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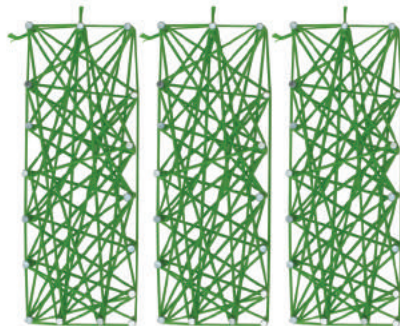
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# Part III

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



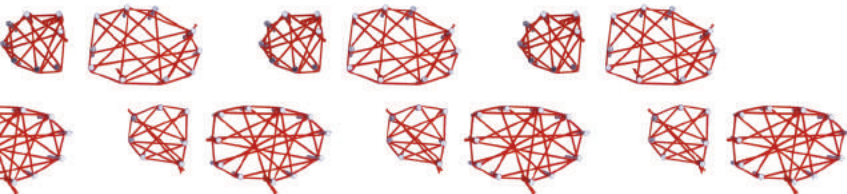


# Chapter 7

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

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## 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.

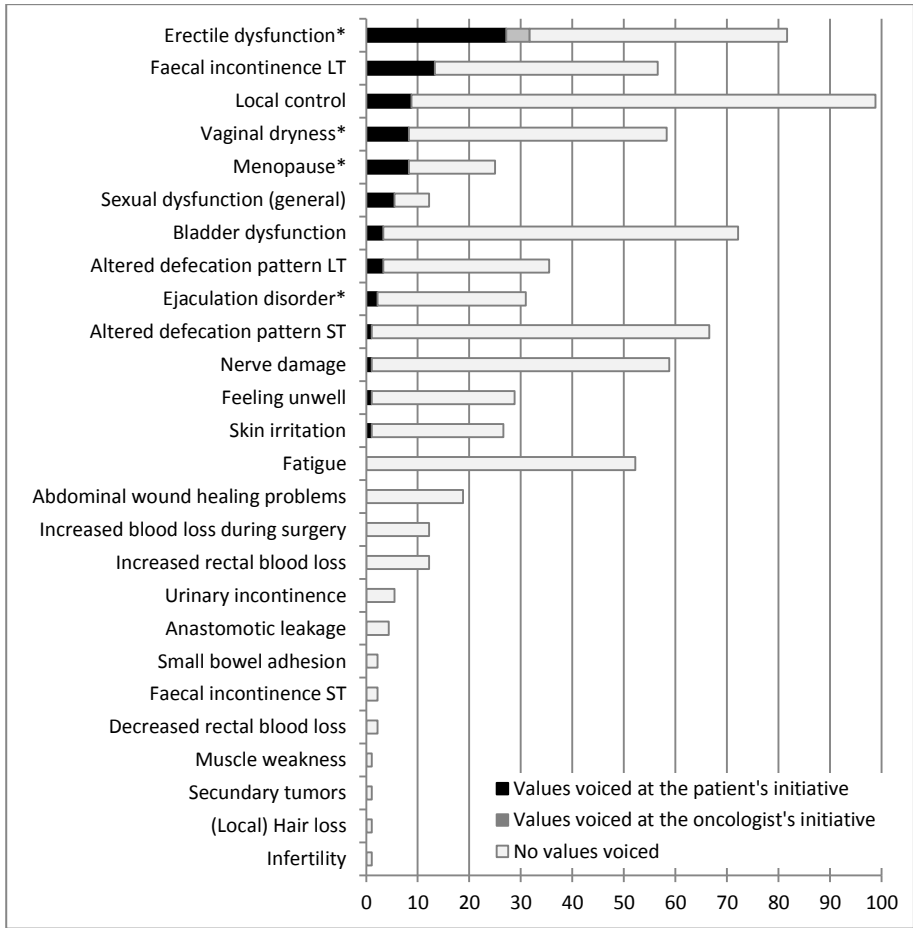
<sup>c</sup> Male radiation oncologists audiotaped a total of 19 consultations (21%).

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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