labels, oncologists attempt to convey a magnitude of the probability that a patient will experience a benefit or harm. The large variation in interpretation of verbal labels shows that the magnitude that an oncologist aims to present using a verbal label will likely not be interpreted as such by individual patients. It is recommended to avoid the use of verbal labels only, to minimize misunderstandings and to prevent patients from consenting to treatments that go against their informed values and preferences.

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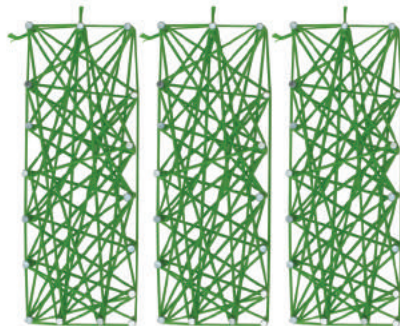
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# Part III

Step 3: Discussing patients' values and preferences and deciding what is best



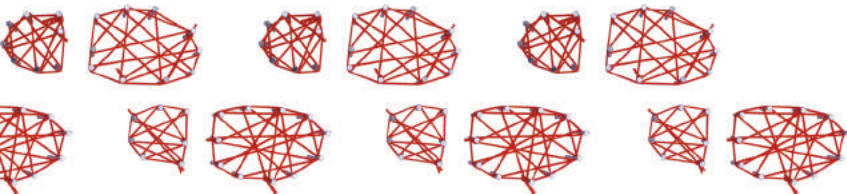


# Chapter 7

## Considering patient values and treatment preferences enhances patient involvement in rectal cancer treatment decision making

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Radiotherapy and Oncology (2015) 117:338-342





## Abstract

**Background:** The shared decision making (SDM) model states that patients' values and preferences should be clarified to choose a strategy that best fits the patient. This study aimed to assess whether values and preferences of rectal cancer patients are voiced and considered in deciding about preoperative radiotherapy (PRT), and whether this makes patients feel more involved in treatment decision making.

**Methods:** Pre-treatment consultations of radiation oncologists and patients eligible for PRT were audiotaped (N=90). Tapes were transcribed and coded to identify patients' values and treatment preferences. Patients filled in a post-consultation questionnaire on their perceived involvement in decision making (N=60).

**Results:** Patients' values were voiced for 62/611 of benefits/harms addressed (10%), in 38/90 consultations (42%; maximum 4 values per consultation), and most often related to major long-term treatment outcomes. Patients' treatment preferences were discussed in 20/90 consultations (22%). In 16/90 consultations (18%), the oncologists explicitly indicated to consider patients' values or preferences. Patients perceived a significant more active role in decision making if their values or preferences had been voiced or considered.

**Conclusions:** Patients' values and treatment preferences are voiced or considered in a minority of consultations. If they are, this increases patients' perceived involvement in the decision making process.

## Background

Shared decision making (SDM) in the clinical encounter has become increasingly important in modern health care, both from an ethical and a clinical point of view.<sup>1;2</sup> Applying the principles of SDM is especially relevant when treatment decisions are preference-sensitive, i.e. in the absence of a 'best choice' from a clinical perspective or when individual patients' valuation of benefits and harms may strongly vary.<sup>3-5</sup> One such preference-sensitive decision is the decision about short-course preoperative radiotherapy (PRT) in the treatment of patients with localized rectal cancer.<sup>6</sup> The beneficial effect of PRT on local control, compared to surgery only, has been clearly demonstrated, but PRT does not convey an additional overall survival benefit.<sup>7</sup> Moreover, PRT is associated with a higher risk of adverse effects, the most important of which are faecal incontinence and sexual dysfunction.<sup>8;9</sup> Research has shown great variation in how individual patients value possible benefits and harms of PRT and these valuations are not consistently related to patient characteristics.<sup>10;11</sup> Moreover, it turns out to be difficult for clinicians to accurately judge patients' values for health outcomes or patients' treatment preferences.<sup>10;12;13</sup> Patients should therefore explicitly voice their values and treatment preferences during the consultation with their radiation oncologist, so that these can be considered in choosing a treatment strategy that best fits the patient. Most SDM models state that clinicians should elicit patients' values and preferences in treatment decision making,<sup>2;14;15</sup> but little research has been conducted on whether this actually happens in daily clinical practice.<sup>16;17</sup>

This study aimed to assess 1) the extent to which patients' values regarding benefits and harms of PRT and patients' treatment preferences are voiced during decision consultations about PRT for rectal cancer, 2) if these values and preferences are explicitly considered in deciding about treatment, and 3) whether patients feel more involved in treatment decision making when their values or preferences are discussed or considered during decision making.

## Methods

### *Study population*

This study was conducted in six of the 21 radiotherapy centers in the Netherlands in the context of a large multicenter study on communication and treatment decision making during decision consultations on PRT for rectal cancer.<sup>18</sup> All patients eligible for short-course PRT followed by a low-anterior resection (sphincter-saving operation) were eligible for inclusion.

All radiation oncologists working in one of these centers and treating patients with rectal cancer were asked to participate.

### *Procedure*

First consultations, usually the only consultation prior to the start of the treatment, of participating radiation oncologists with consecutive eligible rectal cancer patients were audiotaped. Participating patients signed an informed consent form and completed a questionnaire to assess socio-demographic details prior to the consultation. Patients were also asked to fill in a questionnaire within one week after the consultation, to assess their perceived involvement in treatment decision making. Patients who filled in the post-consultation questionnaire more than 14 days after the consultation were excluded from the analyses (N=5). Radiation oncologists were asked to fill in a questionnaire assessing their socio-demographic and work-related details at the start of the study.

The Medical Ethics Committee of Leiden University Medical Center approved the study.

## Measures

Audiotapes of the consultations were transcribed verbatim and coded using an adapted version of the ACEPP (Assessing Communication about Evidence and Patient Preferences) coding scheme.<sup>19</sup> By using this coding scheme, all utterances on patient values concerning health-related benefits and harms of treatment and on patients' treatment preferences were identified. We considered all patient statements on the importance of a specific benefit/harm or on the implication of a benefit/harm for the patient's everyday life as patient values (e.g., "that's my biggest fear, that something will change in that area" (sexual dysfunction); "I'm not someone who finds sex very important, not at my age" (erectile dysfunction); "if I become incontinent, than I won't be able to go to concerts anymore" (long-term faecal incontinence); "I don't want to live in constant fear of it coming back" (local recurrence)). All statements containing an *opinion* of the patient regarding possible treatment strategies were considered as a treatment preference (e.g., "I want the radiotherapy anyway"; "I think we must seize all opportunities to prevent it coming back"; "I actually don't favour undergoing the radiation, I find the risks too great and the benefit too limited"). If a patient consented with the treatment that the oncologist proposed without any further comment or opinion (Oncologist: "so, let's do this?", Patient: "yes"), this was not considered as a treatment preference. Utterances of patients' companions were coded as the patient's, unless the patient contradicted the statements.

First, we coded per benefit or harm addressed whether patients voiced a value (yes/no) and who initiated the matter (oncologist/patient). Second, we coded whether patients made any explicit comments about their treatment preferences (yes/no). Finally, we coded whether oncologists explicitly indicated to consider patients' values and/or treatment preferences in deciding about treatment (e.g. "you have to think about this, it's a difficult choice, everybody weighs these outcomes differently", yes/no), regardless of whether the patient actually voiced a value or treatment preference.

Two raters independently coded the same 10 (11% of total number) audiotapes. Inter-rater agreement was substantial (Cohen's  $K = 0.88$ )<sup>20</sup>. The remaining tapes were coded by either one of the two raters (intra-rater

agreement based on eight (9%) tapes per rater coded twice with a time difference of 19 months, Cohen's  $K = 0.67$  and  $0.87$ ).

In the post-consultation questionnaire, we assessed patients' perceived decisional role using a modified version of the Control Preferences Scale (CPS), in which participants were asked to select one of five statements on decisional role.<sup>21;22</sup> The roles ranged from (A) I made the decision about PRT alone, through (B) I made the decision about PRT after considering my radiation oncologist's opinion, (C) my radiation oncologist and I made the decision about PRT together, (D) my radiation oncologist made the decision about PRT after considering my opinion, to (E) my radiation oncologist made the decision about PRT alone.

### *Statistical analyses*

Descriptive statistics were used to report patients' and oncologists' characteristics, and the number of values and preferences discussed. The number of values discussed was compared by patients' age, gender, being accompanied by a companion during the consultation and patients' educational level with Spearman correlations, Mann-Whitney U-tests, and Kruskal-Wallis tests. The discussion of treatment preferences (yes/no) was compared by patients' age, gender, being accompanied during the consultation and patients' educational level with Chi-square tests and Kruskal-Wallis tests, as applicable. CPS-scores were compared by the discussion of values or preferences (yes/no) and the explicit consideration of values or treatment preferences (yes/no) with Mann-Whitney U-tests. Significance testing was done two-sided at  $\alpha = 0.05$ .

## **Results**

We approached 128 eligible patients, all diagnosed between November 2010 and April 2014. Twelve patients (9%) could not be reached and twenty-one (17%) refused to participate. Ninety-five patients (74%) agreed to have their consultation audiotaped. Five of them were excluded from the analyses because

of incomplete audiotaping. Of the remaining 90 patients, 60 (67%) completed the post-consultation questionnaire, a median of four days after the consultation (range, 0-13). No significant differences were found for patients' age, gender, or educational level between those who did versus did not complete the post-consultation questionnaire. All 21 radiation oncologists approached agreed to participate and audiotaped a median of four consultations (range, 1-11). In Table 1 participant demographic and work-related (radiation oncologists) characteristics are listed.

**Table 1.** Participant characteristics

	N (%)
<b>Patients (N=90)</b>	
Mean age, years $\pm$ s.d. (range)	64 $\pm$ 10.1 (40-87)
Male gender	66 (73)
Educational level <sup>a</sup>	
Low	17 (33)
Intermediate	32 (44)
High	26 (22)
Companion present at consultation	80 (89)
Perceived decisional role <sup>b</sup>	
Patient made the decision	4 (7)
Patient made the decision after considering the radiation oncologist's opinion	13 (22)
Radiation oncologist and patient made the decision together	22 (37)
Radiation oncologist made the decision after considering the patient's opinion	12 (20)
Radiation oncologist made the decision	9 (15)
<b>Radiation oncologists (N=21)</b>	
Mean age, years $\pm$ s.d. (range)	40 $\pm$ 6.5 (27-52)
Male gender	6 (29) <sup>c</sup>
Median time since specialization, years (range)	6 (0-20)
Median number of rectal cancer patients per month (range)	3 (1-8)

<sup>a</sup> Educational levels included low = completed no/primary school; intermediate = completed lower general secondary education/vocational training; or high = completed pre-university education/high vocational training/university. Eighteen patients did not respond to this question.

<sup>b</sup> As assessed in the post-consultation questionnaire, filled in by N=60 patients.

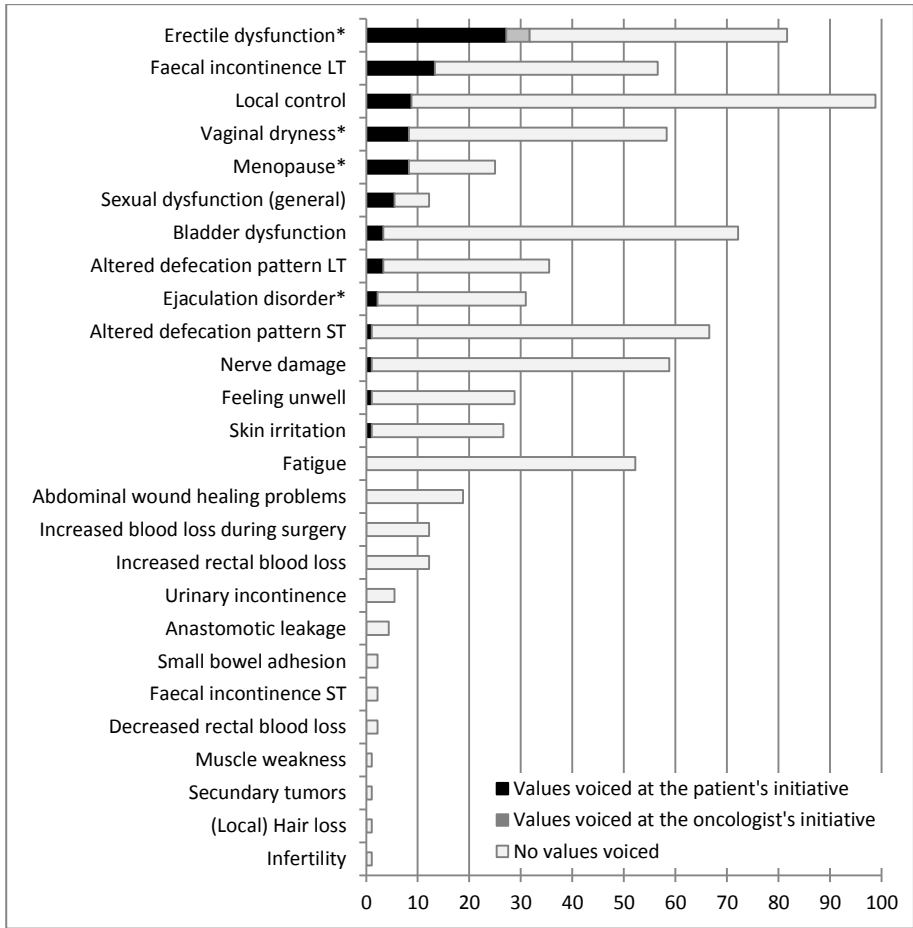
<sup>c</sup> Male radiation oncologists audiotaped a total of 19 consultations (21%).

Oncologists and patients discussed patients' values in 29/90 consultations (32%), patients' treatment preferences in 11/90 consultations (12%), or both in 9/90 consultations (10%). In the other 41/90 consultations (46%), neither patient's values, nor their treatment preferences were addressed.

Per consultation, a median of seven benefits and harms of PRT were addressed (range, 2-12), summing up to in total 611 discussions on benefits and harms in the 90 consultations. Patients' values concerning these benefits and harms were voiced in 62/611 cases (10%), in 38/90 consultations (42%, maximum of 4 values per consultation). Values most often related to sexual dysfunction (N=30/62, 48%, e.g., erectile dysfunction or ejaculation disorder (men), vaginal dryness (women) or sexual problems in general), long-term faecal incontinence (N=12/62, 19%), and local control (N=8/62, 13%) (Figure 1). Of these 62 discussions on patient values, three (5%) were initiated by the radiation oncologist, all concerning erectile dysfunction in male patients, for example by inviting patients to express their opinion on a harm (see Figure 1). The patients initiated all other discussions.

Patients' treatment preferences were discussed in 20/90 consultations (22%). In 15 of these 20 cases (79%), patients expressed a preference to undergo PRT, in the other five cases (21%) patients expressed a preference to forego PRT.

There was no significant association between the number of values discussed or whether or not treatment preferences were discussed, and patients' age, gender or educational level, or being accompanied during the consultation.



**Figure 1.** Percentage of times that a patient's value relating to benefits/harms of PRT was voiced, and initiative.

Abbreviations: ST = short term; LT = long term. Note: The total length of the bars per benefit/harm represents the percentage of consultations in which the benefit/harm was addressed. \*As percentage of consultations with patients from relevant patient group (male/female patients).



In deciding about PRT, the radiation oncologists explicitly indicated to consider patients' values in 1/90 consultations (1%), patients' treatment preferences in 10/90 consultations (11%), or both in 5/90 consultations (6%).

Of the consultations in which patients' values or treatment preferences were discussed, the oncologist also explicitly indicated to consider these in treatment decision making in 4/38 and 6/20 cases (11% and 30%), respectively. In the one consultation in which the voiced value was explicitly considered in decision making, the oncologist indicated that the patient's treatment preference was of importance as well. In this case, the patient indicated that he needed more time to form a preference and a second consultation was scheduled.

In addition, there were seven consultations in which the oncologists indicated that they wanted to consider the patient's treatment preference, but the patient did not voice any. In five of these consultations, the oncologist recommended PRT and the patient consented. In the other two consultations, the decision was postponed and the oncologist and the patient agreed to a follow-up appointment by telephone.

Patients' perceived role in deciding about PRT is shown in Table 1. Overall, patients perceived they had a significantly more active role in deciding about PRT (lower CPS-score) when they had voiced more values ( $\rho=-0.33$ ,  $p<0.01$ ), or when they had put forward their treatment preference to their radiation oncologist ( $U=214$ ,  $z=-2.8$ ,  $p<0.01$ ). Patients also perceived they had a significantly more active role when the oncologist had indicated to consider the patient's values or preferences in deciding about PRT, compared to when the oncologist had not ( $U=147.5$ ,  $z=-2.98$ ,  $p<0.01$ ).

## Discussion

The SDM model states that after informing patients on possible treatment options, possible benefits and harms and their respective probabilities, patients' values and preferences should be clarified or elicited in the decision making process.<sup>2;14;15</sup>

The first aim of this study was to assess the extent to which rectal cancer patients voice their values regarding benefits and harms of PRT and their treatment preferences during decision consultations. In less than half of the consultations, patients expressed one or more values. In total, patients expressed their values regarding only a small portion of all benefits and harms of PRT discussed; and in almost all cases at their own initiative. If patients explicitly voiced their values, these most often concerned long-term major outcomes of PRT, such as local recurrence, fecal incontinence, or sexual dysfunction. This is consistent with previous research in which we showed that rectal cancer patients as well as radiation oncologists consider these outcomes important, and necessary to address during this consultation.<sup>23</sup> Patients' treatment preferences were discussed in about one out of five consultations. The literature shows that overall, rectal cancer patients require only a small beneficial effect of PRT to consider it worthwhile, but large variation exists in individual treatment preferences,<sup>10</sup> and it is difficult for clinicians to predict patients' values or preferences.<sup>10;24</sup> Therefore, we must be alert to the 'silent misdiagnosis' of patients' values and treatment preferences.<sup>24</sup> After providing patients with all relevant information, oncologists can invite patients to share their ideas, concerns and expectations. Although this has been recommended in the literature,<sup>25</sup> research shows that in daily clinical practice, this only happens in limited extent.<sup>17</sup> Only after discussing and understanding how the patient values trade-offs between benefits and harms of treatment, can the radiation oncologist recommend a strategy that best fits the patient.

The second aim of the study was to assess the explicit consideration of patients' values and treatment preferences in treatment decision making. In less than one out of five consultations, the radiation oncologists *explicitly* indicated to consider the patient's values or treatment preferences in deciding

about PRT. It is noteworthy that in seven consultations, the oncologist stated that the patient's treatment preference was of importance in deciding about treatment, but the patient did not voice a preference and the oncologist did not probe any further. In an earlier study, we showed that radiation and medical oncologists rarely express to their patients, as a reason for the encounter, that a treatment decision needs to be made.<sup>26</sup> Many patients might not realize that foregoing (neo-)adjuvant treatment is a viable option and that their values and treatment preferences are of importance in the treatment decision. Therefore, a statement from the oncologist that the patient's values and treatment preferences are to be considered might take patients by surprise. Patients may need more encouragement from the oncologist, or, as some patients in our study indicated, more time to form and express their values and treatment preferences. When facing a preference-sensitive health-related decision, time pressure should not be at stake and individuals should be able to take at least days before committing to an option.<sup>27</sup>

The last aim of this study was to assess whether patients feel more involved in treatment decisions when their values or treatment preferences are voiced or considered. Most patients felt they had shared the decision with their radiation oncologist at least to some extent, but the results showed that they perceived a more active role when their values or preferences had been addressed during the consultation, or when the oncologist indicated to consider the patient's values or preferences in the decision making process. Our findings are consistent with theoretical models on SDM.<sup>2;14;15;24</sup> Discussing and explicitly considering patients' values and preferences will thus not only help choosing what is best for the patient, it will also make patients feel more involved in the treatment decision, which has been shown to lead to better patient outcomes.<sup>28</sup> As can be seen from a number of recent publications, the interest in the possible harms of rectal cancer treatment, and of other cancer treatments as well, is rising.<sup>29;30</sup> Our study is thus timely in showing the importance of discussing patients' valuations of such harms of treatment in the decision-making process.

A strength of our study is that by audiotaping the consultations, we were able to observe the actual communication between radiation oncologists and patients and did not depend on radiation oncologists' or patients' recall. Our study also has limitations. First, we only examined verbal communication. We found that almost all values were voiced at the initiative of the patient, but we do not have information on whether the radiation oncologists gave non-verbal cues to patients to express their opinion. Second, because of relatively small numbers of patients included per radiation oncologist, we were unable to assess associations between the variation in values and treatment preferences addressed and oncologists' characteristics.

It is noteworthy that participating patients and radiation oncologists were informed on the overall aims of the study. If they were actually aware of our aims to assess the communication on benefits and harms of PRT, and the patient's role in deciding about treatment at the time of the consultation, than our findings most probably are overestimations of the number of times that patients' values and treatment preferences are discussed in daily clinical practice.

In recent years, there has been interest in the value of so-called values clarification methods to give patients insight in how they value benefits and harms of treatment.<sup>31</sup> In a follow-up study, we offer rectal cancer patients such a tool prior to their consultation with the radiation oncologist,<sup>32</sup> and will evaluate the effect of the tool on the communication about patients' values and on patients' participation in the decision-making process.

In conclusion, our study shows that rectal cancer patients' values and treatment preferences regarding PRT are voiced or considered in a minority of consultations in which a treatment decision needs to be made. Discussing or considering values or preferences enhances patients' perceived involvement in the treatment decision. This brings empirical support to the SDM model that states that after providing patients with relevant information, patients' values and preferences should be clarified or elicited before choosing a treatment that best fits the individual patient.

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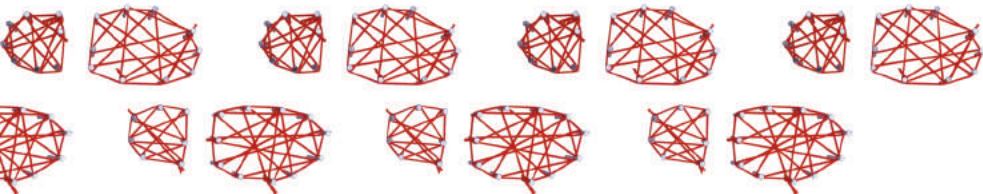


# Chapter 8

## Treatment preferences and involvement in treatment decision making of patients with endometrial cancer and clinicians

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## Abstract

**Background:** Vaginal brachytherapy (VBT) in high-intermediate risk endometrial cancer (EC) provides a significant reduction in the risk of local cancer recurrence, but without survival benefit and with increased mucosal atrophy. Five-year local control is estimated to be similar for VBT and a watchful waiting policy (WWP), in which patient receive VBT combined with external radiation in case of a recurrence. Our aim was to assess treatment preferences of EC patients and clinicians regarding VBT and WWP, and to evaluate their preferred and perceived involvement in treatment decision making.

**Methods:** Interviews were held with 95 treated EC patients. The Treatment Trade-off Method was used to assess minimally-desired benefit from VBT in local control. Patients' preferred and perceived involvement in decision making were assessed using a questionnaire. Seventy-seven clinicians completed a questionnaire assessing their minimally-desired benefit and preferred involvement in decision making.

**Results:** Minimally-desired benefit of VBT was significantly lower for patients than for clinicians (median=0 vs 8%,  $p<0.001$ ), for irradiated than for non-irradiated patients (median=0 vs 6.5%,  $p<0.001$ ), and for radiation oncologists than for gynecologists (median=4 vs 12%,  $p<0.001$ ). Substantial variation existed within the groups of patients and clinicians. Participants preferred the patient and clinician to share in the decision about VBT. However, irradiated patients indicated low perceived involvement in actual treatment decision making.

**Conclusion:** We found variation between and within patients and clinicians in minimally-desired benefit from VBT. However, the recurrence risk at which patients preferred VBT was low. Our results showed that patients consider active participation in decision making essential.

## Introduction

Endometrial cancer (EC) is the most common gynecological malignancy in western countries, with an incidence of 15-25 per 100,000 women per year.<sup>1</sup> In most cases primary treatment consists of total hysterectomy and salpingo-oophorectomy. Several randomized trials have established the role of radiotherapy in high-intermediate risk EC.<sup>2-4</sup> Vaginal brachytherapy (VBT) provides a highly significant reduction in the risk of vaginal cancer recurrence (with freedom from local cancer recurrence, from now on termed 'local control'), but without survival benefit.<sup>5</sup> However, VBT is associated with side effects such as mucosal atrophy.<sup>5,6</sup> An alternative to standard postoperative VBT could be a watchful waiting policy (WWP), in which patients are treated with radiotherapy only if they develop a vaginal relapse. The ultimate five-year local control including treatment for relapse is estimated to be similar for VBT and WWP.<sup>7</sup> However, treatment of a vaginal relapse is more intensive, as it consists of both External beam radiotherapy (EBRT) and VBT. With WWP, about 86% of EC patients will remain disease-free and will not require radiotherapy at all.<sup>7</sup> Therefore, the question remains if upfront treatment with VBT for all EC patients with high-intermediate risk factors or WWP should be preferred. This question is the rationale of the fourth Post-Operative Radiation Therapy in Endometrial Carcinoma (PORTEC-4) trial, in which a watchful waiting policy is randomly compared to VBT.<sup>8</sup>

No studies have been done on preferences of EC patients' and clinicians' preferences with regard to treatment strategies and treatment outcomes, despite the potential benefits of VBT not necessarily outweighing its potential side-effects. At the same time, WWP can be perceived as 'doing nothing'. Research has shown that cancer patients feel that 'doing nothing' is no choice, and experience considerable pressure, also from family members and doctors, to seek active treatment.<sup>9-11</sup> Most studies on preferences in other cancer settings have reported on situations where the benefit of active treatment is larger than foregoing treatment. In the present case though, the ultimate five-year local control is estimated to be very high and similar for both treatment strategies.

We expect individual patients to value treatment strategies and outcomes very differently, and thus, the treatment decision seems highly suitable for involving patients.<sup>12;13</sup> Involving patients in decision making facilitates incorporating their preferences in treatment decisions.<sup>14</sup> This is especially relevant since preferences are difficult to predict based on socio-demographic factors or disease characteristics,<sup>15;16</sup> and patients and clinicians repeatedly have been shown to value treatment outcomes differently.<sup>14;17;18</sup> Research has shown that patients are willing to accept a higher chance of local recurrence to improve functional outcomes of treatments.<sup>19-22</sup> Clinicians tend to underestimate patients' preference for less toxic treatments, as well as their preferred involvement in decision making.<sup>18;19</sup>

The aim of this study was to assess minimally-desired benefit from VBT, in terms of local control and compared to WWP, of EC patients and treating clinicians (radiation oncologists and gynecologists). Also, patients' preferred and perceived roles in treatment decision making were examined, as well as clinicians' decisional role preferences.

## **Materials and Methods**

### *Study population – patients and clinicians*

Participants were EC patients, randomly selected from hospital databases and approached via their treating clinician. Selection criteria were: having undergone surgery with or without VBT between 2007 and 2013, aged under 90 years, and having no history of other malignancies. We aimed to include 100 EC patients, half of whom had been treated with surgery alone (low risk EC), and half with surgery followed by VBT (high-intermediate risk EC).

For the clinician study, we approached all 198 clinicians of the Dutch Gynecologic Oncology Group via email. After two weeks, clinicians received a reminder.

## *Study procedures*

Individual face-to-face interviews were held with each patient to assess minimally-desired benefit from VBT. Five interviewers were trained and adhered to a strict interview script. Socio-demographic details, medical history, and preferred and perceived involvement in decision making were assessed by self-report questionnaire in the weeks before the interview. Clinicians were asked to fill out a web-based questionnaire in which their treatment preferences, socio-demographic factors and work-related details and attitudes towards treatment decision making were assessed. The Medical Ethics Committee of Leiden University Medical Center approved the study.

## *Measures*

Patients' minimally-desired absolute benefit from VBT, in terms of five-year local control and compared to WWP, was assessed face-to-face using the Treatment Tradeoff Method (TTM).<sup>23</sup> Patients were asked to imagine that they had recently been diagnosed with EC and that their clinician offered them two treatment strategies. We made explicit that the situation was hypothetical and did not refer to their situation. After sequentially offering the information on the TTM board (Figure 1), we started with presenting a 14% risk of cancer recurrence at five years for treatment A (surgery alone) and a 2% risk of cancer recurrence for treatment B (surgery and VBT). We then asked patients to weigh recurrence rate, side effects and burden of treatments and to indicate which treatment strategy they preferred at this 12% benefit of treatment B. Next, the probability of local recurrence after surgery alone was varied systematically and patients were asked each time which treatment they preferred. Patients' minimally-desired benefit (recurrence rate with WWP minus the 2% recurrence rate after VBT) was searched by bracketing the recurrence rate either within the range of 2 to 14 out of 100, (if their initial preference was treatment B: surgery and VBT, indicating that they required a benefit of 12% or less) or within the range of 15 to 100 out of 100 (if their initial preference was treatment A: surgery alone, indicating that they required more than 12% benefit). For example, when a patient indicated that she preferred treatment B at a 12% benefit, we then presented a probability of local recurrence after surgery alone of 2% (no benefit of treatment) and asked which treatment she would prefer. If she indicated to prefer treatment A, we

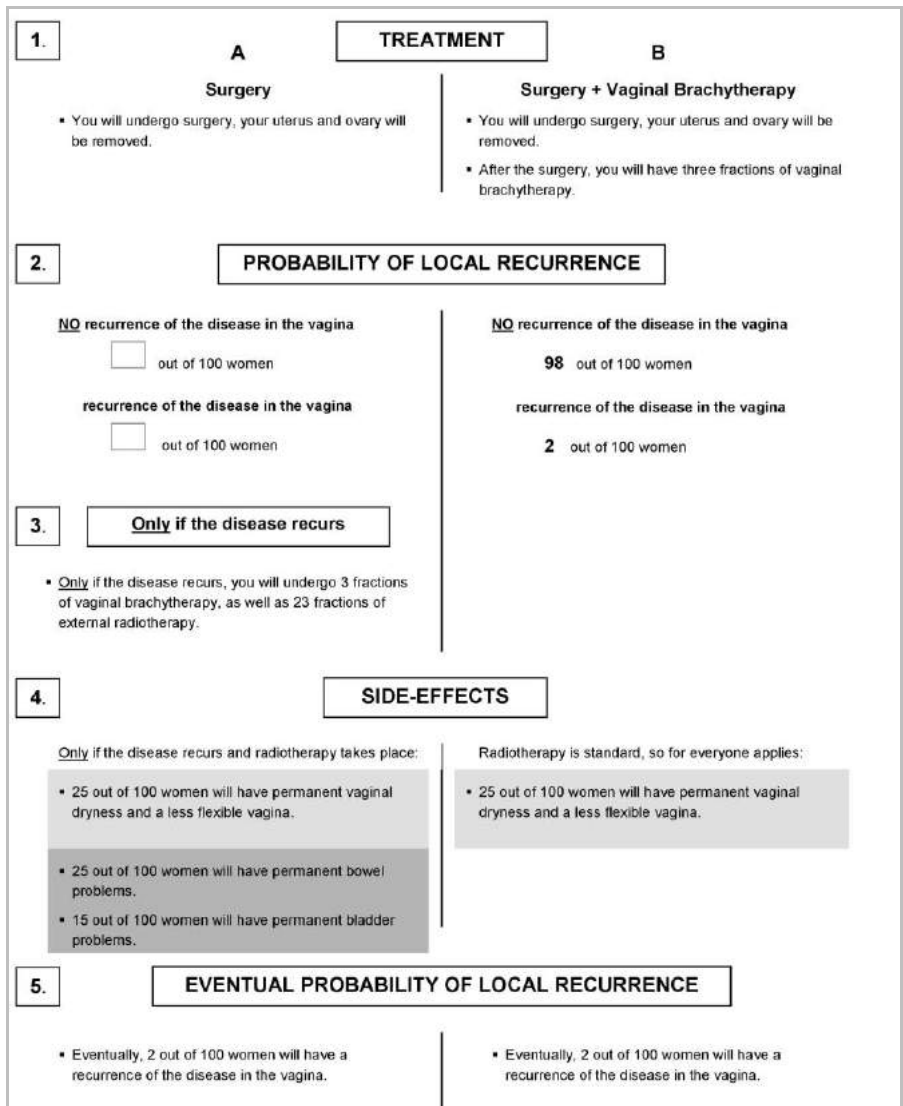
then presented a probability of local recurrence after surgery alone of 8% (6% benefit of treatment) and again asked which treatment she would prefer. The probability of local recurrence after surgery alone was varied until patients' minimally-desired benefit was reached. We built in a check for understanding in patients preferring VBT for no additional benefit by lowering the recurrence rate after surgery alone to 0% (a 2% disadvantage of VBT).

We pilot-tested a self-administered format of the TTM in 10 treated EC patients. Patients evaluated this format to be too difficult because of the high amount of (new) medical information. We therefore decided to use the traditional face-to-face format for the TTM in patients. Clinicians were offered the TTM as part of an online questionnaire. Instead of sequentially offering the information, all information was given to them at once. Clinicians were asked at which minimally-desired absolute benefit of VBT they would prefer VBT, and recurrence rate was not systematically varied.

We assessed patients' and clinicians' preferred decisional role using a modified version of the Control Preferences Scale (CPS), in which participants were asked to select one of five statements on roles in treatment decision making.<sup>24;25</sup> The roles ranged from (A) the patient makes the decision about VBT alone, through (C) the patient makes the decision together with the clinician, to (E) the clinician makes the decision on VBT alone.

Irradiated patients had actually faced the decision whether or not to undergo radiation. We explored to what extent they felt they had been involved in this decision by asking them: To what extent did you have space to 1) think about benefits and harms of VBT, 2) give your opinion on the benefits and harms of VBT, and 3) participate in decision making to your preferred extent. They could respond to each question using a score between 1 (not at all) to 7 (a lot). Finally, we asked: Do you feel you had a choice in the decision about whether or not to undergo VBT? Responses could be negative, affirmative or 'I don't know'.

Both patients' and clinicians' questionnaire contained additional questions regarding socio-demographic details, medical history (patients) and work-related details (clinicians).



**Figure 1.** Information presented in the TTM on treatment options. The numbers in the margin represent the order in which the board was built up. The initially offered figures for surgery only were 86 out of 100 women having no recurrence, 14 having recurrence, thus implying a 12% benefit of VBT compared to WWP. The light grey boxes represent potential side effects of VBT, dark grey represent potential side effects of EBRT.

## *Statistical analysis*

Descriptive statistics were used to describe participant characteristics and minimally-desired benefit from VBT (TTM). Preferred benefit scores were not normally distributed, so we present medians and compared between groups with Mann-Whitney U tests. Using  $\chi^2$  tests, patients and clinicians were compared on decisional role preferences (CPS) and perceived involvement, after subdivision into two categories by merging response categories 1-3 and 5-7. Significance testing was done two-sided at  $\alpha = 0.05$ .

## **Results**

### *Participants*

In total, 140 eligible patients, treated between 2007 and 2013, were approached. Of these patients, 95 (68%) were interviewed and completed the questionnaire. Of the 198 clinicians approached, 77 (39%; 52 gynecologists, response rate 32%; 25 radiation oncologists, response rate 69%) completed the online questionnaire including the TTM. In Table 1 participant demographic characteristics, and treatment (patients) and work-related (clinicians) characteristics are listed.

### *Treatment preference and minimally-desired benefit from VBT*

In Table 2 minimally-desired benefit from VBT in terms of local control and compared to WWP is listed. Figure 2 shows the cumulative proportion of participants preferring VBT according to minimum benefit. Overall, minimally-desired benefit was significantly lower for patients than for clinicians (median=0 vs 8%,  $U=1709$ ,  $z=-5.8$ ,  $p<.001$ ). Irradiated patients required a significantly lower benefit than non-irradiated patients (median=0 vs 6.5%,  $U=509$ ,  $z=-5.08$ ,  $p<.001$ ). There was no significant association between minimally-desired benefit from VBT and patients' age, educational level, having a partner or children, or co-morbidity. Minimally-desired benefit was significantly lower for radiation

oncologists than for gynecologists (median=4 vs 13%,  $U=293$ ,  $z=-3.2$ ,  $p=.001$ ). There was no significant association between minimally-desired benefit from VBT and clinicians' age, gender, institution (academic/non-academic), years since specialization or number of EC patients treated per year.

**Table 1.** Participant characteristics

	N (%)
<b>Patients (N=95)</b>	
Median age, years (range)	68 (46-90)
Median time since diagnosis, months (range)	6 (1-62)
Treatment	
Surgery	42 (44)
Surgery + radiotherapy	53 (56)
Number (none or 1) of co-morbidities	46 (50)
Partner (yes)	71 (75)
Children (yes)	75 (79)
Educational level <sup>a</sup>	
Low	41 (46)
Intermediate	28 (31)
High	20 (23)
Region of inclusion (Leiden)	54 (57)
<b>Clinicians (N=77)</b>	
Specialty	
Radiation oncology	25 (33)
Gynecologic oncology	24 (31)
Gynecology (focus on oncology)	28 (36)
Median age, years (range)	48 (33-65)
Median time since specialization, years (range)	10 (0-36)
Median number of EC patients per year (range)	20 (0-70)
Male gender	31 (40)
Current institution (academic)	27 (35)

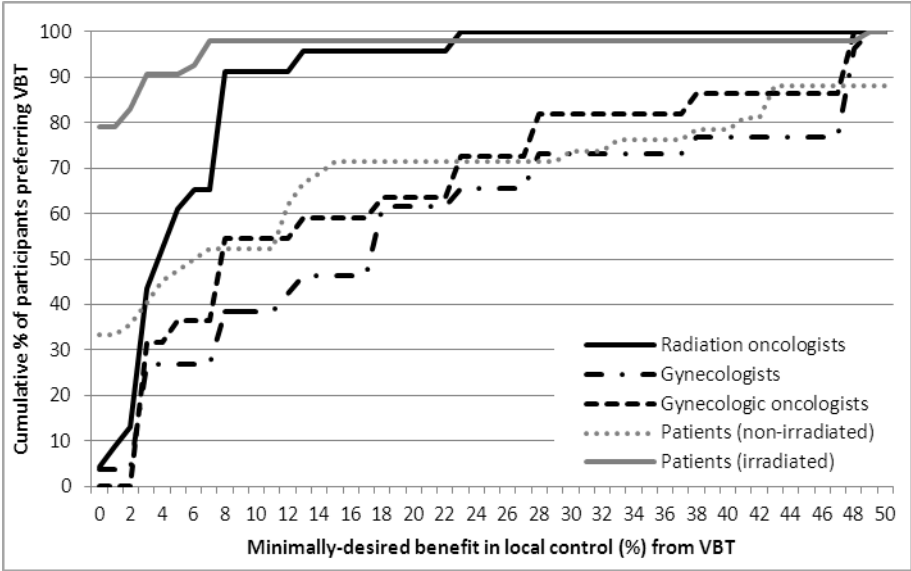
<sup>a</sup> Educational levels included low = completed no/primary school, intermediate = completed lower general secondary education/vocational training; or high = completed pre-university education/high vocational training/university. Six patients did not respond to this question.



**Table 2.** Minimally-desired benefit in local control from VBT

	Median desired benefit	Range	Preferring VBT at 0% benefit
<b>Patients (N=95)</b>			
Irradiated	0% } *	0- 49%	42 (79%)
Non-irradiated	6% } *	0-100%	14 (33%)
<b>Clinicians (N=77)</b>			
Radiation oncologists	4% } *	0- 23%	1 (4%)
Gynecologic oncologists	8% } *	0- 49%	0 (0%)
Gynecologists	17% } *	3- 48%	1 (4%)

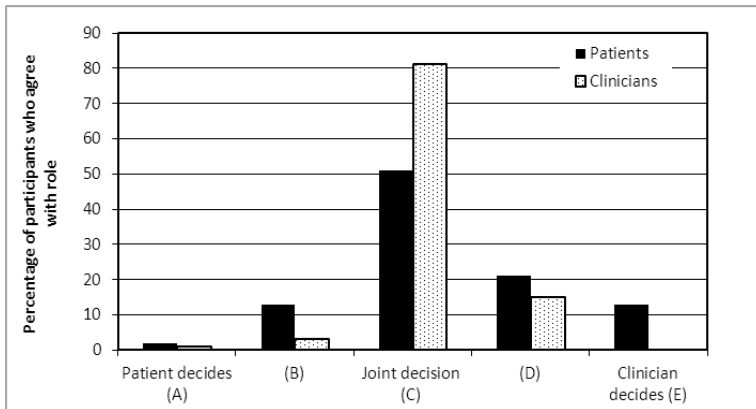
\*  $p \leq 0.001$



**Figure 2.** Cumulative proportion of participants preferring VBT over WWP according to minimum percentage of benefit in local control. Numbers of non-irradiated patients do not add up to 100% because of those declining VBT for a benefit up to 50% (12%).

### Preferred involvement

Figure 3 depicts the patients' and clinicians' preferences regarding their role in the decision about VBT in the treatment of EC. No significant associations were found between decisional role preferences and patients' treatment, age, educational level, having a partner or children, or co-morbidity. Clinicians who had specialized more recently had a stronger preference for a more active clinician's role in deciding about VBT ( $\chi^2=6.87, p < 0.05$ ). No significant associations were found between decisional role preferences and clinicians' age, gender, specialization, institution (academic/non-academic), or number of EC patients treated per year.



**Figure 3.** Patients' (N=94) and clinicians' (N=77) decisional role preferences in deciding about VBT.

### Perceived actual involvement in decision making about VBT

A majority of irradiated patients indicated that they had lacked space to think about benefits and harms of VBT (42%), give their opinion on these benefits and harms (43%) or participate in decision-making to their preferred extent (45%), with a high within-subject overlap between the responses to the three questions. Older patients ( $\geq 68$ ) more often indicated not to have been involved in the decision to their preferred extent ( $\chi^2= 7.37, p < 0.05$ ). Otherwise, there were no

significant associations between perceived involvement and patients' time since diagnosis, educational level, having a partner or children, or co-morbidity.

A total of 44% of irradiated patients indicated they felt they had had no choice regarding VBT. There were no significant associations between whether patients felt they had had a choice and patients' age, educational level, having a partner or children, or co morbidity.

## **Discussion**

This study had a dual objective. Firstly, to assess patients' and clinicians' minimally-desired benefit from VBT, in terms of local control (defined as freedom from local cancer recurrence at 5 years) and compared to WWP. Secondly, to assess patients' and clinicians' preferred involvement in this decision, as well as perceived actual involvement in this decision of irradiated EC patients.

Our study showed considerable variation between, as well as within, patients and clinicians in their minimally-desired benefit from VBT compared to WWP. Patients preferred VBT at a lower minimal benefit than clinicians. Furthermore, irradiated patients and radiation oncologists preferred VBT at a lower minimal benefit than, respectively, non-irradiated patients and gynaecologists. The variation within groups could not be explained by socio-demographic factors or work-related characteristics. The difference in minimally-desired benefit between clinicians from different specialties has also been shown in earlier research, with clinicians generally requiring less benefit from the treatment of their specialty.<sup>26;27</sup> Because patients highly value clinicians' recommendations, these can lead patients to make or agree with decisions that go against what they would otherwise prefer.<sup>28;29</sup> The importance of clinicians' recommendations and the substantial variance in both patients' and clinicians' treatment preferences highlight the need for involving EC patients in decisions about VBT.

Overall, most patients preferred VBT at a low benefit in local control, although the ultimate five-year local control is estimated to be similar for both

treatment strategies. Choosing VBT despite no benefit in five-year local control is possibly explained by patients preferring to seek active treatment,<sup>9</sup> and seeking to be assured of being disease-free sooner. Another explanation could be that patients want to make sure they have done everything possible, as opposed to 'doing nothing'.<sup>10</sup> Furthermore, patients might consider possible side effects of VBT as relatively mild, compared to possible side effects of EBRT.

Two clinicians (8%) and 56 patients (59% of total; 79% of irradiated patients) indicated to choose VBT at no additional benefit. We assumed their answers implied a strong preference for VBT or 'active treatment' rather than as indication of misunderstanding. Because deleting them would bias the minimally-desired benefit upwards, we decided against removing them from the analysis. This preference of treatment despite no benefit is a seemingly non-rational answer and has been found in earlier studies, especially amongst irradiated patients.<sup>14;30</sup> It is possibly caused by anticipated regret and a wish to of have done everything one could. Another possible explanation is positive experiences with VBT and post hoc justification. The latter implies that patients may have a desire to justify the prior decision as being the correct one.<sup>30</sup> In particular, none of these included patients had experienced a relapse and they could have assumed that this was a result of VBT.

The large majority of patients and clinicians preferred both the patient and clinician to share in the decision about VBT. However, individual differences occur in the interpretation of sharing decisions, which may range from receiving information or assent to a treatment recommendation to actively deciding on treatment.<sup>31;32</sup> Clinicians should be aware of patients' wish to participate in treatment decisions and involve them as much as possible to the patient's preferred extent.

A possible limitation of this study is the different methods used in assessing minimally-desired benefit in the patient versus clinician group. We intended to measure minimally-desired benefit in a direct way through an online questionnaire in both groups. However, after pilot-testing the self-report questionnaire, we concluded that this method was not feasible for participants unfamiliar with the complicated medical information. Patients as well as clinicians evaluated the methods used as clear (data not shown). Another possible limitation is that patients in our study had already started or finished

their treatment. Due to logistical reasons, we were unable to include patients at the moment they were actually facing this treatment decision.

In the PORTEC-4 trial, a postoperative WWP is compared with standard VBT in a randomized clinical trial.<sup>8</sup> This study will provide data on overall side effects and quality of life of treated EC patients. Furthermore, results will show whether the exact relapse rate after WWP is indeed around 14%, and whether the five-year local control, including treatment for relapse, is indeed similar for both treatment strategies. Our study shows that for a benefit of 12%, over 90% of radiation oncologists, but less than 50% of gynecologists would recommend VBT, while most of the patients would prefer VBT. Clinicians should be aware of this variation and be transparent to their colleagues and patients on their considerations to recommend one or the other treatment strategy.

In conclusion, our results showed a considerable variation between, as well as within, patients and clinicians in how they value local control, harms, and burden of treatment. We recommend that clinicians inform patients on the benefits and harms of treatment strategies, elicit patients' preferences and consider these preferences in their treatment recommendation.

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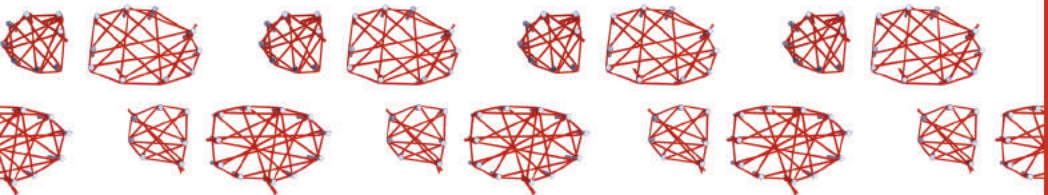






# Chapter 9

## General discussion





With the rapid advances in the field of medicine, more and more treatment strategies can become available for the same condition – making decision making more complex. Involving patients in a shared decision making (SDM) process is increasingly the preferred approach to making healthcare decisions when more than one reasonable option is available.<sup>1-3</sup> These decisions are called ‘preference-sensitive’.<sup>4;5</sup> Examples include decisions about (neo-)adjuvant cancer treatments. Foregoing these treatments is often a clinically viable option,<sup>6-8</sup> making the involvement of patients in selecting the best treatment strategy crucial.

There are several arguments for following the principles of SDM. SDM is associated with improved patient satisfaction, lowered anxiety and decisional conflict and may improve quality of life and reduce physical complaints.<sup>9-11</sup> Also, SDM may reduce unwarranted practice variation, and by that, possibly reduces health care costs and waste as well.<sup>12-14</sup> Evidence on costs and cost-effectiveness is equivocal,<sup>15-17</sup> and advocates of SDM argue that costs should not overshadow the underlying principles of SDM. The main imperative for SDM “must rest on the principles of good clinical practice, respecting patients’ right to know. Patients’ informed preferences should be the basis for professional actions”.<sup>18</sup> In the Netherlands, the importance of patient involvement in treatment decision making is acknowledged by the minister of Health, Welfare and Sport, Edith Schippers.<sup>19</sup> Indeed, the legislation (Medical Treatment Agreements Act, WGBO) states that healthcare providers are obligated to inform patients on possible treatment strategies, in writing if desired by the patient.<sup>20</sup>

Still, some question the feasibility of SDM in daily clinical practice, and claim that SDM fails to acknowledge the imbalance in knowledge and power between the clinician and the patient.<sup>21;22</sup> Time constraints, patients’ incapability, or clinical situation are often cited as barriers for SDM.<sup>23;24</sup> Indeed, in daily clinical practice, it still seems challenging to follow the principles of SDM.<sup>25;26</sup>

To accomplish SDM, three key steps need to be followed:

Step 1: Creating choice awareness,

Step 2: Discussing treatment options in detail, and

Step 3: Discussing patients' values and preferences and deciding what is best.<sup>2:27;28</sup>

Taking these three steps as the starting point, our aim was to assess to what extent the key steps of SDM are followed in daily clinical practice in preference-sensitive decisions on (neo-)adjuvant cancer treatment. In this chapter, we give an overview of the main findings, and discuss them in relation to the existing literature on SDM. Subsequently, recommendations for future research and clinical practice are provided.

## **Step 1. Creating choice awareness**

### *'Making a treatment decision' as a reason for the encounter*

The first step in SDM is for both the clinician and the patient to acknowledge that there is a decision to be made. This step has received relatively little attention in the literature to date,<sup>26</sup> even though it is pivotal for SDM.<sup>2</sup> Prior research found that many patients facing a decision with marked trade-offs between benefits and harms were not aware that a treatment decision had to be made.<sup>29</sup> Oncologists can create choice awareness by explicitly stating that making a treatment decision is the reason for the encounter. Our research showed that oncologists rarely express this need to make a treatment decision, and instead, use the consultation to explain the one treatment strategy they have to offer (Chapter 2). By that, oncologists miss a crucial opportunity to create choice awareness and to engage patients in the SDM process. Our findings align with results from a systematic review by Couët and colleagues.<sup>26</sup> They described studies that used the OPTION instrument, which is used to observe the extent to which clinicians involve patients in decision making.<sup>26;30</sup> OPTION is often used to measure SDM, even though the scale only assesses

clinicians' behaviour. Couët found that awareness of treatment choice was created in only one in three studies. This is still higher than the 3% that we found in our study, which might be due to the differing clinical contexts. The only studies that identified the creation of some degree of choice awareness were outside the field of oncology.

### *Creating choice awareness as part of setting an agenda*

Stating a reason for the encounter can be seen as a part of setting an agenda for the consultation. Evidence suggests that collaboratively setting an agenda increases patient centeredness in various ways – increased patient and clinician satisfaction, greater patient empowerment, and more two-way information exchange to support individualized treatment decisions.<sup>31-33</sup> Collaboratively agenda setting, creating choice awareness, and indicating that the patient's views count may help patients realize that multiple treatment strategies are available and a decision needs to be made. To date, research on agenda setting has mainly been conducted within primary care. In future research, the effects of collaboratively setting an agenda and creating choice awareness in the pre-treatment consultations in specialty care on patients' satisfaction, empowerment, and involvement, and on the extent of two-way information exchange should be further explored.

Appropriately creating choice awareness might be a simple, inexpensive, yet effective step in empowering patients to participate in treatment decision making. In our study described in Chapter 2, we were unable to assess whether an oncologist explicitly mentioning that a treatment decision needs to be made is associated with enhanced patient involvement in decision making, given the small number of consultations where this occurred. Therefore, in a recent pilot study, we offered lay people – as proxies for newly-diagnosed cancer patients – reasons for the encounter as stated in daily clinical practice. Results suggest that the stated reason for the encounter can have a significant effect on people's perception of choice.

### *Choosing between two treatments versus declining treatment*

The option of foregoing (neo-)adjuvant treatment was not explicitly addressed as a viable one in any analysed consultation with rectal or breast cancer patients. Earlier research on preference-sensitive treatment decisions has found similar results.<sup>25;34;35</sup> Alternative options or the option of foregoing treatment may be presented only when a patient is not eligible for a certain treatment.<sup>36</sup> This approach is not concordant with the SDM model or informed consent norms. To patients, choosing between two possible treatment strategies – for example surgery alone or radiotherapy followed by surgery in rectal cancer – might feel less burdensome than declining the one treatment the oncologist has on offer.<sup>37</sup> Therefore, if foregoing (neo-)adjuvant treatment is a viable option, it should explicitly be presented as such.

### *Best timing for creating choice awareness*

Above, we have focused on the pre-treatment consultation as the time point to create choice awareness. However, the best timing to create choice awareness might be prior to this consultation. During multidisciplinary team meetings, almost all patients are discussed and possible treatment strategies are identified for each individual. In the case of preoperative radiotherapy for rectal cancer, the surgeon discusses the treatment recommendation from the multidisciplinary team with the patient.<sup>25</sup> To facilitate SDM, clinicians should be aware that the recommendation from the multidisciplinary team is not a final decision, especially in preference-sensitive decisions – as this would leave little to no room for patients' values and preferences to be considered. Indeed, research shows that clinicians mainly focus on medical information exchange and rarely discuss patients' characteristics or preferences in multidisciplinary team meetings.<sup>38;39</sup> If the recommendation from the team is presented as a final decision early on in the healthcare experience, patients may perceive this as the 'right' treatment and it could be difficult to later create awareness of choice. Returning to the case of preoperative radiotherapy in rectal cancer, the surgeon could, for example, explicitly indicate that the patient will be referred to a radiation oncologist to talk about the preoperative radiotherapy, and the pros and cons of this neo-adjuvant treatment. Such statement will help patients

realize that there is more than one reasonable option available, and that a decision still needs to be made. We must ensure that throughout the whole healthcare system, the principles of SDM are followed in making preference-sensitive decisions in collaboration with the patient. Thus, the first step of SDM reaches beyond one consultation; the multidisciplinary team discussion and the referring clinician(s) should be part of the process of creating choice awareness as well.

Taking this one step further, the best timing to create choice awareness might even be prior to the specialty consultation, namely before becoming a patient and entering the healthcare system. Even before individuals experience the emotions that accompany a serious diagnosis as cancer, they can be made aware that healthcare treatment decisions need to be made and that their views count. In the Netherlands, cancer societies (for example 'KWF Kankerbestrijding'), patient advocacy groups (for example 'Darmkanker Nederland'), and the Foundation for Idealistic Advertising (SIRE, Stichting Ideële Reclame) may be the best organizations to be involved in such a national advertising program.

### *Creating choice awareness in clinicians*

One reason why oncologists rarely create choice awareness could be that they themselves perceive little choice. As we have shown in Chapter 8, there is considerable variation between clinicians in their preferred treatment, and they generally seem to prefer the treatment of their specialty. This has been shown in earlier research as well.<sup>40;41</sup> It is important that clinicians are aware of their preferences and make these preferences transparent to their colleagues and patients. National treatment guidelines aid in identifying preference-sensitive decisions and creating choice awareness in clinicians. In general, treatment guidelines provide little or no recommendation on the patient's role in deciding about treatment. The Dutch treatment guideline on colorectal cancer is the exception, as it explicitly states that the decision on preoperative radiotherapy is difficult and should involve the patient.<sup>6</sup> Also, in the latest revision of these guidelines, several treatment recommendations have been rewritten to provide more room to choose between multiple treatment strategies. For all adjuvant



cancer treatments that may be preference-sensitive decisions, treatment recommendations should consider a similar approach. Preference-sensitive decisions could be identified and described as such in the guidelines, and the relevance of patient's views in deciding about treatment should explicitly be incorporated.<sup>42-44</sup>

### *Clinical recommendations*

#### Step 1. Creating choice awareness.

- Be aware that the recommendation from the multidisciplinary team is not a final decision.
- When referring patients: State that the patient will be referred to another clinician to discuss the pros and cons of the possible treatment strategy/strategies.
- At the start of the consultation: State that there are multiple treatment strategies available, that a decision needs to be made, and that the patient's views matter.
- If foregoing adjuvant treatment is a viable option, present it as such.

#### **Step 2. Discussing treatment options in detail**

##### *Communicating benefits and harms of treatment options*

Most cancer patients in developed countries prefer to have as much information as possible, regardless of whether it is positive or negative.<sup>45,46</sup> Regarding treatment harms, over nine out of ten cancer patients indicate to have a strong need for this information.<sup>47</sup> At the same time, the more information is given, the less patients usually remember.<sup>48</sup> Depending on the total amount of information given, it is expected that about 40-80% of information is forgotten immediately after the consultation.<sup>49</sup> Research suggests that this percentage decreases when information is tailored to the patient's frame of reference.<sup>50;51</sup> These

caveats do not imply that information should not be provided, but rather highlight the importance of consensus on which information should be given.

In Chapter 3 we showed considerable variation both in the number and type of benefits and harms that were discussed during pre-treatment consultations between radiation oncologists and rectal cancer patients. This variation was seen between and within radiation oncologists. We found no consistent association between the oncologists' information provision and patient characteristics. These findings imply that some patients receive limited information, while other patients are informed extensively on their treatment option(s). We expect that these findings are not specific to this clinical case and that such variation might be present in information provision in other preference-sensitive decisions as well.<sup>25</sup> The variation in information provision indicates a lack of clarity on which benefits and harms should be discussed with patients, and this hampers the process of SDM.

In our study described in Chapter 4, we reached consensus among treated rectal cancer patients and radiation oncologists on which benefits and harms of preoperative radiotherapy should be discussed in the pre-treatment consultation. We composed a core list of topics that should always be addressed. Interestingly, all topics on the core list are long-term benefits and harms of rectal cancer treatment. We assessed congruence between the results of our consensus-study and daily clinical practice and found that on average, patients receive information on fewer than half of the topics from the core list. Even more striking, local control (the benefit of preoperative radiotherapy) was the only topic from the core list that was addressed in almost one in ten patients. None of the harms was discussed. Previously, Pass and colleagues found that cancer patients actually notice that benefits of treatment are discussed more often than harms.<sup>52</sup>

The need for implementing our core list in daily clinical practice has been clearly demonstrated. Incorporating the core list in the Dutch guidelines for the treatment of rectal cancer will be the first step.<sup>6</sup> Using our core list as a checklist during the consultation can help clinicians to structure their conversation on the benefits and harms of treatment. Also, the core list could be offered to patients

prior to the consultation to encourage them to discuss certain topics with their radiation oncologist.

In our Delphi-study, we found considerable overlap between topics that patients and oncologists consider necessary to be addressed during pre-treatment consultations. We also showed that patients are capable of prioritizing those benefits/harms that they think are most important. Patients' perspectives are valuable when creating such core lists, and the method we used seems feasible for creating core lists for other treatments and other cancer types.<sup>53;54</sup> A first step to ensure that patients are informed consistently and sufficiently throughout their treatment process is to develop a core list for the pre-surgery consultation between the surgeon and the rectal cancer patient.

### *Time pressure as a barrier*

For oncologists, time pressure may be an important barrier to using our core list in daily clinical practice.<sup>23</sup> In general, many fear that following the principles of SDM will lengthen the duration of consultation and present clinicians with greater time constraints than they already have.<sup>23;28;55</sup> In Chapter 3 we found that consultations last longer when more benefits and harms were addressed. However, in the current practice, a median of seven benefits and harms are discussed with patients eligible for short-course preoperative radiotherapy followed by a low anterior resection. For this patient group, our core list consists of only seven benefits/harms for female, and eight for male patients, which is similar to the current standard practice.

Although we found an increase of consultation length for the discussion on benefits and harms, we have no information on the association between consultation length and overall degree of SDM. Discussing benefits and harms of treatment is required by law and does not necessarily constitute SDM. However, there is no systematic increase in consultation duration when SDM is implemented.<sup>56</sup> In the Netherlands, several health insurers have indicated that hospitals can claim costs for the extra time that clinicians may need to inform patients, even if these efforts do not lead to active treatment.<sup>57</sup> Unfortunately,

no more than one in four hospitals offered this opportunity for extra time to their clinicians in the past year.<sup>58</sup> Policy makers and health insurers should expand their collaboration and commitment to stimulating person-centred care that is unconstrained by time or reimbursement incentives for active treatment.

### *Communicating probabilities*

Communicating probabilities relevant to the treatment decision is complex but essential, as probabilities often are the foundation of clinicians' treatment recommendations and help determine the importance of potential benefits and harms. Research has shown that the format (i.e., words, numbers) in which probabilistic information is presented can have significant effects on patients' interpretation of probability and on their readiness to undergo treatment.<sup>59-61</sup> In a literature review on risk communication, Zipkin and colleagues recommended avoiding the use of only verbal labels (non-numerical probability statements) to improve patients' understanding, since there is a high degree of variability in their interpretation.<sup>62-66</sup> We confirmed these findings in our study described in Chapter 6, where we found considerable variation in how individuals interpret the verbal labels frequently-used in oncology. This variability could be especially problematic when clinicians communicate probabilities relevant to decision making.

In Chapter 5, we found that radiation oncologists almost always mention probabilities of the beneficial effect of preoperative radiotherapy on local control. In contrast, probabilities of harms of treatment often go unmentioned. We found no consistent association between the oncologists' provision of probabilities and patient characteristics, except that oncologists mentioned significantly fewer probabilities to less educated patients. If radiation oncologists communicated probabilities of local recurrence, they tended to present a relative risk, stating that preoperative radiotherapy will reduce the probability of local recurrence by half. In line with recommendations from Zipkin and colleagues, the radiation oncologists also presented the absolute risk or the absolute risk reduction in most cases.<sup>62</sup> This approach helps to avoid steering patients towards one treatment strategy. In preoperative radiotherapy in rectal cancer, numerical probabilities are available and known to most Dutch

oncologists.<sup>6;67-69</sup> We found that radiation oncologists only used verbal labels to convey a probability in one-third of the cases, despite the potential pitfall of variability in interpretation.

We did not find an association between formats the oncologists used to convey probabilities and the correctness of patient's estimates. In general, we found that patients tended to *overestimate* the probability of getting a local recurrence if adjuvant treatment with radiotherapy is foregone, and to *underestimate* the probability of harms occurring after radiotherapy treatment. This has been found in previous research as well.<sup>70</sup> As it could have been difficult for patients to remember the exact probabilities mentioned, we also assessed whether patients estimated the correct *effect* of radiotherapy treatment on major treatment outcomes. Most patient estimated the effect of radiotherapy on local control correctly. In contrast, the effect on harms was most often estimated incorrectly. Over one-third of patients believed that adding radiotherapy to surgical treatment decreases the probability of faecal incontinence, while in fact, preoperative radiotherapy increases the risk from about 40 to 60% in patients without a stoma.<sup>71</sup> This suggests that many patients are overly optimistic and believe that there is no harm in undergoing preoperative radiotherapy. An explanation for this belief might be sought in post hoc justification. In most cases, the treatment decision had already been made when we assessed patients' understanding. As a result patients may have had the desire to justify the decision of undergoing preoperative radiotherapy as being the correct one, and one which will do them no harm.<sup>72</sup> Individuals might have an optimistic bias, where they *perceive* that they are at less risk than their peers, enabling them to meet their psychological needs, such as hope and reassurance.<sup>70;73</sup>

### *Evidence-based medicine and shared decision making*

In recent years, the relationship between SDM and evidence-based medicine has been increasingly recognized and explored.<sup>74</sup> Evidence-based medicine has contributed to the understanding that many treatment strategies have marginal benefits, next to possible harms.<sup>18</sup> In an SDM process, evidence can be brought into the consultation, and can be discussed with the patient, along with

discussions on the patient's preferences.<sup>75</sup> These patient's preferences are, in addition to the medical evidence, a core ingredient of evidence-based medicine. If patients are not provided with the evidence, or if they do not understand the provided evidence, they are unable to form evidence-informed preferences, leading to preferences that might not be 'true'.<sup>74;75</sup> The steps of SDM are inextricably linked to evidence-based medicine.<sup>74</sup> Oncologists should be careful to mention both benefit and harms of treatment with corresponding probabilities whenever possible and stay alert to patients' potential misunderstanding.<sup>76</sup>

In the example of preoperative radiotherapy in rectal cancer, evidence on benefit and harms of treatment – together with the numerical probabilities – is available and known to most Dutch oncologists. For many other treatments, this might not (yet) be the case. It could be that the occurrence of benefit or harms of treatment have not been established in randomized trials, that they have been established but not reported in literature, or that available evidence is conflicting. Randomized trials might have a focus on harms of treatment, but the specified outcomes might not necessarily be the same that patients believe are important. We must therefore ensure that all clinical trials assess and report possible harms of treatment that are of interest to the patient.

It is also conceivable that clinicians, especially when they treat patients with different kinds of diseases, are unable to constantly be up to date with the latest evidence. In our studies on rectal (Chapter 3) and endometrial (Chapter 8) cancer, clinicians indicated that they treat about two or three patients per month, on average, with these conditions. In both studies, there were clinicians that reported treating fewer patients per month. Thus, all clinicians' knowledge of the evidence and recommendations from the guidelines may not be completely up to date, which is undesirable for relatively common diseases like rectal cancer. Regarding the provision of information, one way of enabling clinicians to communicate the latest evidence to their patients is to provide them with easy-to-use tools.<sup>53</sup> Examples of such easy-to-use within-consultation tools are Option Grids, developed by Elwyn and colleagues.<sup>77</sup> These grids are summary tables of answers to questions that patients frequently ask, accompanied by a document containing the latest evidence.<sup>78</sup> Also, prediction models, such as Adjuvant online for early-stage breast cancer, might help clinicians in using the latest available evidence, and in determining and communicating personalized probabilities.<sup>79</sup> More general, we must ensure that

all patients are *treated* by a clinician who is up to date and experienced in treating patient with their disease.<sup>53</sup> Centralizing care may be one way to accomplish this.<sup>53</sup> Centralizing care could be done on an institutional level, or on a clinician level (specialization), meaning that clinicians are required to treat a minimum number of patients per year. To come to this minimum number, clinicians could cover multiple (regional) institutes. Specialized nurse practitioners could also play a role in supporting oncologists in informing patients; however, we must ensure that providing information on benefits and harms of treatment takes place before the treatment decision is made. The latter might sound evident, but a recent study showed that harms of treatment are often presented after deciding on adjuvant treatment.<sup>80</sup>

#### *Clinical recommendations*

##### Step 2. Discussing treatment options in detail.

- Discuss both benefits and harms of treatment with the patient.
- Create and use a core list of benefits and harms to assist the discussion on adjuvant treatment.
- Avoid the use of verbal labels (non-numerical statements) when possible.<sup>62</sup>
- When presenting a relative risk (“half the risk”), present absolute risks as well (“from 11 to 6%”).<sup>62</sup>
- Stay alert to the patient’s potential misunderstanding and regularly check the patient’s understanding.

##### **Step 3. Discussing patients’ values and preferences and deciding what is best**

As Street and de Haes stated, “clinicians are experts in medical options and their clinical implication, but patients are experts in terms of the impact of these decisions on their everyday living”.<sup>81</sup> In the previous paragraphs, we have seen how oncologists provide patients with relevant information on the treatment(s). This is minimal and necessary – but not sufficient – condition for SDM. It is

crucial that patients convey their values regarding benefits and harms of treatment and their treatment preferences to their treating oncologist.

### *Discussing and considering patients' values and treatment preferences*

Involving patients in the decision making process is justified by the extent to which patients' values and preferences regarding treatments and treatment outcomes differ.<sup>82</sup> As research has shown great variation in patients' values and preferences,<sup>83:84</sup> and how difficult it is to predict these<sup>84-86</sup> it is important for clinicians to explore the patient's values and treatment preferences so that these can be considered in choosing a treatment strategy that best fits the patient.<sup>87</sup> The SDM model states that patients' values and treatment preferences should be elicited,<sup>2:27:88</sup> but the evidence available suggests that this does not happen in daily clinical practice.<sup>89-91</sup>

In Chapter 7 we showed that rectal cancer patients' values concerning benefits and harms of preoperative radiotherapy are discussed for only one out of ten benefits/harms addressed. Overall, more than half of patients did not voice any values during their consultation with the radiation oncologist. If values regarding benefits or harms of treatment were discussed, they most often concerned long-term major outcomes of radiotherapy, such as local recurrence, faecal incontinence and different aspects of sexual dysfunction. This is consistent with our findings in Chapter 4, where we showed that patients and oncologists consider these long-term major outcomes necessary to discuss in the pre-treatment consultation. Patients' treatment preferences were voiced in only about one in five consultations.

Evidence shows that it is difficult for clinicians to predict patients' values or treatment preferences, and we must therefore be alert to the 'silent misdiagnosis' of these values and preferences.<sup>92</sup> After providing patients with all relevant information, oncologists can explicitly invite patients to share their views.<sup>30</sup> In our study described in Chapter 7, we showed that this happens in about one in five consultations. In these consultations, the radiation oncologist explicitly indicated that the patient's views were to be considered in deciding about preoperative radiotherapy. In several consultations, the patient did not voice any values or treatment preferences in response to the oncologist's



invitation, and the oncologist did not probe any further. Patients' non-response might be due to the unexpected invitation from oncologists to voice their values and treatment preferences. As discussed above (Chapter 2), oncologists rarely indicate upfront that a treatment decision needs to be made. Therefore, many patients might not realize that foregoing (neo-)adjuvant treatment is a viable option and that they may use the provided information to think about their values and treatment preferences and discuss these with their oncologist.<sup>93</sup> Appropriately creating choice awareness might be a first step for patients to realize that their values and treatment preferences are of importance in the treatment decision, and that they should therefore voice these views and participate in treatment decision making.

Despite the above, most patients with rectal cancer felt they had shared the treatment decision with their radiation oncologist to some extent (Chapter 7). We found that patients perceived a more active role in treatment decision making when their values or treatment preferences had been discussed during the consultation, or when the oncologist indicated to consider these values or preferences in the decision making process. This is an important finding, which is consistent with the SDM model. We thus showed that discussing and explicitly considering patients' values or preferences will not only help choosing what is best for each individual patient, it will also make patients feel more involved in deciding about treatment. Perceived active involvement has been shown to lead to better patient outcomes.<sup>9,94</sup>

### *Preference for active treatment*

On average, rectal cancer patients require only a small beneficial effect of preoperative radiotherapy to consider it worthwhile,<sup>83</sup> which we also found true for patients with endometrial cancer regarding postoperative vaginal brachytherapy. However, large variation existed between patients in individual treatment preferences (Chapter 8).<sup>83</sup> Previous research has shown that cancer patients have a strong preference for seeking active treatment.<sup>37</sup> Cancer patients also describe considerable pressure from family members, clinicians or support groups to seek active treatment.<sup>37</sup> In our study described in Chapter 8,

more than half of the irradiated and non-irradiated patients with endometrial cancer indicated choosing postoperative vaginal brachytherapy, even if it would have no additional benefit. This seems irrational, but has been found in earlier studies as well.<sup>72;83</sup> The strong preference for active treatment is possibly caused by anticipated regret and the wish to have done everything one could. We must be aware that the 'best' treatment option, for some patients, may not only depend on the medical outcomes that patients can expect to experience, but also on whether these outcomes are achieved actively or passively.<sup>95</sup> As stated above, the principles of SDM are especially relevant when there is more than one medically *reasonable* option available and the treatment decision is preference-sensitive. SDM does not imply that *all* possible treatment strategies, including medically *unreasonable* options, are offered to patients.

### *Involvement in the decision making process versus involvement in the final decision*

One of the most often used arguments against implementing SDM is that patients do not want to participate in decision making.<sup>23;96</sup> In Chapter 8 we showed that most patients with endometrial cancer preferred to share the decision with their clinician. This has also been found in previous research, in cancer care and other settings.<sup>97-99</sup> Some argue that clarifying the patient's desired role should be a separate step or sub-step in the SDM model.<sup>96;100</sup> If so, research implies that this step should occur after providing the patient with information. Many patients who are initially hesitant to be actively involved in decision making, prefer a more active role once they have received information on possible treatment options.<sup>101</sup> It is important to realize that SDM is comprised of an entire process of steps to be taken, instead of just a final decision only.<sup>96</sup> Even if the patient does not wish to make the final decision, the clinician should create choice awareness, discuss the treatment options in detail and elicit the patient's values and preferences in order to incorporate the patient's view in a treatment recommendation. By that, a treatment recommendation does not hamper the process of SDM, as long as this recommendation is based on both available evidence and patient views.

### *Values clarification methods*

Our study described in Chapter 7 showed that patients' values and treatment preferences are not systematically elicited during the pre-treatment consultations. We have seen that the patient might need more encouragement from the oncologist, or, as some patients in our study indicated, more time to think about their preferences. One way of helping patients to gain insight on their values and preferences is to offer them methods to help them become clear on their values.<sup>102</sup> This values clarification method can be completed prior to the consultation, or perhaps even better: following the consultation but prior to the treatment decision. We are working on the implementation of such a tool regarding preoperative radiotherapy in rectal cancer.<sup>103-105</sup> The effect of this tool on the communication about patients' values and preferences during the consultation, and on patients' participation in the decision making process, as well as the patients' satisfaction with the tool will be evaluated.

### *Decision support tools*

In the course of this chapter, several tools to support the conversation between clinicians and patients and the process of treatment decision making, such as Option Grids, prediction models and values clarification methods, have been mentioned. These tools are so-called 'decision support tools'. Decision support tools are developed to encourage an SDM process, but it is important to be very clear that using decision tools is not equivalent to SDM.<sup>106</sup> Nationally as well as internationally, significant investments have been made in the development and implementation of these interventions.<sup>107;108</sup> The value of decision support tools focusing on the second and third step of SDM has been clearly demonstrated,<sup>107</sup> but despite great efforts, they have not yet become part of routine clinical practice.<sup>109;110</sup> Several barriers for implementation are mentioned in the literature, such as lack of clinical support, competing priorities and scheduling problems.<sup>109</sup> One could doubt whether the development and maintenance of such disease-specific tools is, at this point in time, the first priority. As stated earlier, concentrating on the first step of SDM and creating choice awareness in all patients – or in all citizens – might be a universal, simple, inexpensive, yet effective way in empowering patients to participate in medical decision making.

Once there is a change of mind set and people are aware that there are choices to be made in healthcare and that their personal views matter, the effect of disease-specific decision support tools might be enlarged. Choice awareness can be seen as a prerequisite for SDM.

### *Clinical recommendations*

Step 3. Discussing patients' values and preferences and deciding what is best.

- Indicate that the patient's views are important to consider in treatment decision making.
- Explicitly invite patients to share their values regarding benefits and harms of treatment and their treatment preferences.
- SDM is not about the decision, it is about the conversation.<sup>111</sup> Even if the patient refers the final decision to you, make a treatment recommendation based on the patient's values and preferences.

## **Conclusion**

In this thesis, we aimed to gain insight in the process of shared decision making in the setting of adjuvant cancer treatments. We observed clinician-patient consultations in daily clinical practice, and developed a core list of information that should be provided in the pre-treatment consultation. We showed that the key steps of shared decision making are followed to a limited extent. Choice awareness is rarely created in pre-treatment consultations on (neo-)adjuvant cancer treatment, and the option of foregoing these treatments is omitted consistently (Step 1). There is large variation in information provision on possible treatment strategies. Patients tend to overestimate the beneficial effect of treatment, and to underestimate the probability of harms (Step 2). Finally, patients' values and treatment preferences are elicited in only a minority of consultations. If patients voice their values or treatment preferences, or if the oncologist indicates to consider these, patients perceive a significant more

active role in the decision making process (Step 3). Our results show that opportunities are missed to engage patients in a process of shared decision making, but small changes in doctor-patient communication can facilitate patients' involvement in deciding about treatment.

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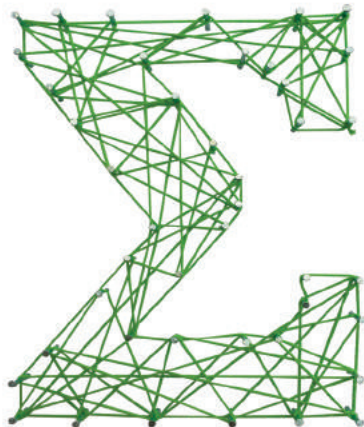
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# Summary

## Summary in Dutch





## Summary

In healthcare settings, shared decision making is increasingly the preferred approach to making decisions when more than one reasonable option is available ('preference-sensitive' decisions). To accomplish shared decision making, three key steps are followed: 1) Creating choice awareness, 2) Discussing treatment options in detail, and 3) Discussing patients' values and preferences and deciding what is best. Taking these three steps as the starting point, the overall aim of this thesis was to assess to what extent the key steps of shared decision making are followed in preference-sensitive decisions regarding (neo-)adjuvant cancer treatment in daily clinical practice.

### *Part I. Creating choice awareness*

The first step in shared decision making is for both the clinician and the patient to define and/or explain the problem and to acknowledge that a decision needs to be made. Both parties should be aware that more than one reasonable option is available and that there is no 'best choice'. If doing nothing (for example, foregoing adjuvant treatment) is a viable option, it should be presented as such.

In **Chapter 2**, we assess whether in pre-treatment consultations on (neo-)adjuvant cancer treatment, oncologists explicitly state that a treatment decision needs to be made as a 'reason for the encounter'. Our results show that oncologists rarely express this need. Instead, they use the consultation to explain the one treatment strategy that they recommend. The option of foregoing (neo-)adjuvant treatment is consistently omitted during the pre-treatment consultation, which might lead to the patient not realizing that this is a viable option. Failing to perform the first key step of a shared decision making process, oncologists miss a crucial opportunity to engage patients and facilitate shared decision making.

## *Part II. Discussing treatment options in detail*

The second step in shared decision making is to discuss the possible treatment options in more detail. All relevant benefits and harms of the presented options should be addressed, as well as their respective probabilities, which can help weighing the benefits and harms.

In **Chapter 3**, we describe what information radiation oncologists provide about possible benefits and harms of preoperative radiotherapy during the pre-treatment consultation with rectal cancer patients. We found considerable variation between and within radiation oncologists in information provision, which could not be explained by patient characteristics. Oncologists addressed between 2 and 13 benefits/harms per consultation, adding up to a total of 30 different treatment outcomes mentioned in 81 consultations.

Given the large variation in information provision, we then reached consensus among radiation oncologists and rectal cancer patients on which benefits and harms should be addressed during the pre-treatment consultation in **Chapter 4**. We conducted a four-round Delphi study in which we asked radiation oncologists and rectal cancer patients to indicate the importance of addressing each benefit/harm. Oncologists and patients reached consensus that six topics should be addressed with all patients: local control, survival, long-term altered defecation pattern, faecal incontinence, perineal wound healing problems, and advice to avoid pregnancy. Additionally, three items should be discussed with male patients: erectile dysfunction, ejaculation disorder, and infertility, and four with female patients: vaginal dryness, pain during intercourse, menopause, and infertility. Of note, all items in the final core list are long-term benefits and harms. Finally, in this chapter, we assess the congruence between the core list from the Delphi-study and daily clinical practice. On average, less than half of the topics from the core list were addressed during the consultation. Almost one in ten patients received no information on any adverse effects that should have been addressed, according to both radiation oncologists and patients.

**Chapter 5** describes whether and how radiation oncologists provide probabilistic information during the pre-treatment consultations with rectal cancer patients, and how patients estimate probabilities of major treatment outcomes after this consultation. Results showed that in almost two-third of the times that a benefit or harm was discussed, the oncologist also mentioned the probability of its occurrence, albeit significantly less frequently to patients with lower education. Oncologists virtually always mention probabilities of the beneficial effect of preoperative radiotherapy on local control but probabilities of harms often go unmentioned. After the consultation, patients tended to overestimate the probability of getting a local recurrence if preoperative radiotherapy is foregone (e.g., treatment with surgery alone), and to underestimate the probability of harms occurring after radiotherapy treatment. The effect of preoperative radiotherapy on local recurrence was most often interpreted correctly. In contrast, the effect of preoperative radiotherapy on faecal incontinence and sexual dysfunction was often estimated incorrectly. Over one-third of patients believed that adding radiotherapy to the main surgical treatment decreases the probability of faecal incontinence.

The verbal labels (non-numeric probability statements) used to convey probabilities during these pre-treatment consultations were offered to a sample of adult Dutch population, as proxies for newly-diagnosed cancer patients, in **Chapter 6**. We found considerable variation in how individuals interpreted the verbal labels, with significantly lower estimates in the context of cancer recurrence compared to nausea. Participants with low numeracy tended to differentiate less between the labels. The same tendency was found for educational level and health literacy, but not statistically significant.

### *Part III. Discussing patients' values and preferences and deciding what is best*

In the third step, patients' ideas, concerns, and expectations should be discussed and considered. Both parties should decide what is best and agree on the follow-up, which could also imply postponing the final decision.

**Chapter 7** focuses on the extent to which rectal cancer patients' values concerning benefits and harms of treatment, and patients' treatment preferences are voiced and explicitly considered when deciding about



preoperative radiotherapy. Results showed that less than half of patients voice one or more values during the consultation. In total, patients only expressed their values regarding one of ten benefits and harms addressed. Patients' treatment preferences were discussed in one in five consultations. If patients' values or treatment preferences had been addressed or if the oncologist indicated that these were of importance when deciding about treatment, the patient perceived that he or she had a significantly more active role in the decision making process.

In **Chapter 8**, we explore treatment preferences of patients with endometrial cancer and treating clinicians regarding postoperative vaginal brachytherapy and a postoperative watchful waiting policy. We also evaluate their preferred and perceived involvement in treatment decision making. Our results showed that patients prefer brachytherapy over a watchful waiting policy for a lower treatment benefit in local control than clinicians. Irradiated patients and radiation oncologists required a significantly lower minimally desired benefit than non-irradiated patients and gynaecologists, respectively. However, there was substantial variation within the groups of patients and clinicians. Most participants preferred the patient and clinician to share in the decision about brachytherapy, but irradiated patients – who had actually faced the decision whether or not to undergo radiation – perceived a low involvement in deciding about treatment.

### *Conclusion*

We aimed to gain insight in the process of shared decision making in (neo-) adjuvant cancer treatments. To this end, we observed clinician-patient consultations in daily clinical practice, and developed a core list of information that should be provided in the pre-treatment consultation. We showed that the key steps of shared decision making are only followed to a limited extent. Our results show that opportunities are missed to engage patients in a process of shared decision making. Subsequently, recommendations for future research and clinical practice are provided.

## Samenvatting (Dutch Summary)

Gedeelde besluitvorming of 'shared decision making' is de afgelopen decennia steeds belangrijker geworden in de gezondheidszorg, zeker als het gaat om voorkeursgevoelige beslissingen. Om te spreken van een succesvol proces van gedeelde besluitvorming, zijn er drie belangrijke stappen die gevolgd dienen te worden: 1) Creëren van keuzebewustzijn, 2) In detail bespreken van behandelingsopties, en 3) Bespreken van de waarden en voorkeuren van patiënten en besluiten wat te doen. Met deze drie stappen als uitgangspunt, was het doel van dit proefschrift om kennis te vergaren over de mate waarin de stappen van gedeelde besluitvorming worden genomen bij voorkeursgevoelige beslissingen rondom (neo-)adjuvante oncologische behandelingen in de dagelijkse klinische praktijk.

### *Deel I. Creëren van keuzebewustzijn*

De eerste stap in gedeelde besluitvorming is dat zowel de arts als de patiënt de zorgvraag definiëren en/of uitleggen en erkennen dat er een beslissing gemaakt moet worden. Beide partijen moeten zich ervan bewust zijn dat er meerdere opties zijn en dat er geen overduidelijke 'beste optie' is. Als een afwachtend beleid (of, bij voorbeeld, afzien van adjuvante behandeling) een reële optie is, dan dient deze als zodanig te worden gepresenteerd.

In **Hoofdstuk 2** hebben we onderzocht of oncologen expliciet aangeven dat het pre-behandelingsconsult rondom (neo-)adjuvante behandeling bedoeld is om een behandelingskeuze te maken. Uit de resultaten bleek dat oncologen zelden met de patiënt bespreken dat er een behandelingskeuze gemaakt moet worden. In de meeste consulten gaven oncologen aan dat de patiënt op consult was om uitleg over de adjuvante behandeling te krijgen. De optie om af te zien van adjuvante behandeling werd in geen enkel consult besproken, waardoor patiënten zich wellicht niet realiseren dat dit een mogelijke optie is. Doordat oncologen de eerste stap in het proces van gedeelde besluitvorming overslaan, missen zij een cruciale kans om patiënten te betrekken en om het proces van gedeelde besluitvorming te faciliteren.

## *Deel II. In detail bespreken van behandelingsopties*

De tweede stap in gedeelde besluitvorming is dat de mogelijke behandelingsopties in detail worden besproken. De relevante voor- en nadelen van alle opties dienen te worden besproken, evenals de kansen op deze voor- en nadelen. Het bespreken van de kansen kan lastig zijn, maar deze kansen zijn belangrijk om de voor- en nadelen af te wegen.

In **Hoofdstuk 3** beschrijven we de informatievoorziening over mogelijke voor- en nadelen van preoperatieve radiotherapie bij rectumcarcinoom. We onderzochten welke voor- en nadelen worden besproken in het pre-behandelingsconsult tussen de radiotherapeut en de patiënt met een rectumcarcinoom. Er was aanzienlijke variatie, in *hoeveel* en *welke* voor- en nadelen van preoperatieve radiotherapie besproken werden voorafgaand aan de behandeling. Deze variatie werd gevonden zowel tussen radiotherapeuten als per radiotherapeut en kon niet verklaard worden op basis van karakteristieken van de patiënt. Oncologen adresseerden tussen de 2 en 13 voor-/nadelen per consult. In de 81 geanalyseerde consulten tezamen werden 30 verschillende voor- en nadelen besproken.

Vanwege de gevonden variatie in informatievoorziening, wilden wij in **Hoofdstuk 4** consensus bereiken tussen radiotherapeuten en patiënten met een rectumcarcinoom over welke voor- en nadelen in het pre-behandelingsconsult besproken zouden moeten worden. In een Delphi consensusstudie, bestaande uit vier ronden, vroegen we radiotherapeuten en patiënten om per voor-/nadeel aan te geven of deze besproken dient te worden. De radiotherapeuten en patiënten bereikten overeenstemming dat zes onderwerpen met alle patiënten besproken moeten worden, namelijk: lokale controle, overleving, veranderd ontlastingspatroon op lange termijn, fecale incontinentie, perineale wondgenezingsproblemen en het advies om zwangerschap te voorkómen. Daarnaast bereikten zij consensus dat drie onderwerpen met mannelijke patiënten besproken moeten worden, namelijk erectiestoornissen, zaadlozingsproblemen, en onvruchtbaarheid; en vier met vrouwelijke patiënten, namelijk vaginale droogheid, pijn bij gemeenschap, menopauze en onvruchtbaarheid. In dit hoofdstuk onderzochten we eveneens de congruentie tussen de kernlijst van voor- en nadelen die door de radiotherapeuten en patiënten was samengesteld met de dagelijkse klinische praktijk. We vonden

dat gemiddeld minder dan de helft van de onderwerpen op de kernlijst in het consult werden besproken. Eén op de tien patiënten werd over geen enkel nadeel van de kernlijst geïnformeerd.

**Hoofdstuk 5** beschrijft óf en op welke manier radiotherapeuten kansen communiceren tijdens het pre-behandelingsconsult met patiënten met een rectumcarcinoom. Ook beschrijft het hoofdstuk hoe de patiënten de kansen van de belangrijkste behandelingsuitkomsten na afloop van het consult inschatten. In twee-derde van de gevallen dat een voor- of nadeel werd besproken, noemden de radiotherapeuten ook bijbehorende kansen. Dit gebeurde echter significant minder vaak bij patiënten met een lagere opleiding. Radiotherapeuten gaven in bijna alle gevallen dat lokale controle besproken werd ook kansinformatie, maar lieten kansen over nadelen van radiotherapie vaker achterwege. Patiënten hadden de neiging om de kans op een lokaal recidief, indien wordt *afgezien* van preoperatieve bestraling, te *overschatten*. Daarnaast *onderschatten* zij de kans op nadelen van preoperatieve radiotherapie. Hoewel het *effect* van radiotherapie op locale controle door de meeste patiënten goed werd ingeschat, werd het effect op fecale incontinentie en seksuele problemen vaak verkeerd geïnterpreteerd. Ruim een derde van de patiënten dacht dat preoperatieve radiotherapie de kans op fecale incontinentie verkleint.

De kanswoorden (zoals ‘soms’, ‘vaak’) die tijdens de pre-behandelingsconsulten werden gebruikt om een kans uit te drukken, zijn aangeboden aan een steekproef van de volwassen Nederlandse bevolking, als proxies voor nieuw gediagnosticeerde oncologische patiënten, in **Hoofdstuk 6**. We onderzochten hoe individuen deze frequent gebruikte kanswoorden interpreteren in de context van twee uitkomsten van oncologische behandelingen. De resultaten lieten een aanzienlijke variatie zien in hoe deze kanswoorden worden geïnterpreteerd. De kansen werden significant lager ingeschat bij kanswoorden in de context van een lokaal recidief, vergeleken met de context van misselijkheid. Deelnemers met een lage cijfervaardigheid (“numeracy”) maakten minder onderscheid in de interpretatie van de verschillende kanswoorden. Dezelfde tendens werd gevonden voor opleidingsniveau en gezondheidsvaardigheden (“health literacy”).

*Deel III. Bespreken van de waarden en voorkeuren van patiënten en besluiten wat te doen.*

In de derde stap van gedeelde besluitvorming dienen de waarden, verwachtingen en zorgen van patiënten te worden besproken en te worden meegenomen in het bepalen van een behandeling. Beide partijen moeten het eens zijn met de beslissing en met de vervolgstappen. Dit kan ook inhouden dat de beslissing wordt uitgesteld.

**Hoofdstuk 7** beschrijft in hoeverre de waarden van patiënten ten opzichte van voor- en nadelen van preoperatieve radiotherapie bij rectumcarcinoom, en hun behandelingsvoorkeuren worden besproken en expliciet worden meegenomen in de behandelingsbeslissing. Onze resultaten lieten zien dat minder dan de helft van de patiënten met een rectumcarcinoom één of meerdere waarden uitten tijdens het pre-behandelingsconsult. In totaal uitten patiënten hun waarden voor ongeveer één op de tien voor-/nadelen besproken. In één op de vijf consulten gaven patiënten aan welke behandeling hun voorkeur had. Als patiënten hun waarden of hun behandelingsvoorkeuren uitten, of als de radiotherapeut aangaf dat deze belangrijk zijn in het maken van een beslissing, ervoeren patiënten een significant grotere betrokkenheid in de besluitvorming.

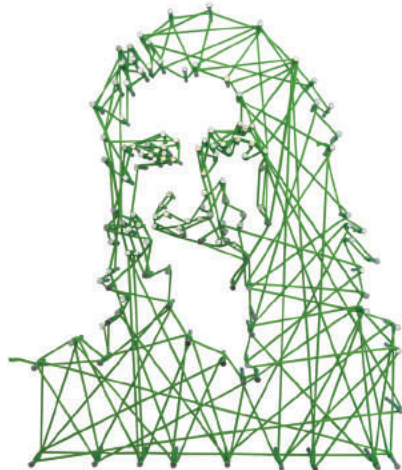
In **Hoofdstuk 8** onderzochten we de behandelingsvoorkeuren van patiënten met een endometriumcarcinoom en behandelend artsen ten opzichte van postoperatieve vaginale brachytherapie en een postoperatief afwachtend beleid. Daarnaast brachten we in kaart in hoeverre zij betrokken wilden worden in de besluitvorming en wat de ervaren betrokkenheid van reeds bestraalde patiënten was. Vergeleken met de artsen gaven de patiënten voor een lagere baat in lokale controle de voorkeur aan postoperatieve brachytherapie. Bestraalde patiënten en radiotherapeuten hadden daarnaast een significant lagere baat van brachytherapie nodig om voor deze behandeling te kiezen dan niet-bestraalde patiënten en gynaecologen. Er was echter grote variatie binnen en tussen de groepen van patiënten en artsen in de gewenste baat. Hoewel de meeste artsen en patiënten samen de behandelingsbeslissing zouden willen maken, gaven bestraalde patiënten (die daadwerkelijk voor de keuze hadden gestaan) aan dat zij beperkt betrokken waren in de beslissing.

## *Conclusie*

Het doel van dit proefschrift was om inzicht te krijgen in het proces van gedeelde besluitvorming rondom adjuvante oncologische behandelingen. Hiertoe hebben we consulten tussen artsen en patiënten geobserveerd in de dagelijkse klinische praktijk, en een kernlijst ontwikkeld van onderwerpen die tijdens het consult besproken dienen te worden. We lieten zien dat de drie stappen van gedeelde besluitvorming slechts beperkt worden genomen. Onze resultaten maken duidelijk dat er kansen worden gemist om patiënten te betrekken in een proces van gedeelde besluitvorming. In het proefschrift geven we aanbevelingen voor toekomstig onderzoek, en voor de dagelijkse klinische praktijk.



# About the author







## Curriculum Vitae

Marleen Kunneman was born on July 3rd 1985 in Nijmegen, the Netherlands. She obtained her Master's degree in Clinical Linguistics at the Radboud University Nijmegen, in collaboration with Leiden University, in 2010. After completing an internship at the department of Neurology at the Rijnland Rehabilitation Center, and under supervision of Prof. Niels Schiller, she wrote her Master thesis on acquired language impairments (Kunneman et al., 2012).

Marleen started her PhD project on doctor-patient communication and shared decision making at the Department of Medical Decision Making of the Leiden University Medical Center in 2011, supervised by Dr. Arwen Pieterse, Prof. dr. Anne Stiggelbout and Prof. dr. Corrie Marijnen and funded by the Dutch Cancer Society (KWF Kankerbestrijding). In 2012, she received a travel grant from the Dutch Cancer Society for a four-months visit to the Decision Laboratory of the Cochrane Institute of Primary Care and Public Health (Cardiff University, Wales). One year later, she received a Steffens award for junior investigators to attend the Summer school of the European Association for Communication in Healthcare (EACH) in Gremmelin, Germany.

During her PhD, Marleen was a member of the committee revising the Dutch guidelines for the treatment of colorectal cancer, where she co-authored the chapter 'Communication and Decision Making'. She further was a member of the working committee for scientific research of the Dutch Society for Psychosocial Oncology (NVPO). She is involved in EACH as secretary of yEACH (early career committee) and member of rEACH (research committee). During her PhD, Marleen has taught shared decision making and (risk) communication to medical students, oncology nurses and surgical registrars.

Since April 2015, Marleen has been working as a post-doctoral researcher at the Department of Medical Psychology of the Academic Medical Center in Amsterdam, in collaboration with the VUmc Alzheimer Center. She also has a Research Collaborator appointment at the Mayo Clinic (Minnesota, United States) where she works with investigators at the Knowledge and Evaluation Research Unit (KER Unit). The focus of her work continues to be on doctor-patient communication during clinical encounters and shared decision making.

## Scientific publications

### *Peer-reviewed publications*

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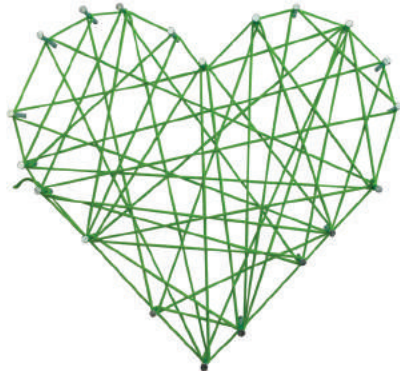
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