CHAPTER 1

General introduction
Introduction

It is increasingly accepted that it is important to take into account patients’ preferences and values in medical decision making, both from a medical ethics perspective and from a quality of care perspective [1,2]. Shared decision making (SDM), in which clinicians and patients work together to select tests and treatments, using the best available evidence with incorporating patients’ preferences [3-5], is now seen as a desired goal for patient-centered oncology care [6-8]. SDM is also gaining ground in thoracic oncology, where often multiple treatment options exist. Recent improvements in the treatment of lung cancer include improved surgical procedures and radiotherapy techniques, which have led to less toxicity and/or improved outcomes. Specific improvements include thoracoscopic surgery [9] and advances in high-precision radiotherapy [10]. The latter has allowed patients with an early stage lung cancer to also undergo a curative non-surgical treatment in the form of stereotactic ablative radiotherapy (SABR), instead of surgery [11].

The central aim of this thesis was to investigate the current situation regarding SDM in patients with stage I non-small cell lung cancer (NSCLC), exploring several issues relevant for SDM in practice, namely: 1) the perspectives of patients (i.e. what are their views regarding participation in treatment decision making and what aspects in decision making do they find important?); 2) the perspectives of clinicians (i.e. what are their views regarding patient participation in treatment decision making and what influences their current treatment recommendations for stage I NSCLC patients?); and 3) the information available for patients (i.e. what information about the new treatment option SABR is currently available on the Internet for stage I NSCLC patients and how can this information be improved?).

Shared decision making

In recent years, the SDM model has grown in importance, both in health policy and practice. SDM lies somewhere between a paternalistic approach (i.e. where clinicians make decisions based on clinical evidence and personal experience on behalf of their patients) [12] and an informed decision making model (i.e. where the clinician presents information to the patient on all available treatment options with all their advantages and disadvantages, and allows the patient to make a decision) [13-15]. The main reasons why SDM has gained importance include the wish to reduce practice variation in healthcare and the ethical imperative that patients have a right to participate in healthcare decisions [16,17].

Practice variation describes the phenomenon that patients who have the same health concerns or problems do not necessarily receive the same health care from different
institutions. Such variation can exist at a clinician level, at the service level, and at a geographic level. Variations in medical practice may be undesirable, as the provision of care should be based on clinical evidence and patients’ preferences, as is also stated in concepts of evidence-based medicine [18,19]. When decisions are ‘preference sensitive’, that is when there is no single best treatment option because evidence on the benefit-harm ratio is insufficient or this ratio is dependent on values of patients, it should be patients’ preferences that mainly drive decisions, and not physicians’ preferences [20,21]. Although some variation is likely to remain in an SDM process as a result of diversity of patients’ preferences, this variation should no longer be related to the service or geographic area in which healthcare is delivered. The trend of personalized medicine has further increased the significance of individual preferences in treatment decisions [22], likely leading to more variation, but this variation can be seen as warranted variation rather than unwarranted variation.

Another driver of SDM has been the ethical imperative that patients should have autonomy in choosing to receive or reject treatment options. This autonomy is thought to contribute to patients’ control to live their lives the way they want and thus to their well-being [1,15]. Previous studies have shown that patients do want to participate in healthcare decisions [23-25]. In order to empower patients, it is important to ensure that they receive well-balanced information and that they have freedom of choice regarding medical options [26]. There is evidence suggesting that patients need more and different information than they usually receive from health professionals [23,27-29]. Current standards in medical ethics and law encourage SDM and information provision to patients. For example, SDM has been incorporated into the European Cancer Patient’s Bill of Rights [16], the U.S. Patient Protection and Affordable Care Act and the Salzburg Statement of shared decision making [30]. In the Netherlands, three laws in which patients’ rights are anchored (i.e., WGBO, Wklcz and WMCZ) are currently being reformed to produce a single new law (i.e., Wet kwaliteit, klachten en geschillen zorg (Wkkgz)). This new law will have a specific section on information provision to patients, and healthcare professionals will be requested to provide reliable information on quality of care, patient experiences with care, and scientific evidence on available treatment options to optimize shared decision making [31,32].

**When is SDM appropriate?**

When patients are more engaged in decisions about their treatment, they are more likely to express confidence in the decisions made, to be satisfied with the care provided and to trust their providers [33]. SDM has also been associated with improved treatment compli-
and better quality of life [34], positive patient experiences with care [35], improved patient knowledge about treatment options [36], and use of less invasive procedures [37]. Evidence for the effectiveness of SDM regarding satisfaction with decision making, anxiety, and health outcomes are still inconclusive however [36,38]. All in all, these figures are quite positive and suggest that SDM has the potential to contribute to patient empowerment, and to a reduction of medical practice variation.

Traditionally, SDM has been advocated for ‘preference sensitive decisions’ in curative healthcare. When new treatment options are available that are equal to the more conventional options in terms of survival, as in the case of stage I NSCLC treatment, preference sensitive decisions obviously become more apparent (i.e. equipoise about treatment options). Several scholars have recently argued that SDM is more broadly suitable for all kinds of decisions, including in end of life and palliative care, considering the positive figures outlined above [39,40]. Although a particular new treatment or a no treatment option may not be as effective as more aggressive care in terms of survival, such options may nonetheless constitute reasonable options for some patients to consider, and thus constitute equipoise [41].

On the other hand, other researchers and clinicians have argued that SDM may not be suitable or practiced in the same way in all clinical situations. For example, some situations involve very complex medical decisions and/or evoke choice stress and/or highly affect-laden risk perceptions among patients [42,43]. The question of how SDM should be practiced in such situations has not been answered yet.

**Barriers and facilitators of SDM**

It is widely accepted that implementing SDM in practice is challenging [4]. Although many health professionals feel that they encourage patients to participate in treatment decisions [44], observational studies and patients’ own reports show that medical opinion rather than patients’ preferences tends to dominate decisions [45,46]. For adequately incorporating SDM in a consultation, professionals need specific communication skills and tools. Patients need relevant information that is well-balanced and easy to understand, and often need to be supported to be involved in decision making [47,48]. Barriers for these processes can be patients’ difficulties in comprehending information provided due to the complexity of this information, but also due to limited health literacy\(^1\) and –numeracy\(^2\)

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1. The degree to which individuals obtain, process, understand, and communicate about health-related information, in order to make informed health decisions [55]
2. The degree to which individuals have the capacity to access, process, interpret, communicate, and act on numerical, quantitative, graphical, biostatistical, and probabilistic health information needed to make effective health decisions [56]
skills. Because patients require appropriate skills, knowledge, beliefs and motivation in order to actively participate [49-52], it is recognized that active participation can be difficult for many patients [53]. From the professionals’ perspective, essential barriers are time constraints, perceived lack of applicability of SDM due to patient characteristics and due to the particular clinical situation [54]. Three essential facilitators of SDM identified in a review of Gravel et al. (2006) were healthcare professionals’ motivation, their perception that SDM leads to a positive impact on the clinical process, and their perception that SDM is practical and useful. In order to address the above-mentioned barriers for SDM implementation, typical strategies used are training of medical students and professionals in SDM knowledge, attitudes and competencies as well as incorporating patient decision aids (PDAs) in clinical practice [14].

Decision support
PDAs are structured instruments providing evidence-based information to patients about the options, as well as sections dedicated to risk information and to eliciting patient preferences. As such, they guide patients in weighing pros and cons of the decision options, and in value clarification. Currently, there is much interest for compact versions of PDAs, such as option grids [57], that take less time for professionals and patients to complete, but nonetheless compare treatment options in a systematic way. PDAs are known to positively influence several factors important for effective information processing, such as knowledge of the options, feeling informed and being confident about the preferred treatment, and accurate risk perceptions [36]. Importantly, PDAs generally lead to more patient participation in decision making, with more congruence between patients’ preferences and their ultimate decisions [36].

Lung cancer
An area where SDM is of growing interest is lung cancer, which is the most commonly diagnosed cancer worldwide with an estimated 1.8 million cases [58]. The incidence is expected to increase in the near future due to an aging population [59,60]. In the Netherlands, 11900 new lung cancer cases were diagnosed in 2014, making it the fourth most common cancer in both men and women [61]. Lung cancers are classified into two groups, based on histological cell type: small cell lung cancer and non-small cell lung cancer (NSCLC). The latter sub-type is most common and accounts for approximately 80-85% of all lung cancer diagnosis [62]. There are three types of NSCLC: squamous cell carcinoma, adenocarcinoma and large cell (undifferentiated) carcinoma. In addition, there are four stages of NSCLC (i.e. stages I to IV), where stage I represents small tumors localized in the lung itself and stage IV describes metastatic tumors that have spread to differ-
ent lobes of the lung or to other organs. The clinical stage of NSCLC influences the feasibility and appropriateness of particular treatments.

**Treatment options for stage I NSCLC**
Two curative treatment options are currently available for stage I NSCLC, namely a surgical resection and SABR, which involves the use of high-precision delivery of high-dose radiotherapy in an outpatient setting, in 3-8 fractions. Surgical resection is considered the standard of care in medically operable patients [63]. However, many patients with stage I NSCLC are unable to undergo surgery, for example because of age, frailty and tobacco-related comorbidities, or because they are not willing to accept surgery-related risks [11,63,64]. The 5-year overall survival rate in untreated patients is 6% - 14% [65,66]. SABR is associated with few side-effects and long-term local tumor control- and survival rates similar to that reported for surgery [68,69] and its use has increased in the Netherlands since 2003 [67]. Although no randomized controlled trials directly comparing SABR and surgery have yet completed accrual, the available comparative effectiveness data clearly suggest that SABR results in comparable outcomes to surgery [11,70]. Whereas Dutch hospitals initially used SABR only in more elderly and frail patients [71], growing numbers are now treating fitter patients with stage I NSCLC [72,73]. Since these patients are, at least theoretically, in a position to choose between these two treatment options, this trade-off makes stage I NSCLC an appropriate and compelling case for SDM.

**Patient decision making about lung cancer treatment**
Few studies have focused on patient decision making in the lung cancer context. Some have reported that lung cancer patients prefer complete disclosure of information about topics such as symptoms, prognosis, potential benefits and complications of treatment, and treatment preferences [74,75]. As was reported for other patient groups, patients with lung cancer also prefer to share decisions with their clinician [35,76,77]. Calls are thus increasingly made to ensure that clinicians discuss treatment options with lung cancer patients while supporting patient needs [78]. Consultations with lung cancer patients are however challenging, as this disease has a high mortality rate, which makes the consultation stressful to patients as well as to family members and clinicians [79]. This high level of anxiety may impact on the amount of information that patients understand and recall later and perhaps also the wish to participate in decisions. Patients with lung cancer may not always make well-informed decisions as they may not always understand their situation well enough [80]. In general, previous findings suggest that SDM in stage I NSCLC may be appropriate for this patient group, but that it might be complex in practice due to the fact that: (a) clinicians might differ in their perceptions of
the optimal treatment; and (b) patients might not adequately process needed information required for SDM due to emotional and stressful factors related to the poor outcomes. It might well be that in practice, for example, medical opinion dominates treatment choice, possibly leading to unwarranted variations in medical practice.

**Design of this thesis and research questions**

The central aim of this thesis was to investigate the current situation regarding SDM in patients with stage I NSCLC, exploring several issues relevant for SDM in practice.

This thesis consists of three parts:

**Part 1: Stage I lung cancer patients' perspectives on decision making**

The main research question addressed was:

"What is the patient's perspective on patient participation in treatment decision making, and what aspects do stage I NSCLC patients find important?"

**Chapter 2** describes a review on the congruence between patients' preferred and perceived participation in medical decision making. In **chapter 3**, we investigated how patients with stage I NSCLC experienced the treatment decision making process and which factors they found important (retrospective interviews) and quantitatively assessed the importance patients attached to different SDM aspects.

**Part 2: Clinicians' perspectives on stage I lung cancer decision making**

The main research question addressed was:

"What is the clinician's perspective on patient participation in treatment decision making and what influences clinicians' treatment recommendations for stage I NSCLC patients?"

**Chapter 4** describes a binary choice experiment with hypothetical cases that identified how different patient- and clinician-related characteristics influenced treatment recommendations of clinicians treating patients with stage I NSCLC. In **chapter 5**, we further explored this clinician decision making in relation to the stated treatment preferences of patients. This was done using secondary analyses of the data from the binary choice experiment from chapter 4.
Part 3: Information provision to stage I lung cancer patients
The main research question addressed here was:
“*What information about the new treatment option SABR is currently available on the Internet for stage I NSCLC patients and how can this information be improved?*”

Chapter 6 describes an analysis of websites providing patient information on SABR for stage I NSCLC patients. In chapter 7, we report on a qualitative user test of a patient website on SABR.
Finally, in chapter 8, the general conclusions are formulated, and implications for healthcare practice, health policy and research are described.
Reference list


61. Integral Cancer Center the Netherlands. Available at: www.iKNL.nl.


