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Author: Kunneman- van Unnik, Helena Josefina Antonia Maria (Marleen)

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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.¹ 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.^{1;2} 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.^{1;2} 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.³

In 1972, Veatch first used the term 'sharing of decision making' in the scientific literature.² Yet, it was not until the mid-1990's, Charles and colleagues' landmark paper,⁴ that shared decision making gained momentum.^{5;6} 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'".⁷ Nowadays, shared decision making is increasingly advocated as the preferred approach to making healthcare decisions when more than one reasonable strategy is available.^{4;6;8} 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,¹ and reduces unwarranted practice variation.⁹ By avoiding the provision of unwanted interventions, it may reduce health care costs and waste.¹⁰ Moreover, shared decision making is associated with improved patient satisfaction with the treatment decision and care, as well as lower anxiety and decisional conflict.^{11;12} 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.^{13;14} 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.^{1;15} Others claim that time constraints, patients' incapability or the particular clinical situation may make shared decision making inapplicable.^{16;17} Indeed, in daily clinical practice, following the principles of shared decision making seems challenging.^{18;19}

Effective versus preference-sensitive decisions

For medical decision making, two distinct types of decisions exist: effective and preference-sensitive.^{20:21} 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,²²⁻²⁴ 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.^{25:26} Nevertheless, due to good local control achieved with surgery alone, the number needed to treat to prevent one local recurrence is high.^{25:26} Furthermore, PRT has not been shown to yield a survival benefit.^{25:27} PRT has also been associated with adverse outcomes, such as higher probabilities of faecal incontinence and sexual dysfunction than surgery alone.^{26:28} 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.²⁹ 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.²²

Current (inter-)national clinical guidelines apply relatively broad eligibility criteria for adjuvant chemotherapy and/or endocrine therapy in early-stage breast cancer.²³ 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.³⁰ 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.³¹ 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.^{32:33} Watchful waiting is an alternative to postoperative VBT, where patients are only treated with radiotherapy if they develop a vaginal relapse.³⁴ 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.²⁴ 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.^{35:36}

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.^{4-6;37,38} Key words in proposed definitions and in the concept of shared decision making are 'patient values', 'patient preferences', 'options', 'partnership', 'patient participation' and 'deliberation'.⁵ There are various theoretical models for the implementation of shared decision making in daily clinical practice.^{6;39:40} 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.^{6,41} 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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