# Measuring shared decision making in oncology: an informed approach

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# MEASURING SHARED DECISION MAKING IN ONCOLOGY: AN INFORMED APPROACH

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To every thing there is a season, and a time to every purpose under the heaven.

*Ecclesiastes 3:1, King James Version*

## TABLE OF CONTENTS

# GENERAL INTRODUCTION

Shared decision making (SDM) between patient and healthcare professional about treatment options is becoming 'the new normal' in the Netherlands, envisioned Bruno Bruins, the former Dutch minister of Health in 2019.[1] The Dutch Federation of Medical Specialists considers that SDM should become a habit[2] and, consequently, it may become the new normal. 'The new normal' has gained a completely different meaning in the Netherlands since 2020. It refers to the behaviours asked from each individual to slow the spread of COVID-19.[3] For example, here and elsewhere people have been asked to avoid physical contact and to wash their hands frequently.[4, 5] The recommended behaviours have repeatedly been communicated by the government and are quite easy in themselves, but still adherence has been low. Evidently, commitment to new behaviours is not easy, even for simple behaviours. In contrast, SDM between patient and healthcare professional involves two or more individuals who need to commit to complex behaviours during and outside the clinical consultation. Communication about these behaviour changes by healthcare professional organisations, among others is challenging, and they may not easily become routine for patients and healthcare professionals.

In 1972, Veatch described the contractual model in which there is true sharing of ethical authority and responsibility between patient and physician, next to sharing of decision making. Ten years later, ethically valid informed consent was stated to involve a process of SDM.[6] In the 1990's several journals published papers on SDM,[7-9] and Charles and colleagues presented the first SDM model in 1997 (see Box 1).[10] The BMJ embraced patient partnership with a contribution by Charles and colleagues[11] and by a illustrating it as a tangoing couple on their cover in 1999, upon Charles et al. revisiting their SDM model.[12] In 2006, Makoul & Clayman identified 31 separate concepts used to explicate SDM, from 161 different definitions.[13] A year later, Moumjid et al. concluded that while clear SDM definitions were available, they were poorly cited and that the term SDM was being used inconsistently.[14] Over the following years, the number of publications on SDM increased rapidly.[15]

In 2011 the Salzburg statement called upon patients and healthcare professionals 'to work together to be coproducers of health', with specific tasks for each of them.[16] To date, a range of implementation activities have been undertaken to support SDM, such as: training of healthcare professionals,[17, 18] development of pocket cards for healthcare professionals,[19] and development of patient decision aids.[20, 21] Dutch national campaigns have been launched ('3 goede vragen',[22, 23] 'consultkaart',[24] 'begin een goed gesprek'[25]) to create awareness about SDM, informed by e.g., the AskShareKnow,[26, 27] the Ask 3 questions campaigns,[28] and Option Grids.[29] SDM has even been established by Dutch law; the Dutch Medical Treatment Agreement Act (Wet op de geneeskundige behandelovereenkomst (WGBO)) which regulates the rights and obligations of patients, was adapted recently (January 1, 2020) and now includes reference to SDM.[30]

**Box 1.** First SDM model by Charles et al.[10, 12]

1. At a minimum, both the physician and patient are involved in the treatment decision-making process.
2. Both the physician and patient share information with each other.
3. Both the physician and the patient take steps to participate in the decision-making process by expressing treatment preferences.
4. A treatment decision is made, and both the physician and patient agree on the treatment to implement.

## SDM measurement challenges

While many SDM implementation activities have been launched, measurement difficulties remain.[31-33] In 2011, Scholl et al. identified 28 SDM measurement instruments from the literature and concluded that further psychometric testing was needed, since validity had often not been sufficiently investigated.[34] Moreover, these and more recent measurement instruments only assess healthcare professionals behaviour, or include patient and healthcare professional behaviour in one item. This makes it impossible to assess the patients' role, while their responsibilities have been clearly emphasized since the first SDM models.[10, 12] Measurement of behaviours outside consultations is also lacking, while SDM extends to the world outside the consultation room.[35]

In previous research, patients and healthcare professionals have been involved in the development of SDM measurement instruments to a limited extent only, even though this is recommended.[36] This lack of involvement may partly explain poor correlations between SDM assessments from different viewpoints,[33, 37-40] including an independent observer (e.g., OPTION-5[41]), the patient (e.g., SDM-Q-9,[42]), or the healthcare professional (e.g., SDM-Q-Doc[43]). Patient and healthcare professional involvement will likely improve the content validity of the measurement instruments and for questionnaires, their feasibility and acceptability.

Last but not least, for most existing measurement instruments, the developers apparently have assumed a reflective model, as they assessed factor structure and/or internal consistency. They have thereby neglected the formative nature of the SDM construct. That is, SDM in itself may not be something already present, in contrast to e.g., intelligence.[44, 45] SDM is formed by the behaviours of patients and healthcare professionals, both during and outside consultations. What these behaviours entail, may vary per context. Together the items of a measurement instrument form the construct, while for e.g., intelligence, the items reflect the construct. A consequence of assuming a formative measurement model is that another approach is needed to inform item selection and to determine the validity of a measurement instrument.

## Aim and outline

We aimed to develop and validate questionnaires to assess the SDM process in oncology from both the patient and the physician viewpoint. We chose the participant perspective and decided to develop questionnaires instead of a coding scheme to be completed by an independent observer, since questionnaires are far more easy to use in research. To guide our development and validation process, we used the original COnsensus-based

Standards for the selection of health Measurement INstruments (COSMIN) checklist[46, 47] and wrote two reviews: one on published SDM measurement instruments and one on published SDM models. Next, we used several consecutive studies to develop, test, and validate the questionnaires. We chose to develop the questionnaires specifically for oncology, since cancer patients often face preference-sensitive decisions,[48] a decision type for which SDM is considered to be the appropriate approach.[49] Cancer patients' treatment preferences vary[50, 51] and often differ from physicians' treatment preferences.[52, 53] Survival, for example, may be weighed differently by patients and physicians.[52] To ensure that treatment is in line with individual patients' preferences, cancer patients' involvement in decision making is of utmost importance. Fortunately, most cancer patients prefer an active or collaborative role in treatment decision making.[54-56]

In chapter 2, we present an overview of existing SDM measurement instruments and an assessment of the level of evidence for 10 measurement properties. This assessment was informed by the methodological quality of the respective validation study or studies, and by the psychometric quality of the measurement properties. In chapter 3, we present an overview of models defining SDM between a patient and a healthcare professional, the components making up the models, who is seen as responsible for the occurrence of the SDM components, the inclusion of the components over time, and we present a frequency map of SDM components per healthcare setting. In chapter 4, views of stakeholders are integrated into a model of SDM in oncology. Chapter 5 describes the development and first testing of the iSHAREpatient and iSHAREphysician. These questionnaires aim to measure SDM in oncology, from the viewpoint of the patient and of the physician, respectively. In chapter 6 we demonstrate construct validity of the iSHAREpatient and iSHAREphysician, test-retest agreement of the iSHAREpatient, and agreement between scores on the iSHAREpatient and iSHAREphysician. In chapter 7 the main findings are summarized and discussed, including strengths and limitations, practice implications, suggestions for future research and concluding remarks.

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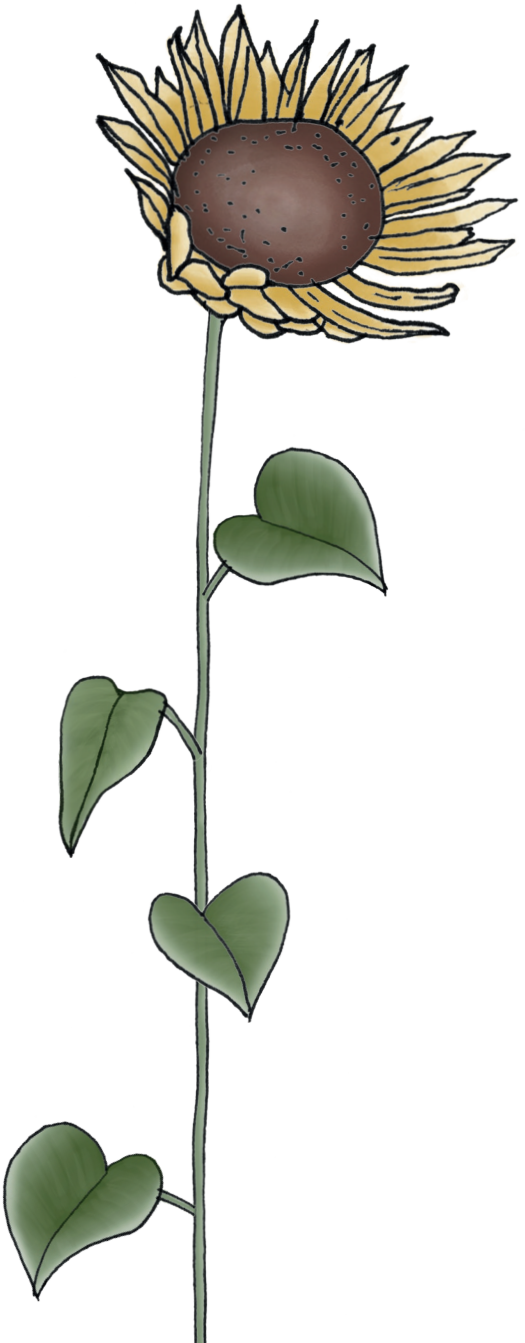

# 2

# THE QUALITY OF INSTRUMENTS TO ASSESS THE PROCESS OF SHARED DECISION MAKING: A SYSTEMATIC REVIEW

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## ABSTRACT

### Objective

To inventory instruments assessing the process of shared decision making and appraise their measurement quality, taking into account the methodological quality of their validation studies.

### Methods

In a systematic review we searched seven databases (PubMed, Embase, Emcare, Cochrane, PsycINFO, Web of Science, Academic Search Premier) for studies investigating instruments measuring the process of shared decision making. Per identified instrument, we assessed the level of evidence separately for 10 measurement properties following a three-step procedure: 1) appraisal of the methodological quality using the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist, 2) appraisal of the psychometric quality of the measurement property using three possible quality scores, 3) best-evidence synthesis based on the number of studies, their methodological and psychometrical quality, and the direction and consistency of the results. The study protocol was registered at PROSPERO: CRD42015023397.

### Results

We included 51 articles describing the development and/or evaluation of 40 shared decision-making process instruments: 16 patient questionnaires, 4 provider questionnaires, 18 coding schemes and 2 instruments measuring multiple perspectives. There is an overall lack of evidence for their measurement quality, either because validation is missing or methods are poor. The best-evidence synthesis indicated positive results for a major part of instruments for content validity (50%) and structural validity (53%) if these were evaluated, but negative results for a major part of the instruments when inter-rater reliability (47%) and hypotheses testing (59%) were evaluated.

### Conclusions

Due to the lack of evidence on measurement quality, the choice for the most appropriate instrument can best be based on the instrument's content and characteristics such as the perspective that they assess. We recommend refinement and validation of existing instruments, and the use of COSMIN-guidelines to help guarantee high-quality evaluations.

## 1. INTRODUCTION

There is growing recognition that shared decision making (SDM) is imperative as a decision making model in clinical practice when more than one option is medically relevant or when patient preferences vary strongly. Various conceptual models describe what the process of SDM between healthcare providers and patients entails.[1, 2] Many of these models describe steps that have to be taken as part of SDM. In a recent paper, Stiggelbout and colleagues identify four key steps: *"(1) the professional informs the patient that a decision is to be made and that the patient's opinion is important; (2) the professional explains the options and their pros and cons; (3) the professional and the patient discuss the patient's preferences and the professional supports the patient in deliberation; (4) the professional and patient discuss the patient's wish to make the decision, they make or defer the decision, and discuss follow-up."*[2] SDM aims to promote patient autonomy, to limit practice variation, and ensure that treatment decisions reflect patient preferences.[1, 3, 4] Research shows that the occurrence of SDM in routine clinical practice is still limited.[5, 6] Current research agenda focuses on studies on the level of SDM seen in clinical care,[5] effects of training and tools for healthcare providers and patients to promote SDM in the clinical practice,[7, 8] and the effect of SDM on psychosocial and physical patient outcomes.[9-11] The quality of these studies highly depends on the availability of psychometrically sound instruments to assess the actual realization of SDM. It is notable that the SDM measures used vary greatly with regard to their characteristics, such as the source of the data and the perspective of the scorers (self-report questionnaires based on the experience of patients or providers versus coding schemes applied by independent raters to audio- or video-taped consultations).[12] These differences can impact research outcomes, as might be the case for a review on the relationship between SDM and patient health outcomes which found that the perspective from which SDM is measured affects the associations found with health outcomes.[8] Furthermore, it is not clear if there are differences in measurement quality between different instruments. To assist researchers in their choice of the most feasible, reliable, and valid SDM measure, and to optimally improve existing instruments, insight into measurement quality of the existing measures is needed.

Previous literature reviews have provided an overview of existing instruments, but have not systematically appraised the quality of the instruments' measurement properties in a process that accounts for the methodological quality of their validation.[12-15] Concerning the instruments' measurement quality, the existing reviews only presented results on reliability and validity testing in a descriptive manner. None of the previous reviews systematically appraised the quality of the measurement properties of existing instruments, taking into account the methodological quality of their validation studies. In any study, poor methodological quality can bias the results. Consequently, when drawing conclusions on the quality of measurement instruments, one should appraise and correct for the risk of bias arising from the methods applied in the validation studies of the instruments under investigation.[16] Therefore, we aim to perform a systematic literature review that presents an overview of all SDM process instruments and their measurement quality, by answering the following research question: What is the measurement quality of existing instruments measuring the process of SDM, taking into account the methodological quality of the available validation studies?

This systematic review was registered at PROSPERO: CRD42015023397 Available from: *https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=23397.*

## 2. METHODS

### 2.1 Search strategy

Seven electronic databases (PubMed, Embase, Emcare, Cochrane, PsycINFO, Web of science, Academic Search Premier) were systematically searched for peer-reviewed articles in May 2015 and the search was updated on September 1, 2017. A librarian experienced in systematic searches of academic databases assisted the researchers in developing and performing the search strategy. Our search strategy was developed in line with recommendations and existing search filters specifically developed for systematic reviews, assessing the measurement quality of measurement instruments in the medical field, described by Terwee and colleagues.[17] We combined three search groups with the Boolean operator AND: Group I consisted of search terms presenting the construct of interest, i.e., SDM; group II consisted of search terms for instrument types, such as questionnaire and coding schemes; and group III consisted of search terms for measurement properties. Index terms specific for each database (such as MESH and Major terms in PubMed) were combined with free-text words. We added a fourth search group using the Boolean operator NOT, to exclude specific publication types such as editorials. The search strategy is presented in Appendix A. We then reviewed all articles citing the of articles that meet our inclusion criteria to check for additional relevant articles with a publication date prior to October 10, 2017. Furthermore, we contacted a network of SDM researchers via the Shared-I mailing list (*Shared-I@shared-I.org*; *http://www.psych.usyd.edu.au/mailman/listinfo/shared-I*) and asked them to inform us of any ongoing studies related to the development or evaluation of instruments measuring the process of SDM.

### 2.2 Selection of eligible articles

The search aimed to include all articles that describe the development or evaluation of instruments that measure the SDM process, which is an assessment of the actual realization of SDM in clinical practice. Articles that evaluate instruments measuring antecedents of SDM (e.g., preferred role in decision making) or SDM outcomes (such as decisional regret) were not included. The inclusion criteria are presented in detail in Table 1. To check eligibly for inclusion, each article retrieved in the search was independently assessed by two members of the research team (MB, HB-R, FG, IPS, IS, AP). In a twofold process, researchers reviewed the titles and abstracts of each article. If these indicated potential inclusion, the full-text of the article was assessed using the inclusion criteria. Disagreements were resolved in consensus between the two reviewers and a third reviewer was consulted if necessary.

**Table 1.** Eligibility criteria

Inclusion criteria

1. The article had to describe a primary study in which the development or evaluation of one or more instruments occurred.
2. Instruments under investigation:
   a. were developed with the aim of measuring the process of SDM between a patient (with or without family) or proxy and a healthcare provider; or
   b. were evaluated in their ability to measure the process of SDM even though they were not originally developed to measure the process of SDM; or
   c. were developed or evaluated in their ability to measure patient participation in decision making. To guarantee a focus on SDM, these instruments should assess at least one of four key steps of SDM:[8, 18, 19]
      i. explaining that a decision has to be made,
      ii. discussing all relevant treatment options and their associated benefits and harms,
      iii. discussing patients' ideas, concerns and expectations and supporting patients in the process of deliberation, before reaching a decision,
      iv. patient involvement in making the final decision.
3. The article had been peer-reviewed. (Not applicable to unpublished work received via the SHARED e-mail list.)
4. The article was written in English, Dutch, or German.

Exclusion criteria

To guarantee that the instrument under investigation measures a decision making process that includes both the healthcare provider and the patient, the following two exclusion criteria were applied:

1. Articles investigating instruments that measure inter-professional SDM that does not include the participation of patients.
2. Articles about instruments developed or evaluated for the measurement of SDM about screening. These decisions often rather relate to informed decision making and thus crucially differ from SDM in two aspects:
   a) the healthcare provider is not necessarily involved in making the decision;
   b) a decision usually is not needed by a certain time point.

No restrictions were held for:

1. The type of measurement instrument (e.g. self-report questionnaire or coding scheme),
2. The healthcare setting in which the instrument was evaluated.

## 2.3 Data extraction

For each included article we extracted data on the methods (setting, healthcare provider sample, patient sample, data collection and coders in case of observer-based data), and results for 10 measurement properties (see Table 2). In case an article describes the evaluation of multiple instruments, the data extraction was performed separately for each instrument under investigation. The extracted data is presented in the online Supporting Information (*https://figshare.com/articles/dataset/The_quality_of_instruments_to_assess_the_process_of_shared_decision_making_A_systematic_review/5892685?file=10499863*); this data is a summary of the methods and results of the included validation studies and informs the quality appraisals that we performed, as described in section 2.5. For each instrument identified by the included articles we extracted i) the instrument's measurement aim and construct, ii) the measurement characteristics, i.e., underlying measurement model, number of subscales and items, response scale, and score range, and iii) details on the development

process. For each included article, the data was extracted by one and checked by a second project team member (HB-R, FG, IPS, IS, AP, AS); disagreements between these two were discussed until consensus was reached. In case of doubt a third researcher was consulted. Only information listed in the included article was extracted and considered for assessment, unless the article specifically referred to some other source for this information.

**Table 2.** Definition of measurement properties based on COSMIN[20] and Terwee et al.[21]

| Measurement property | Definition |
|---|---|
| **I. Reliability** | |
| **Internal consistency** | The degree to which items in a (sub)scale are intercorrelated, thus measuring the same construct. |
| **Reliability** | The extent to which subjects can be distinguished from each other, despite measurement errors (relative measurement error). |
| **Measurement error/ Agreement** | The degree to which the scores on repeated measures are close to each other (absolute measurement error). |
| **II. Validity** | |
| **Content validity** | The degree to which the instrument is an adequate reflection of the construct to be measured. |
| **Construct validity** | |
| Structural validity | The degree to which the scores of the instrument are an adequate reflection of the dimensionality of the construct to be measured. |
| Hypotheses testing | The degree to which the scores of the instrument are consistent with hypotheses, based on the assumption that the instrument validly measures the construct to be measured. |
| Cross-cultural validity | The degree to which the performance of the items on a translated or culturally adapted instrument are an adequate reflection of the performance of the items of the original version of the instrument. |
| **Criterion validity** | The degree to which the scores of the instrument are an adequate reflection of a 'gold standard'. |
| **III. Responsiveness** | |
| **Responsiveness** | The ability of the instrument to detect changes over time in the construct measured. |
| **Interpretability** | Interpretability is the degree to which one can assign qualitative meaning- that is, clinical or commonly understood connotations – to an instrument's quantitative scores or change in scores. |

## 2.4 Quality appraisal of measurement properties of SDM instruments

For each instrument, we appraised the quality of ten measurement properties (see Table 2) described in the validation studies in two ways. First, we rated the quality of the methods used to evaluate the measurement properties of an instrument; from here on referred to as the appraisal of methodological quality. Second, we rated the measurement properties based on the results of the validation studies. Data from these two appraisals were combined to provide a best-evidence synthesis of the quality of the measurement properties for each instrument included.

### 2.4.1 Appraisal of methodological quality

To appraise the methodological quality we used the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist.[20, 22, 23] The COSMIN checklist describes how ten different measurement properties should ideally be evaluated and provides scoring criteria for the methodological quality appraisal. For each measurement property, the quality of the methods used to evaluate it is scored by a number of items (ranging from 4 to 18) on a four-point rating scale: "excellent", "good", "fair", or "poor". For some items, the lowest response options were "good" or "fair". The scoring criteria for each category on the rating scale are uniquely defined per item. The overall score per measurement property was determined by taking the lowest item-level score for that specific measurement property. That is, if one item in a property was rated as "poor" then the entire property was rated as "poor". For instruments following item response theory (IRT), specific IRT criteria were scored, instead of internal consistency and structural validity. There are no COSMIN criteria to appraise methodological quality for the property interpretability. Therefore, for interpretability we only inventoried if two aspects of interpretability were evaluated, i.e., floor and ceiling effects, and minimal important change value. More information on COSMIN and the checklist items can be found on *http://COSMIN.nl*.

The 10 measurement properties and their definitions based on COSMIN[20] and Terwee et al.[21] are presented in Table 2. Due to variability in the field regarding names used for measurement properties, we classified the measurement properties evaluated in included articles using the terminology and definitions of COSMIN[20] and Terwee et al.[21] (see Table 2) rather than the labels given by the authors of the articles. For example, if authors used the term 'convergent validity testing' to designate the testing of hypotheses about the relationship of the instrument under investigation with another existing instrument measuring related constructs, we extracted and evaluated this information using COSMIN criteria for hypotheses testing.

We scored reliability separately for test-retest reliability (applicable to questionnaires only), inter-rater reliability, and intra-rater reliability (the latter two being applicable to coding schemes only). Items about reliability that were not applicable to the inter-rater reliability and intra-rater reliability of coding schemes, were omitted in the rating of the methodological quality of validation studies evaluating coding schemes, i.e., for intra-rater reliability item 7 *(Were patients stable in the interim period on the construct to be measured?)*; for inter-rater validity: item 6 *(Was the time interval stated?)*, item 7 *(Were patients stable in the interim period on the construct to be measured?)*, and item 8 *(Was the time interval appropriate?).*

We applied two modifications to the COSMIN rating. First, we diminished the impact of the item "Was there a description of how missing items were handled?" on the total score for a measurement property. This item is included in the rating of most measurement properties and often received the lowest possible score, a "fair" rating. This score often was the lowest score on the measurement property and would then obscure how the other methodological aspects for that measurement property were rated. We therefore decided to let this item have less impact on the final score by upgrading the total score on a measurement property

in case the score on this specific item was the lowest of all scores. E.g., if all items for the measurement property had received "good" or "excellent" rating, and the score on this specific item was a "fair", the total score was set on "good", or: if all items had been rated as "excellent" and the score on this specific item was a "fair", the total score was set at "good". Second, we adapted the rating of content validity. The COSMIN checklist requires that for content validity testing, three types of relevance should be assessed, regarding a) the construct to be measured, b) the study population, and c) the purpose of the measurement instrument. These requirements are quite stringent and therefore we have adapted the scoring of these three items as follows: If one or two types of relevance were missing, the concerning items were not scored. The score for items concerning the type of relevance that was assessed was downgraded by one score. That is, an excellent score for content validity testing was only possible when two or more types of relevance had been assessed.

### 2.4.2 Appraisal of the measurement properties

To rate the measurement property of an instrument within a particular study, we used three possible quality scores: a positive rating (labelled +), an inconclusive rating (labelled ?), and a negative rating (labelled -). The criteria we used were based on Terwee et al.[21] and Schellingerhout et al.[24, 25] and are presented in Table 3.

**Table 3.** Quality criteria for results on measurement properties based on Terwee et al.[21]

| Measurement property | Criteria for appraisal of the results on measurement properties evaluation |
|---|---|
| **Internal consistency** | + Cronbach's alpha(s) are ≥ 0.70. |
| | ? Not able to score because of unclear or missing information, e.g., the dimensionality is not known or Cronbach's alpha(s) are not presented. |
| | - Criteria for '+' not met. |
| **Reliability** | + ICCagreement/weighted Kappa ≥ 0.70 OR ICCconsistency/ICC without approach stated/Pearson's r ≥ 0.80 OR unweighted kappa/or kappa without approach stated ≥ 0.80. |
| | ? Not able to score because of unclear or missing information, e.g., neither ICC, Kappa, nor Pearson's r is determined. |
| | - Criteria for '+' not met. |
| **Measurement error/ Agreement** | + MIC ≥ SDC OR MIC outside the LOA OR convincing arguments that agreement is acceptable. |
| | ? Not able to score because of unclear or missing information, e.g. SEM, SDC not calculated, or MIC not defined. |
| | - Criteria for '+' not met. |
| **Content validity** | + Target group and/or experts considered all items to be relevant AND considered the item set to be complete. |
| | ? Not able to score because of unclear or missing information, e.g. no results on item relevance according to experts reported. |
| | - Criteria for '+' not met. |

**Construct validity**

| | | |
|---|---|---|
| Structural validity | + | **For exploratory factor analyses:** Factors chosen explain at least 50% of variance OR factors chosen explain less than 50% of variance but the choice is justified by the authors. **For confirmatory factor analyses:** (The goodness of fit indicators fulfil the following requirements: (CFI or TLI or GFI or comparable measure >0.90) AND (RMSEA or SRMR < 0.08)) AND (results confirm models with the original factor structure OR results confirm a model with slight changes if these changes are justified by the authors. |
| | ? | **For exploratory factor analyses:** Not able to score because of unclear or missing information, e.g. explained variance not mentioned. **For confirmatory factor analyses:** Not able to score because of unclear or missing information, e.g., no fit indices are presented. |
| | - | Criteria for '+' not met. |
| Hypotheses testing | + | (At least 75% of the results are in accordance with the hypotheses AND, if calculated, the correlation with an instrument measuring the same construct is ≥ 0.50) AND correlations with related constructs are higher than with unrelated constructs if calculated. |
| | ? | Not able to score because of unclear or missing information, e.g. no correlations with related construct are calculated. |
| | - | Criteria for '+' not met. |
| Cross-cultural validity | + | The original factor structure is confirmed AND no important DIF found. If only one of these properties are investigated: either the factor structure is confirmed OR no important DIF found. |
| | ? | Not able to score because of unclear or missing information, e.g. no confirmative factor analyses is performed nor the DIF is investigated. |
| | - | Criteria for '+' not met. |
| Criterion validity | + | Correlations with chosen gold standard ≥ 0.70, OR AUC ≥ 0.80, OR (specificity AND sensitivity ≥ 80). |
| | ? | Not able to score because of unclear or missing information. |
| | - | Criteria for '+' not met. |
| **Responsiveness** | + | Correlations of change scores of the target instrument with an instrument measuring the same construct are ≥ 0.40 OR at least 75% of the results are in accordance with the hypotheses OR AUC ≥ 0.70) AND Correlations of change scores of the target instrument with an instrument measuring a related constructs are higher than with unrelated construct if calculated. |
| | ? | Not able to score because of unclear or missing information, e.g. no correlations of change score with related constructs are calculated or no AUC investigated. |
| | - | Change score correlation with an instrument measuring the same construct < 0.40 OR < 75% of the results are in accordance with the hypotheses OR AUC < 0.70 OR change score correlations with related constructs are lower than with unrelated constructs. |

| | |
|---|---|
| **Interpretability** | *No quality scoring performed* |
| **Item response theory (IRT)** | + At least limited evidence for unidimensionality or positive structural validity AND no evidence for violation of local independence: Rasch: standardized item-person fit residuals between -2.5 and 2.5; OR IRT: residual correlations among the items after controlling for the dominant factor < 0.20 OR Q3's < 0.37 AND no evidence for violation of monotonicity: adequate looking graphs OR item scalability >0.30 AND adequate model fit: Rasch: infit and outfit mean squares ≥ 0.5 and ≤ 1.5 OR Z-standardized values > -2 and <2 OR IRT: G2 >0.01. Optional additional evidence: Adequate targeting; Rasch: adequate person-item threshold distribution; IRT: adequate threshold range. No important DIF for relevant subject characteristics (such as age, gender, education), McFadden's R2 < 0.02. |
| | ? Model fit not reported. |
| | - Criteria for '+' not met. |

+ = positive result for a measurement property

? = result of measurement property is unknown

- = negative result for a measurement property

ICC = intraclass correlation coefficients; MIC = minimal important change; SDC = smallest detectable change; LOA = limits of agreement; SEM = standard error of measurement; CFI = comparative fit index; TLI = Tucker-Lewis index; GFI = goodness of fit index; RMSEA = root mean square error of approximation; SRMR = standardized root mean square residual; DIF = differential item functioning; AUC = area under the receiver operating characteristic curve.

### 2.4.3 Best-evidence synthesis

As recommended by Terwee et al.[16] we determine the overall quality of a particular measurement property of an instrument. We used the approach of Schellingerhout and colleagues,[24, 25] in which the results from the different articles are synthesized for each instrument by combining: the appraisal of methodological quality of the studies (see 2.5.1), the appraisal of the measurement property (see 2.5.2), the number of studies assessing the property, and the consistency of the results in case of multiple validation studies. For this overall rating, five levels of evidence were applied: unknown evidence (?), conflicting evidence (+/-), limited (+ or -), moderate (++ or --), and strong evidence (+++ or ---). The latter three could point in either a positive or negative direction, which we indicated by respectively using the plus sign and minus sign. The scoring criteria are presented in Table 4.

Two members of the research team (HB-R, FG, IPS, IS, AP) rated the methodological quality and measurement properties of each article, with discrepancies discussed until consensus was reached. In case of doubt a third team member was consulted. For the methodological quality appraisal, consensus had to be reached on the item-level, not only on the total scores per measurement property rated. One team member performed the best-evidence synthesis (FG) and a second (AP) checked it. Team members who were co-author of an included article were not involved in data extraction and quality appraisals of that article. For instruments consisting of multiple subscales, we performed the quality appraisals of the methods and properties separately for each subscale. To provide an overall score for a measurement property for these instruments, we used the lowest subscale scores as input for the data synthesis.

**Table 4.** Levels of evidence for the best-evidence synthesis

| Level of evidence | Rating | Criteria |
|---|---|---|
| **Strong** | +++ or --- | Consistent findings in multiple studies of good methodological quality |
| | | OR one study of excellent methodological quality |
| **Moderate** | ++ or -- | Consistent findings in multiple studies of fair methodological quality |
| | | OR one study of good methodological quality |
| **Limited** | + or - | One study of fair methodological quality |
| **Conflicting** | +/- | Conflicting findings |
| **Unknown** | ? | Only studies of poor methodological quality |

A plus sign (+) indicates positive results for a measurement property evaluation and a minus sign (-) indicates negative results for a measurement property evaluation, e.g., + stands for limited evidence for positive results and --- stands for strong evidence for negative results for a measurement property.

# 3. RESULTS

## 3.1 Search results

The primary search in seven databases retrieved 13.026 articles, of which, after removing duplicates, 7484 unique hits were screened for inclusion. Another 1104 unique articles were identified by the citation check of all articles that were eligible for inclusion in this systematic review. After title abstract screening, 217 articles were assessed for eligibility based on their full-text. In total, fifty one articles met our inclusion criteria (Figure 1), of which forty five derived from the primary search, one from the citation check, 4 trough the call in the e-mail list of SDM researchers and 1 via hand search. The 51 included articles describe the development and/or evaluation of 40 unique instruments that assess the process of SDM (Figure 2). In total 21 instruments were originally developed versions, 4 were revised versions, and 15 were translated versions. In Table 5, we describe the characteristics of the instruments. Most instruments were observer-based coding schemes (N=18), followed by patient questionnaires (N=16) and provider questionnaires (N=4); two were mixed, including two or more instruments assessing multiple perspectives: the dyadic OPTION, consisting of a patient and a provider questionnaire [26] and the MAPPIN'SDM, consisting of a patient questionnaire, a provider questionnaire, and a coding scheme.[27] For the quality appraisal and best evidence synthesis of mixed instruments, we rated the instruments separately for each perspective, resulting in a total number of 43 instruments. The number of validation studies per instrument varied between zero and four. For most instruments (N=28), one validation article has been published.

## 3.2 Best-evidence synthesis

In Table 6, we present the best-evidence synthesis for each measurement property per instrument, (N=43). For seven instruments (all of which questionnaires), moderate or strong positive evidence was found for at least one type of reliability (internal consistency, test-retest reliability, intra-rater reliability, inter-rater reliability, or measurement error) and one type of validity (structural validity, hypotheses testing, cross-cultural validity, or criterion validity): the FPI,[28] the SDM-Q-9 original German version,[29] the SDM-Q-9 Spanish version[30-32]

the SDM-Q-9 Dutch version,[33] the SDM-Q-9-PSY in Hebrew,[34] the SDM-Q-doc original German version,[35] and the SDM-Q-doc Dutch version.[33] Of these instruments however, the SDM-Q-9 Spanish version,[30-32] the SDM-Q-9-PSY in Hebrew[34] and the SDM-Q-doc original German version,[35] are the only instruments without any negative evidence on other measurement properties. In Appendix B, we present the separate ratings for each included article, for

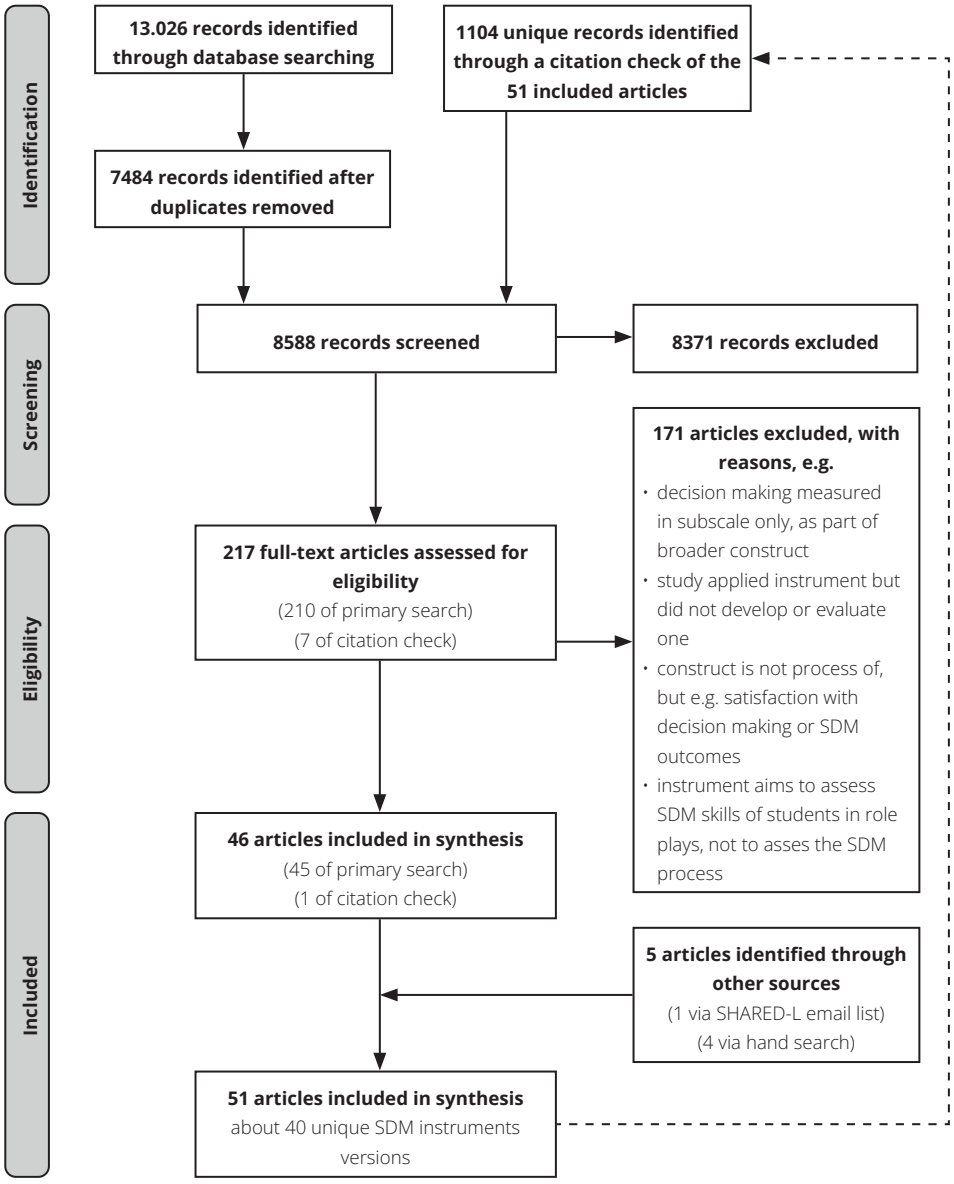


**Figure 1.** Flow diagram of article selection process

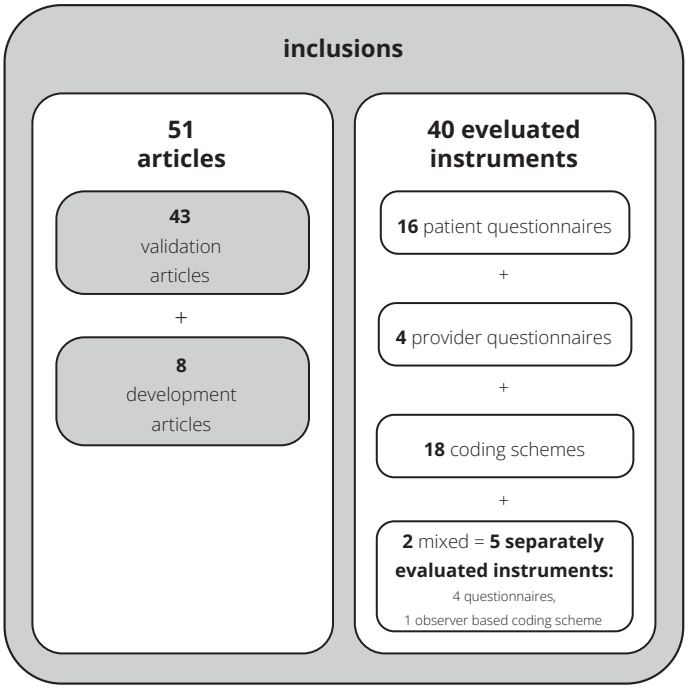


**Figure 2.** Number of included articles and instruments

both the appraisal of the methodological quality and the quality of measurement properties.

### 3.3 Overall results for the quality of validation studies and measurement properties

In the next three sections we will describe overall results on the quality of included studies and instruments, beginning with an overview of measurement properties that have been evaluated for the included instruments (section 3.3.1), the overall results on the methodological quality of the included validation studies (section 3.3.2), and overall results on the best-evidence synthesis (section 3.3.3). To allow for generalization, we present overall results only for measurement properties that have been evaluated in at least five studies (section 3.3.2) or for at least five instruments (section 3.3.3). We do not present overall results on the quality rating of measurement properties (see Methods section 2.4.2), because we regard them as being irrelevant without the correction for methodological quality. The results on the measurement properties evaluation for each included article and each instrument evaluated in the articles can be found in the online Supporting Information (*https://figshare.com/articles/dataset/The_quality_of_instruments_to_assess_the_process_of_shared_decision_making_A_systematic_review/5892685?file=10499863*).

**Table 5.** Characteristics of the instruments measuring the process of SDM regarding the construct and the instruments' measurement features

| Instrument | 1st author, publication year | Perspective | Version | Language | Target setting | Measurement aim | Construct and its definition | Measurement model (formative versus reflective) | Number of Subscales (total number of items) 1. name of subscales 1(# items), 2. Name of subscales 2 (# items), | Response-scale; total score range | Development process a) how construct defined; b) item generation; c) item selection; d) pilot test e) (cultural) adaptation/ translation process |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Patient questionnaires** | | | | | | | | | | | |
| **PPC** Patients' preferences for control | Bradley, 1996[36] | Patient | Original | assumed to be English | Generic | Patient desire for involvement in making medical decisions in general and in 10 scenarios depicting different acute and chronic medical situations | Not reported | Not applicable because exists of 1 item only | 1 (1) | 7-point scale: 1=I prefer that my doctor tell me what to do to 7=I prefer that I make the decision without any information or recommendation from the doctor; not reported | a) Literature; b) by authors (family physician, internist, social worker), based on the literature, clinical scenarios were then reviewed by family physicians (N=2); c) not reported; d) lay people (N=12) assessed readability and understanding of items; e) n/a |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **CPS post** Control Preferences Scale (actual role) | Degner, 1997[37] | Patient | Original | assumed to be English | Generic | Consumer preferences regarding participation in healthcare decisions (Aim for CPS post not reported) | **Control preferences:** Control preferences is the degree of control an individual wants to assume when decisions are being made about medical treatment (Definition for perceived actual role not reported) | Not applicable because exists of 1 item only | 1 (1) | 5 role descriptions: A=I prefer to make the decision about which treatment I will receive to E=I prefer to leave all decisions regarding treatment to my doctor, (labels for assessing actual role not reported), two possible procedures: Order of 5 cards with role descriptions (card sort task) or selection of 1 role ("pick one" approach); not reported | Card sort task, preferred role: a) Literature and qualitative work by authors; b) participant observation; c) not reported, d) pilot test 1: Tested in 60 cancer patients and problematic statements revised; pilot test 2: Tested in 30 cancer patients and cartoons added; e) n/a |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **FPI** Facilitation of Patient Involvement Scale | Martin, 2001[28] | Patient | Original | assumed to be English | Generic | Degree to which patients perceive that their provider actively facilitate or encourage them to be involved in their own healthcare | **Facilitating or promoting a patient's involvement in care:** Facilitating or promoting a patient's involvement in care entails communicating openly with the patient, giving information, and allowing the patient to express his or her views and opinions | Assumed to be reflective as Cronbach's alpha calculated | 1 (9) | 6-point scale: 1=none of the time to 6=all of the time; not reported | a) Unclear; b) based on literature review; c) expert review (N=17 research psychologists) of face validity, content overlap, and ambiguity, led to removal and modification of items; d) not reported; e) n/a |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **COMRADE** Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness | Edwards, 2003[38] | Patient | Original | assumed to be English | Generic | Effectiveness of risk communication and treatment decision making in consultations | **Risk communication:** Risk communication is the open two-way exchange of information and opinion about risk, leading to better understanding and better (clinical) management decisions; **Effective decisions:** Effective decisions are decisions that are informed, consistent with personal values and acted upon | Assumed to be reflective as Cronbach's alpha calculated | 2 (20); 1. Risk communication (10), 2. Confidence in decision (10) | Unclear; total score range for each subscale: 0-100 | a) Literature; b) existing instruments identified through systematic literature review, semi-structured focus group interviews with patients (N=49), and interviews with general practitioners (N=6); c) in an iterative process the (group) interview data plus written feedback on face validity, simplicity and ambiguity of items led to revision and elimination of items; d) 72 patients at five general practices completed the questionnaire after consultation with a doctor and 20 of these patients were interviewed on item clarity; e) n/a |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **SDM-Q** Shared Decision-Making Questionnaire | Simon, 2006[39] | Patient | Original | German | Generic | SDM process in clinical encounters | **SDM**: An SDM process consists of the following nine sequential steps: 1. Disclosure that a decision needs to be made, 2. Formulation of equality of partners, 3. Equipoise statement, 4. Informing on the benefits and risks of options, 5. Investigation of patient's understanding and expectations, 6. Identification of preferences, 7. Negotiation, 8. Shared decision, 9. Arrangement of follow-up | IRT | 1 (11) | 4-point scale: 0=strongly disagree to 4=strongly agree; not reported | a) Literature and nominal group technique-based discussions; b) Delphi method; c) pilot testing and item fit analysis; d) piloted in readability tests with patients as well as experts in questionnaire development; e) n/a |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **SDM-Q-9**<br>9-item Shared Decision-Making Questionnaire | Kriston, 2010[29] | Patient | Revision | German | Generic | SDM process in clinical encounters | **SDM**: SDM is as an interactive process in which both parties (patient and provider) are equally and actively involved and share information in order to reach an agreement, for which they are jointly responsible | Assumed to be reflective based on comment in discussion | 1 (9) | 6-point scale: 0=completely disagree to 5 =completely agree; 0-45, rescaled range: 0-100 | a) Literature review and previous SDM-Q instrument; b) author-generated based on research experience; c) equally weighted criteria: face validity by researchers (N=2), and by acceptance, discrimination, difficulty in primary care sample (N=1163); d) not reported; e) n/a |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **SDM-Q-9** (Spanish) | De las Cuevas, 2014[32] | Patient | Translation | Spanish | Generic | SDM process in clinical encounters | **SDM**: SDM is an interactive process of clinical decision making that ensures that both patient and physician are equally and actively involved and share information to reach an agreement, for which they are jointly responsible | Reflective | 1 (9) | 6-point scale: 0=completely disagree to 5=completely agree; not reported | a) Literature; b-d) n/a; e) following 5 steps according to guideline, including multiple forward and multiple backward translations and consensus discussions with translators and authors of original instrument; rating of content validity and understandability and semantic and content equivalence of the German and Spanish versions by independent experts (primary care physicians, psychiatrists, psychologists) (N=5). Pre-test of the final version in adult patients (N=12) at one of two primary care health centres. No further modifications were necessary after this pre-test. |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **SDM-Q-9** (Dutch) | Rodenburg, 2015[33] | | Translation | Dutch | Generic | SDM process during a consultation | **SDM**: In partnership with their providers, patients are encouraged to consider the likely harms and benefits of available treatment options, communicate their preferences, and select the option that best fits these | Assumed to be reflective as Cronbach's alpha calculated | 1 (9) | 6-point scale: 0=completely disagree to 5=completely agree; 0-45, rescaled range: 0-100 | a) Literature; b-d) n/a; e) multiple forward-backward translations of the original German version by two native Dutch and two native German speakers, comparison and discrepancy discussion in consensus meeting with four team members, including author of original German version; final version presented to clinicians for their opinion on wording (N not reported) |
| **SDM-Q-9 Psy** (Hebrew) | Zisman-Ilani, 2016[34] | Patient | Translation | Hebrew | Psychia-try | Decision making processes and SDM practice in real-time consultations with people with serious mental illness who are currently hospitalized in psychiatric hospitals | **SDM**: SDM is an interactive process in which patient and provider are equally and actively involved and share information to reach an agreement about treatment for which they are jointly responsible | Assumed to be reflective as Cronbach's alpha calculated | 1 (9) | 6-point scale: 0=completely disagree to 5=completely agree; not reported | a) Literature; b-d) n/a; e) authors translated and made a few contextual and lingual adaptations based on the guidelines for cross-cultural adaptation by Beaton et al. 2000, Spine 25, 3186–3191 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **SDM-Q-9** (English) | Alvarez, 2017[30] | Patient | Translation | English | Generic | To evaluate patient-reported SDM from a patient-provider visit based on the patient's perception. | **SDM**: SDM is" a form of patient-provider communication where both parties bring expertise to the process and work in partnership to make a decision" (Duncan, Best, & Hagen, 2010). | Assumed to be reflective as Cronbach's alpha calculated | 1 (9) | 6-point scale: 0=completely disagree to 5 =completely agree; 0-45, rescaled range: 0-100 | a-d) n/a; e) translated version used |
| **CollaboRATE** | Elwyn, 2013[40] | Patient | Original | English | Generic | Extent of SDM in clinical encounters | **SDM**: SDM consists of three core elements: 1. Provision of information or explanation to the patient about relevant health issues or treatment options, 2. Elicitation of the patient's preferences related to the health issues or treatment options, 3. Preference integration | Formative | 1 (3) | Two possible versions: a) CollaboRATE-10: 10-point scale: 1=no effort was made to 10=every effort was made; 0-100; b) CollaboRATE-5: 5-point scale: 1=no effort was made to 4=every effort was made; 0-12 | a) Adapted from literature; b) generated based on construct definition by authors, c) items refined through cognitive interviews; d) 30 participants completed questionnaire; e) n/a |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **CollaboRATE** (Swedish) | Rosenberg, 2017[41] | Patient | Translation | Swedish | Generic | Shared decision making | Not provided | Assumed to be reflective as Cronbach's alpha is calculated | 1 (3) | 5-point scale: 0=no effort was made to 4=every effort was made, 0-12 | b-d) n/a; e) First permission to translate was obtained by developers. Second, independent translation by 2 researchers, native Swedish speakers fluent in English, independently translated the instrument into Swedish. Third, retranslation into English by a third researcher, native English speaker also fluent in Swedish, and with no previous knowledge of the original instruments. Fourth, possible transcultural differences between the original and the translated versions were discussed in the research team with the purpose of making the instrument culturally equivalent in order to promote a sound content validity. |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **SMDMQ** Taiwan Shared Medical Decision Making Questionnaire | Chang, 2014[42, 43] * | Patient | Original | Taiwanese | Generic | Shared medical decision making process | **Shared medical decision making**: Four components define the shared medical decision making process: 1. Patient Autonomy, 2. Control preference, 3. Patients' perceived involvement, 4. Risk information communication | IRT | 1 (15) | Not reported; 0-15 | a) Literature review; b) author generated; c) original 25 items were reduced to 16 based on experts' opinion (N=12) on content validity and relevance; 1 further item was removed based on Rasch analyses; d) not reported; e) n/a |
| **SDM Process Score** | Fowler, 2016, in progress [44] | Patient | Original | assumed to be English | Generic | Quality of decision making at a clinical practice or site | **SDM**: In SDM, patients are faced with potential medical tests or treatments for which there are reasonable options, and they should be informed about those options, including the known pros and cons, and should have a voice in making the decisions | Unclear | 1 (4) | Items 1-2: 4-point scale: 0=not at all to 3=a lot, dichotomized into 0=not at all or a little to 1=some or a lot, items 3-4 dichotomous: 0=no, 1=yes; 0-4 | a) Literature; b) based on previous questionnaire; c) not reported; d) cognitive testing with patients for relevance and clarity of items; e) n/a |

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| **MADM** Mother's Autonomy in Decision Making scale | Vedam, 2017[45] | Patient | Original | English | Primary maternity care | Women's autonomy and role in decision making during maternity care | **SDM**: no definition given | Assumed to be reflective as Cronbach's alpha calculated and based on items | 1 (7) | 6-point scale: 1=completely disagree to 6 =completely agree; 6-42 | a) Literature review; b) items from validated SDM instrument (SDM-Q_9) adapted to maternity setting and new items developed based on feedback from community consultation; c) Expert review and community consultation; d) questionnaire "pilot tested with several women from target population" and revised to improve clarity and logic; e) not applicable |

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| **Dyadic OPTION** (Swedish) | Rosenberg, 2017[41] | Patient | Translation | Swedish | Generic | Perceived patient involvement in shared decision making with the purpose of accessing the dual perspective while using identical items and construct for the patient and the provider version of the questionnaire | Not provided | Assumed to be reflective as Cronbach's alpha is calculated, but original scale was formative | 1 (12) | 4-point scale: 1=strongly disagree to 4=strongly agree; 12-48 | a-d) n/a; e) First permission to translate was obtained by developers. Second, independent translation by 2 researchers, native Swedish speakers fluent in English, independently translated the instrument into Swedish. Third, retranslation into English by a third researcher, native English speaker also fluent in Swedish, and with no previous knowledge of the original instruments. Fourth, possible transcultural differences between the original and the translated versions were discussed in the research team with the purpose of making the instrument culturally equivalent in order to promote a sound content validity. |

| Instrument | 1st author, publication year | Perspective | Version | Language | Target setting | Measurement aim | Construct and its definition | Measurement model (formative versus reflective) | Number of Subscales (total number of items) 1. name of subscales 1(# items), 2. Name of subscales 2 (# items), | Response-scale; total score range | Development process a) how construct defined; b) item generation; c) item selection; d) pilot test e) (cultural) adaptation/ translation process |
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| **Provider questionnaires** | | | | | | | | | | | |
| **SDM-Q-Doc** Shared Decision Making Questionnaire - provider version | Scholl, 2012[35] | Provider | Original | German | Generic | Providers' perspective of the SDM process | **SDM**: Nine practical steps of the SDM process are: 1. Disclosure that decision needs to be made, 2. Formulation of equality of partners, 3. Equipoise statement, 4. Informing on the benefits and risks of options, 5. Investigation of patient's understanding and expectations, 6. Identification of preferences, 7. Negotiation, 8. Shared decision, 9. Arrangement of follow-up | Assumed to be reflective as Cronbach's alpha calculated | 1 (9) | 6-point scale: 0=completely disagree to 5=completely agree; 0-45, rescaled range 0-100 | a) Literature; b, c) adapted existing questionnaire to assess patient perception of SDM (SDM-Q-9); d) completion rates of providers were used as indicator of acceptance: item level completion rate range 94-95%; e) n/a |

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| **SDM-Q-Doc** (Persian) | Ebrahimi, 2014[46] | Provider | Translation | Persian | Generic | Providers' point of view on SDM | **SDM**: SDM is presenting information for patients to involve them in finalizing the suitable treatment option | Assumed to be reflective as Cronbach's alpha calculated | 1 (9) | 6-point scale: 0=completely disagree to 5=completely agree; 0-45 | a) Literature; b-d) n/a; e) Translated from English to Persian by two bilingual experts (1 physician, 1 researcher aware of research objectives); back-translation by a native English speaker (fluent in Persian; unaware of research aims); back-translation was sent for content check to original authors and their recommendations were considered |
| **SDM-Q-Doc** (Dutch) | Rodenburg, 2015[33] | Provider | Translation | Dutch | Generic | SDM process during a consultation | **SDM**: In partnership with their clinicians, patients are encouraged to consider the likely harms and benefits of available treatment options, communicate their preferences, and select the option that best fits these | Assumed to be reflective as Cronbach's alpha calculated | 1 (9) | 6-point scale: 0=completely disagree to 5=completely agree; 0-45, rescaled range: 0-100 | a) Literature; b-d) n/a; e) multiple forward-backward translations of the original German version by two native Dutch and two native German speakers, comparison and discrepancy discussion in consensus meeting with four team members, including author of original German version; final version presented to clinicians for their opinion on wording (N not reported) |

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| **SDM-Q-Doc** Shared Decision-Making Questionnaire–Physician version | Calderon, 2017[47] | Provider | Translation | Spanish | Generic | Physicians' perspectives on SDM processes | Not reported | Assumed to be reflective as factor analysis is performed | 1 (9) | 6-point scale: 0=completely disagree to 5=completely agree; 0-45 | a) Literature; b-d) n/a; e) using guidelines for cross-cultural adaptation of self-reported measures; two independent bilingual translators (English, Spanish) translated the English version (a translation of the original German version) into Spanish. Translators reached consensus on the translation of words, phrases and items. Four independent physicians and psychologist rated understandability, translation equivalences and content validity. Another two bilingual translators who were blind to the original English version back translated the revised Spanish version; study directors compared and synthesized the back-translation with the original English questionnaire, and determined the final version. The final version was pre-tested in 34 adult patients no modifications were necessary. |

| Instrument | 1st author, publication year | Perspective | Version | Language | Target setting | Measurement aim | Construct and its definition | Measurement model (formative versus reflective) | Number of Subscales (total number of items) 1. name of subscales 1(# items), 2. Name of subscales 2 (# items), | Response-scale; total score range | Development process a) how construct defined; b) item generation; c) item selection; d) pilot test e) (cultural) adaptation/ translation process |
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| **Observer based coding schemes** | | | | | | | | | | | |
| **IDM** Elements of Informed Decision Making | Braddock, 1999[48] | Observer | Original | English | Generic | Characterize the completeness of informed decision making during consultations as a function of the complexity of the decision | **Informed decision making**: Informed decision making is a meaningful dialogue between provider and patient | Unclear | 1 (7) | Frequencies for two scores: a) if item is required (yes/no), b) if item is present (yes/no); not applicable | a) Literature review and professional consensus; b) earlier work of author and iterative group techniques among providers and laypersons to define completeness for basic, intermediate and complex decisions, and to determine complexity of specific kinds of decisions; c) not reported; d) not reported; e) n/a |

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| **DSAT** Decision Support Analysis Tool | Guimond, 2003[49] | Observer | Original | assumed to be English | Generic | Providers' use of decision support and related communication skills during clinical encounters | **SDM**: In an SDM situation, patients' and practitioners' active cognitive and affective participation is imperative for the success of the interaction. Providers actively elicit patients' points of view, help them to express themselves openly, and ask questions about issues that affect decision making | Unclear | 2 Parts: Part 1, 6 categories of decision support skills (22): 1. Discuss decision making status (5), 2. Discuss knowledge/ information (5), 3. Discuss values (4), 4. Discuss support (3), 5. Discuss commitment to act (1), 6. Discuss learning for future decisions (3) and Behaviour not classified (1). Part 2, 4 categories of communication skills (14): 1. Managing the encounter (4), 2. Listening (5), 3. Questioning (2), 4. Sending messages (2) and Behaviour not classified (1) | Frequency of behaviour; not reported | a) Literature and theoretical models; b) existing instrument; c) a panel of researchers, clinicians, and specialists in decision support and communication revised and re-classified the existing instrument; d) not reported; e) n/a |

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| **DSAT-10** Brief Decision Support Analysis Tool | Stacey, 2008[50] | Observer | Revision | English | Generic | Decision support skills | **Decision support**: Decision support is preparing clients for decision making by providing tailored information, clarifying values, and enhancing self-help skills in decision-making and implementation | Unclear | 1 (5 elements encompassing 10 assessment criteria) | dichotomous: present vs. absent; 0-10 | a) Based on the Ottawa Decision Support Framework; b) used items from existing DSAT instrument; c) changed and removed items, simplified scoring procedure; d) five coders trained on original DSAT instrument coded encounters between standardized patients and experienced call centre nurses, their findings were discussed and the DSAT-10 was adjusted based on findings; e) n/a |

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| **OPTION** Observing Patient Involvement scale | Elwyn, 2003[51] | Observer | Original | English | Generic | Extent to which providers involve patient in the decision making process during a consultation | **Patients' engagement in decisions by providers**: Competences of providers to engage patients in decisions: 1. Problem definition (and agreement), 2. Explaining that legitimate choices exist in many clinical situations (i.e., professional "equipoise"), 3. Portraying options and communicating risk about a wide range of issues, 4. Conducting the decision process or its deferment | Assumed to be reflective as Cronbach's alpha calculated | 1 (12) | 5-point scale: 0=strongly agree to 4=strongly disagree; scale range: 0-100 | a) Literature review and assessment of clinical practice; b) based on a theoretical framework defining clinical competences of patient involvement in decision making in clinical consultations, developed based on previous instruments review, appraisal of existing research, and qualitative studies with clinicians and patients; c) iterative pilot study with three cycles over a 12 month-period using simulated consultations (N=6), with GP informants (N=5) and one non-clinical rater (N=1); d) non-clinical raters (N=2) rated audiotaped consultations (N=7) and gave feedback on feasibility and acceptability of instrument; e) n/a |

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| **OPTION** (revised) | Elwyn, 2005[52] | Observer | Revision | English | Generic | Extent to which clinicians involve patients in decision making processes | **Involving patients in decision making**: The process of involving patients in decision making is constituted of clinicians involving patients in the process of understanding the nature of the problem, understanding that there are uncertainties and different likelihoods of harms and benefits, and finally that the patient, if they wish, can influence the decision itself | Assumed to be reflective as Cronbach's alpha calculated | 1 (12) | 5-point scale: 0=behaviour is not observed to 4=behaviour is observed and executed to a high standard; 0-100 | a) Unclear; b-d) n/a; e) existing coding scheme for which labels of response categories were revised based on user feedback with a shift from an attitudinal to a magnitude-based scale |

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| **OPTION** (Italian) | Goss, 2007[53] | Observer | Translation | Italian | Generic | Extent to which providers involve patients in decisions | Not reported | Assumed to be reflective as Cronbach's alpha calculated | 1 (12) | 5-point scale: 0=behaviour is not observed to 4=behaviour is observed and executed to a high standard; 0-48, rescaled range: 0-100 | a) Missing; b-d) n/a; e) translation of the original English version into Italian by two native Italian speakers and compared to reach consensus. This version was checked for language fluency by a teacher of Italian, was then back-translated into English and compared to the original version by a native English speaker. Subsequently an expert panel reached agreement on a final version. After training of the coders, they added more specific criteria definitions for some items to assist in the interpretation of the items; e) n/a |
| **OPTION** (revised) (German) | Hirsch, 2011[54] | Observer | Translation | German | Generic | Extent to which providers involve patients in decisions | Not reported | Assumed to be reflective as Cronbach's alpha calculated | 1 (12) | 5-point scale: 0=behaviour is not observed to 4=behaviour is observed and executed to a high standard; not reported | a) Not reported; b-d) n/a; e) authors refer to other publication describing 4-stage translation process |

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| **OPTION (revised and modified)** (German) | Keller, 2013[55] | Observer | Translation | German | Generic | Extent to which providers involve patients in decisions and active involvement of patients | Not reported | Assumed to be reflective as Cronbach's alpha calculated | 1 (12) | 5-point scale: 0=not observed to 4=active involvement of patient is observed (in earlier version, this was: 'high standard'); 0-48 | a) Not reported; b-d) n/a; e) existing scale (German OPTION), the label of response category four was modified |
| **OPTION**[12] (Dutch) | Stubenrouch, 2016[56] | Observer | Translation | Dutch | Generic | Extent to which healthcare providers involve patients in decision-making | **SDM**: SDM is the process in which both healthcare providers and patients participate to make decisions about their health management strategies, using the best available evidence | Unclear | 1 (12) | 5-point scale: 0=no effort to 4=exemplary effort; 0-60, rescaled range: 0-100 | a) Literature; b-d) n/a; e) Dutch version was already available, but after 2 trained coders applied the instrument, the manual was refined to include more extended descriptions of scoring levels |

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| **Observer OPTION**[5 item] | Elwyn, 2013[57] | Observer | Revision | English | Generic | Essential requirements of SDM when providers make an effort to involve patients in decisions | **SDM**: SDM is composed of justifying deliberative work, followed by the steps of describing options, information exchange, preference elicitation, and preference integration | Formative | 1 (5) | 5-point scale: 0=no effort to 4=exemplary effort; 0-100 | a) Literature; b-d) n/a; e) items selected from pre-existing shared decision making instrument (Observer OPTION12), items selection based on analysis of SDM models and response patterns with OPTION12 |

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| **OPTION**[5] (Dutch) | Stubenrouch, 2016[56] | Observer | Translation | Dutch | Generic | Extent to which healthcare providers involve patients in decision-making | **SDM**: SDM is the process in which both healthcare providers and patients participate to make decisions about their health management strategies, using the best available evidence. | Assumed to be formative as is stated for the original version of this instrument | 1 (5) | 5-point scale: 0=no effort to 4=exemplary effort; 0-20, rescaled range: 0-100 | a) Literature; b-d) n/a; e) 4 members of the research team, who are native Dutch speakers, translated the original English items independently. All four Dutch translations were back translated by an English speaker with fluent command of the Dutch language. The Dutch versions were revised until agreement was reached. Subsequently, after 2 trained coders applied the instrument, the manual was refined to include more extended descriptions of scoring levels |

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| **RPAD** Rochester Participatory Decision-Making Scale | Shields, 2005[58] | Observer | Original | assumed to be English | Generic | Provider behaviours that encourage participatory decision making | **Participatory decision making**: Participatory decision making consists of 2 processes: expert problem solving and decision making. Problem solving is the province of providers whose expertise informs their judgment to determine treatment options. Decision making involves patients working with the provider to determine which treatment options best satisfy the patient's preferences | Unclear | 1 (9) | 3-point scale: 0=no evidence to 1=description of optimal provider behaviour; 0-9 | a) Literature; b) incorporated items suggested in the literature that indicate physician behaviour that encourages patient participation in decision making; c, d) original scale was pilot tested on 10 audio recordings with items that were never coded (N=5) being discarded, 5 new items were added by authors to complete set; e) n/a |

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| **DAS-O** Decision Analysis System for Oncology | Brown, 2010[59] | Observer | Original | assumed to be English | Oncology | Quality of key aspects of SDM during oncology consultations in which treatment options, including clinical trials are discussed | **SDM**: Major evaluation criteria for judging adequacy of SDM from provider and patient perspective: 1. Patient understanding of information and the evidence underpinning the treatment choice, 2. Doctor tailoring of information and involvement to the needs of the patient and facilitation of patient decision making by balancing different options and clarifying values, 3. Patient adjustment to and satisfaction with various aspects of the decision making process and the ultimate decision | Unclear | 5 (70); 1. Establishing the physician-patient team (22), 2. Following a consultation pathway (13) 3. Providing information about standard treatments and clinical trials (20), 4. Promoting clarity (7), 5. Avoiding coercion (8) | 3-point scale: 0=absent, 1=basic, 2=extended; 0-140 | a) Literature review; b) qualitative analyses of audiotaped general oncology consultations (N=26) performed by expert panel from diverse disciplines (ethics, cancer medicine, psycho-oncology, linguistics) following constant comparison method and Systemic Functional Linguistic Approach; c) expert consensus; d) pilot test: authors refer to other publication |

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| **SDM Scale** Shared Decision-Making Scale | Singh, 2010[60] | Observer | Original | assumed to be English | Oncology | SDM behaviours used by cancer specialists in their consultations | **SDM**: In an SDM model, the patient is given information regarding their disease and possible treatments and is a participant along with the provider in medical decision making | Assumed to be reflective as Cronbach's alpha is calculated | 3 (18); 1. Treatment (7), 2. Evidence (8), 3. Patient challenges (3) | 2-point scale: 0=absent, 1=present or non-applicable; total score: 0-18, subscale 0-10 | a) Literature review; b, c) based on literature (including another coding system) a list with key themes and provider behaviours in a consultation was made and reviewed by a team of medical oncologists, oncology nurses and health psychologists; d) coding system created by the team was applied to consultations (N=5), reviewed, and appropriate adjustments were made; e) n/a |

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| **PES** Parental Engagement Scale | Kearney, 2011[61] | Observer | Original | no items yet available | Paediatric palliative care | Parental engagement in decision making and planning for seriously ill children during paediatric palliative care consultations | **Parental engagement**: Parental engagement is a psycho-behavioural construct that denotes not just parental presence but effective participation | Unclear | 3 (not reported); 1. Information-centred dialogue, 2. Insightful participation, 3. Achievement of a collaboratively agreed-upon plan | Not reported; ?-9 (lowest score not reported) | a) Literature review and deductive conceptual reasoning; b, c) first: analysis of consultation narratives with content analyses approach, second: integrative process of construct refinement by two researchers based on an iterative process of grouping categories and identifying observable indicators of behaviour for each category; expert content validity checks with clinical experts in paediatric palliative care (N=3), no results reported; d) actual scoring by two researchers, process not further described; e) n/a |

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| **DEEP-SDM** Detail of Essential Elements and Participants in Shared Decision Making | Clayman, 2012[62] | Observer | Original | English | Generic | Essential elements of shared decision making | **SDM**: SDM is based on the premise that patients should be involved to the extent that they wish, and their values and preferences are crucial to deciding the "right" course of action | Unclear | 1 (13) | Frequencies, except for the item "Degree of decision sharing: 9-point scale: 1=physician-led decision to 9=patient-led decision; not applicable | a) Literature; b) revised previous patient choice instrument and added components; c) not reported; d) two coders independently applied coding scheme to video-recorded consultations of two samples (Sample 1, early stage breast cancer, N=9; Sample 2, metastatic breast cancer patients, N=20), modifications and additions were made to the codebook and the examples within definitions to be more inclusive; e) n/a |

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| **Shared decision making rating** | Salyers, 2012[63] | Observer | Original | assumed to be English | Psychiatry | Level of shared decision making in psychiatric visits | **SDM**: SDM is a collaborative process between a provider and a consumer of health services that entails sharing information and perspectives, and coming to an agreement on a treatment plan | Unclear | 1 (9) | 3-point scale: 0=absent to 2=complete; 0-18 | a) Literature; b) an existing coding scheme (Elements of Informed Decision Making Scale) was adapted based on iterative process of individual coding and consensus discussions, a code to one element was added and ratings were added to i) assess who initiated each element to better identify consumer activity and ii) to classify the level of agreement about decision between provider and consumer; c) not reported; d) pilot phase in which inter-rater reliability was 80% for initial coding, 100% after conferencing; e) n/a |

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| **MAPPIN'SDM**$_{norge}$ (Norge) | Kienlin, 2016 (epub ahead of print)[64] | Observer | Translation | Norwegian | Generic | Patient involvement | Not reported | Unclear | 3 (11 items each) | 5-point scale: 0=behaviour not observed to 4=behaviour observed to an excellent standard; not reported | a) Not reported; b-d) n/a; e) pre-existing instrument (MAPPIN'SDM); forward-backward translation, refinement and consensus in research panel including author of original instrument |

| Instrument | 1st author, publication year | Perspective | Version | Language | Target setting | Measurement aim | Construct and its definition | Measurement model (formative versus reflective) | Number of Subscales (total number of items) 1. name of subscales 1(# items), 2. Name of subscales 2 (# items), | Response-scale; total score range | Development process a) how construct defined; b) item generation; c) item selection; d) pilot test e) (cultural) adaptation/ translation process |
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| **Mixed instruments** | | | | | | | | | | | |
| **Dyadic OPTION** (including two questionnaires Dyadic OPTION[Patient] and Dyadic OPTION[Clinician]) | Melbourne, 2010[65] | Patient, Provider | Original | English | Generic | Extent to which patients have been involved in (shared) decision making | **Participation in decision making**: Participation in decision making, in particular where attempts are made to share decisions, requires both parties to address the issues of decisional equipoise, compare the features of options and achieve consensus about the best actions | Unclear | 1 (12) | 4-point scale: strongly agree to strongly disagree; 0-100 (not specified how to calculate) | a) Literature; b, c) observer OPTION adapted for use as questionnaire and cognitive debriefing interviews; d) three rounds of cognitive debriefing interviews, each round consisted of N=9 participants: N=3 general practitioners and N=6 members of the general public, total N=18. Changes were made after each round; e) n/a |

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| **MAPPIN'SDM Inventory** (including a patient questionnaire, a doctor questionnaire and a coding scheme) (with the possibility to calculate a compound measure, called the SDM Meeting its concept's Assumptions (SDMmass)) | Kasper, 2012[27] | Patient, provider, observer | Original | German | Generic | Interrelations of SDM indicators administered from different perspectives (doctor, patient, observer); (For the SDMmass: Integrative compound measure of SDM) | **Involvement in terms of behaviour**: behaviours attempting to involve the two parties in the decision-making process, i.e., efforts undertaken by doctor or patient to make the particular SDM issue explicit (and by doing so involve each other in the communication). **Result or extent of actual involvement achieved**: perceived (communication) result in terms of SDM, i.e., did the patient or provider feel involved in the communication during the consultation. **SDM**: two way exchange of information within provider-patient dyad involved in decision making. | Assumed to be reflective as Cronbach's alpha calculated | 3 observer scales (15 items each): 1. Observer's perspectives on doctor's SDM behaviour (Obsdoctor) (15), 2. Observer's perspectives on patient's SDM behaviour (Obspatient) (15), 3. Observer's perspectives on both parties SDM behaviour (Obsdyad) (15); 4 questionnaire scales (15): 1. Doctor's perspective on SDM behaviour (Qdocdyad(b)) (15), 2. Doctor's perception of SDM result (Qdocdyad(r)) (15), 3. Patient's perspective on SDM behaviour (Qpatdyad(b)) (15), 4. Patient's perception of SDM result (Qpatdyad(r)) (15) | Questionnaires: 5-point scale: 0=not at all to 4=absolutely true, coding system: 5-point scale: 0=poor performance to 4=excellent performance; not reported (scale range of SDMmass: 0 (no SDM)-1 (perfect SDM) | a) Literature review; b) observer scale: OPTION-12 instrument revised and items added by authors to address identified gaps to create a provider instrument, the wording of this instrument was then changed to apply to patient or dyad; questionnaires based on observer instrument; c) n/a; d) questionnaire piloted with physicians (N=10) and patients (N=10) resulting in item rewording and addition of explanations; e) n/a |

*Reference 42 and 43 both present results of the development and validation for the SMDMQ (Taiwanese), however the results presented seem the exact same in both articles, therefore reference 43 was left out in the data extraction and analysis and also not included in the number of included articles.

**Table 6.** Best level of evidence for each measurement property *per instrument* measuring the process of SDM (N=43)

| | Evaluation studies | Internal consistency | | Test - retest reliability | | Inter-rater reliability | | Intra-rater reliability | | Content validity | | Structural validity/ Item response theory (IRT) | | Hypotheses testing | | Cross-cultural validity | | Criterion validity | | Responsiveness | |
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| **Instrument**[reference(s) to validation study] | # | # | S | # | S | # | S | # | S | # | S | # | S | # | S | # | S | # | S | # | S |
| **Patient questionnaires (N=16)** | | | | | | | | | | | | | | | | | | | | | |
| PPC[66] | 1 | n.a. | | 0 | | n.a. | | n.a. | | 0 | | n.a. | | 1 | ? | n.a. | | 0 | | 0 | |
| CPSpost[66, 67] | 2 | n.a. | | 0 | | n.a. | | n.a. | | 0 | | n.a. | | 2 | ++ | n.a. | | 0 | | 0 | |
| FPI[28] | 1 | 1 | ++ | 1 | + | n.a. | | n.a. | | 0 | | 1 | ++ | 1 | - | n.a. | | 0 | | 0 | |
| COMRADE[38, 68] | 2 | 1 | ? | 0 | | n.a. | | n.a. | | 0 | | 2 | -- | 2 | - | n.a. | | 0 | | 0 | |
| SDM-Q[39] | 1 | n.a. | | 0 | | n.a. | | n.a. | | 0 | | IRT:1 | IRT: -- | 1 | ? | n.a. | | 0 | | 0 | |
| SDM-Q-9[29, 69] | 2 | 2 | +++ | 0 | | n.a. | | n.a. | | 0 | | 1 | +++ | 1 | -- | n.a. | | 0 | | 0 | |
| SDM-Q-9 (Spanish)[30-32] | 3 | 3 | +++ | 0 | | n.a. | | n.a. | | 1 | ? | 2 / IRT:1 | +++ / IRT:++ | 0 | | 2 | + | 0 | | 0 | |
| SDM-Q-9 (Dutch)[33] | 1 | 1 | +++ | 0 | | n.a. | | n.a. | | 0 | | 1 | +++ | 1 | - | 0 | | 0 | | 0 | |
| SDM-Q-9 Psy (Hebrew)[34] | 1 | 1 | ++ | 0 | | n.a. | | n.a. | | 0 | | 1 | ++ | 1 | + | 0 | | 0 | | 0 | |
| SDM-Q-9 (English)[30] | 1 | 1 | +++ | 0 | | n.a | | n.a | | 0 | | 0 | | 0 | | 1 | ? | 0 | | 0 | |
| CollaboRATE[70] | 1 | n.a. | | 0 | | n.a. | | 1 | ++ | 0 | | n.a. | | 1 | - | n.a. | | 0 | | 1 | ? |
| CollaboRATE (Swedish)[41] | 1 | 1 | ? | 1 | - | n.a | | n.a | | 0 | | 0 | | 1 | - | 0 | | 0 | | 0 | |
| SMDMQ (Taiwanese)[42, 43]* | 1 | n.a. | | 0 | | n.a. | | n.a. | | 1 | ? | IRT:1 | IRT:-- | 0 | | n.a. | | 0 | | 0 | |
| SDM Process Score[44] | 1 | 0 | | 0 | | n.a. | | n.a. | | 0 | | 0 | | 1 | + | n.a. | | 0 | | 0 | |
| MADM[45] | 1 | 1 | +++ | 0 | | n.a | | n.a | | 0 | | 1 | ? | 1 | ? | n.a | | 0 | | 0 | |
| Dyadic OPTION patient version (Swedish)[41] | 1 | 1 | ? | 1 | - | n.a | | n.a | | 0 | | 0 | | 1 | - | 0 | | 0 | | 0 | |

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Provider questionnaires (N=4)** | | | | | | | | | | | | | | | | | | | |
| SDM-Q-Doc[35] | 1 | 1 | +++ | 0 | | n.a. | | n.a. | | 0 | | 1 | +++ | 0 | | n.a. | | 0 | |
| SDM-Q-Doc (Persian)[46] | 1 | 1 | ? | 1 | ? | n.a. | | n.a. | | 0 | | 0 | | 0 | | 0 | | 0 | |
| SDM-Q-Doc (Dutch)[33] | 1 | 1 | +++ | 0 | | n.a. | | n.a. | | 0 | | 1 | +++ | 1 | - | 0 | | 0 | |
| SDM-Q-Doc (Spanish)[47] | 1 | 1 | ? | 0 | | n.a. | | n.a. | | 1 | ? | 1 | ? | 1 | ? | 0 | | 0 | |
| **Observer-based coding schemes (N=18)** | | | | | | | | | | | | | | | | | | | |
| IDM[71] | 1 | 0 | | n.a. | | 0 | | 0 | | 0 | | 0 | | 1 | - | n.a. | | 0 | |
| DSAT[49, 72] | 2 | 0 | | n.a. | | 1 | ? | 0 | | 0 | | 0 | | 2 | +/- | n.a. | | 0 | |
| DSAT-10[50] | 1 | 0 | | n.a. | | 1 | -- | 0 | | 0 | | 0 | | 0 | | n.a. | | 0 | |
| OPTION[51, 72] | 2 | 0 | ? | n.a. | | 1 | -- | 1 | ? | 0 | | 1 | -- | 2 | -- | n.a. | | 0 | |
| OPTION (revised)[52, 71, 73, 74] | 4 | 1 | ? | n.a. | | 3 | -- | 2 | ? | 0 | | 1 | --- | 2 | - | n.a. | | 0 | |
| OPTION (Italian)[53] | 1 | 1 | + | n.a. | | 1 | + | 1 | + | 0 | | 1 | ? | 0 | | 0 | | 0 | |
| OPTION (revised)(German)[54] | 1 | 1 | ? | n.a. | | 1 | - | 0 | | 0 | | 1 | ++ | 1 | - | 0 | | 0 | |
| OPTION (revised and modified (German)[55] | 1 | 1 | ? | n.a. | | 1 | ? | 0 | | 0 | | 0 | | 1 | ? | 0 | | 0 | |
| OPTION[12] (Dutch)[56] | 1 | 0 | | n.a. | | 1 | ? | 0 | | 0 | | 0 | | 0 | | 0 | | 0 | |
| Observer OPTION[5 item, 74, 75] | 2 | n.a. | | n.a. | | 2 | -- | 1 | ? | 0 | | n.a. | | 2 | ++ | n.a. | | 0 | |
| OPTION[5] (Dutch)[56] | 1 | n.a. | | n.a. | | 1 | ? | 0 | | 0 | | n.a. | | 1 | + | 0 | | 0 | |
| RPAD[58] | 1 | 0 | | n.a. | | m | m | m | m | 0 | | 0 | | 1 | - | n.a. | | 0 | |
| DAS-O[59, 72]** | 1 | 0 | | n.a. | | 1 | ? | 1 | ? | 1 | ++ | 0 | | 1 | - *** | n.a. | | 0 | |
| SDM Scale[60] | 1 | 1 | ? | n.a. | | 1 | ? | 1 | ? | 0 | | 1 | ? | 1 | + | n.a. | | 0 | |
| PES[no validation study published] | 0 | 0 | | n.a. | | 0 | | 0 | | 0 | | 0 | | 0 | | n.a. | | 0 | |
| DEEP-SDM[no validation study published] | 0 | 0 | | n.a. | | 0 | | 0 | | 0 | | 0 | | 0 | | n.a. | | 0 | |
| Shared decision-making rating[63] | 1 | 0 | | n.a. | | 1 | ? | 0 | | 0 | | 0 | | 0 | | n.a. | | 0 | |
| MAPPIN'SDM$_{norge}$ (Norwegian)[64] | 1 | 0 | | n.a. | | 1 | - | 0 | | 0 | | 0 | | 1 | - | 0 | 1 | ? | 0 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Mixed instruments (N=2 measuring N=5 different perspectives)** | | | | | | | | | | | | | | | |
| dyadic OPTION[Patient 26] | 1 | 0 | | 0 | n.a. | | n.a. | 0 | | 0 | 1 | - | n.a. | 0 | 0 |
| dyadic OPTION[Clinician 26] | 1 | 0 | | 0 | n.a. | | n.a. | 0 | | 0 | 1 | + | n.a. | 0 | 0 |
| MAPPIN'SDM patient questionnaire[27, 76] **** | 1 | 1 | ? | 0 | n.a. | | n.a. | 1 | ++ | 0 | 1 | - | n.a. | 0 | 0 |
| MAPPIN'SDM doctor questionnaire[27, 76] **** | 1 | 1 | ? | 0 | n.a. | | n.a. | 1 | ++ | 0 | 1 | - | n.a. | 0 | 0 |
| MAPPIN'SDM coding scheme[27, 76, 77] **** | 2 | 0 | | n.a. | 2 | -- | 0 | 0 | | 0 | 2 | -- | n.a. | 0 | 0 |

S = result of best-evidence synthesis. n.a. = the measurement property is not applicable to this instrument. m = missing. Rating: +++/ --- Strong level of evidence for positive/negative results, ++/ -- Moderate level of evidence for positive/negative results, +/- Limited evidence for positive/negative results, +/- Conflicting evidence, ? = Unknown, due to poor methodological quality, empty cell = No synthesis possible due to a lack of validation studies for this measurement property. Measurement error was left out from the Table because it has not been evaluated for any of the instruments included.

# = number of studies on which the best-evidence synthesis regarding the measurement property was based

*Reference 42 and 43 both present results of the development and validation for the SMDMQ (Taiwanese), however the results presented seem the exact same in both articles, therefore reference 43 was left out for the data extraction and analysis and also not included in the number of included articles.

** Reference 59 and 72 both present hypotheses testing for the DAS-O, however reference 72 was based on the same dataset as reference 59, therefore reference 72 was left out for the data extraction and analysis and also not included in the number of included articles.

*** There is a negative score for hypotheses testing because the authors had hypothesized that correlations would be medium-sized but they actually found strong relationships with instruments measuring the same construct.

**** Reference 27 and 76 both present results about internal consistency for the MAPPIN'SDM patient and doctor questionnaire and about inter-rater reliability for the MAPPIN'SDM coding scheme, however reference 76 made use of the same dataset as reference 27, therefore reference 76 was left out for the data extraction and analysis and also not included in the number of included articles.

### 3.3.1 Overall results on which measurement properties are evaluated

The measurement property evaluation results are presented in Table 7. The number of instruments for which each of the different measurement properties have been evaluated, taking into account whether the property was applicable or not, is presented in Table 7, column 2 and 3. Two measurement properties were evaluated in more than two-thirds of the instruments: hypotheses testing, and intra-rater reliability in case of coding schemes. Seven measurement properties were evaluated in less than one-third of instruments: Test-retest reliability, measurement error, content validity, cross-cultural validity, criterion validity, responsiveness, and the floor and ceiling effects and minimal important change values, both aspects of interpretability. Of note, internal consistency and structural validity were evaluated for a majority of questionnaires, but a minority of coding schemes.

### 3.3.2 Overall results on the methodological quality of included validation studies

The methodological quality used was excellent or good in at least half of the studies for the measurement properties of content validity (50%) and structural validity (82%) (Table 8). The methodological quality was poor in at least half of the studies for the measurement properties of internal consistency (52%), inter-rater reliability (53%), intra-rater reliability (75%), and content validity (50%). The quality of validation studies was more often good or excellent for questionnaires than for coding schemes with regard to internal consistency (58% in case of questionnaires, none in case of coding schemes) and structural validity (92% in case of questionnaires, 40% in case of coding schemes). A rating of “poor” in the quality assessment of internal consistency testing was most often due to a lack of factor analysis (COSMIN checklist for internal consistency, item 5) or lack of an internal consistency statistic for subscales (COSMIN checklist for internal consistency, item 7). For inter- and intra-rater reliability testing, a rating of “poor” was most often due to small sample sizes (COSMIN checklist for reliability, item 3) or to the application of statistical methods that were inappropriate for the measurement level of the scale (COSMIN checklist for reliability, items 11-14).

**Table 7.** Overall results on best-evidence synthesis per measurement property of instruments measuring the process of SDM (N=43)

| Measurement property | Applicable to instruments | Evaluated for instruments | | Overall level of evidence | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Unknown | | Negative* | | Conflicting | | Positive* | |
| | N | N | % | N | % | N | % | N | % | N | % |
| **Internal consistency** | | | | | | | | | | | |
| Total | 36 | 22 | (61) | **12** | **(55)** | 0 | (0) | 0 | (0) | 10 | (46) |
| Questionnaires | 19 | 16 | (84) | **7** | (44) | 0 | (0) | 0 | (0) | **9** | **(56)** |
| Coding schemes | 17 | 6 | (35) | **5** | **(83)** | 0 | (0) | 0 | (0) | 1 | (17) |
| **Test-retest reliability** | | | | | | | | | | | |
| Total | 24 | 4 | (17) | - | - | - | - | - | - | - | - |
| Questionnaires | 24 | 4 | (17) | - | - | - | - | - | - | - | - |
| Coding schemes | 0 | n.a. | n.a. | - | - | - | - | - | - | - | - |
| **Inter-rater reliability** | | | | | | | | | | | |
| Total | 19 | 15 | (79) | **7** | (47) | 7 | (47) | 0 | (0) | 1 | (7) |
| Questionnaires | 0 | n.a. | n.a. | - | - | - | - | - | - | - | - |
| Coding schemes | 19 | 15 | (79) | **7** | (47) | 7 | (47) | 0 | (0) | 1 | (7) |
| **Intra-rater reliability** | | | | | | | | | | | |
| Total | 19** | 7 | (37) | **5** | **(71)** | 0 | (0) | 0 | (0) | 2 | (29) |
| Questionnaires | 0** | 1 | n.a. | - | - | - | - | - | - | - | - |
| Coding schemes | 19 | 6 | (33) | **5** | **(83)** | 0 | (0) | 0 | (0) | 1 | (17) |
| **Measurement error** | | | | | | | | | | | |
| Total | 43 | 0 | (0) | - | - | - | - | - | - | - | - |
| Questionnaires | 43 | 0 | (0) | - | - | - | - | - | - | - | - |
| Coding schemes | 43 | 0 | (0) | - | - | - | - | - | - | - | - |
| **Content validity** | | | | | | | | | | | |
| Total | 43 | 6 | (14) | **3** | **(50)** | 0 | (0) | 0 | (0) | **3** | **(50)** |
| Questionnaires | 24 | 5 | (21) | **3** | **(50)** | 0 | (0) | 0 | (0) | **3** | **(50)** |
| Coding schemes | 19 | 1 | (5) | - | - | - | - | - | - | - | |
| **Structural validity** | | | | | | | | | | | |
| Total | 36 | 15 | (42) | 4 | (27) | 3 | (20) | 0 | (0) | **8** | **(53)** |
| Questionnaires | 19 | 10 | (56) | 2 | (20) | 1 | (10) | 0 | (0) | **7** | **(70)** |
| Coding schemes | 17 | 5 | (29) | 2 | (40) | 20 | (40) | 0 | (0) | 1 | (20) |
| **Hypotheses testing** | | | | | | | | | | | |
| Total | 43 | 32 | (74) | 5 | (16) | **19** | **(59)** | 1 | (43) | 7 | (22) |
| Questionnaires | 24 | 19 | (79) | 4 | (21) | **11** | **(58)** | 0 | (0) | 4 | (21) |
| Coding schemes | 19 | 13 | (68) | 1 | (8) | **8** | **(62)** | 1 | (8) | 3 | (23) |
| **Cross-cultural validity** | | | | | | | | | | | |
| Total | 15 | 2 | (13) | - | - | - | - | - | - | - | - |
| Questionnaires | 9 | 2 | (22) | - | - | - | - | - | - | - | - |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Coding schemes | 6 | 0 | (0) | - | - | - | - | - | - | - | - |
| **Criterion validity** | | | | | | | | | | | | |
| Total | 43 | 1 | (2) | - | - | - | - | - | - | - | - |
| Questionnaires | 24 | 0 | (0) | - | - | - | - | - | - | - | - |
| Coding schemes | 19 | 1 | (5) | - | - | - | - | - | - | - | - |
| **Responsiveness** | | | | | | | | | | | | |
| Total | 43 | 1 | (2) | - | - | - | - | - | - | - | - |
| Questionnaires | 24 | 1 | (4) | - | - | - | - | - | - | - | - |
| Coding schemes | 19 | 0 | (0) | - | - | - | - | - | - | - | - |
| **Interpretability: Floor and ceiling effects** | | | | | | | | | | | | |
| Total | 43 | 11 | (26) | - | - | - | - | - | - | - | - |
| Questionnaires | 24 | 7 | (29) | - | - | - | - | - | - | - | - |
| Coding schemes | 19 | 4 | (21) | - | - | - | - | - | - | - | - |
| **Interpretability: Minimal important change** | | | | | | | | | | | | |
| Total | 43 | 0 | (0) | - | - | - | - | - | - | - | - |
| Questionnaire | 24 | 0 | (0) | - | - | - | - | - | - | - | - |
| Coding schemes | 19 | 0 | (0) | - | - | - | - | - | - | - | - |

Colour-coding is used to indicate that a specific measurement property had a particular direction regarding the best level of evidence in ≥ 50% of instruments (blue=unknown, red=negative and green=positive) and the best evidence synthesis was performed for at least five instruments. n.a. = not applicable.

* Results in negative or positive direction have either a "limited", "moderate" or "strong" level of evidence, based on the best-evidence synthesis.

** The measurement property intra-rater reliability is usually not applicable to questionnaires. Authors of one questionnaire have used this type of evaluation as an alternative for test-retest reliability assessment.

### 3.3.3 Overall results on the best evidence synthesis of included instruments

The best available evidence was unknown for 50% or more of the instruments for the measurement properties of internal consistency, intra-rater reliability, and content validity due to poor methods (Table 7). For two measurement properties, the best available evidence indicated positive results (limited, moderate, or strong) for 50% or more of the instruments: Content validity and structural validity. The best available evidence indicated negative results (limited, moderate, or strong) for hypotheses testing for 59% of the instruments and for inter-rater reliability for 47% of the instruments. Results for questionnaires were overall more positive and for coding schemes more often unknown regarding internal consistency and structural validity.

**Table 8.** Overall results on methodological quality of the studies that evaluated measurement properties of instruments measuring the process of SDM, as based on COSMIN checklist scoring

| Measurement property | Total number of assessments | Methodological quality rating | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Poor | | Fair | | Good | | Excellent | |
| | N | N | % | N | % | N | % | N | % |
| **Internal consistency** | | | | | | | | | |
| Total | 25 | **13** | **(52)** | 1 | (4) | 5 | (20) | 6 | (24) |
| Questionnaires | 19 | **8** | **(42)** | 0 | - | 5 | (26) | 6 | (32) |
| Coding schemes | 6 | **5** | **(83)** | 1 | (17) | 0 | - | 0 | - |
| **Inter-rater reliability** | | | | | | | | | |
| Total | 19 | **10** | **(53)** | 4 | (21) | 5 | (26) | 0 | - |
| Questionnaires | 0 | | | | | | | | |
| Coding schemes | 19 | **10** | **(53)** | 4 | (21) | 5 | (26) | 0 | - |
| **Intra-rater reliability** | | | | | | | | | |
| Total | 8 | **6** | **(75)** | 1 | (13) | 1 | (13) | 0 | - |
| Questionnaires | 1 | 0 | - | 0 | - | 1 | (100) | 0 | - |
| Coding schemes | 7 | **6** | **(86)** | 1 | (14) | 0 | - | 0 | - |
| **Content validity** | | | | | | | | | |
| Total | 6 | **3** | **(50)** | 0 | - | **3** | **(50)** | 0 | - |
| Questionnaires | 5 | 3 | (60) | 0 | - | 2 | (40) | 0 | - |
| Coding schemes | 1 | 0 | - | 0 | - | 1 | (100) | 0 | - |
| **Structural validity** | | | | | | | | | |
| Total | 17 | 2 | (12) | 1 | (6) | **8** | **(47)** | **6** | **(35)** |
| Questionnaires | 12 | 0 | - | 1 | (8) | **6** | **(50)** | **5** | **(42)** |
| Coding schemes | 5 | 2 | (40) | 0 | - | 1 | (20) | 1 | (20) |
| **Hypotheses testing** | | | | | | | | | |
| Total | 39 | 8 | (21) | **26** | **(67)** | ~~4~~5 | (13) | 0 | - |
| Questionnaires | 21 | 5 | (24) | **13** | **(62)** | 3 | (14) | 0 | - |
| Coding schemes | 18 | 3 | (17) | **13** | **(72)** | 2 | (11) | 0 | - |

Colour-coding is used to indicate that the assessment of a specific measurement property had a particular level of quality in ≥ 50% of studies (red=poor, yellow=fair and green=good or excellent) and the assessment had been done in at least five studies; we summed the categories 'good' and 'excellent' for this purpose.

## 4. DISCUSSION

The aim of this systematic review was to provide an overview of the measurement quality of existing instruments measuring the process of SDM. In total, 40 instruments were included in our analysis; primarily patient questionnaires or observer-based coding schemes, but also a few provider questionnaires and 'mixed' instruments. There is a general lack of evidence for the appraisal of most measurement properties. This is either because the property was not evaluated, or because the methodology applied was of poor quality. The best-evidence synthesis indicated positive results for at least half of the instruments that have investigated content validity (50%) and structural validity (53%), but negative results for a major part of instruments that have been evaluated for inter-rater reliability (47%) and hypotheses testing (59%). We will highlight the results that in our opinion are most relevant for further validation of existing instruments and the development of new instruments, and provide recommendations for future research.

### 4.1 Lack of detailed description and assessment of the construct

During data extraction, we noticed that instrument developers often only provided a vague definition of the construct being measured or none at all. Furthermore, or as a consequence of this, for only 14% of the instruments content validity testing was described, (including assessment of item relevance and comprehensiveness of the item set for the measured construct). Additionally, the underlying measurement model was made explicit for only two instruments, with a formative model applied in both instances. The major difference between reflective and formative models is the direction of causality between the construct and its items. In formative models the latent construct of interest is a result of independent items measured (causal indicators), whereas in reflective models the latent construct determines the items (effect indicators) being measured.[78, 79] Therefore, exploratory factor analysis and internal consistency are only relevant for reflective models. In 2011, Wollschläger called upon the SDM field to reach consensus on the most suitable underlying model,[80] but it appears that the field is only slowly responding to this call. For most questionnaires, the authors apparently assumed a reflective model as they assessed factor structure and/or internal consistency. However, this practice may have resulted from a lack of a clear definition of the construct, which is needed to correctly specify the underlying measurement model (see Jarvis et al. 2003, Table 3),[78] or from the assumption that assessing these properties is required, even when inappropriate. Following the steps Jarvis presents to decide on the most suitable model, we suggest that it may be more suitable to assume a formative model to measure the process of SDM. Definitions of the SDM process often contain required but independent steps, each of which do not necessarily relate to each other. Changes in one or more of these steps result in changes in levels of SDM, but changes in SDM are not necessarily reflected in changes in all items. That is, a physician explaining that a decision has to be made will increase measures of the SDM process, but increases in the SDM process will not necessarily be reflected in a physician explaining that a decision has to be made. Choosing a formative model has implications for the development of an instrument, as factor structure and internal consistency are not relevant to determine validity of instruments with formative models, and thus cannot inform the selection of the items. For instrument with formative models, content validity testing is therefore even more relevant to make the final selection of items. We want to stress the importance of a clear construct definition and sound content

validity testing as a first step in the development and validation of measurement instruments. In any case, the choice of the underlying model should be explicitly described.

### 4.2 Lack of stability

Test-retest evaluations of questionnaires were performed infrequently (for 17% of questionnaires). The main barrier might be that it cannot be assumed that patients' and providers' views are stable between test and retest. Decisions might have been made and/or acted upon which can bias how participants look back on decision processes. Despite these barriers, from a psychometric point of view, lack of stability evaluations of the questionnaires compromises the interpretation of questionnaire results. As an alternative, the developers of the CollaboRATE used analogue patients to determine the intra-rater reliability of their questionnaire.[70] Investigating the validity of this and other methods as possible equivalents for test-retest reliability testing may prove valuable for psychometric testing of SDM measures.

Inter-rater reliability of coding scheme scores has often been assessed but these assessments frequently show negative results, raising questions about the stability of the scores. Caution should be applied when comparing observer scores between studies when intra-rater reliability is poor. Training might improve agreement between the coders within a study. However, training does not automatically improve inter-rater agreement between research groups. More detailed definitions of items and response scales and more frequent consensus discussions throughout the coding process limit the opportunity for subjective interpretation of the items, and thus might improve inter-rater reliability further.

### 4.3 Hypotheses testing: poor results or poor hypotheses?

The best-evidence synthesis showed that results on hypotheses testing, as a means to assess construct validity, indicated negative results for more than half of the instruments for which this was evaluated. The hypotheses tested (see online supporting information - *https://figshare.com/articles/dataset/The_quality_of_instruments_to_assess_the_process_of_shared_decision_making_A_systematic_review/5892685?file=10499863*) that were not confirmed often assessed relationships with instruments that measure (slightly) different constructs (e.g., satisfaction with decision, patients' information seeking preference, anxiety). Also, hypotheses about relationships with instruments that measure the same construct, whether measured from the same or from a different perspective, were often not confirmed or did not reach the threshold for positive results for correlation coefficients of ≥0.50. This leads us to conclude that poor results for hypotheses testing might reveal methodological problems regarding the suitability of comparators that authors have chosen–which is not accounted for in our COSMIN rating. Until we reach consensus on how to define the process of SDM and on whether SDM viewed from the perspective of the provider, patient, or observer can be regarded as the same construct, authors should be careful in formulating hypotheses for construct validity testing. A good alternative for hypotheses testing about the relationship between instruments that define the construct differently or that measure the same construct but from another perspective could be to assess known group differences.

### 4.4 Lack of insight into the ability to measure change and to interpret change

Measurement properties relevant to the validity and interpretation of change scores have barely been studied. This is in line with what Scholl et al. already concluded in 2011. Measurement error, responsiveness (evaluated once but using poor methods)[70] and minimal important change values are unknown for the instruments included, even though they are indispensable for interpreting results of intervention studies. Anchor-based methods that make use of an external criterion[81] are well-suited to determine which change is regarded as relevant in terms of important improvements or deteriorations of the process of SDM. Another obstacle however is that the determination of measurement error is essential for the interpretation of minimal important change values, but its determination might face the same barriers as the test-retest evaluation.

### 4.5 Strengths and limitations of the review

A first strength of our study was the comprehensive search in multiple online databases, for which we set no time limits on publication date, nor did we exclude any type of instrument (i.e. patient questionnaires, provider questionnaires or observer based coding schemes). Second, two raters and when necessary three, evaluated the eligibility of articles, extracted the data, and performed the quality appraisal for each measurement property. We therefore expect our results to be highly valid. Third, to provide an unbiased appraisal of the measurement quality of included instruments, we took into account the results and methodological quality of all their validation studies for the best-evidence synthesis and we rated methodological quality based on the widely-accepted COSMIN standards. Fourth, due to the high number of included instruments, we were able to provide insight into overall trends on the existence of measurement property evaluations, their quality, and the overall quality of instruments. This insight makes it possible to provide general recommendations on how to improve the quality of SDM process instruments and their validation studies.

Our study has some limitations. First, to be eligible for inclusion an article must describe a study that aimed to develop a SDM-process instrument or that validates a SDM-process instrument. We might have missed relevant articles if development or validation of an instrument was not explicitly mentioned in either its title or its abstract. Second, an overrepresentation of data may have biased our best-evidence synthesis. That is, the number of validation studies influences the rating of the best level of evidence and strictly speaking, one should correct this number for those instances when validation studies have been performed once, but authors have published about the same data in multiple articles, but with slightly different foci. We corrected for this phenomenon three times; for the SMDMQ (Taiwanese), the DAS-O and the MAPPIN'SDM (see the footnotes underneath Table 6). However, we cannot state with certainty that overrepresentation is not at stake for other instruments. We recommend more explicit reporting of multiple data use when publishing secondary analyses. Third, our analysis was limited to the evaluation of the measurement properties of existing SDM process instruments. It does not include a detailed analysis of the content of these instruments. To gain more insight into what exactly they measure and what not, further research on the operationalization of existing SDM process instruments is needed. Furthermore, our quality evaluation of SDM process instruments is only applicable for research settings and at a group level. No conclusions can be drawn on the suitability

of these instruments for other purposes, such as for the evaluation of individual healthcare providers' SDM skills. With the current emphasis on value-based healthcare, the applicability of instruments measuring the process of SDM within routine clinical settings needs to be investigated in future research.

## 4.6 Conclusions

A large number of instruments are available to assess the SDM process, but, evidence is lacking regarding the measurement quality of these instruments, partly because measurement properties have not been evaluated at all, partly because the validation studies are of poor quality. Clearly, this does not imply that existing instruments measuring the process of SDM are of poor quality, but that often their quality is unknown. In practice, the choice for the most appropriate instrument can therefore best be based on the content of the instrument and other characteristics of the instruments that suit best the aim of the study and the resources available for the study, such as the perspective that is assessed and the number of items. We suggest the following recommendations for quality improvement of existing instruments and their validation studies:

- Provide a clear definition of the construct of SDM process.
- Perform content validity analyses prior to further validation.
- Include large-enough sample sizes in validation studies; improvement of sample sizes is especially needed for inter- and intra-rater reliability testing of coding schemes.
- Seek alternative ways to evaluate test-retest reliability of questionnaires for the process of SDM.
- Find ways to improve inter-rater reliability of coding schemes; e.g., by providing more detailed descriptions of coding scheme items.
- Include constructs that are as similar as possible to the process of SDM when formulating hypotheses to evaluate construct validity, and, alternatively, make use of known-group differences testing.
- Determine minimal important change values to inform the interpretation of change scores in intervention studies.

Above all, we recommend to further evaluate and refine existing instruments and to adhere as best as possible to the COSMIN guidelines[20, 21, 23] to help guarantee high-quality evaluations.

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## Appendix A.

### Search strategy

### PubMed

((("Decision Making"[majr:noexp] OR decision making[tiab] OR decision making[ot] OR decisionmaking[tiab] OR decisionmaking[ot]) AND (professional-patient relations[majr] OR ((Patient[tiab]) AND (provider[tiab] OR physician[tiab] OR professional[tiab] OR doctor[tiab]) AND (relation[tiab] OR relations[tiab] OR contact[tiab] OR communication[tiab] OR interaction[tiab] OR interactions[tiab])) OR ((Patient[ot]) AND (provider[ot] OR physician[ot] OR professional[ot] or doctor[ot]) AND (relation[ot] OR relations[ot] OR contact[ot] OR communication[ot] OR interaction[ot] OR interactions[ot])) OR Patient participation[majr] OR Patient Participation[tiab] OR patient participation[ot] OR patients participation[tiab] OR patients participation[ot] OR patient's participation[tiab] OR patient's participation[ot] OR patient involvement[tiab] OR patient involvement[ot] OR patients involvement[tiab] OR patients involvement[ot] OR patient's involvement[tiab] OR patient's involvement[ot] OR consultation*[tiab] OR encounter[tiab] OR consultation*[ot] OR encounter[ot])) OR shared decision[tiab] OR shared decision[ot] OR shared decisions[tiab] OR shared decisions[ot] OR shared decisionmaking[tiab] OR shared decisionmaking[ot] OR SDM[tiab] OR SDM[ot] OR Shared medical decision[tiab] OR Shared medical decision[ot] OR Shared treatment decision[tiab] OR Shared treatment decision[ot] OR Shared medical decisions[tiab] OR Shared medical decisions[ot] OR Shared treatment decisions[tiab] OR Shared treatment decisions[ot] OR Shared clinical decision[tiab] OR Shared clinical decision[ot] OR Shared clinical decisions[tiab] OR Shared clinical decisions[ot])

AND

(Health Care Surveys [majr:noexp] OR "Outcome and Process Assessment (Health Care)"[majr:noexp] OR "Outcome Assessment(Health Care)"[majr:noexp] OR "Patient Outcome Assessment"[majr:noexp] OR "Questionnaires"[majr] OR scale[tiab] OR scale[ot] OR scales[tiab] OR scales[ot] OR instrument[tiab] OR instrument[ot] OR instruments[tiab] OR instruments[ot] OR questionnaire[tiab] OR questionnaire[ot] OR questionnaires[tiab] OR questionnaires[ot] OR survey[tiab] OR survey[ot] OR surveys[tiab] OR surveys[ot] OR assess*[tiab] OR assess*[ot] OR coding scheme[tiab] OR coding scheme[ot] OR coding schemes[tiab] OR codingscheme[tiab] OR codingscheme[ot] OR codingschemes[tiab] OR codingschemes[ot] OR rating[tiab] OR rating[ot] OR ratings[tiab] OR ratings[ot] OR selfreport[tiab] OR selfreport[ot] OR self report[tiab] OR self report[ot] OR selfreports[tiab] OR selfreports[ot] OR self reports[tiab] OR self reports[ot] OR "Checklist"[majr] OR measure[tiab] OR measure[ot] OR measures[tiab] OR measures[ot] OR "observation"[majr] OR observation[tiab] OR observation[ot] OR observations[tiab] OR observations[ot])

AND

(instrumentation[sh] OR methods[sh] OR Validation Studies[pt] OR Comparative Study[pt] OR "psychometrics"[MeSH] OR psychometr*[tw] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)"[MeSH] OR outcome assessment[tw] OR outcome measure*[tw] OR "observer variation"[MeSH] OR observer variation[tiab] OR "Health Status Indicators"[MeSH] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency"[tiab]

OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tiab] OR precision[tiab] OR imprecision[tiab] OR "precise values"[tiab] OR test–retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tiab] OR ((replicab*[tiab] OR repeated[tiab]) AND (measure[tiab] OR measures[tiab] OR findings[tiab] OR result[tiab] OR results[tiab] OR test[tiab] OR tests[tiab])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR factor analysis[tiab] OR factor analyses[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR item discriminant[tiab] OR interscale correlation*[tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR meaningful change[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab])
NOT
("addresses"[Publication Type] OR "biography"[Publication Type] OR "case reports"[Publication Type] OR "comment"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "festschrift"[Publication Type] OR "interview"[Publication Type] OR "lectures"[Publication Type] OR "legal cases"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "patient education handout"[Publication Type] OR "popular works"[Publication Type] OR "congresses"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "practice guideline"[Publication Type]) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms])

See *https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0191747#sec028* for the search strategy used in Academic Search Premier, Cochrane, Embase, Emcare, PsycINFO, and Web of Science.

## Appendix B.

### Methodological quality and quality of measurement properties of each article per measurement property and instrument version

| Instrument | 1st author, year | Internal consistency | | Test-retest reliability | | Inter- rater reliability | | Intra-rater reliability | | Content validity | | Structural validity/ Item response theory (IRT) | | Hypotheses testing | | Cross-cultural validity (G) / Criterion validity (H)/ Responsiveness (I) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | M | R | M | R | M | R | M | R | M | R | M | R | M | R | M | R |
| **Patient questionnaires** | | | | | | | | | | | | | | | | | |
| PPC | Entwistle, 2001[66] | n.a. | | n.i. | | n.a. | | n.a. | | n.i. | | n.a. | | poor | - | | |
| CPSpost | Entwistle, 2001[66] | n.a. | | n.i. | | n.a. | | n.a. | | n.i. | | n.a. | | poor | - | | |
| | Kremer, 2008[67] | n.a. | | n.i. | | n.a. | | n.a. | | n.i. | | n.a. | | good | + | | |
| FPI | Martin, 2001[28] | good | + | fair | + | n.a. | | n.a. | | n.i. | | good | + | fair | - | | |
| COMRADE | Edwards, 2003[38] | n.i. | | n.i. | | n.a. | | n.a. | | n.i. | | fair | + | poor | - | | |
| | Knapp, 2009[68] | poor | + | n.i. | | n.a. | | n.a. | | n.i. | | good | - | fair | - | | |
| SDM-Q | Simon, 2006[39] | n.a. | | n.i. | | n.a. | | n.a. | | n.i. | | IRT: good | - | poor | - | | |
| SDM-Q-9 | Kriston, 2010[29] | excellent | + | n.i. | | n.a. | | n.a. | | n.i. | | excellent | + | n.i. | | | |
| | Scholl, 2012[69] | good | + | n.i. | | n.a. | | n.a. | | n.i. | | n.i. | | good | - | | |
| SDM-Q-9 (Spanish) | De las Cuevas, 2014[32] | poor | + | n.i. | | n.a. | | n.a. | | poor | ? | good | + | n.i. | | CC: fair | + |
| | Alvarez, 2016[30] | good | + | n.i. | | n.i. | | n.i. | | n.i. | | n.i. | | n.i. | | CC: poor | + |
| | Ballesteros, 2017[31] | good | + | n.i. | | n.i. | | n.i. | | n.i. | | CFA: good / IRT: good | CFA: +/ IRT: + | n.i. | | | |
| SDM-Q-9 (Dutch) | Rodenburg-VandenBussche, 2015[33] | excellent | + | n.i. | | n.a. | | n.a. | | n.i. | | excellent | + | fair | - | | |

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SDM-Q-9 PSY (Hebrew) | Zisman-Ilani, 2016[34] | good | + | n.i. | | n.a. | | n.a. | | n.i. | | good | + | fair | + | | |
| SDM-Q-9 (English) | Alvarez, 2016[30] | excellent | + | n.i. | | n.i. | | n.i. | | n.i. | | n.i. | | n.i. | | CC: poor | + |
| CollaboRATE | Barr, 2014[70] | n.a. | | n.i. | | n.a. | | good | + | n.i. | | n.a. | | fair | - | R: poor | ? |
| CollaboRATE (Swedish) | Rosenberg, 2017[41] | poor | + | fair | - | n.i. | | n.i. | | n.i. | | n.i. | | fair | - | | |
| SMDMQ (Taiwanese) | Chang, 2014[42, 43] * | n.a. | | n.i. | | n.a. | | n.a. | | poor | ? | IRT: good | - | n.i. | | | |
| SDM Process Score | Fowler, in progress[44] | n.i. | | n.i. | | n.a. | | n.a. | | n.i. | | n.i. | | fair | + | | |
| MADM | Vedam, 2017[45] | excellent | + | n.i. | | n.i. | | n.i. | | n.i. | | excellent | ? | poor | ? | | |
| Dyadic Option patient version (Swedish) | Rosenberg, 2017[41] | poor | + | fair | - | n.i. | | n.i. | | n.i. | | n.i. | | fair | - | | |
| **Provider questionnaires** | | | | | | | | | | | | | | | | | |
| SDM-Q-Doc | Scholl, 2012[35] | excellent | + | n.i. | | n.a. | | n.a. | | n.i. | | excellent | + | n.i. | | | |
| SDM-Q-DOC (Persian) | Ebrahimi, 2014[46] | poor | + | poor | - | n.a. | | n.a. | | n.i. | | n.i. | | n.i. | | | |
| SDM-Q-Doc (Dutch) | Rodenburg-VandenBussche, 2015[33] | excellent | + | n.i. | | n.a. | | n.a. | | n.i. | | excellent | + | fair | - | | |
| SDM-Q-Doc (Spanish) | Calderon, 2017[47] | poor | ? | n.i. | | n.i. | | n.i. | | poor | ? | good | ? | poor | ? | | |
| **Observer-based coding schemes** | | | | | | | | | | | | | | | | | |
| IDM | Weiss, 2008[71] | n.i. | | n.a. | | n.i. | | n.i. | | n.i. | | n.i. | | fair | - | | |
| DSAT | Guimond, 2003[49] | n.i. | | n.a. | | poor | - | n.i. | | n.i. | | n.i. | | fair | - | | |
| | Butow, 2010[72] | n.i. | | n.a. | | n.i. | | n.i. | | n.i. | | n.i. | | fair | + | | |
| DSAT-10 | Stacey, 2008[50] | n.i. | | n.a. | | good | - | n.i. | | n.i. | | n.i. | | n.i. | | | |
| OPTION | Elwyn, 2003[51] | poor | + | n.a. | | good | - | poor | - | n.i. | | good | - | good | - | | |
| | Butow, 2010[72] | n.i. | | n.a. | | n.i. | | n.i. | | n.i. | | n.i. | | fair | + | | |
| OPTION (revised) | Elwyn, 2005[52] | poor | - | n.a. | | good | - | poor | - | n.i. | | excellent | - | n.i. | | | |
| | Weiss, 2008[71] | n.i. | | n.a. | | n.i. | | n.i. | | n.i. | | n.i. | | poor | - | | |
| | Kasper, 2011[73] | n.i. | | n.a. | | poor | + | poor | + | n.i. | | n.i. | | fair | - | | |
| | Vortel, 2016[74] | n.i. | | n.a. | | poor | - | n.i. | | n.i. | | n.i. | | n.i. | | | |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| OPTION (Italian) | Goss, 2007[53] | fair | + | n.a. | fair | + | fair | + | n.i. | | poor | ? | n.i. | | |
| OPTION (revised) (German) | Hirsch, 2011[54] | poor | + | n.a. | fair | - | n.i. | | n.i. | | good | + | fair | - | |
| OPTION (revised and modified) (German) | Keller, 2013[55] | poor | + | n.a. | poor | - | n.i. | | n.i. | | n.i. | | poor | - | |
| OPTION[12] (Dutch) | Stubenrouch, 2016[56] | n.i. | | n.a. | poor | - | n.i. | | n.i. | | n.i. | | n.i. | | |
| OPTION[5 item] | Barr, 2015[75] | n.a. | | n.a. | good | - | poor | + | n.i. | | n.a. | | good | + | |
| | Vortel, 2016[74] | n.a. | | n.a. | poor | + | n.i. | | n.i. | | n.a. | | poor | + | |
| OPTION[5] (Dutch) | Stubenrouch, 2016[56] | n.a. | | n.a. | poor | - | n.i. | | n.i. | | n.a. | | fair | + | |
| RPAD | Shields, 2005[58] | n.i. | | n.a. | m | m | m | m | n.i. | | n.i. | | fair | - | |
| DAS-O | Brown, 2011[59,72] *** | n.i. | | n.a. | poor | - | poor | - | good | + | n.i. | | fair | -** | |
| SDM Scale | Singh, 2010[60] | poor | - | n.a. | poor | ? | poor | ? | n.i. | | poor | - | fair | + | |
| PES | Kearny, 2011[61] | n.i. | | n.a. | n.i. | | n.i. | | n.i. | | n.i. | | n.i. | | |
| DEEP-SDM | Clayman, 2012[62] | n.i. | | n.a. | n.i. | | n.i. | | n.i. | | n.i. | | n.i. | | |
| Shared decision making rating | Slayers, 2012[63] | n.i. | | n.a. | poor | + | n.i. | | n.i. | | n.i. | | n.i. | | |
| MAPPIN'SDM$_{norge}$ | Kienlin, 2016[64] | n.i. | | n.a. | fair | - | n.i. | | n.i. | | n.i. | | fair | - | CV: poor - |
| **Mixed instruments** | | | | | | | | | | | | | | | |
| Dyadic OPTION[Patient] | Melbourne, 2011[26] | n.i. | | n.i. | n.a. | | n.a. | | n.i. | | n.i. | | fair | - | |
| Dyadic OPTION[Clinician] | Melbourne, 2011[26] | n.i. | | n.i. | n.a. | | n.a. | | n.i. | | n.i. | | fair | + | |
| MAPPIN'SDM patient questionnaire | Kasper, 2012[27,76] **** | poor | + | n.i. | n.a. | | n.a. | | good | + | n.i. | | fair | - | |
| MAPPIN'SDM doctor questionnaire | Kasper, 2012[27,76] **** | poor | + | n.i. | n.a. | | n.a. | | good | + | n.i. | | fair | - | |
| MAPPIN'SDM coding scheme | Kasper, 2012[27,76] **** | n.i. | | n.a. | fair | - | n.i. | | n.i. | | n.i. | | fair | - | |
| | Kasper, 2012[77] | n.i. | | n.a. | good | - | n.i. | | n.i. | | n.i. | | fair | - | |

**Note:** Measurement error is not presented as one of the measurement properties because it has not been evaluated in any of the articles. M = result of the methodological quality appraisal with a score on the 4-point rating scale based on the COSMIN: poor, fair, good, excellent. R = result of the quality of measurement property appraisal with three possible categories: + = positive, ? = inconclusive, - = negative. n.i. = not investigated. n.a. = not applicable. m = missing. CFA = confirmative factor analysis.

*Reference 42 and 43 both present results of the development and validation for the SMDMQ (Taiwanese), however the results presented seem the exact same in both articles, therefore reference 43 was left out in the data extraction and analysis and also not included in the number of included articles.

** There is a negative score for hypotheses testing because the authors had hypothesized that correlations would be medium-sized but they actually found strong relationships with instruments measuring the same construct.

** Reference 59 and 72 both present hypotheses testing for the DAS-O, however reference 72 was based on the same dataset as reference 59, therefore reference 72 was left out for the data extraction and analysis and also not included in the number of included articles.

**** Reference 27 and 76 both present results about internal consistency for the MAPPIN'SDM patient and doctor questionnaire and about inter-rater reliability for the MAPPIN'SDM coding scheme, however reference 76 made use of the same dataset as reference 27, therefore reference 76 was left out for the data extraction and analysis and also not included in the number of included articles.

**Online supporting information. Extracted data.**

*https://figshare.com/articles/dataset/The_quality_of_instruments_to_assess_the_process_of_shared_decision_making_A_systematic_review/5892685?file=10499863*

# 3

# KEY COMPONENTS OF SHARED DECISION MAKING MODELS: A SYSTEMATIC REVIEW

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## ABSTRACT

### Objectives

To 1) provide an up-to-date overview of shared decision making (SDM)-models, 2) give insight in the prominence of components present in SDM models, 3) describe who is identified as responsible within the components (patient, healthcare professional, both, none), 4) show the occurrence of SDM components over time, and 5) present an SDM map to identify key SDM components per healthcare setting.

### Design

Systematic review.

### Eligibility criteria

Peer-reviewed articles in English presenting a new or adapted model of SDM.

### Information sources

Academic Search Premier, Cochrane, Embase, Emcare, PsycINFO, PubMed, and Web of Science were systematically searched for articles published up to and including September 2, 2019.

### Results

Forty articles were included, each describing a unique SDM model. Twelve models were generic, the others were specific to a healthcare setting. Fourteen were based on empirical data, 26 primarily on analytical thinking. Fifty-three different elements were identified and clustered into 24 components. Overall, '*Describe treatment options*' was the most prominent component across models. Components present in >50% of models were: '*Make the decision*' (75%), '*Patient preferences*' (65%), '*Tailor information*' (65%), '*Deliberate*' (58%), '*Create choice awareness*' (55%), and '*Learn about the patient*' (53%). In the majority of the models (27/40), both healthcare professional and patient were identified as actors. '*Describe treatment options*' and '*Make the decision*' are the two components which are present in most models in any time period. '*Create choice awareness*' stood out for being present in a markedly larger proportion of models over time.

### Conclusions

This review provides an up-to-date overview of SDM models, showing that SDM models quite consistently share some components but that a unified view on what SDM is, is still lacking. Clarity about what SDM constitutes is essential though for implementation, assessment, and research purposes. A map is offered to identify key SDM components.

## 1. INTRODUCTION

Shared decision making (SDM) between patients and healthcare professionals is gradually becoming the norm across Western societies as the model for making patient-centred healthcare decisions[1, 2] and achieving value-based care.[3, 4] SDM is based on the thought that healthcare professionals are the experts on the medical evidence and patients are the experts on what matters most to them.[3] Systematic reviews of published SDM models date back to 2006 and 2007.[5, 6] Makoul and Clayman concluded that there is no unified SDM model, and proposed a set of essential elements to form an integrative model of SDM (e.g., *Define and/or explain the problem, Discuss pros/cons, Patient values/preferences, Make or explicitly defer decision*).[5] From their perspective, elements can be initiated either by patients or healthcare professionals, and they purposively abstained from identifying actors in their model so as not to place sole responsibility on either. Soon after, a second systematic review concluded that the focus of SDM models is placed on information exchange and on the involvement of both patient and healthcare professional in making the decision.[6] Since then, SDM has gained attention exponentially, with new SDM models emerging, and with what SDM specifically entails remaining under debate.[3, 7, 8] Moreover, in a systematic review of measures to assess SDM we noted that developers of SDM measures often only vaguely define the SDM construct or do not define it at all.[9] Meanwhile, there are calls to extend the conceptualization of SDM, such as by focusing on the person facing the decision rather than on a consultation,[10] or by shifting the focus of SDM to relationship-centred care[11] or to humanistic communication.[12]

Clarity about what SDM constitutes in a specific situation is essential for training, implementation, policy, and research purposes. This systematic review aims to 1) provide an up-to-date overview of SDM models, 2) give insight in the prominence of components present in SDM models, 3) describe who is identified as responsible within the components (i.e., patient, healthcare professional, both or none), 4) show the occurrence of SDM components over time, and 5) present an SDM map to easily identify key SDM components per healthcare setting.

## 2. METHODS

In the following we use the term model for both models and definitions, for sake of readability. These terms may have a slightly different meaning but are often used interchangeably. No ethical approval was required. We registered this systematic review at PROSPERO: CRD42015019740.

### 2.1 Search strategy

Seven electronic databases (Academic Search Premier, Cochrane, Embase, Emcare, PsycINFO PubMed, and Web of Science) were systematically searched for articles published from inception up to and including September 2, 2019. The search terms “shared decision” and related terms such as “shared medical decision”, “shared treatment decision” and “shared clinical decision”, and their plural forms, as well as the broadly used abbreviation SDM were used to search in title and keywords. The search was restricted to peer-reviewed scientific articles; to publications in English for pragmatic reasons; and to publications about humans. See Appendix A for our complete search strategy.

### 2.2 Eligibility criteria

During the screening of titles and abstracts we determined whether the term model or definition was used, and if not, whether it could be expected that the authors would provide a new or adapted SDM model. Full-text articles were excluded if they were not externally peer-reviewed or not written in English. Full-text articles were included if the authors explicitly described a new model of the SDM process between a patient and one or more healthcare professionals, or if the authors had adapted an existing model based on own insights or research outcomes, and if the model was described comprehensibly, i.e., in enough detail to explain the process. We therefore excluded articles in which the authors only referred to a model described elsewhere, only mentioned the concept of SDM, or explained it briefly only. Also, the focus was on models that assumed a competent patient, i.e., a patient that was able to participate in the decision making process.

### 2.3 Selection process

Three researchers (AP, HB-R, FG) independently reviewed titles and abstracts of the first 100 records and discussed inconsistencies until consensus was obtained. Then, in pairs, the researchers independently screened titles and abstracts of all articles retrieved. In case of disagreement, consensus on which articles to screen full-text was reached by discussion. If necessary, the third researcher was consulted to make the final decision. Next, two researchers (AP, HB-R) independently screened full-text articles for inclusion. Again, in case of disagreement, consensus was reached on inclusion or exclusion by discussion and if necessary, the third researcher (FG) was consulted.

### 2.4 Data extraction

We extracted the description of each SDM model (i.e., the verbatim text describing the model) as well as the following general characteristics: first author, year of publication, name of the model (if applicable), healthcare setting, and development process (i.e., informed by existing literature or by data collected with the purpose to inform the model; for the latter, we extracted methods and respondents). Using a standardized extraction form, one researcher (AP or HB-R) extracted the data, the other researcher verified it, and inconsistencies were discussed until consensus was reached.

### 2.5 Data analysis

We separated each SDM model description into text fragments, i.e., the smallest piece of text conveying a single constituent of the model, often delineated by conjunctions or punctuation. We then first classified all text fragments using elements, starting out with the list of 32 elements that Makoul and Clayman reported.[5] We refined or split elements, or added new elements if necessary. Elements may describe specific behaviours (e.g., *List options*) but need not (e.g., *Patient values*). Second, we determined the actor for each classified text fragment. An actor was defined as the person identified to be responsible for the occurrence of the behaviour or result described in the text fragment (i.e., no actor identified, patient and healthcare professional, only patient, or only healthcare professional). To illustrate, for *Patient values* it may be stated in the text fragment that healthcare professionals need to ask about patients' values, or that patients need to express their values. In the first case, the

actor would be the healthcare professional; in the second, the patient. Note that the actor identified for the same element that is present in different SDM models may differ between models, depending on the actor identified by the authors of the respective models. Third, we clustered elements representing a shared theme into overarching components taking into account the underlying text fragments, and formulated a name for each component, e.g., *Provide neutral information, Advocate patient views*. Clustering of elements into components was based on the content of the elements and regardless of actor. For the ensuing components, we now again determined the actor(s), based on the actors identified for the constituting elements. For each analysis step, one researcher (HB-R or AP) performed the analysis, the other verified it, and inconsistencies were discussed until consensus was reached. To depict a possible trend in the occurrence of components in SDM models over time, we grouped the SDM models by publication date into four different time periods (i.e., until 2010, 2010-2014, 2015-2017, since 2018), each containing approximately the same number of models. We calculated in how many of the models during a particular time period each component was present, as a percentage.

### 2.6 Patient and public involvement

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to interpret the results. Patients were not invited to contribute to the writing or editing of this document.

## 3. RESULTS

The search yielded 4164 unique records. Forty articles were included in this review, from 34 different first authors, each describing a unique model (Figure 1). The articles were published from 1997 up to and including September 2, 2019. See appendix B for the model descriptions.

### 3.1 General characteristics of the models

#### 3.1.1 Healthcare settings

Twelve SDM models were generic (i.e., specified as such or no healthcare setting specified).[5, 13-23] The other 28 SDM models had been developed for a particular healthcare setting or patient group, namely primary care,[24-29] screening,[30, 31] the inpatient setting,[32] paediatrics,[33-35] mental healthcare,[36-38] emergency care,[39, 40] oncology care,[41, 42] chronic care,[43, 44] nursing care,[45] physical therapy,[46] older patients,[47, 48] serious illness,[49, 50] or diabetes.[51]

#### 3.1.2 Decision types

Thirteen models were focused more or less explicitly on treatment decision making,[14, 17, 28, 34, 36, 38, 41-43, 46, 48, 49, 51] two on screening,[30, 31] one on test and treatment decision making,[50] one on disease prioritization and treatment,[44] one on goals and actions,[27] and one on decisions regarding diagnostic testing, treatment, or follow-up.[19] For the other 21 models, the authors did not explicitly state the type of decision.[5, 13, 15, 16, 18, 20-26, 29, 32, 33, 35, 37, 39, 40, 45, 47]

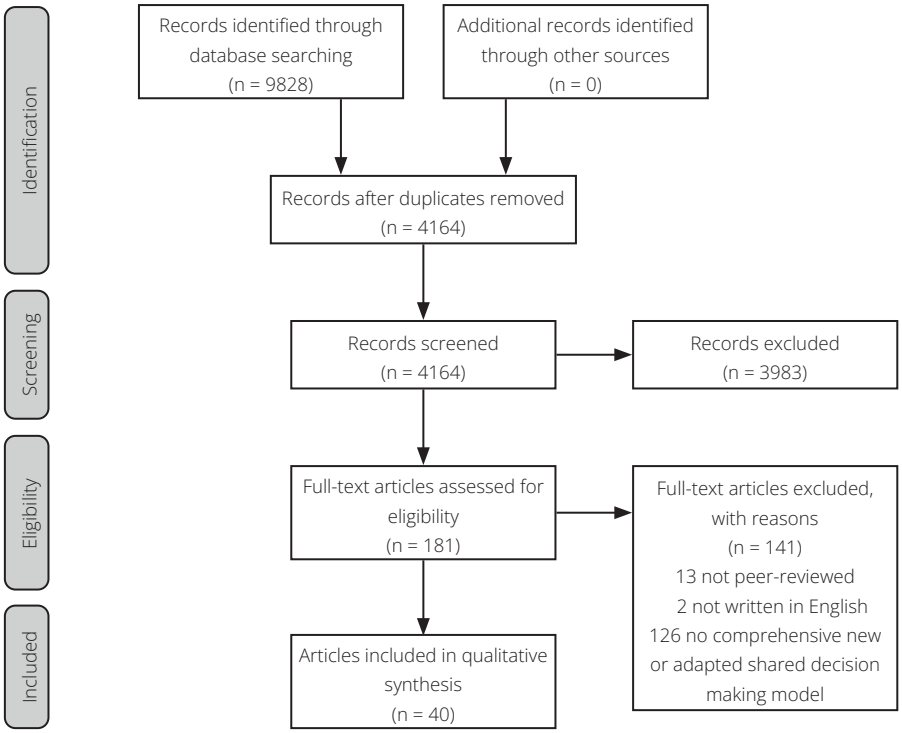


**Figure 1.** Flow diagram of article selection process

### 3.1.3 Development processes

All authors referred to the broader SDM literature including SDM models, although existing SDM models may not have explicitly formed the origin of their own model. Twenty-one SDM models were explicitly based on one or more of the SDM models included in this review.[5, 15, 17, 18, 20, 22, 23, 25-29, 31, 32, 38, 39, 43, 45-47, 51] Appendix B shows that especially the models of Charles,[17, 49] Towle,[16] Elwyn,[14, 29] and Makoul[5] informed other SDM models. Two-thirds of the models (26/40) were further or solely based on analytical thinking of the authors (i.e., no data were collected in patients and/or healthcare professionals with the purpose to inform the model); of note, empirical data collected for other purposes may have informed these models.[5, 14, 15, 17, 19, 21, 22, 24, 28, 30-35, 38-41, 43-46, 48-50] The development of the other models (14/40) was informed by empirical data gathered with the purpose to inform the model.[13, 16, 18, 20, 23, 25-27, 29, 36, 37, 42, 47, 51] These empirical data were collected in individual and/or focus group interviews with patients (4/14),[13, 36, 37, 51] healthcare professionals (1/14),[29] patients and healthcare professionals (1/14),[16] patients, members of the general population, healthcare professionals, and researchers (1/14),[42] or in patient representatives, healthcare professionals, managers, and others from unnamed professions (1/14).[26] Between four and 54 patients and between six and 49 healthcare professionals participated in the individual or focus group interviews (not all patient numbers reported for one qualitative study). Further, data were collected in a Delphi study with patients, healthcare professionals and academics (1/14),[47] in research work

groups with patients and healthcare professionals (1/14),[18] in a consensus study involving healthcare professionals, an anthropologist and a community health specialist (1/14),[25] and in a three-round consultation of academics, patients and healthcare professionals (1/14).[20] Finally, 76 consultations (one consultation of 26 pre-dialysis patients and two consultations of 25 breast cancer patients) were audiotaped and analysed (1/14),[23] and eight consultations were audiotaped and analysed, and patients, healthcare professionals and experts were interviewed (1/14).[27]

### 3.2 Components within the models

We identified 53 different elements in the descriptions of the SDM models and clustered these in 24 overarching components (Table 1). Figure 2 visualizes the components; the surface of a particular circle indicates in how many of the 40 SDM models the component was mentioned. *Describe treatment options* was the component most frequently present in any of the SDM models; it was included in 35/40 models (88%). Other components present in more than half of the models were: *Make the decision* (75%), *Patient preferences* (68%), *Tailor information* (65%), *Deliberate* (58%), *Create choice awareness* (55%), and *Learn about the patient* (55%). The component *Reach mutual agreement* was present in 35% of the models. For a majority (9/14, 64%) of these models the patient and the healthcare professional had to agree on the final decision, but not in all. Components identified in 10% of the models at most were: *Healthcare professional expertise* (10%) and *Patient expertise* (8%).

## 3.3 Actors

#### 3.3.1 Within models

Thirty-seven of the 40 models identified one or more actors, in two models actors were not mentioned at all,[15,20] and the authors of one model stated that they purposively did not define actors.[5] In 21/37 models both patient and healthcare professional were identified as actors;[13, 16-19, 22, 27, 28, 31, 34, 36, 42-51] in four of these, patients' role was implicit,[27, 31, 34, 47] and in one both patients' and healthcare professionals' role were implicit.[22] Three models identified the patient and several healthcare professionals as actors,[25, 26, 30] three models identified the underaged patient, the parent, and the healthcare professional as actors.[33, 35, 38] Ten models identified solely the healthcare professional as actor.[14, 21, 23, 24, 29, 32, 37, 39-41]

#### 3.3.2 Within components

The colour of the line around the components in Figure 2 shows how often a particular actor or actors were mentioned for the elements constituting that component. The healthcare professional was often identified as the sole actor within components. In other cases, either the patient, both the patient and the healthcare professional, or no actor was identified for elements constituting a component. The following actor or actors were identified in more than half of the models in which these components were present: the healthcare professional in *Support decision making process* (92%), *Advocate patient views* (69%), *Prepare* (67%), *Learn about the patient* (64%), *Describe treatment options* (63%), *Offer time* (63%), *Provide neutral information* (63%), *Provide recommendation* (60%), *Healthcare professional preferences* (57%), *Create choice awareness* (55%), and *Tailor information* (54%); both healthcare professional and patient in *Reach mutual agreement* (57%); no actor in *Healthcare professional expertise* (100%), *Patient expertise* (67%) and *Gather support and information* (56%).

**Table 1.** Components, their constituting elements, and how often they are part of the 40 shared decision making models

| Components | Elements | Frequency |
|---|---|---|
| advocate patient views | patient advocacy<br>patient opinion is important | 12 (30%) |
| create choice awareness | equipoise<br>make need for decision explicit | 22 (55%) |
| deliberate | deliberation~<br>negotiation~ | 23 (58%) |
| describe treatment options | benefits/risks (pros/cons)*<br>feasibility of option(s) | 35 (88%) |
| | list options^ | |
| | present evidence* | |
| determine roles in decision making process | all parties have a legitimate interest in the decision*<br>formulation of equality of partners<br>involves at least two people*<br>patient's decisional role preference^<br>process determination or evaluation | 14 (35%) |
| determine next step | arrange follow-up* | 19 (48%) |
| | implementation | |
| foster partnership | mutual respect* | 12 (30%) |
| | partnership* | |
| gather support and information | patient accesses information<br>support with decision | 8 (20%) |
| healthcare professional expertise | doctor knowledge~ | 4 (10%) |
| healthcare professional preferences | healthcare professional preferences<br>healthcare professional values | 7 (18%) |
| learn about the patient | check/clarify understanding healthcare professional^ | 21 (53%) |
| | learn about the patient | |
| make the decision | document (discussion about) decision | 30 (75%) |
| | make or explicitly defer decision* | |
| | patient retains ultimate authority over decision | |
| | revisiting decision | |
| offer time | offer time | 8 (20%) |
| patient expertise | patient expertise | 3 (8%) |
| patient preferences | patient concerns<br>patient goals of care<br>patient preferences~<br>patient values~ | 26 (65%) |
| patient questions | patient questions | 8 (20%) |

| | | |
|---|---|---|
| prepare | prepare (prior to consultation) | 6 (15%) |
| provide information | information exchange*<br>medical information<br>patient information | 17 (43%) |
| provide neutral information | unbiased information* | 8 (20%) |
| provide recommendation | doctor recommendation~ | 10 (25%) |
| reach mutual agreement | mutual agreement* | 14 (35%) |
| set agenda | decide on agenda for the consultation<br>define/explain problem* | 9 (23%) |
| support decision making process | assess what patient needs to make decision<br>doctor guidance in decision making process<br>identify and address emotions | 11 (28%) |
| tailor information | ascertain preferred (format for) information*<br>check/clarify understanding patient^<br>flexibility/individualized approach*<br>use clear language | 26 (65%) |

~ split element from review Makoul & Clayman;[5] the original element contained two different constituents.

* original element from review Makoul & Clayman.[5]

^ refined element from review Makoul & Clayman;[5] we added the appropriate verb or relevant actor.

### 3.4 Time trends

Four models of SDM were published up to 2001.[16, 17, 29, 49] No new models were published between 2001 and 2006, and then another four models in 2006.[5, 15, 28, 43] From then on, numbers increased rapidly from 2015 onwards, and half of the models were published since then. Figure 3 shows how often components appeared in models by time period: until 2010 (N=10 models), 2010 until 2015 (N=9 models), 2015 until 2018 (N=11 models), 2018 up to and including September 2 2019 (N=10 models). There is some variation in which components were present in SDM models over time. *Describe treatment options* and *Make the decision* were present in more than half of the SDM models in any time period, while *Patient expertise*, *Healthcare professional expertise*, and *Prepare* were present in relatively few models only in any time period, although the latter shows a steady increase over time. *Create choice awareness* was present in markedly more models from 2010 onwards than before. The presence of several components in models showed a more or less marked decrease over time, including *Healthcare professional preferences* since 2010, *Support decision making process*, *Provide recommendation*, and *Reach mutual agreement* since 2015, and *Determine roles in decision making process* since 2018. The extent to which the other components were present in models fluctuates over time, without a clear pattern. The most prominent components in the most recent models in order of occurrence include *Describe treatment options*, *Make the decision*, *Tailor information*, *Deliberate*, *Learn about the patient*, and *Determine next step*.


**Figure 2.** Components of shared decision making models, and actors identified within components

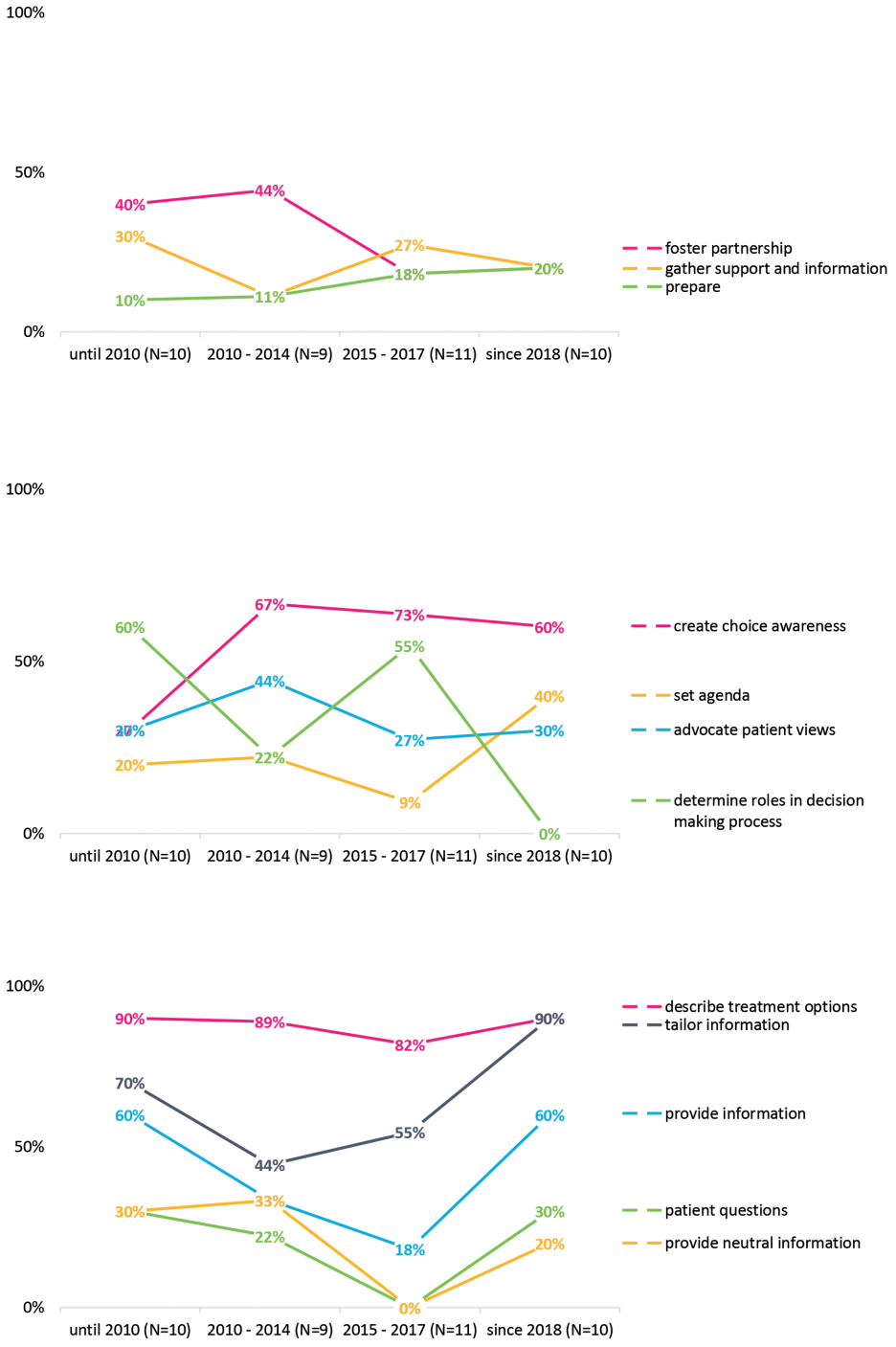


**Figure 3.** Appearance of components in shared decision making models over time

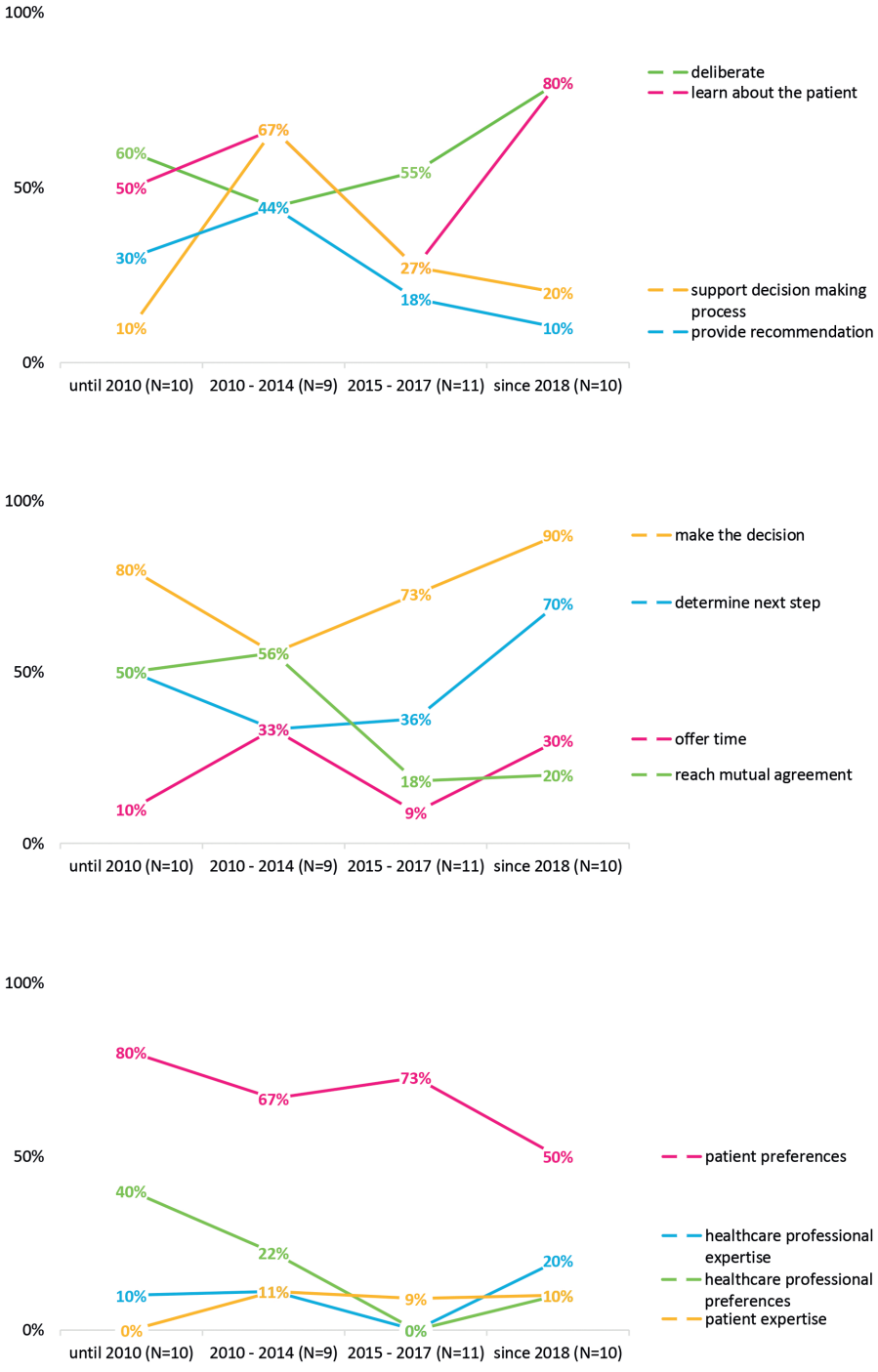


**Figure 3.** Appearance of components in shared decision making models over time

### 3.5 Shared decision making map

We present a map to depict which components seem most relevant to SDM, by healthcare setting (Figure 4). On the Y-axis, the components are shown in order of frequency from top to bottom, across SDM models. On the X-axis, the healthcare settings are shown in order of number of existing SDM models from left to right. How often a particular component was present in SDM models within a healthcare setting is colour-coded. The SDM map thus helps identify 1) what components make up SDM models, 2) how often components are present in SDM models overall, 3) how often components are present in SDM models within a particular healthcare setting. The SDM map shows some components to be part of SDM models in almost any healthcare setting (e.g., *Describe treatment options, Make the decision, Patient preferences*), and how the inclusion of other components differs between settings (e.g., *Create choice awareness, Provide recommendation, Offer time*). The SDM map may help users to critically reflect on the rightful presence or absence of components in particular healthcare settings.

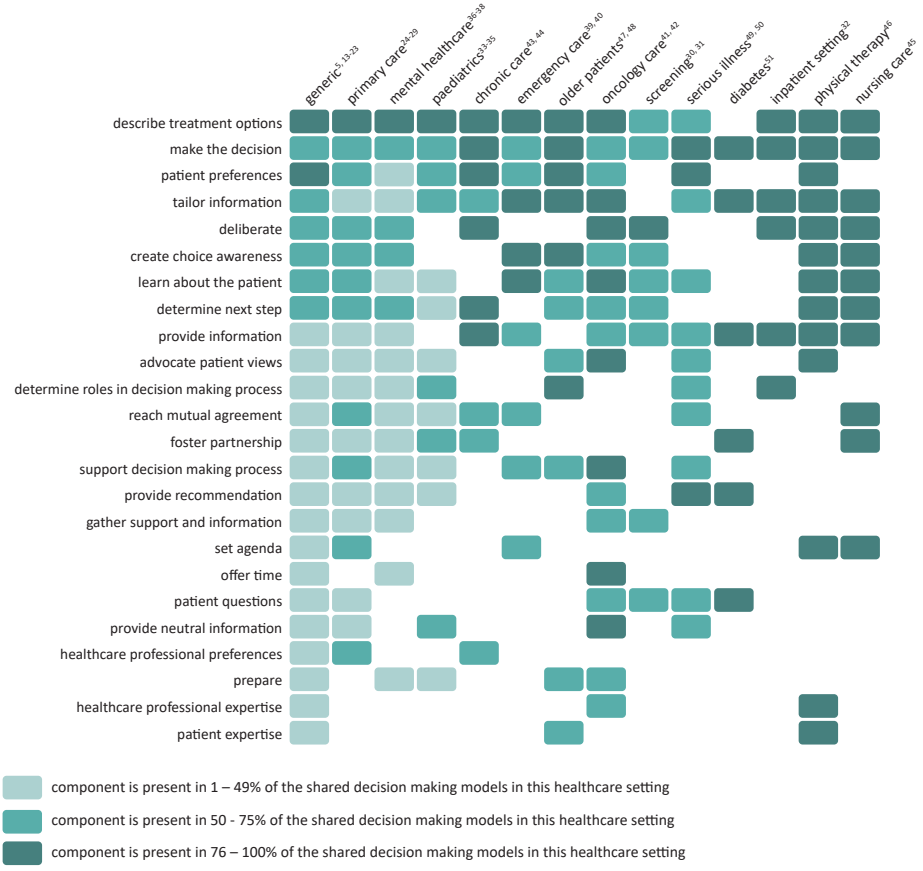


**Figure 4.** Map of shared decision making components by healthcare setting and frequency of occurrence

## 4. DISCUSSION

Our review provides an inventory of the 40 SDM models currently available. Many models defining SDM are of relatively recent date: half of the models included were published in 2015 or later. Similarities between models exist but significant heterogeneity still remains, as others have noted before.[5] This may not be surprising considering the fact that almost half of the models have been developed for a variety of decisions relating to screening, diagnostic testing or treatment decisions, and that 28 of the non-generic models have been developed for 13 different healthcare settings.

Over a decade ago, Makoul and Clayman noted the low frequency with which authors defining SDM recognized and cited previous work in the field; they found one-third of articles with a conceptual model failed to cite any other model.[5] Our review shows that authors at least referred to existing literature about SDM, also when they did not base their own model on an earlier SDM model. Especially the relatively older models that Charles,[17, 49] Towle,[16] Elwyn,[14, 29] and Makoul[5] and their colleagues developed have each informed at least six other SDM models. These authors therefore have had a significant impact on thinking about what constitutes an SDM process. They and others have further published adapted versions of their own models. Components specific to these models are therefore prominently present in our SDM map. Further and remarkably, views of patients and/or healthcare professionals, the ones who enact SDM in clinical practice, were only assessed to inform fourteen of the 40 models. This may have resulted in underrepresentation of components that patients and healthcare professionals consider to be indispensable in current thinking about what constitutes SDM.

As may be expected, the component *Describe treatment options* was present in the vast majority of models. The transfer of information about treatment options is clearly key to SDM, and patients need this information to be able to participate in SDM. However, conveying treatment information to patients in itself does not safeguard that patients are actually able to participate.[52, 53] For the component *Reach mutual agreement*, two ways of framing appeared: mutual agreement about the final decision is a requisite in part of the models, while in others this requirement is not formulated explicitly, or specifically relates to the process required to reach a decision rather than to the final decision itself. It may be of minor importance who makes the final call or whether all parties involved fully agree that the option chosen is the best possible option for this patient in this situation, as long as the process is shared.[42] *Patient expertise* and *Healthcare professional expertise* were rarely present in SDM models. Since the first is often mentioned as the rationale for SDM,[17, 54] it may not be surprising that it is not part of the definition of SDM. The authors' focus may be more on how to uncover this expertise (e.g., *Learn about the patient*) when describing the SDM process than the expertise itself.

*Creating choice awareness* clearly caught attention since 2010. Choice awareness has been defined as "acknowledging that the patient's situation is mutable and that there is more than one sensible way to address or change this situation",[55] and been put forward as pivotal in achieving SDM for some time.[2] However, despite the inclusion of this behaviour in models, it is seldom seen in clinical practice.[55-57] Both *Provide a recommendation* and

*Healthcare professional preferences* are less and less present in SDM models, suggesting that authors ideally see that healthcare professionals' preferences influence patients as little as possible. One may question if this is ideal from patients' perspective, as many patients consider receiving a treatment recommendation part of SDM.[13, 42, 58] Importantly, providing a recommendation that integrates informed patient preferences may indeed help patients in deciding what option they would prefer, and perfectly fits with SDM. Our results further show that the calls that were recently made to extend the conceptualization of SDM e.g., by focusing on the person facing the decision rather than on a consultation,[10] or by explicitly including time outside of consultations[42] would indeed add new aspects to the conceptualizations of SDM so far. *Offer time* and *Gather support and information* e.g., are part of relatively few models and typically convey attention to time outside of consultations and to the involvement of other stakeholders in the process, such as informal caregivers.[18, 42] Future SDM models may use a triadic approach towards SDM, in which the role of the caregiver is explicit.[59]

It is noteworthy that in one-fourth of the models overall, only the healthcare professional is identified as the actor in SDM, that is, is seen as responsible for the occurrence of an SDM process. This does not align with the formal acknowledgement in 2011 of patients' role in making SDM happen in the Salzburg statement on SDM.[60] It bears the question whether it is justified to put the onus of achieving SDM on healthcare professionals only, and how patients can truly participate in an SDM process if they are not recognized as active participants. It is especially important to acknowledge patients' role in SDM models since patients formulate their own responsibilities in SDM, in qualitative studies asking about SDM.[13, 18, 42] Authors of SDM models should therefore carefully consider patients' role in SDM. Also, we recommend that authors who develop an SDM model clarify each actor's role. Doing so will help elucidate whose behaviour(s) should be targeted when aiming to improve SDM levels, or measured when aiming to evaluate SDM levels. This will facilitate the development of appropriate interventions and of valid measurement instruments. Also, authors of future SDM models may want to involve patients and healthcare professionals in the development process of their models, to ensure that these reflect the views of those who enact SDM in practice.

This study provides a systematic overview of SDM models published so far. A first potential limitation of the review is that we excluded articles based on title/abstract screening that did not provide evidence of presenting an SDM model. We may therefore have missed models. Second, the first criterion in the assessment of full-text articles was if they had gone through external peer-review. This criterion was difficult to apply at times, as information was lacking in this respect. We therefore chose an inclusive strategy and may have included articles that have not gone through external peer-review. Third, for some models it was difficult to distinguish what the authors saw as context and what as integral to the SDM process. Also, it was sometimes difficult to determine from the description what the authors considered to be essential to the SDM process and what was e.g., an example of possible behaviour in the context of SDM.

The existence of SDM models that vary in emphasis does not seem problematic to us per se. What an SDM process exactly entails may differ by healthcare setting, and it may thus be helpful to have different models and choose the one that fits one's purposes best. Striving

for one unified model may even be unrealistic and counterproductive. Also, existing models may be adapted or extended if this proves useful. However, striving for consensus on the core of what SDM is, is desirable to align research, training, and implementation efforts. The pursuit of consensus begs the question as to whom should ideally be involved in deciding on the essence of SDM. Until consensus is reached, we call authors to report the model they use, whichever it is. Being explicit about the SDM model used is necessary to develop SDM measures, understand results on the occurrence of SDM and its effects, to develop and implement interventions, and for training and policy purposes. When developing an intervention, it is also important to report whether the intervention targets one or more components of the SDM process. For healthcare professionals who aim to share decisions with their patients, it is good to realise that there is no consensus in the field, only that certain components are more key to SDM than others. Our SDM map is a practical visual tool to easily identify the most relevant components when enacting SDM in clinical practice, what components may be of more or less relevance to a particular healthcare setting, and provides a basis for what should be included in training and decision support interventions.

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# Appendix A.

## Search strategy

### PubMed

(shared decision[ti] OR shared decision[ot] OR shared decisions[ti] OR shared decisions[ot] OR shared decisionmaking[ti] OR shared decisionmaking[ot] OR SDM[ti] OR SDM[ot] OR Shared medical decision[ti] OR Shared medical decision[ot] OR Shared treatment decision[ti] OR Shared treatment decision[ot] OR Shared medical decisions[ti] OR Shared medical decisions[ot] OR Shared treatment decisions[ti] OR Shared treatment decisions[ot] OR Shared clinical decision[ti] OR Shared clinical decision[ot] OR Shared clinical decisions[ti] OR Shared clinical decisions[ot])
NOT ("addresses"[Publication Type] OR "biography"[Publication Type] OR "comment"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "festschrift"[Publication Type] OR "interview"[Publication Type] OR "lectures"[Publication Type] OR "legal cases"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "patient education handout"[Publication Type] OR "popular works"[Publication Type] OR "congresses"[Publication Type] OR "practice guideline"[Publication Type]) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms])
AND english[la]

### Embase

(shared decision*.ti OR SDM.ti OR Shared medical decision*.ti OR Shared treatment decision*.ti OR Shared clinical decision*.ti OR ((shar*) ADJ5 (decis*)).ti) NOT ("editorial"/ OR "letter"/ OR conference abstract.pt OR conference review.pt) NOT (exp "Animals"/ NOT exp "humans"/) AND english.la

### Cochrane

("shared decision" OR "shared decisions" OR "shared decisionmaking" OR "SDM" OR "Shared medical decision" OR "Shared treatment decision" OR "Shared medical decisions" OR "Shared treatment decisions" OR "Shared clinical decision" OR "Shared clinical decisions" OR (share* AND decis*)): TI OR ("shared NEXT decision" OR "shared NEXT decisions" OR "shared NEXT decisionmaking" OR "SDM" OR "Shared NEXT medical NEXT decision" OR "Shared NEXT treatment NEXT decision" OR "Shared NEXT medical NEXT decisions" OR "Shared NEXT treatment NEXT decisions" OR "Shared NEXT clinical NEXT decision" OR "Shared NEXT clinical NEXT decisions" OR (share* NEXT decis*)):TI

### Emcare

(shared decision*.ti OR SDM.ti OR Shared medical decision*.ti OR Shared treatment decision*.ti OR Shared clinical decision*.ti OR ((shar*) ADJ5 (decis*)).ti) NOT ("editorial"/ OR "letter"/ OR conference abstract.pt OR conference review.pt) NOT (exp "Animals"/ NOT exp

"humans"/) AND english.la 2

### Web of Science

TI=("shared decision*" OR "Shared medical decision*" OR "Shared treatment decision*" OR "Shared clinical decision*" OR (shar* NEAR/5 decis*)) AND la=english NOT ti=("veterinary" OR "rabbit" OR "rabbits" OR "animal" OR "animals" OR "mouse" OR "mice" OR "rodent" OR "rodents" OR "rat" OR "rats" OR "pig" OR "pigs" OR "porcine" OR "horse" OR "horses" OR "equine" OR "cow" OR "cows" OR "bovine" OR "goat" OR "goats" OR "sheep" OR "ovine" OR "canine" OR "dog" OR "dogs" OR "feline" OR "cat" OR "cats")
[excluding] DOCUMENT TYPES: ( BOOK REVIEW OR NEWS ITEM OR MEETING ABSTRACT OR EDITORIAL MATERIAL )

### PsycINFO

TI("shared decision*" OR "Shared medical decision*" OR "Shared treatment decision*" OR "Shared clinical decision*" OR (shar* N5 decis*)) NOT TI("veterinary" OR "rabbit" OR "rabbits" OR "animal" OR "animals" OR "mouse" OR "mice" OR "rodent" OR "rodents" OR "rat" OR "rats" OR "pig" OR "pigs" OR "porcine" OR "horse" OR "horses" OR "equine" OR "cow" OR "cows" OR "bovine" OR "goat" OR "goats" OR "sheep" OR "ovine" OR "canine" OR "dog" OR "dogs" OR "feline" OR "cat" OR "cats")
AND la=english
Limiters: Journal Articles (549) / Dissertations (50)

### Academic Search Premier

TI("shared decision*" OR "Shared medical decision*" OR "Shared treatment decision*" OR "Shared clinical decision*" OR (shar* N5 decis*)) NOT TI("veterinary" OR "rabbit" OR "rabbits" OR "animal" OR "animals" OR "mouse" OR "mice" OR "rodent" OR "rodents" OR "rat" OR "rats" OR "pig" OR "pigs" OR "porcine" OR "horse" OR "horses" OR "equine" OR "cow" OR "cows" OR "bovine" OR "goat" OR "goats" OR "sheep" OR "ovine" OR "canine" OR "dog" OR "dogs" OR "feline" OR "cat" OR "cats")
AND la=english
Limiters: Article

# Appendix B.

## Shared decision making (SDM) models (N=40) in order of publication year and first author

| First author, publication year | SDM model |
|---|---|
| Charles, 1997[49]<br><br>Explicitly informed the following models:[5, 17, 18, 22, 24-26, 28, 32, 38, 45, 51] | Four minimum or necessary criteria for classifying a physician-patient decision making interaction as SDM (i.e., necessary but not always sufficient). SDM involves that:<br>**1. At least the physician and the patient are involved** (Often more than two participants are involved, such as a relative, a friend or another physician);<br>**2. Both parties share information** (The physician should: a) Establish a conducive atmosphere so that the patient feels that her views about various treatment options are valued and needed, b) Elicit patient preferences, c) Transfer technical information on treatment options, risks and their probable benefits in an as unbiased, clear and simple a way as is possible, d) Help the patient to conceptualize the weighing process of risks versus benefits, and ask patients questions in order to ensure that patients' preferences are based on facts, e) Share his treatment recommendation and/or affirm the patient's treatment preference; The patient should be willing to take responsibility for disclosing preferences, asking questions, weighing and evaluating treatment alternatives, and formulating a treatment preference);<br>**3. Both parties take steps to build a consensus about the preferred treatment;**<br>**4. An agreement is reached on the treatment to implement.** |
| Charles, 1999[17]<br><br>Explicitly informed the following models:[5, 22, 24-26, 28, 32, 38, 43, 45, 51] | The SDM model has three analytical stages (These may occur together or in an iterative process):<br>**1. Information exchange** (Information exchange is two-way, from physician to patient and from patient to physician. The physician must inform the patient of all information that is relevant to making the decision (information about available treatment options, the benefits and risks of each and potential effects on the patient's psychological and social well-being); The patient needs to provide information on issues raised (Values, preferences, lifestyle, beliefs and knowledge about illness and its treatment) to ensure that both the physician and patient evaluate the information of the physician within the context of the patient's specific situation and needs);<br>**2. Deliberation about treatment options** (i.e., the process of expressing and discussing treatment preferences) (The deliberation has an interactional nature, and both physician and patient are assumed to have a legitimate investment in the treatment decision (The patient because her health is at stake and the physician out of concern for the patient's welfare). The physician and patient (plus potential others) need (both) to be willing to engage in the decision making process by expressing treatment preferences. The interaction process to be used to reach an agreement may be explicitly discussed at the outset of the encounter or may evolve implicitly as the interaction unfolds);<br>**3. Deciding on the treatment to implement** (Both parties, through the deliberation process, work towards reaching an agreement and both parties have an investment in the ultimate decision made). |

Towle, 1999[16]

Explicitly informed the following models:[5, 22, 24-26, 29, 32, 38]

**Competencies (knowledge, skills, abilities) for physicians for informed SDM include:**

1. Develop a partnership with the patient;
2. Establish or review the patient's preferences for information;
3. Establish or review the patient's preferences for role in decision making and the existence and nature of any uncertainty about the course of action to take;
4. Ascertain and respond to patient's ideas, concerns, and expectations;
5. Identify choices and evaluate the research evidence in relation to the individual patient;
6. Present (or direct patient to) evidence; Help patient to reflect on and assess the impact of alternative decisions with regard to the patient's values and lifestyle;
7. Make or negotiate a decision in partnership with the patient and resolve conflict;
8. Agree an action plan and complete arrangements for follow up.

**Preliminary list of competencies for patients for informed SDM include:**

1. Define (for oneself) the preferred doctor patient relationship;
2. Find a physician and establish, develop, and adapt a partnership;
3. Articulate (for oneself) health problems, feelings, beliefs, and expectations in an objective and systematic manner;
4. Communicate with the physician in order to understand and share relevant information clearly and at the appropriate time in the medical interview;
5. Access information;
6. Evaluate information;
7. Negotiate decisions, give feedback, resolve conflict, agree on an action plan.

Elwyn, 2000[29]

Explicitly informed the following models:[5, 15, 22, 25, 26 ,38]

Sequence of skills (competences) to involve patients in healthcare decisions:

**1. Implicit or explicit involvement of patients in the decision making process** (Patients should fully understand that there is an opportunity to take part in a decision and that they are expected to take an active role);

**2. Explore ideas, fears, and expectations of the problem and possible treatments;**

**3. Portrayal of equipoise and options** (List options that are reasonably available, including, where relevant, the option of taking no action, and portraying options in an open, non-directive manner);

**4. Identify preferred data format and provide tailor-made information;**

**5. Checking process: Understanding of information and reactions** (Explore patients' ideas, fears, and expectations of possible options);

**6. Checking process: Acceptance of process and decision making role preference** (Involving the patient to the extent they desire to be involved. Role preference should be ascertained after options have been described);

**7. Make, discuss or defer decisions** (Ability to make transition from 'describing and checking' to achieving a decision, even if result is to postpone the process);

**8. Arrange follow-up** (Offer opportunity to reconsider issues on another occasion, even if a firm decision has been made).

Makoul, 2006[5]

Explicitly informed the following models:[15, 24-26, 32, 38]

**Essential elements of SDM comprise:**

1. Define and/or explain the problem;
2. Present options;
3. Discuss pros/cons (benefits/risks/costs);
4. Patient values/preferences;
5. Discuss patient ability/self-efficacy (i.e., to follow through with a plan);
6. Doctor knowledge/recommendations;
7. Check/clarify understanding;
8. Make or explicitly defer decision;
9. Arrange follow-up.

Montori, 2006[43]

Explicitly informed the following models:[25, 26, 45, 51]

Phases of shared treatment decision making as they apply to chronic care decisions:

**1. Establishing an ongoing partnership** (Relationship is between 'patient team' (patient, members of patient's network, patients with same condition) and 'healthcare team' (healthcare professionals, educators, personal trainers), partnership takes place in the healthcare space and the patient's space);

**2. Information exchange** (Clinician shares 'technical' information about available choices and their potential outcomes; Patient shares technical information they obtained from other sources and information about personal and social context; Patient and clinician both share their values and preferences);

**3. Deliberating on options** (Process of considering the pros and cons for each one of the relevant choices, and clinicians and patients working together to identify the best strategy);

**4. Deciding and acting on the decision** (Patients and the healthcare team work on strategies to implement and support the decision in the patient's own space; Clinician should be willing to revisit the decision).

Murray, 2006[28]

Explicitly informed the following models:[22, 25, 26]

**Doctor and patient:**

**1. Decide on an agenda for a consultation** (Exchange information (concerns, preferences and reasons for prioritizing), deliberate (listen to and respect the others' perspective), negotiate/decide on agenda for this consultation);

**2. Decide on a treatment plan** (Doctor provides information about natural history of disease, and technical and medical information about treatment options, including pros and cons; If patient has accessed health information then agreement should be reached on the information to be used in the decision making process; Patient provides information on treatment preferences; Doctor provides information on preferences; Doctor and patient negotiate an agreed management plan, including opportunity for a change in decision if circumstances alter).

Simon, 2006[15]

**Steps in SDM process:**

1. Disclosure that a decision needs to be made;
2. Formulation of equality of partners;
3. Equipoise statement;
4. Informing on the options' benefits and risks;
5. Investigation of patient's understanding and expectations;
6. Identification of preferences;
7. Negotiation;
8. Shared decision;
9. Arrangement of follow-up.

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| Peek, 2008[51]<br><br>Explicitly informed the following model:[45] | **SDM consists of three conceptual domains:**<br>**1. Information-sharing** (Physicians explain/give information, listen, answer questions, and use layman's terms; Patients tell 'their story', report symptoms/answer questions, ask questions, and 'have a say');<br>**2. Physician recommendations** (A single option is offered or multiple options are offered with single medical doctor recommendation);<br>**3. Decision making** (Patients follow the recommendation regardless (in case of single option offered), make their own choice (in case of multiple options offered with single medical doctor recommendation), agree/disagree in the office, or decide to adhere/non-adhere once at home). |
| Lown, 2009[18]<br><br>Explicitly informed the following model:[45] | **Six categories of patient and physician themes and corresponding attitudes and behaviours that enhance SDM:**<br>**1. Patient and physician act in relational ways** (Patient and physician each seek a personal connection, and demonstrate trust and consideration and/or empathy; Physician uses non-verbal behaviour to connect with the patient, and takes time during the encounter and afterwards);<br>**2. Patient feelings, preferences and information about self** (Patient is aware of and expresses feelings, recognizes and expresses personal priorities and preferences about participation and care, considers significant others' needs when making choices, describes symptoms and their personal significance, and answers questions honestly; Physician listens and explores patient's personal information, feelings, needs and preferences, and conveys respect for those);<br>**3. Patient and physician discuss information and options** (Patient and physician each are willing to listen and be open to ideas from the other; Patient asks questions, shares understanding of information, and explains thinking process; Physician provides medical information, elicits questions, and adjusts information-giving to the patient's needs and preferences, presents options, including risks and benefits, based on recent literature, is honest about limits of physician's knowledge and scientific information, and presents opinion);<br>**4. Patient and physician seek information, support and advice** (Patient gathers support from significant others, and gathers information from sources other than this physician; Physician demonstrates willingness to seek and/or seeks additional information and encourages the patient to do the same, acknowledges/seeks and respects the expertise of other professionals, and seeks personal support);<br>**5. Patient and physician share control/negotiate a decision** (Patient and physician accept risk or uncertainty; Patient advocates for self within the relationship, and negotiates / agrees to disagree; Physician validates patient self-advocacy, integrates patient's feelings and preferences into a mutual decision, and includes significant others in discussion);<br>**6. Patient and physician act on behalf of the patient** (Patient takes responsibility for acting on agreed upon plans; Physician advocates for the patient). |

Karkazis, 2010[34]

**Six-step model for the SDM process:**

1. Set the stage and develop an appropriate team (Well before the clinical consultation consider the range of expertise needed, how to frame the decisions to parents, and how to enhance parents' understanding of the decision);
2. Establish (parents') preferences for information and discuss the role of all parties in making a decision; 3. Identify and address (parents') emotions that might interfere with (parents') effective participation in the decision making process;
4. Define (parents') concerns about the (child's) diagnosis and explore how (parents') weigh values in order to outline treatment options in a way that addresses (parents') concerns (Clinicians must acknowledge to the parents that clinicians' values are not more "right" than theirs, and help parents consider their own assumptions and biases);
5. Identify options and present evidence (Identify and present all options objectively, including no surgery, the possible consequences of each option in a realistic way, how likely the consequences are, and type and quality of the evidence underlying options), provide a recommendation based on what evidence or other argument, explore (parents') ideas and assumptions, and correct misperceptions relating to the options;
6. Share responsibility for making a decision, which need not be shared (The values of the parents (and child when appropriate) should guide the decision making process).

Légaré, 2011[25]

Assumes that at least two healthcare professionals from different professions collaborate to achieve SDM with the patient, either concurrently or sequentially.

Explicitly informed the following models:[26, 32]

Six-step interprofessional SDM model at the individual (micro) level:

**1. Patient with a health condition and Equipoise** (Patient presents a health problem that requires a decision; Professionals share their knowledge and understanding of the options with the patient while recognizing equipoise (i.e., more than one option exists, including the option to maintain the status quo) and the need for a decision));

**2. Exchange of information** (The health professional(s) and the patient share information about the potential benefits and harms of the options);

**3. Clarification of values/preferences** (Values clarification by all actors involved in the decision making process; Values of all actors may influence the decision; All actors should understand the values that are at play);

**4. Feasibility of the options** (The interprofessional team, including the patient, analyses the feasibility of the options before determining individual preferences);

**5. Preferred choice/Actual decision** (The patient identifies his preferred option with help from others. Ideally the final decision is agreed upon by all, and the healthcare professional must at least endorse the decision);

**6. Implementation and health outcomes** (Supporting the patient so that the option chosen has a favourable impact on the health outcomes that he values most. The extent to which the option is implemented as planned and health outcomes must be evaluated to further inform the decision making process).

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| Légaré, 2011[26]<br><br>Explicitly informed the following model:[32] | For the SDM process to be interprofessional, at least two healthcare providers from different professions must collaborate with the patient either concurrently or sequentially. SDM is an iterative six-step process:<br>**1. Decision to be made** (A health professional makes explicit that a choice needs to be made and identifies more than 1 option);<br>**2. Information exchange** (The health professional(s) and the patient share information about potential harms and benefits, including evidence-based information and information on the affective and emotional aspects of the decision);<br>**3. Clarification of values/preferences** (Values clarification by all actors involved in the decision making process; Values of all actors may influence the decision; All actors should understand the values that are at play);<br>**4. Feasibility of the options** (The interprofessional team, including the patient, analyses the feasibility of the options before determining individual preferences);<br>**5. Preferred choice/Actual decision** (The patient identifies his preferred option with help from others. Ideally the final decision is agreed upon by all, and the healthcare professional must at least endorse the decision);<br>**6. Implementation and outcomes** (The patient should be supported so that the option chosen has a favourable impact on the outcomes that the patient values most; The extent to which the option is implemented as planned and outcomes must be evaluated to further inform the decision making process). |
| Elwyn, 2012[14]<br><br>Explicitly informed the following models:[20, 22, 23, 27, 32, 37, 39, 47] | Three key steps of SDM for clinical practice:<br>**1. Choice talk** (Step back, making sure that patients are aware that a choice exists and know that reasonable options are available, this may be initiated by either patient or clinician, justify choice, i.e., preferences matter, check reaction and defer closure.);<br>**2. Option talk** (Check knowledge, list options, providing more detailed information about treatment options including harms and benefits, explore preferences, provide patient decision support, and summarize);<br>**3. Decision talk** (Focus on preferences, elicit preferences, supporting the work of considering preferences and deciding what is best, move to a decision, and offer review).<br>The clinician supports deliberation throughout the process. Deliberation defined as: A process where patients become aware of choice, understand their options, and have time and support to consider 'what matters most to them'. |
| Elwyn, 2013[22] | Three-talk model of SDM:<br>**1. Justify:** Explain the need to deliberate about a decision, create a partnership to support the work – 'team talk';<br>**2. Inform:** Two-way exchange of high-quality information and opinions – 'options talk';<br>**3. Elicit:** Listen to patient's preferences about treatment and outcome goals, concerns, and priorities;<br>**4. Integrate:** 'diagnose preferences', make recommendations, seek patient's views, and make or defer decisions – 'decision talk'. |

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| Eliacin, 2014[36] | **SDM is a process with three key components:**<br>1. Information sharing between patient and provider;<br>2. General discussion about treatment options;<br>3. Final decision that is mutually agreed upon by provider and the patient.<br>The patient-provider relationship is an essential foundation for shared decision making and facilitates the implementation of the three components of shared decision making. |
| Kane, 2014[41] | Six-step process model of SDM:<br>**1) Invite the patient to participate** (Let patient know that he/she has options and that patient's goals and concerns are a key part of decision making process);<br>**2) Present available treatment options;**<br>**3) Provide balanced information on benefits and risks** (Ensure patients correctly understand information);<br>**4) Assist patients in evaluating options based on their goals, make sure to understand patients' preferences;**<br>**5) Facilitate deliberation and decision making** (Let patients know they have time for considering treatment choices, and ask what else they need to feel comfortable making decisions);<br>**6) Implement SDM** (Identify and present next steps, assess patient understanding, and discuss any possible challenges with implementation). |
| Shay, 2014[13]<br><br>Explicitly informed the following model:[45] | Patients' conceptual definition of SDM includes two key phases of SDM:<br>Phase 1: An interactive exchange, Phase 2: Making the decision.<br>Phase 1 includes four interdependent components:<br>**1. Mutual exchange of information** (Patient shares concerns or problems; Physician shares relevant medical information and treatment options);<br>**2. Open-mindedness and respect for one another** (Physicians bring in medical expertise, patients bring in their unique knowledge about their body and symptoms; Physician and patient should both listen and be open-minded about what the other says. Physicians should: a) Make time to talk with a patient on a more personal level and b) Respect the expertise of the patient, solicit patients' thoughts and concerns, and take time to answer questions before forming a recommendation);<br>**3. Patient self-advocacy** (Patients are responsible to advocate for themselves throughout the SDM process (Ask questions, guide the conversation if needed, share opinions, and speak up if needed));<br>**4. Physician should provide a personalized recommendation and explain the reasoning for the recommendation in general and for the individual patient.**<br><br>In Phase 2 a decision is made that is in the best interest of the patient.<br>*About half of the patients:* Decision making is mutual between the patient and physician.<br>*The other half of patients:* Ultimately the patient always decides. The patient has to take final responsibility, even if patient and physician shared in the communication process leading to the decision. |

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| Volk, 2014[24]<br><br>Explicitly informed the following model:[46] | Six steps process for achieving SDM:<br>**1. Describe the need for a decision** (Describe health issue or decision, communicate uncertainty, and emphasize need for a decision);<br>**2. Review the options** (Discuss the options, provide balanced explanation of pros and cons of each option, provide probabilities, and assess patient's comprehension);<br>**3. Explore patient's values** (Discuss patient's views of the options, and explore patient's values);<br>**4. Determine patient's preferred role in making the decision;**<br>**5. Negotiate a course of action** (Assess patient's readiness to make a decision, elicit patient's initial preferences for the options, provide a recommendation if the patient prefers this, and negotiate a mutually agreed upon course of action);<br>**6. Make plans for follow-up** (Help undecided patients to access additional support to make the decision, make plan to review the decision or deferment, and document in the medical record the discussion, the use of decision aid (if applicable) and the decision).<br>**Four behaviours are important throughout the SDM process:** 1) Encourage patient questions, 2) Provide guidance in decision making process, 3) Tailor information to patient, 4) Establish a partnership with patient. |
| Gillick, 2015[50] | **Re-engineered SDM (goal-centric):**<br>1. Physician clarifies the patient's underlying health status (Make sure the patient understands the diagnosis, prognosis, and likely trajectory of disease in the context of their other medical problems);<br>2. Physician initiates conversation about goals of care, asks patient to prioritise their goals of care (Patients should think about what is most important personally, given some understanding of their medical condition and how that condition is likely to evolve over time);<br>3. Physician formulates the prioritised goals in terms of the three major medical goals of care (life-prolongation, maintenance of function, maximising comfort) in ways acceptable to patient;<br>4. Physician translates goals of care in a specific treatment based on the physician's knowledge of the consequences of the various treatments;<br>5. Patient retains the ultimate authority to accept or reject the proposed treatment. |
| Stiggelbout, 2015[19]<br><br>Explicitly informed the following model:[31] | **The following steps are distinguished:**<br>1. The professional informs the patient that a decision is to be made and that the patient's opinion is important;<br>2. The professional explains the options and the pros and cons of each relevant option;<br>3. The professional and patient discuss the patient's preferences; The professional supports the patient in deliberation;<br>4. The professional and patient discuss patient's decisional role preference, make or defer the decision, and discuss possible follow-up. |

Grim, 2016[37]

A model for SDM in mental health services, with five steps:

**1. Preparation** (Before the meeting: Develop agenda (Inform the patient about the purpose and estimated duration of the meeting prior to the meeting), and provide user with decision support);

**2. Choice talk** (Step back, offer choice, justify choice (i.e., preferences matter), check reaction, defer closure. Physician provides guidance to the patient in this step);

**3. Option talk** (Check knowledge (Patient should be open to have his/her knowledge corrected), list options, describe options, harms and benefits in language devoid of medical jargon, explore patient's preferences (Provider should support patient in considering the pros and cons and to assess implications of the options), and summarize);

**4. Decision talk** (Focus on preferences, elicit preferences, offer time to considerate the options, move to a decision, offer to make a recommendation if patient so wishes, and offer review of what has been discussed);

**5. Follow up** (Make further contact with provider possible after decision has been made, plan return visit for review and follow-up, make it possible for patient to follow one's progress, to know how long a decision will remain in effect, and to review or revisit a decision).

Decision support is important during all steps of the decision process.

Jansen, 2016[48]

Steps for shared decision making process about deprescribing in older people:

**1. Creating awareness that options exist:** Clinician and patient acknowledge that a decision can be made about continuation or discontinuation of medicines, and that this requires input from both clinician and patient;

**2. Discussing the options and their benefits and harms:** Ensuring that the patient knows what options are available (including the option to continue medicines) and understands the process of deprescribing, the expected benefits and harms of each option, and how likely they are to occur;

**3. Exploring patient preferences for the different options:** Help patients identify their preferences, goals, and priorities regarding deprescribing;

**4. Making the decision:** Integrating the patient's preferences and priorities with information on benefits and harms. Decisions may be made by the patient, made collaboratively, or deferred to the clinician.

Langer, 2016[38]

The sample SDM model consists of six steps:

**1. Discuss preferred roles in treatment planning;**

**2. Specify decisions to be made;**

**3. Present the available options for each decision** (The top few choices for each decision should
be presented);

**4. Determine pros and cons of each option** (Elicitation of the pros and cons from each decision maker's perspective);

**5. Design preliminary treatment plan** (The clinician and family discuss the pros and cons of each option and formulate an initial treatment plan);

**6. Implement progress monitoring** (Continually evaluate the effectiveness of the treatment plan through targeted assessment measures so that adjustments can be made).

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| Van de Pol, 2016[47] | SDM is seen as a dynamic process. The model consists of the following six steps:<br>**1. Preparation** (History, review of previous discussion or documentation regarding treatment in general or on specific issues and problem analysis (Functional assessment of all current problems));<br>**2. Goal talk** (Explain that disease has occurred and that choices need to be made, explain that every patient has own preferences and priorities, identify proxy decision maker if appropriate, identify patient values and goals of care, and elicit goals of care);<br>**3. Choice talk** (Summarise the preceding steps and verify your recapitulation, explain that there are several treatment possibilities and offer choice, always including option of no treatment, invite patient/proxy to formulate treatment aim and support the patient, convey that only the patient can be the expert on treatment aims, priorities and preferences, and check if the patient/proxy has understood everything;<br>**4. Option talk** (List personalised treatment options, discuss risks, benefits and side effects of every treatment option, check which risks and side effects the patient is willing to take, and observe how the patient reacts;<br>**5. Decision talk** (Inquire if the patient/proxy is ready to make a decision, and if not, go back to the preceding steps, focus on the preferences of the patient and make a decision with the patient/proxy. If the patient wants the doctor to decide, discuss this explicitly, and connect to the identified patient values, goals of care and treatment aims);<br>**6. Evaluation talk** (Discuss the decision making process. If not everybody is satisfied with the decision making process, enquire about the dissatisfaction and go back to a preceding step. Prepare a treatment plan based on the decision). |
| Dobler, 2017[30] | **SDM lung cancer screening counselling entails:**<br>1. Clinician and patient work together to determine whether lung cancer screening makes intellectual, emotional, and practical sense given the patient's overall personal and medical situation, as well as their informed preferences and values;<br>2. A conversation aid is used to support communication about the relative benefits and harms of screening or not, using tailored estimates of risk and state-of-the-art information design. |
| Elwyn, 2017[20] | The SDM process is a fluid transition between three different kinds of talk:<br>**1. Team talk** (Work together, describe choices, offer support, and ask about goals);<br>**2. Option talk** (Discuss alternatives, using risk communication principles);<br>**3. Decision talk** (Get to informed preferences, and make preference-based decisions). |
| Park, 2017[33] | SDM in paediatrics consists of four attributes:<br>**1. The active participation of parents, children, and health professionals;**<br>**2. Collaborative partnership, i.e., mutuality and equality between parents, children and health professionals** (Important components of partnership are open-mindedness, mutual respect, and trust);<br>**3. Reaching a compromise, i.e., reaching an outcome via mutual agreement** (Health professionals define and explain, and present the available options and their advantages and disadvantages; Parents, children, and health professionals establish the outcomes important to the patient and determine patient's preferences, and reach a decision);<br>**4. Common goal for child's health** (Seeking a common goal or shared purpose). |

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| Probst, 2017[40]<br><br>Explicitly informed the following model:[39] | The clinician should initiate the SDM conversation according to four general steps:<br>**1. Acknowledge That a Clinical Decision Needs to Be Made** (The clinician should make it clear what he or she is going to discuss and why. A clear statement should be made indicating that a decision with various options needs to be discussed);<br>**2. Share Information in Regard to Management Options and the Potential Harms, Benefits, and Outcomes of Each** (Information should be provided in a stepwise fashion at a pace the patient can<br>understand. Information should be expressed free of medical jargon);<br>**3. Explore Patient Values, Preferences, and Circumstances** (Ask about and discuss what matters to the patient and what social factors may be at play);<br>**4. Decide Together on the Best Option for the Patient, Given His or Her Values, Preferences, and Circumstances** (The conversation should result in a mutual decision. It is the clinician's responsibility to understand the patient's preferences and values and help him or her make a decision most consistent with these. The clinician should not unduly sway the patient). |
| Rennke, 2017[32] | The multistep SDM pathway consists of the following four steps:<br>**1. Information gathering** (The provider solicits medical history and patient preferences for decision making);<br>**2. Information sharing** (Patient education about the medical issue and available treatments);<br>**3. Decision discussion** (This involves the pros/cons of each option, alternative diagnostic or management strategies, and how these decisions fit with a patient's preferences, abilities and resources, or what has been called 'contextualizing care');<br>**4. Make (shared) decision, Check understanding.** |
| Lenzen, 2018[27] | Practical framework for shared decision making about goals and actions:<br>**1. Preparation:** Informing the patient about the aim of the consultation; Inviting the patient to ask questions or raise points for discussion;<br>**2. Goal setting:** Exploring the patient's current and desired situations; Giving information tailored to the patient; Supporting the patient in formulating feasible goals;<br>**3. Action planning:** Making sure the patient knows that he/she has a choice (Choice talk); Discussing possible options for actions with the patient (Option talk); Deciding on actions together with the patient (Decision talk);<br>**4. Evaluation:** Continuously reflecting on the patient's progress, and adjusting goals and actions. |

Moore, 2018[46]

SDM is an iterative three-stage process:

**1. Prepare for collaboration:** Clinicians communicate that decisions need to be made, options exist, and patient participation can help determine a plan to meet the patient's needs; invite the patient to participate; negotiate priorities;

**2. Exchange information about options, inclusive of patients' values and preferences:** Clinicians identify patient knowledge, concerns and values; Clinicians and patients exchange information about goals and treatment options, with benefits and risks; Clinicians and patients clarify and correct perceptions about options, resources, values, and preferences; Clinicians and patients check for a good match between patient priorities and available options; Clinicians and patients deliberate, and reach a decision or plan or defer the decision; Value the expertise of the patient and the clinician;

**3. Affirm and implement the decision or plan:** Clinicians and patients summarize the plan to confirm mutual understanding, congruence with patient priorities and goals, and the patient's understanding of the condition and its consequence; Clinicians and patients discuss strategies for promoting adherence, assessing success, and modify the plan as needed; Clinicians document the decision-making process, the plan, and expected outcomes.

Probst, 2018[39]

**The SDM process occurs in a conversation and should include the following three steps:**

1. Acknowledge that clinical decision needs to be made with the patient;
2. Engage in conversation with the patient to share information about the current clinical scenario as well as options for future care, while exploring the patient's values, preferences, and circumstances. Every effort must be made to speak in clear language and avoid medical jargon to maximize patient understanding. This step typically happens in a dynamic, circular fashion;
3. Reach an agreement regarding the best plan of action on the basis of the patient's informed preferences.

Rusiecki, 2018[21]

**A circular SDM model in which the order of the steps is fluid:**

1. Identify the issue;
2. Equipoise;
3. List options with pros/cons;
4. Explore patient's values and concerns;
5. Check patient's understanding;
6. Negotiate a decision;
7. Review treatment/follow-up plan.

Saidinejad, 2018[35]

**Principles of shared decision making with patient and caregivers:**

1. A mutually respectful patient-provider relationship;
2. Minimizing communication barriers (language, cultural, social, etc.);
3. Allowing patient to express understanding of the medical problem being treated, available options, and management plan in a meaningful fashion;
4. A transparent and honest discussion of treatment options, as well as risks and benefits;
5. Patients are assisted in understanding the feasibility of each option;
6. Allowing time for the patient/caregiver/family to deliberate and discuss option;
7. Review with patients the choice they opted for, the next steps, and expectation for outcome;
8. Provide strict return precautions.

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| Truglio-Londrigan, 2018[45] | SDM is a comprehensive ongoing process and entails three categories:<br>**1. Communication and Relationship building**<br>Relationship Building - Trust and Respect - The patient identifies a need or question. Individuals enter into a relationship where there is collaboration and sharing of power, and they must work towards building a trusting and respectful relationship. Information Exchange – Communication - Communication is both interpersonal and intrapersonal. The interpersonal communication is the mutual exchange of information and involves active listening. Intrapersonal communication entails: a) Mutual reflection i.e., the provider and patient reflect together via communication, exchanging thoughts about decisions, and patient's perspective, and b) Individual reflection, which takes place autonomously within the individual provider or patient;<br>**2. Working toward shared decision making**<br>(Assessment - The provider must come to know the patient, the patient's family and home/community, and patient's specific preferences. Teaching-learning - Providers teach and provide patients with the necessary information on diagnosis, treatment, and strength of the evidence, in optimal format for patients to learn and understand the information. Balance - Provider should use equipoise if >1 best practices are available. Finding balance requires deliberation and negotiation leading to consensus about the decision. Decision - Consensus about the decision;<br>**3. Action for SDM**<br>Takes action - The patient takes action to see the decision through, which may prompt a re-evaluation of the decision together with the provider. No action - The patient takes no action and may then choose to return to the provider to re-evaluate the decision or not to return. |
| Bomhof-Roordink, 2019[42] | **SDM in oncology whereby oncologist and patient behaviours unfold over time, during as well as outside consultations.**<br>1. Oncologist determines possible treatment options for patients **before or during consultations;**<br>2. Oncologist expresses importance of patient's opinion;<br>3a. Oncologist provides information about the disease, and presents the treatment options including pros and cons and their associated probabilities. Oncologist explains treatment outcomes into some detail at least. Oncologist is open and honest, and his/her information is accurate, clear, and complete. Oncologist determines patient's level of understanding and clarifies any issues if necessary;<br>3b. Patient asks questions when things are not clear;<br>4a. Oncologist learns about the patient;<br>4b. Patient expresses thoughts and feelings openly;<br>5a. Oncologist supports deliberation throughout the decision process, using the knowledge he/she gained about the patient;<br>5b. Patient thinks about what is important for him/her and considers and weighs the options;<br>**6. Outside consultations:** Patient considers treatment options; Patient consults others; Patient accesses information;<br>7a. Oncologist asks about preferences;<br>7b. Patient expresses preferences about the treatment options, after oncologist has asked for it or at own initiative;<br>7c. Oncologist provides a treatment recommendation, and his/her expertise lends him/her the authority to do so;<br>8. Oncologist and/or patient make treatment decision. |

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| Chor, 2019[31] | A five-step framework:<br>1. Identify that a decision needs to be made and acknowledge the equipoise around this decision;<br>2. Explain medical options including the components of the pelvic examination, and the potential medical and psychosocial benefits and harms of the options; Provide patients the opportunity to ask questions;<br>3. Elicit values, preferences, and experiences and engage in how these may inform the decision;<br>4. Jointly arrive at a decision or agree to defer the decision;<br>5. Educate regarding pelvic health and warning signs, and ensure that the patient feels welcome for future follow-up. |
| Joseph-Williams, 2019[23] | 'Implement-SDM':<br>**1. Preparation phase;**<br>**2. Choice introduction;**<br>**3. Increasingly tailored option presentation:** Clinician uses emerging knowledge about the patient's clinical history and preferences to continually tailor the discussion to that individual patient; presentation is responsive and tailored to the needs of individual patients and to contextual factors;<br>**4. Planning discussion:** Emphasis may be on consolidating preferences and making decisions, or on summarising preferences and encouraging an ongoing reflective and iterative process until decision can be made.<br><br>**From Choice introduction through Planning discussion: Clinician, patient and family preferences evolving from prior to informed; Preference checking and elicitation; Decision, emotional, and practical support.**<br>**Multi-stage and distributed (across time and multiple persons) decisions.** |
| Ng, 2019[44] | Dual-layer process of shared decision making:<br>**Layer 1: Disease prioritisation:**<br>**1. Primary care providers (PCPs) provide information on:** Status of patient's medical conditions; Clinical outcomes of each disease (if uncontrolled);<br>**2. Patients provide information about:** Their understanding of each disease and its impact; The disease that they are most concerned about or affects them most;<br>**3. The PCP and patient discuss, negotiate and agree on:** The disease(s) to focus on for this consultation; When to revisit the other diseases.<br><br>**Layer 2: Treatment prioritisation**<br>**4. PCPs provide information on:** Treatment options available; Pros and cons of each treatment option;<br>**5. Patients provide information on:** Their understanding of each treatment option and its attributes; The treatment attributes that they value most or are concerned of;<br>**6. The PCP and patient discuss, negotiate and agree on:** The treatment option; When to revisit the decision if undecided. |

# 4

# SHARED DECISION MAKING IN ONCOLOGY: A MODEL BASED ON PATIENTS', HEALTHCARE PROFESSIONALS', AND RESEARCHERS' VIEWS

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## ABSTRACT

### Objective

To construct a model of shared decision making (SDM) about cancer treatment by conducting an extensive consultation of stakeholders, informed by the literature.

### Methods

We interviewed 76 stakeholders: cancer patients, potential future patients, oncologists, nurses, and SDM researchers. We asked: "If I say 'Doctors and patients making decisions together about cancer treatment', what does this make you think about?". Ideas were further solicited by presenting 19 cards each describing a possible SDM element. Interviews were inductively coded and analysed, and the emerging themes were integrated into a model.

### Results

The model that was based on participants' views, assigns specific roles in SDM to both oncologists and patients. Oncologists determine possible treatments; emphasise the importance of patients' opinion; explain treatment options; get to know patients; guide patients; and provide treatment recommendations. Patients ask questions; express thoughts and feelings; consider options; offer opinions; and decide or delegate decisions to oncologists. Outside consultations patients search for information, prepare questions, and consider options.

### Conclusions

Next to oncologists' role, cancer patients also have a clear role in SDM about cancer treatment, during and outside consultations. Patients should receive the support they need to fulfil this requirement.

## 1. BACKGROUND

The majority of cancer patients favour active patient participation in decision making[1-3] as do oncologists.[4, 5] What this participation actually entails for shared decision making (SDM) remains inconsistent between models of SDM. The SDM models published to date differ in whose behaviour is seen as key to SDM (i.e., clinicians' only, or both clinicians' and patients').[6]

Despite this lack of clarity several instruments have been developed to measure SDM, which may take a patient, clinician, and/or observer view. Agreement between scores of patients, clinicians, and observers regarding the same consultation is poor.[7-9] These findings suggest that current SDM measures do not refer to a single construct, or that perceptions of SDM occurrence differ depending on the viewpoint.[7] In a recent review of SDM instruments, we noted that frequently developers do not or only vaguely define SDM.[10] We therefore decided that further clarification of the concept of SDM is imperative.

Our focus was on the conceptualization of SDM in oncology, for various reasons. There is a strong impetus but also lack of implementation of SDM in oncology.[11, 12] A better understanding of what SDM about cancer treatment entails, could support its implementation. Further, cancer is exemplary for a potentially life-threatening disease in a care setting surrounded with uncertainties.[12] Moreover, oncologists and cancer patients often meet for the first time when a treatment decision is required, and then need to choose between options that often have irreversible and enduring side-effects,[13] often within a limited time.[14] All this may result in significant feelings of vulnerability and fear in patients.

A communication model of SDM recognizing the communication process as the vehicle for decision making in cancer treatment has been described.[15] We identified only one model in oncology describing the actual SDM process. This model describes oncologist behaviour only,[12] whereas most SDM models from outside oncology also describe patient behaviour more or less explicitly.[6] Also, qualitative studies in oncology indicate that both patients and oncologists consider patient behaviours part of SDM.[16-20] Therefore, the aim of the present study was to construct a model of SDM about cancer treatment by conducting an extensive consultation of stakeholders, informed by the literature.

## 2. METHODS

### 2.1 Study design

In the Netherlands, patients most often make treatment decisions with their oncologist in outpatient clinics, increasingly supported by oncology nurses in a separate consultation. Individual interviews were held with cancer patients, potential future patients, oncologists (i.e., surgeons, medical oncologists, radiotherapists, pulmonologists, gynaecologists, and urologists), nurses, and SDM researchers, to determine what constitutes SDM in oncology. Potential future patients were members of the general population. They may face a cancer diagnosis in the future, but are not influenced by the experience of making actual cancer treatment decisions. This is relevant as the cancer patients that we interviewed often mostly described and justified their personal experiences. We report the study according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines (Appendix A).[21]

The Medical Ethical Committee of the Leiden University Medical Centre (LUMC) approved the study (P14.207), which was conducted according to the Dutch Medical Research Involving Human Subjects Act.

### 2.2 Participant recruitment

Oncologists from one academic medical centre (LUMC) and two non-academic hospitals (Haga Hospital, The Hague, and Reinier de Graaf, Delft) in the Netherlands were approached and interviewed. These oncologists were each asked to recruit two cancer patients (any diagnosis) who were ≥18 years old, had a life expectancy of over six months and were currently scheduled for a (pre-) treatment consultation (referred to as 'current patients' below). Additionally, we asked five oncologists from different specialties to each approach five disease-free patients who were ≥18 years old and had ended anti-tumour treatment (excluding hormonal therapy) six to 24 months earlier.

We contacted all current and disease-free patients who agreed to participate to plan an interview at their home or at the hospital, for current patients in combination with an existing appointment, whichever they preferred. Disease-free and current patients did not receive reimbursement except for travel expenses for disease-free patients. Potential future patients were recruited through advertisements in local newspapers, were interviewed at the LUMC, and received a gift card worth twenty euros. Eligibility criteria were: aged >30 years, never diagnosed with cancer, never attended oncology consultations, no cancer diagnosis in significant others in the past six months, no chronic disease, and no healthcare training. We applied purposive sampling to ensure diversity with regard to gender, age, and education. We approached oncology nurses who are involved in decision making and SDM researchers through our network. All professionals were interviewed at their workplace. We obtained written informed consent from current, disease-free and potential future patients.

### 2.3 Data collection

The interview guide (Appendix B) was informed by a systematic literature search conducted in October 2014 on what SDM in oncology constitutes according to cancer patients and oncologists.[16-19, 22]

We started the interview with questions on the participant's demographic characteristics, and for professionals, work-related details. Second, we asked this question: "If I say 'Doctors and patients making decisions together about cancer treatment', what does this make you think about?". In Dutch, there is not one generally-accepted term for SDM, and the terms used have slightly different semantic connotations. We also know from the literature that cancer patients consider the concept of participation in decision making unfamiliar,[19] so we chose the most easy variant: 'making decisions together' (samen beslissen in Dutch). We asked about doctors, but emphasised that they could think of other relevant healthcare providers, and that we wished to hear their views on SDM, rather than specific descriptions of their consultations. We started out with this open-ended question to allow the participants to respond based on their personal views. We compiled a list of probes and additional questions to elicit more in-depth responses (Appendix B). We kept focus on whether aspects

were or were not SDM-specific, but we did not explicitly ask whether aspects were required for SDM or not. Third, to encourage further elaboration we presented the participants with 19 paper-based cards, each describing one SDM element, collected from qualitative studies about SDM in oncology[16-19, 22] and from often-cited SDM models[12, 14, 23, 24] (Appendix B). Finally, we asked patients about their disease characteristics.

Our interview guide was pilot-tested for feasibility with two research assistants and one clinician.[25] Next, one of three trained interviewers (HBR, NvDB, MBT) conducted the interviews, which lasted 30-60 minutes. During some interviews with current cancer patients, a companion was present, who sometimes corroborated what a patient said, or answered questions asked of the patient; these responses were coded if relevant to our research question. Each interview was audiotaped and transcribed verbatim.

We thoroughly evaluated the transcripts of the first few interviews within each participant group to ensure that we were collecting answers to our research question. The interview guide was adapted in an ongoing process throughout the study, as is common in qualitative research.[26]

Data saturation, defined as no new themes emerging in the last three consecutive interviews, was determined based on the interviews with current patients only, for pragmatic reasons.

### 2.4 Data analysis

Three coders (MJF, MBT, NvDB) coded the transcripts per participant group. The three coders first independently coded all the transcripts of the current patients, and regularly compared their coding. Two of the three coders then independently coded the transcripts from the other participant groups. Code labels were detailed, and developed inductively. The same list of labels was used to code each participant group, and extended whenever necessary. The coders finalised the coding in consensus meetings. During the coding process, the research team met regularly to discuss emerging issues and the findings. The definitive coding was entered in Atlas.ti, version 7.5.12.

One researcher (HBR) clustered the codes of the interviews with the current patients and then those of the interviews with the oncologists based on the code labels. Next, two researchers (NvDB, HBR) independently checked whether each formed cluster indeed represented a coherent collection of codes, based on the underlying data fragments, i.e. axial coding. If necessary, they moved particular codes to different clusters, combined clusters, built new clusters, or renamed clusters, all in consensus. Then the researchers independently examined the codes of the remaining participant groups that had not yet been included in a cluster up to that point. In consensus, they determined to which cluster it belonged or whether a new cluster should be formed. Finally, the researchers identified the clusters that are part of the SDM process itself, and those that represent SDM barriers or facilitators; only the former are reported here. This resulted in an overview of clusters for each participant group separately. Those clusters were organised into themes and integrated into a model for all participant groups.

In the following, we focus on the common denominator among participant groups. When striking contradictions emerged from the analysis, either within a participant group or between groups, these are explicitly described. When only one participant group mentioned a theme, we state this. Quotations were selected to illustrate the themes and were translated into English (HBR, AHP).

## 3. RESULTS

### 3.1 Participants

We performed interviews with 76 participants, between July 2015 and September 2016 (Table 1). Twenty-three oncologists were approached, and 16 participated. Thirty current patients provided informed consent, 22 of them actually agreed to be interviewed. Current patients who did not agree to be interviewed often mentioned disease and/or treatment related reasons. At the time of the interview, 17 were or had been treated with curative intent, five with palliative intent. Eight disease-free patients were invited and agreed to be interviewed. Thirty-one of the 38 potential future patients who contacted us were eligible, and 16 were purposively selected and interviewed. We approached eight nurses and interviewed the six who reported to be involved in decision making. Nine SDM researchers were approached and eight of them agreed to be interviewed. Data saturation was reached in current patients.

**Table 1.** Characteristics of current and disease-free patients, potential future patients, oncologists, oncology nurses, and SDM researchers

| | N or Mean (SD) |
|---|---|
| **Current and disease-free patients** | 30 |
| Sex, female | 14 |
| Age, years | 62 (11.6) |
| Primary tumour type | |
| *Colorectal* | 12 |
| *Lung* | 5 |
| *Prostate* | 4 |
| *Endometrial* | 4 |
| *Oesophagus* | 1 |
| *ENT* | 1 |
| *Mamma* | 1 |
| *Ovarian* | 1 |
| *Bone* | 1 |
| Education level | |
| *Low* | 4 |
| *Intermediate* | 18 |
| *High* | 8 |
| **Potential future patients** | 16 |
| Sex, female | 9 |
| Age, years | 58 (11.0) |

| | |
|---|---|
| Education level | |
| *Low* | 2 |
| *Intermediate* | 6 |
| *High* | 8 |
| **Oncologists** | 16 |
| Sex, female | 6 |
| Age, years | 48 (10.6) |
| Years since start oncologist training | 12.3 (9.0) |
| Specialty | |
| *Medical Oncology* | 4 |
| *Surgery* | 4 |
| *Pulmonology* | 2 |
| *Radiotherapy* | 2 |
| *Urology* | 2 |
| *Gynaecology* | 2 |
| **Oncology nurses** | 6 |
| Sex, female | 5 |
| Age, years | 46.2 (9.8) |
| Specialty | |
| *Medical oncology* | 3 |
| *Palliative care* | 1 |
| *Gynaecology* | 1 |
| *Urology* | 1 |
| **SDM researchers** | 8 |
| Sex, female | 5 |
| Age, years | 51.9 (5.7) |
| Function | |
| *Researcher* | 4 |
| *Researcher/clinician* | 2 |
| *Policy maker* | 2 |

### 3.2 Participants' views about what SDM in oncology entails

Participants often immediately mentioned specific roles for both patients and oncologists when asked what the phrase 'Doctors and patients making decisions together about cancer treatment' made them think about. They rarely first described a more general process, without any specific actor.

> *Then you think that you are going to draw up a plan together [silence]. Then you discuss together. The doctor discusses the options and then you sort of start to look into whether it fits or is useful or anything. (potential future patient, male, 65, intermediate education level)*

Participants emphasised oncologists' expertise, based on medical knowledge and experience. Each participant group mentioned this, although the exact wording differed. This expertise comes with responsibilities, and is reflected in oncologists informing, guiding, and giving patients treatment recommendations. Conversely, the participants identified a

lack of expertise in patients, as patients have no medical training.

> *So I think for sure that in deciding together, then the expert and the lay person and the feeling of the lay person work together, and the expertise of the expert. (current patient, male, 67, high education level)*

One patient stated that patients can have medical expertise from searching the internet. An SDM researcher explicitly emphasised that patients are experts on their own lives and on living with the disease. Generally, current and disease-free patients and potential future patients focused more than other participants on what patients should do in an SDM process, while SDM researchers and health professionals focused more explicitly on oncologists' behaviours.

Overall, eight themes were identified and are described below, and these were integrated into a model of SDM (Figure 1). SDM in oncology includes both the consultation and the time outside the consultation. Most oncologist and patient SDM behaviours during consultations are reciprocal. For example, when patients ask for information, oncologists provide information. Similarly, oncologists provide information and patients ask questions about it. It is of minor importance *who* is responsible for making the final decision, the focus is on the distinct roles *during* the SDM process.

### 3.2.1 Determine possible treatment options

Oncologists determine the possible treatment options for patients before or during consultations, based on medical and patient factors. Oncologists may explicitly mention which treatment options are possible and which are not.

> *If I go to the solicitor […], then I go and see how the request I have fits within the law. And it is also a little bit like that the other way round I think when you visit the doctor, then you also expect that he has thought up for you if something is or is not compatible with life. (oncologist, female, 35, medical oncologist)*

### 3.2.2 Express importance of patient's opinion

The SDM researchers stated that during consultations, oncologists should invite patients to become involved in decision making. The other participants additionally mentioned more specific oncologist behaviours underlining the importance of patients' opinion: oncologists state during consultations that a) there is a choice to be made between various options, b) it is the intention to make decisions together, c) the patient's opinion is important, and/or d) the patient decides. Patients only mentioned c and potential future patients only mentioned b, both in response to the paper-based cards.

> *I mean, a patient visits a doctor with a particular health concern or problem and the doctor can, I think actually in all cases, there are some exceptions, but in fact in all cases he can say that he is the expert, but only regarding the medical content, but that the decision also depends on the preference of the patient. So that he makes it clear that there is a choice to be made in which the patient can take part. (SDM researcher, male, 54, researcher)*

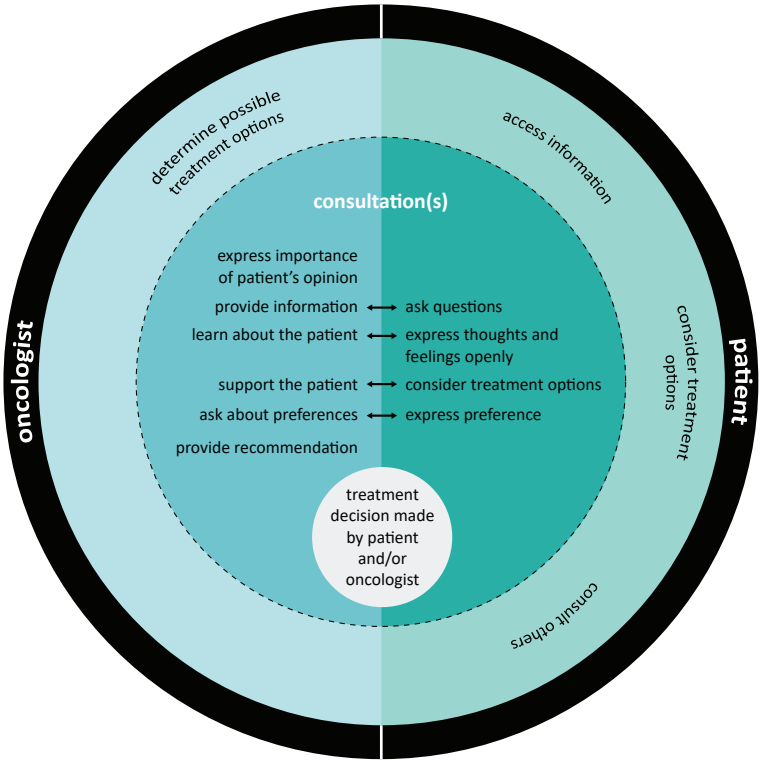


**Figure 1.** Model of shared decision making (SDM) in oncology, depicting oncologist and patient behaviours as they unfold over time, during as well as outside consultations

### 3.2.3 Provide information and ask questions

Oncologists provide information about the disease, and present the treatment options; they include the pros and cons and the associated probabilities. Oncologists explain treatment outcomes into some detail at least. Oncologists are open and honest, and their information is accurate, clear, and complete.

> *Properly tell what is going on and not play hide and seek. (current patient, male, 71, high education level)*

Some participants mentioned this to be especially relevant as contradictory information confuses and disturbs patients, as online information may do. Oncologists determine their patients' level of understanding, and clarify any issues if necessary. Patients ask questions when things are not clear.

### 3.2.4 Learn about the patient and express thoughts and feelings openly

Oncologists make efforts to get to know their patients, for example by asking what is important for them.

*Everyone has a different perspective on life. […]How you, with whom, how you grew up or not, in how you see things and how you cope with things. So you, we all cope differently with illness and with anxiety. And that's also your job for some part, to try and figure that out, and to find out what the hidden agenda is and so that you can provide everyone with the best care. (oncologist, female, 39, gynaecologist)*

The patients and potential future patients explicitly mentioned that patients should express their thoughts and feelings openly.

*Also be clear towards, towards the doctor. First. (Interviewer: And be clear about what?) About your feelings and healing process and what you want. (current patient, female, 58, intermediate education level)*

An oncologist pointed out, however, that oncologists cannot force patients to express themselves.

### 3.2.5 Support the patient and consider treatment options

Patients think about what is important for them, consider and weigh the options and their pros and cons, including the associated probabilities. Patients use the information that they received from their oncologist, or found themselves, to figure out the best option for themselves. Oncologists support this deliberation throughout the decision process, using the knowledge they gained about the patient to do so.

*The whole idea of SDM is that the patient has the most important voice in it of course.[ silence] And as a doctor you should coach that, counsel well […]. You should not let a patient swim. So throw all the information over the wall and say: well, please tell me. (oncologist, male, 44, surgeon)*

### 3.2.6 Consider treatment options outside the consultation

The participants consider time outside the consultation as part of SDM. Patients use this time before, after, or in-between consultations to consider the treatment options and discuss these with their family, friends, acquaintances, or general practitioner.

*But I would indeed say wait a day or so or two days, talk about it, and think about it for a moment. And then maybe make another appointment. That seems to me. ((Interviewer: You're saying; talk about it for a moment?) Yes, with the family, talking about it with the partner, children. (Interviewer: At home too..) Let it sink in for a bit, because it can be overwhelming and you cannot do that right away, it just is not possible. I think. (disease-free patient, female, 66, intermediate education level)*

This time can further be used to search for information and/or prepare questions. Some participants explicitly mentioned that patients are never obliged to search for information.

### 3.2.7 Provide recommendation and express preference

Oncologists provide treatment recommendations and their expertise lends them the authority to do so.

*It's like with a boiler-serviceman, he can say what's needed to make that boiler run well and that doctor can also advise me there. (Interviewer: And you say which boiler it should be?) Yes, exactly. (current patient, male, 70, high education level)*

Some participants mentioned that treatment recommendations should be substantiated with patient preferences. Patients express their opinion on the treatment options, after oncologists have asked for it or at their own initiative.

### 3.2.8 Make the treatment decision

Participants across groups expressed different ways in which final decisions can be made. Some said that patients make the decision, since it concerns their own body and life.

> *Well, I think the decision lies with yourself. If you think like, I do absolutely not feel like it. It sounds terrible to me to do all that. Then you should not do it. But that decision lies with you. Nobody can force you. It is your own body. (current patient, male, 71, high education level)*

Others described it more as patients deciding by accepting or rejecting oncologists' treatment recommendation, and by oncologists then respecting patients' choice.

> *But there are patients who do not want to have surgery for breast cancer. As professional this is quite hard to take. In the end you have to respect that, that it is a choice. (oncologist, male, 44, surgeon)*

Others again mentioned that oncologists should decide for patients when patients do not want to decide.

> *You lead the conversation. If not do it, this, if do it, that, what is your life? What do you think is important? What do you think is not important? That is what you offer and a patient can go into it. […] And some patients say 'Fine, you decide because you know what is best for me'. Fine, but then that also, that doesn't matter. (nurse, male, 49, medical oncology)*

The participants explained that patients ultimately decide, as they always have the right to refuse a treatment proposal. A few participants explicitly mentioned that making the final decision cannot be done together; ultimately the oncologist or the patient formulates the decision.

## 4. DISCUSSION

To the best of our knowledge, this is the first conceptualization of SDM in oncology informed by such an extensive consultation of stakeholders. We interviewed a large number of stakeholders, providing rich data and representing a broad range of opinions. Our interview method was open and gave participants full opportunity to share their views. All these perspectives were integrated into a comprehensive model of SDM in oncology. Our model suggests that oncologists have a prime role in the SDM process but that patients have an important role as well. This finding is in line with several SDM models developed for other settings.[6]

Importantly, time outside consultations is an essential part of SDM in oncology, and not merely a facilitator. That is, SDM extends to the world of the patient and is not confined to the space where oncologists and patients meet. Others recently advocated that SDM in fact 'needs to centre on the person, rather than the medical encounter'.[27] Outside the consultation, patients can consider their options, consult others, or search for information,

all as part of the SDM process. Indeed, ideas of patients' family members about treatment options may influence patients.[28] Furthermore, cancer patients are known to search for information beyond consultations, e.g. on the internet, in books, through other media, or by consulting others with experience with cancer.[16, 29-31] Our and others'[32] findings highlight the importance of including a so-called "Time Out" in cancer treatment decision making, with at least two consultations, to make important decisions. Our findings further have implications for measuring SDM in oncology; it seems essential to include measures of patient behaviours within and outside consultations.

Oncologists get to know their patients, which aligns with the call to clinicians to view the healthcare experience through the patient's eyes.[33] Meanwhile, cancer patients openly share their symptoms, concerns, thoughts, and feelings with their oncologist, corroborating earlier findings among primary care patients and clinicians; patients' honesty was identified as important to SDM, to enable clinicians to support patients.[34, 35] Clinicians, in turn, should explore patients' thoughts, feelings, and fears.[35] Our and others'[20] results suggest that cancer patients need to consider their treatment options, and that oncologists need to support and guide patients in this process.

Providing a treatment recommendation is part of SDM. This finding confirms results from patient interviews in primary care[34] and oncology.[36] This may cause tension; cancer patients may prefer a clear recommendation as part of SDM, but recommendations may influence them in ways they are not aware of.[37] Oncologists should therefore refrain from providing a recommendation too early in the process, before it can involve patients' preferences.
With regard to the final decision, some participants stated that patients make the final call. Other participants reported that within SDM oncologists can make the final decision. These opposed opinions support results on views about SDM from primary care patients.[34] SDM in oncology is an interactive exchange and it seems of minor importance who makes the final call, as long as the process of decision making is about involving patients, eliciting their values, and incorporating these in the final decision.

### 4.1 Study limitations

Our study should be considered in light of several limitations. First, we do not know how many current and disease-free patients were asked to participate by their oncologist and refused, and for what reasons. Also, eight current patients who initially had agreed to participate later refused participation, and they often mentioned their disease and/or treatment as reason. This may have resulted in a sample of patients with a better prognosis or less burdensome treatments. Also, the included patients were highly educated, resulting in potential biases towards a role in SDM that may be challenging for other patients. Secondly, we analysed the data towards the end of completing data collection, and determined data saturation in current patients only, for pragmatic reasons. Post hoc analysis showed that Figure 1 would include the exact same elements if it were only based on perspectives of current patients. Thirdly, we did not perform a member check due to the large sample and because we would risk the need to omit and/or revise findings because participants had reservations regarding our findings, even if it was a correct representation.[38] Fourthly, participants often elaborated solely on their own experiences, which may have limited their considerations of what SDM

looks like. In addition, it is very well possible that participants' role preferences influenced their conceptualisation of SDM. Finally, we did not ask about the order of behaviours as part of the SDM process. In figure 1, we depict an order of behaviours based on what seemed most natural. In reality, it might be that SDM is more of a dynamic process,[35, 39] in which oncologist and patient behaviours are intertwined, rather than following a pre-defined order of demarcated phases.

### 4.2 Clinical implications

Our findings have implications for efforts to implement SDM in oncology. More explicitly than other studies, ours suggests that patients have an active role: it is important in SDM that patients are open about their thoughts and consider their options, during as well as outside consultations. It may be helpful to inform patients that active patient behaviour, such as asking questions, may facilitate SDM.[11] Note that SDM should not be imposed on patients and that some patient behaviour, such as expressing feelings, may be required for an SDM process to occur, but that patients should receive the support they need to fulfil this task. The need for support can very well depend on the extent to which a patient prefers to have a role in decision making, as well as on other patient- or decision-related characteristics. Our findings are based on interviews in which stakeholders were asked specifically about SDM in oncology, the model is likely to be applicable to other clinical settings as well, but this remains to be tested.

### 4.3 Conclusion

SDM in oncology is a dynamic process in which both patients and oncologists have their roles during as well as outside the consultation, and these roles complement each other.

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# Appendix A.

## Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No | Item | Guide questions/description | |
|---|---|---|---|
| **Domain 1: Research team and reflexivity** | | | |
| Personal Characteristics | | | |
| 1. | Interviewer/facilitator | Which author/s conducted the interview or focus group? | HBR, NvDB, MBT (see section 2.3) |
| 2. | Credentials | What were the researcher's credentials? E.g. PhD, MD | MJF, AHP, AMS: PhD; TvdW: PhD, MD; HBR: MSc |
| 3. | Occupation | What was their occupation at the time of the study? | HBR: PhD student; MJF, TvdW, AMS, AHP: senior researcher; NvDB: research assistant; MBT: research assistant and specialized nurse in oncology |
| 4. | Gender | Was the researcher male or female? | HBR, NvDB, MBT, TvdW, AMS, AHP: Female; MJF: Male |
| 5. | Experience and training | What experience or training did the researcher have? | HBR: a two-day qualitative interview course, a two-day Atlas.ti course, experience with previous qualitative study; MJF: training in qualitative data analysis, several qualitative and mixed method studies; NvDB: fifteen years' experience in qualitative interviewing; MBT a two-day qualitative interview course, fifteen years' experience in qualitative interviewing; TvdW: qualitative training as part of career development, 25 years' experience in designing, performing and reporting qualitative research ; AMS: a two-day qualitative interview course, training in qualitative data analysis on the job during PhD research, 20 years' experience in supervision of many qualitative studies; AHP: qualitative training as part of career development award, several qualitative studies |
| Relationship with participants | | | |
| 6. | Relationship established | Was a relationship established prior to study commencement? | No, except for MBT, who knew the nurses and some of the experts that she interviewed |

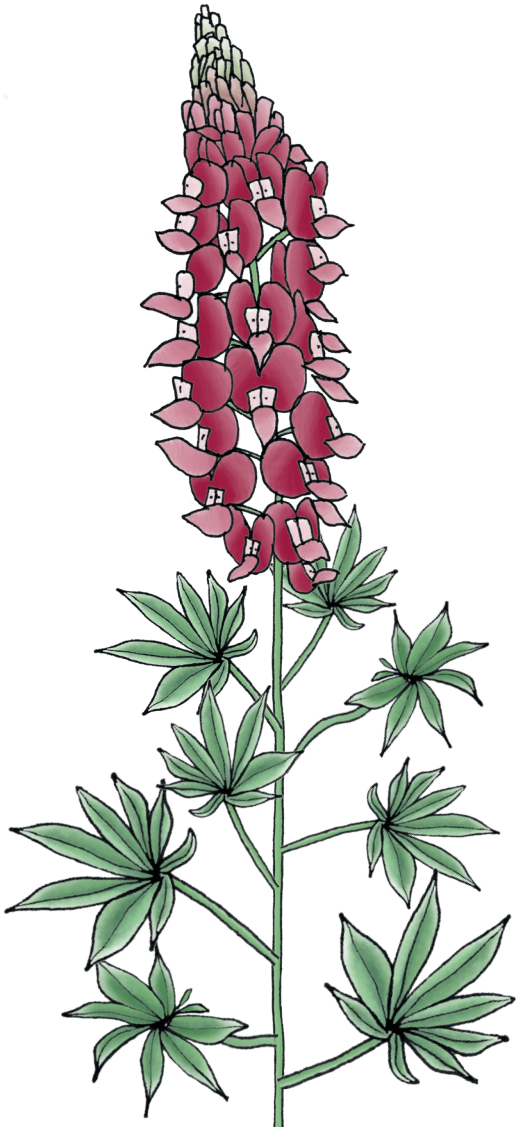
| | | | |
|---|---|---|---|
| 7. | Participant knowledge of the interviewer | What did the participants know about the researcher? *e.g. personal goals, reasons for doing the research* | No direct information about non-interviewing authors; participants knew that the interviewers were the investigators for the study |
| 8. | Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? *e.g. Bias, assumptions, reasons and interests in the research topic* | In some cases, after the interview was completed the interviewer talked further about SDM and/or related issues with the participant during which discussion the interviewers gave their own opinion |
| **Domain 2: study design** | | | |
| Theoretical framework | | | |
| 9. | Methodological orientation and Theory | What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* | Grounded theory (see section 2.4) |
| Participant selection | | | |
| 10. | Sampling | How were participants selected? *e.g. purposive, convenience, consecutive, snowball* | Purposive sampling of potential future patients and convenience sampling of all other participants (see section 2.2) |
| 11. | Method of approach | How were participants approached? *e.g. face-to-face, telephone, mail, email* | Oncologists by email and sometimes by phone, current patients face-to-face, disease-free patients face-to-face or by mail, potential future patients by advertisements, nurse practitioners and SDM researchers by email (see section 2.2) |
| 12. | Sample size | How many participants were in the study? | 76 (see section 3.1) |
| 13. | Non-participation | How many people refused to participate or dropped out? Reasons? | Unclear for some participant groups and described for others (see section 3.1 and 4.2) |
| Setting | | | |
| 14. | Setting of data collection | Where was the data collected? e.g. home, clinic, workplace | Home, hospital or workplace (see section 2.2) |
| 15. | Presence of non-participants | Was anyone else present besides the participants and researchers? | During some interviews with current patients a companion was present (see section 2.3) |
| 16. | Description of sample | What are the important characteristics of the sample? *e.g. demographic data, date* | Reported in Table 1 |

| | | | |
|---|---|---|---|
| Data collection | | | |
| 17. | Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | We present the interview guide (see section 2.2 and appendix B) and it was pilot tested (see section 2.3) |
| 18. | Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. | Audio/visual recording | Did the research use audio or visual recording to collect the data? | Audio recording (see section 2.3) |
| 20. | Field notes | Were field notes made during and/or after the interview or focus group? | Interviewers made notes during interviews as reminders for themselves; notes were not used in the analyses |
| 21. | Duration | What was the duration of the interviews or focus group? | 30-60 minutes (see section 2.3) |
| 22. | Data saturation | Was data saturation discussed? | Yes (see section 2.3, 3.1, and 4.1) |
| 23. | Transcripts returned | Were transcripts returned to participants for comment and/ or correction? | No |
| **Domain 3: analysis and findings** | | | |
| Data analysis | | | |
| 24. | Number of data coders | How many data coders coded the data? | Three (see section 2.4) |
| 25. | Description of the coding tree | Did authors provide a description of the coding tree? | No |
| 26. | Derivation of themes | Were themes identified in advance or derived from the data? | Codes were derived from the data (see section 2.4) |
| 27. | Software | What software, if applicable, was used to manage the data? | Atlas.ti, version 7.5.12 (see section 2.4) |
| 28. | Participant checking | Did participants provide feedback on the findings? | No (see section 4.1) |
| Reporting | | | |
| 29. | Quotations presented | Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? *e.g. participant number* | Yes (see section 3.2) |
| 30. | Data and findings consistent | Was there consistency between the data presented and the findings? | Yes (see results section, table 1, and figure 1) |
| 31. | Clarity of major themes | Were major themes clearly presented in the findings? | Yes (see section 3.2 and figure 1) |
| 32. | Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Yes (see section 3.2.2, 3.2.3, 3.2.4, 3.2.6, 3.2.7 and 3.2.8) |

## Appendix B.

### Interview guide, including statements regarding SDM in oncology

| **1. SDM in oncology** |
|---|
| If I say 'Doctors and patients making decisions together about cancer treatment', what does this make you think about?<br>*Probes:*<br>*If 'making decisions together' would happen the way you think it should look like, what would we see exactly?*<br>*How should 'making decisions together about cancer treatment' look like, according to you?*<br>*What fits with 'making decisions together about cancer treatment' according to you?*<br><br>To what extent do you think 'making decisions together about cancer treatment' is possible?<br><br>To what extent may doctors contribute to making decisions together about cancer treatment? And in which way?<br><br>To what extent may patients contribute to making decisions together about cancer treatment? And in which way?<br><br>To what extent can we speak of 'making decisions together' if a doctor gives a recommendation? |
| **2. Statements about SDM in oncology** |
| *The 19 cards with statements were laid on the table for the participant to look at.*<br><br>Please take a look at the cards and choose the statements that belong most to 'making decisions together about cancer treatment', according to you.<br><br>Patient receives information[16,18,19,22]<br>Patient gives her/his view on the different treatment options[18]<br>Patient asks questions[18,19]<br>Patient tells about feelings and symptoms[18]<br>Patient compares treatment options[16,19]<br>Patient takes responsibility[17]<br>Patient gathers information[16]<br>Patient is involved in making the final decision[16,18,19]<br>Doctor provides the odds of benefits and harms[24]<br>Doctor presents treatment options[19]<br>Doctor helps patient to think about what is important to him/her[23]<br>Doctor indicates that the patient's opinion is important[23]<br>Doctor gives a recommendation[17]<br>Doctor invites patient to be involved in making the decision[12]<br>Doctor states at the beginning of the consultation that it is the intent to make a treatment decision[23]<br>Doctor asks questions[19]<br>Doctor takes responsibility[17]<br>Doctor is involved in making the final decision[14]<br>Tasks are divided between doctor and patient[17] |



# 5

# MEASURING SHARED DECISION MAKING IN ONCOLOGY: DEVELOPMENT AND FIRST TESTING OF THE iSHAREpatient AND iSHAREphysician QUESTIONNAIRES

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## ABSTRACT

### Background

Existing measures to assess shared decision making (SDM) have often been developed based on an ill-defined underlying construct, and many assess physician behaviours only or focus on a single patient-physician encounter.

### Objective

To 1) develop a patient and a physician questionnaire to measure SDM in oncology, and 2) determine their content validity and comprehensibility.

### Methods

A systematic review of SDM models and an oncology-specific SDM model informed the domains of the SDM construct. We formulated items for each SDM domain. Cancer patients and physicians rated content validity in an online questionnaire. We assumed a formative measurement model and performed online field-testing in cancer patients to inform further item reduction. We tested item comprehension in cognitive interviews with cancer patients and physicians.

### Results

We identified 17 domains and formulated 132 items. Twelve cancer patients rated content validity at item level, and 11 physicians rated content validity at domain level. We field-tested the items among 131 cancer patients and conducted cognitive interviews with eight patients and five physicians. These phases resulted in the 15-item iSHAREpatient and 15-item iSHAREphysician questionnaires, covering 13 domains.

### Conclusions

We thoroughly developed the iSHARE questionnaires. They both assess patient and physician behaviours and cover the entire SDM process rather than a single consultation.

## 1. BACKGROUND

*Developing a measurement instrument is not something to be done on a rainy Sunday afternoon. If it is done properly, it may take years.*

*de Vet et al. - 'Measurement in Medicine'[1]*

Shared decision making (SDM) between patient and physician is considered the pinnacle of patient-centred care.[2] As a consequence, there is an urge to establish existing SDM levels and to detect the effect of SDM training and interventions. Measurement instruments to assess the SDM process exist but have demonstrated several issues relating to what they intend to assess and how they have been developed. Recent systematic reviews of SDM measurement instruments concluded that developers often do not or only vaguely define the underlying construct,[3] and that available SDM measurement instruments substantially differ in the domains that they cover.[4] Patient behaviour is part of SDM models,[5] but often-used SDM measurement instruments only assess physician behaviour (e.g., OPTION,[6] CollaboRATE[7]) or include physician behaviour when assessing patient's weighing of treatment options (e.g., SDM-Q-9,[8] SDM-Q-Doc[9]), impeding a transparent assessment of patient's role. The scope of SDM assessments is usually limited to a single consultation, while SDM extends to time outside consultations and is not confined to the space where the patient and physician meet.[10, 11] There is growing awareness of the need for a valid measurement instrument that is capable of capturing the entire SDM process. Such a measurement instrument should be based on a clearly defined construct, and include both patient and physician behaviours, during as well as outside consultations.

Existing SDM measurement instruments vary in terms of the viewpoint from which SDM is reported. This can either be that of an independent observer (e.g., OPTION-5[12]), the patient (e.g., SDM-Q-9,[8] CollaboRATE[7]), the physician (e.g., SDM-Q-Doc[9]), or a combination thereof (e.g., MAPPIN'SDM[13]). Overall, agreement between the different viewpoints has been found to be poor.[14-18] Recently again, a poor agreement (r = 0.14) between the SDM-Q-9 and SDM-Q-doc was found in an oncology setting.[19] Possibly, discrepancies occur because patients and physicians have different perspectives on what SDM entails and because they seldom have been involved in the development of SDM measurement instruments to date. Moreover, guidelines on the evaluation of psychometric properties of health measurement instruments recommend that the target group (i.e., researchers, patients and/or physicians) should be involved in content validity testing,[1] next to conducting cognitive interviews. This has occurred for only six of the 40 existing SDM measurement instruments.[3]

We set out to develop a questionnaire based on an explicit underlying construct, and observing further recommendations on the development of measurement instruments.[1] We considered a questionnaire most appropriate to develop as recording and coding consultations is a time-consuming process. Further, we posit that for the assessment of SDM a formative measurement model should be assumed.[3, 20-22] That is, we view the SDM process as a composite construct that is the result of independent indicators (i.e., the items form the construct), which can, but need not, be correlated with each other. In contrast, the developers of most available SDM measurement instruments have assumed a reflective measurement model,[3] in which the latent SDM construct is responsible for the scores on the indicators (i.e., the items reflect the construct).[1]

We decided to develop an SDM questionnaire for the oncology setting because cancer patients often face preference-sensitive decisions[23, 24] that call for SDM.[25] Cancer patients likely feel highly vulnerable,[26] and decisions need to be made about treatment options that often have severe and irreversible side-effects. At the same time, high levels of uncertainty may exist,[24] and time is often a constraint.[27] We further preferred an oncology-specific questionnaire, as definitions of SDM differ between healthcare settings.[5]

Therefore, the present study aimed to 1) develop a patient and a physician questionnaire to measure SDM in oncology, and 2) determine their content validity and comprehensibility.

## 2. METHODS

### 2.1 Study design

We aimed to develop short questionnaires to measure SDM from the patient and the physician viewpoint, with the same items formulated from the two different perspectives. We even preferred the physician questionnaire to contain a smaller number of items, all part of the patient questionnaire.

We used the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist as a guideline throughout the development process.[28] We describe the different phases in more detail in the sections below and in Figure 1. In sum, we selected domains to define the SDM construct; created an item pool to assess the domains; tested content validity (i.e. relevance and comprehensiveness) of the item pool in cancer patients and of the domains in physicians, and performed a field-test to further inform the selection of domains and items; and determined comprehensibility of the draft versions of the questionnaires in in-person cognitive interviews. Note that the selection of items was informed by the results obtained by field-testing and not based on internal consistency testing and factor analysis, since we assumed a formative measurement model.[1] Further, throughout the development process our goal was to assess domains that were essential for SDM in oncology, in order to be *specific* rather than comprehensive. We adopted this approach so that we would include domains that were unique to SDM, and would assess *shared* decision making rather than other decision-making models. Also, we focused on observable behaviour, assuming that this will contribute to achieving more agreement between patients' and physicians' viewpoints when assessing SDM. We performed a side-study to determine the most appropriate and feasible response scale for the questionnaires (Appendix A)[29] and tested several formats during the cognitive interviews (see section 2.7), to select the final response scale.

### 2.2 Participant recruitment

For content validity testing in patients, we approached cancer patients aged ≥18 years and able to speak and write Dutch, via their physician at the LUMC, through either a letter or during a consultation. Patients willing to participate sent their written informed consent to the researcher, and then received the link to the online survey. For field-testing, we approached cancer patients participating in an online panel (Kanker.nl), who had agreed to be approached for research, by e-mail and sent them the link to the online survey. They

provided informed consent by checking a box at the start of the survey. For the cognitive interviews, we approached cancer patients as described for content validity testing, and scheduled an interview at the LUMC. They received reimbursement for travel expenses. We asked for patients' age and education. The patients further reported their diagnosis (field-testing) or it was obtained from their treating physician (content validity testing and cognitive interviews).

For content validity testing in physicians, we approached physicians treating cancer patients from one Dutch academic hospital (LUMC) and from two Dutch non-academic hospitals (Haga Hospital, The Hague, and Reinier de Graaf, Delft) by e-mail, and sent them the link to the online survey. For the cognitive interviews, we approached physicians from the LUMC by e-mail and if they agreed to participate, we scheduled an interview at their workplace.

## 2.3 Construct definition and item pool creation

To determine the SDM construct, we made a first selection of domains based on 1) an SDM model in oncology informed by the views of cancer patients, healthcare professionals, and SDM researchers,[11] and 2) the first search (up to June 21, 2016) for a systematic review of SDM models across settings.[5]

Next, we shared the list of domains with international SDM experts, and discussed it first by e-mail and then in-person at the 2017 International Shared Decision Making Conference in Lyon, France. The research team made a definitive selection of domains forming the SDM construct.

Finally, we created an item pool for the patient questionnaire by formulating five or more potential items per domain. If available, we used phrasings that patients had used in an earlier interview study[11] and included relevant items from the SDM-Q-9.[30] We asked the international SDM experts for feedback on how well the proposed items reflected the domains, and the research team made a definitive selection of items to present to patients during content validity testing.

## 2.4 Content validity testing in patients

First, we pilot-tested questions asking to rate the importance of each item for the domain to which it belonged among two research assistants from outside the research team. As they both considered almost all items to be very important, we decided it to be more informative to ask patients to select the most important items for each domain. Specifically, we presented the patients with the name and description of each domain of SDM in oncology together with the proposed items, and asked them to choose the three items that they considered most important for each domain. We further asked them to indicate per domain if the proposed items comprehensively represented it. We then presented the complete list of domains, without items, and asked the patients to indicate if they missed one or more domains, or considered one or more domains to be redundant. In the final step, we asked the patients to judge the clarity (yes/no) of the draft introduction of the iSHARE patient questionnaire.

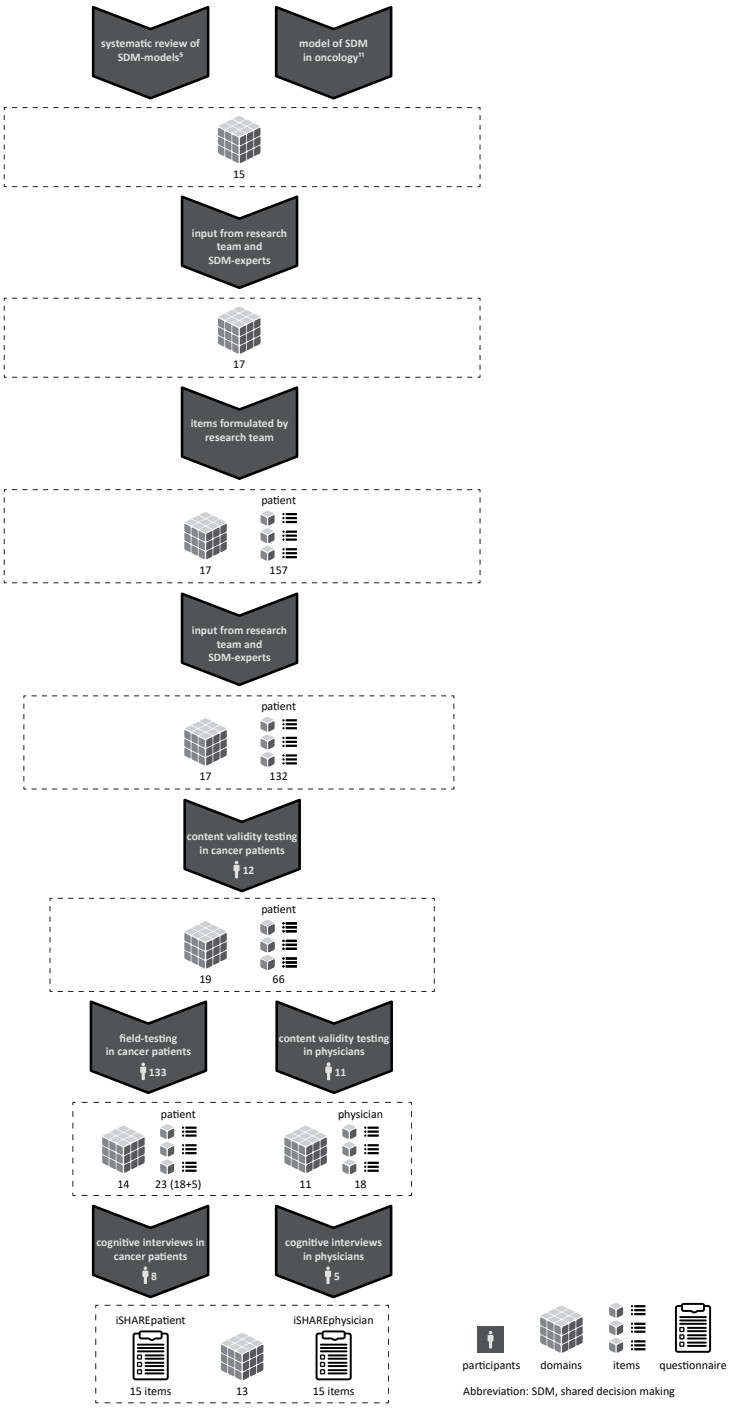


**Figure 1.** Visual representation of the development process of the iSHARE questionnaires.

We aimed to narrow down the total number of selected items to approximately 50. Two researchers (NDB, HBR) independently selected the items to be used for assessing content validity in physicians and field-testing in patients based on the results, discussed their selection, and reached agreement in consultation with the research team.

## 2.5 Content validity testing in physicians

We asked physicians to rate the importance of each domain for SDM in oncology, described as 'doctors and patients making decisions together about cancer treatment', on a seven-point scale ranging from 'not important at all' to 'very important'. Next, we presented the complete list of domains and asked the physicians to indicate if they missed one or more domains or considered one or more domains to be redundant. We then asked which three domains describing patient behaviour and which six domains describing physician behaviour they considered most important for SDM in oncology. These numbers differed because the construct included more domains describing physician than patient behaviour. Finally, in order to create a physician questionnaire that would be as short as possible, we asked which four to six domains of the complete list they considered indispensable in order to assess SDM with a physician questionnaire.

## 2.6 Field-testing in patients

We asked patients to rate the importance of each item for each domain, on a seven-point scale ranging from 'not important at all' to 'very important'; to choose the most important item for each domain; and to indicate for each domain if they missed one or more items. We then presented the complete list of domains, without items, and asked the patients to indicate if they missed one or more domains or considered one or more domains to be redundant. We finally asked which three domains describing patient behaviour and which six domains describing physician behaviour they considered most important for SDM in oncology.

We selected domains for the draft patient questionnaire informed by the results from the field-testing in patients and the content validity testing in physicians. We selected items for the draft patient questionnaire informed by the results from the field-testing in patients. We selected domains for the draft physician questionnaire informed by the four to six domains chosen by physicians in the final step of content validity testing. The items for the draft physician questionnaire were taken from the draft patient questionnaire, but formulated from the physician's viewpoint.

## 2.7 Cognitive interviews in patients and physicians

Two trained researchers (NDB, HBR) conducted individual interviews with patients using the draft patient questionnaire and with physicians using the draft physician questionnaire. We determined comprehensibility of the introduction, the items and several response scales, and we assessed if items should be removed, replaced, or adapted. We adapted the draft questionnaires between interviews, based on the responses. Finally, we made the decision to align the two questionnaires for sake of comparability, and to that end selected the same

items covering the same domains in the two questionnaires, formulated from the different viewpoints.

## 3. RESULTS

### 3.1 Sample characteristics

For the formulation of the construct, we approached five international SDM experts to give feedback on our initial selection of domains, of which four responded and two also participated in the in-person meeting. For the feedback on the items, the same five international SDM experts were approached and three of them responded.

In total, 153 patients and 16 physicians participated in this study (Table 1). For content validity testing, 14 patients initially provided informed consent and 12 of them completed the survey. Eleven of the 18 physicians who we approached participated. In total, 185 patients started with the field-test survey, and 133 completed it. Non-completers (N=52) did not significantly differ from completers regarding age, level of education, or gender. Ten patients provided informed consent to participate in the cognitive interviews of whom eight were interviewed. Five of the six physicians who we approached participated in the cognitive interviews.

### 3.2 Construct definition and item pool creation

The integration of the findings from the SDM model in oncology and the systematic review resulted in a first selection of 15 domains to define the construct of SDM in oncology (Appendix B). We clustered the domains by content in six dimensions. We added two domains informed by feedback from the SDM experts. The 17 domains related to both patient and physician behaviours. We then formulated five to 16 items per domain, resulting in a total list of 157 items to start with. Some items were then removed, reformulated, or added based on feedback from the SDM experts, resulting in five to 11 items per domain, adding up to 132 items.

### 3.3 Content validity testing in patients

We presented the 17 domains with the 132 corresponding items to 12 patients. A number of items that the patients often selected in their top three across domains represented a separate domain, i.e., *"The physician offers room for the patient to contribute to SDM"*, which was added. Further, it was decided to split the domain *"The patient considers what is most important to him/her in the context of the treatment options"* into a variant *inside* versus *outside* the consultation. Content validity testing in patients thus resulted in the selection of 19 domains and 66 corresponding items. Eleven of the 12 patients considered the introduction to be clear.

**Table 1.** Characteristics of the participants by study phase

| | N or Mean (SD) | N or Mean (SD) | N or Mean (SD) |
|---|---|---|---|
| | Content validity testing | Field-testing | Cognitive interviews |
| **Cancer patients** | 12 | 133 | 8 |
| Sex, female | 7 | 75 | 7 |
| Age, years | 67.8 (8.9) | 58.9 (10.8) | 63.0 (11.6) |
| Primary tumour type† | | | |
| *Breast* | 0 | 30 | 2 |
| *Urological* | 4 | 25 | 1 |
| *Haematological* | 0 | 21 | 0 |
| *Gastrointestinal* | 0 | 20 | 4 |
| *Otolaryngology* | 0 | 9 | 0 |
| *Gynaecological* | 5 | 7 | 0 |
| *Lung* | 3 | 7 | 1 |
| *Skin* | 0 | 5 | 0 |
| *Other* | 0 | 9 | 0 |
| Treatment intent | | | |
| *Curative* | 8 | | 5 |
| *Palliative* | 4 | | 3 |
| Education level | | | |
| *Low* | 2 | 8 | 2 |
| *Intermediate* | 4 | 52 | 0 |
| *High* | 6 | 73 | 6 |
| **Physicians** | 11 | | 5 |
| Sex, female | 4 | | 1 |
| Age, years | 51.9 (7.7) | | 48.8 (9.1) |
| Years since start specialist training | 20.2 (8.2) | | 18.8 (8.5) |
| Specialty | | | |
| *Surgery* | 3 | | 1 |
| *Gynaecology* | 2 | | 1 |
| *Pulmonology* | 2 | | 0 |
| *Radiotherapy* | 2 | | 1 |
| *Medical Oncology* | 1 | | 1 |
| *Urology* | 1 | | 1 |

† Patients participating in the field-testing could indicate more than one cancer diagnosis; 10 patients reported >1 diagnosis.

### 3.4 Content validity testing in physicians and field-testing in patients

Eleven physicians assessed content validity of the 19 domains, and during field-testing 133 patients rated the importance of 66 items considering the 19 domains. The respective selection processes resulted in 14 domains with 23 corresponding items for the draft patient questionnaire, and in 11 domains with 18 corresponding items for the draft physician questionnaire. The 11 domains and corresponding items selected for the physician questionnaire were also part of the patient questionnaire.

### 3.5 Cognitive interviews in patients and physicians

Input to the patient and physician cognitive interviews were a draft 24-item patient questionnaire and a draft 18-item physician questionnaire, respectively. The introduction to both the patient and the physician questionnaire explicitly included a statement that the time that the patient and the physician spoke about the treatment options may have entailed one or more conversations. We removed the domain "Physician mentions treatment options" and items that participants considered too much alike. We reworded items that were considered unclear.

The patients indicated that certain questions seemed very similar to each other, although they were asking about different domains. We therefore added a comment to the introduction to the patient questionnaire about the apparent similarity of questions. At the end of the introduction we added a question asking whether the patient considered the introduction to be clear, with the sole aim to stimulate them to actually read the introduction; there is no intent to actually use patients' response to the item in the definitive questionnaire. Finally, we added a sentence to the introduction to the patient questionnaire stressing that the questionnaire is not about satisfaction with the physician.

### 3.6 The iSHAREpatient and iSHAREphysician questionnaires

We named the final versions of the questionnaires the iSHAREpatient (Box 2) and the iSHAREphysician (Box 3) questionnaire. They comprise the same construct, consisting of 13 domains, clustered in six dimensions (Box 1). These are assessed using the same 15 items, formulated from the two different viewpoints. Three items explicitly assess patient behaviour. Each item is scored on a six-point scale that ranges from 'not at all' (0) to 'completely' (5). The questionnaires include two versions of the last item, depending on whether a decision has already been made or not, in order for the questionnaires to be suitable both before and after the final treatment decision has been made.

The weighing of advantages and disadvantages of treatment options during and outside consultations is combined in one item, since patients can do either and do not need to do both. We recommend to assess the time at which patients have weighed treatment options separately, if researchers wish to explore this issue.

We assumed a formative measurement model, and therefore, the most appropriate scores to report on the iSHARE questionnaires are scores per dimension. Dimension scores can be calculated by averaging the scores on the relevant items (range scores, 0-5). It may be

useful to calculate a total score on the questionnaire, which then equals the sum of the scores on the dimensions (range total score, 0-30). Higher scores per dimension and higher total scores indicate higher levels of SDM. A 0-100 total score may be more intuitive, and we therefore recommend a linear transformation of the total score using the following formula: (score/30)*100.

**Box 1.** The construct of SDM in oncology; final selection of domains and corresponding items, and clustering of the 13 domains by dimension

| **Dimension I: Choice awareness** |
|---|
| **1. The physician establishes (creates or checks) choice**<br>The physician makes explicit or checks that patient knows that there is a choice to be made as there is more than one reasonable treatment option available for the condition. |
| **2. The physician expresses that patient opinion is important in process -** *item 9*<br>The physician makes explicit that the patient's opinion about the options and/or what the patient considers important matters, in making the decision about the most appropriate treatment strategy. |
| **Dimension II: Medical information** |
| **3. The physician provides information on the benefits/risks of the treatment options -** *item 1, 2 and 6*<br>The physician explicitly identifies at least one possible benefit and one possible harm of each treatment option. The physician clarifies the trade-off. |
| **4. The physician provides balanced information -** *item 3*<br>The physician gives information in an objective, balanced, neutral way about each treatment option and its benefit(s) and harm(s). |
| **5. The physician checks patient's understanding -** *item 4 and 5*<br>The physician checks patient's understanding of the treatment options and their risks and benefits. |
| **6. The patient asks for clarification -** *item 7*<br>The patient asks for clarification, if something about the treatment options is not clear to him/her and/or asks for more information. |
| **Dimension III: Preferences** |
| **7. The physician checks own understanding of patient's values, goals of care, concerns and/or preferences in context of the treatment options -** *item 10*<br>The physician makes sure to understand patient's values, goals of care, concerns and/or preferences either by explicitly asking clarifying questions or by summarizing what the patient told. |
| **8. The patient expresses values, feelings, concerns, thoughts and preferences in context of the treatment options –** *item 13*<br>The patient expresses feelings, thoughts, values, concerns and preferences openly. Either at the patient's or the physician's initiative. |

| Dimension IV: Deliberation |
|---|
| **9. The physician supports the patient in deliberation -** *item 11*<br>The physician supports the patient in considering what is important to the patient in life in the context of his/her disease and the treatment options, e.g., by probing values and/or their rank order, and/or structuring and/or summarizing the thoughts expressed by the patient.<br><br>**10. The patient considers what is most important to him/her in context of treatment options -** *item 14*<br>The patient considers the treatment options based on what he/she has learned about them. He/she considers what is important to him in life in the context of his disease and the treatment options. He/she thinks about what he/she would want to achieve and would want to avoid. This may happen during as well as outside the consultation. |
| **Dimension V: Time for deliberation** |
| **11. The physician gives the patient room to contribute to SDM -** *item 12*<br>The physician gives the patient room to contribute to SDM, by giving time and space for asking questions and/or expressing values, feelings, concerns, thoughts and preferences and/or considering the treatment options. |
| **Dimension VI: Decision** |
| **12. Make or explicitly postpone decision that is based on patient's preferences / values / goals -** *item 15*<br>A treatment decision is explicitly made, based on patient's preferences / values / goals, either at the patient's or the physician's initiative.<br><br>**13. The physician assesses what the patient needs to make a decision -** *item 16*<br>If the decision is postponed, the physician more or less explicitly ascertains what the patient needs in order to be able to determine what is important to him/her and/or determine his preferred option and/or make the decision, by himself/herself or together with the physician. |

**Box 2.** iSHAREpatient†

**iSHARE: Deciding together on the treatment of cancer**

When completing this questionnaire, please think of the last time you spoke to your doctor in the hospital about the treatment options. This may have been in one or multiple conversations. When you are completing the questionnaire, please think about all these conversations.

The statements are about the doctor and about yourself. Some statements may look similar, but ask about something different.

For each statement, tick the answer that fits best. There are no right or wrong answers, it is your opinion that matters. Your answers will remain anonymous, so the doctor will not see them.

This questionnaire is not about how satisfied you are with your doctor. It is about what your doctor said or did during the conversation.

Do you find the information mentioned above clear?

☐ Yes

☐ No. Please state what is not clear to you: .....

1. The doctor explained what the advantages of the treatment options are

| not at all | hardly | a little | for a large part | almost completely | completely |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

2. The doctor explained what the disadvantages of the treatment options are
3. The doctor explained the advantages and disadvantages of each treatment option equally well
4. The doctor checked whether I understood the advantages of the treatment options
5. The doctor checked whether I understood the disadvantages of the treatment options
6. The doctor told me how the treatment options differ from each other
7. I asked questions about the treatment options
8. At the beginning of the conversation, the doctor said that there was a choice with regard to my treatment
9. The doctor said that it matters what I think is important
10. The doctor checked whether he/she understood what was important to me
11. The doctor helped me to weigh up the advantages and disadvantages of the treatment options
12. The doctor gave me time to weigh up the advantages and disadvantages of the treatment options (during or after the conversation)
13. I told the doctor what was important to me
14. I weighed up the advantages and disadvantages of the treatment options (before, during or after the conversation)

*Has a decision about treatment been made?*

☐ *Yes, the decision has been made* → *please fill in question 15 below*

☐ *No, the decision has not been made* → *please fill in question 16 below*

15. The decision takes into account what I consider to be important
16. The doctor has discussed with me what I need in order to weigh up the advantages and disadvantages of the treatment options

† This is an English translation of the original Dutch iSHAREpatient questionnaire. A translation agency translated the iSHAREpatient using a forward-backward approach.

**Box 3.** iSHAREphysician†

**iSHARE: Deciding together on the treatment of cancer**

When completing this questionnaire, please think about the consultation in which you discussed the decision about the treatment with the patient. You may have had several consultations with the patient about this decision. When you are completing the questionnaire, please think about all these consultations.

The statements are about the patient and about yourself. There are no right or wrong answers.

1. I explained what the advantages of the treatment options are

| not at all | hardly | a little | for a large part | almost completely | completely |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

2. I explained what the disadvantages of the treatment options are
3. I explained the advantages and disadvantages of each treatment option equally well
4. I checked whether the patient understood the advantages of the treatment options
5. I checked whether the patient understood the disadvantages of the treatment options
6. I told the patient how the treatment options differ from each other
7. The patient asked questions about the treatment options
8. At the beginning of the conversation, I said that there was a choice with regard to the patient's treatment
9. I said that it matters what the patient thinks is important
10. I checked whether I understood what was important to the patient
11. I helped the patient to weigh up the advantages and disadvantages of the treatment options
12. I gave the patient time to weigh up the advantages and disadvantages of the treatment options (during or after the conversation)
13. The patient told me what was important to him/her
14. The patient weighed up the advantages and disadvantages of the treatment options (before, during or after the conversation)

*Has a decision about treatment been made?*

☐ *Yes, the decision has been made* → *please fill in question 15 below*

☐ *No, the decision has not been made* → *please fill in question 16 below*

15. The decision takes into account what the patient considers to be important
16. I discussed with the patient what he/she needs in order to weigh up the advantages and disadvantages of the treatment options

†This is an English translation of the original Dutch iSHAREphysician questionnaire. The translation is based on the translation of the iSHAREpatient.

## 4. DISCUSSION

In this study, we designed the iSHAREpatient and the iSHAREphysician questionnaires to assess SDM in oncology, based on a thorough development process. The iSHARE questionnaires contain the same items, formulated from the two different viewpoints. Both questionnaires assess patient as well as physician behaviours, and aim to assess the SDM process during all consultations relevant to making the decision as well as during time outside of consultations. The iSHARE questionnaires may be used simultaneously or separately in future studies, depending on the research question. We decided that it would be most feasible for future studies if the two questionnaires would contain the smallest possible number of items. Throughout the development process we therefore constantly prioritized domains and items, using the input provided by SDM experts, patients, and physicians. Further, SDM measurement instruments from a patient viewpoint often seem to assess satisfaction rather than the extent to which SDM occurred.[18] We made every effort to clarify to patients that the questionnaire is not about satisfaction, by making this explicit in the introduction of the questionnaire. The iSHARE questionnaires were developed for oncology. Yet, they are not formulated in ways that are specific to oncology and the questionnaires may thus prove useful in other settings as well. Use of the iSHARE questionnaires to assess SDM in non-Dutch cancer settings and/or in other disease settings requires additional content validity testing.

The iSHARE questionnaires have some distinguishing features. First, the total score is not a function of who makes the final decision. This is consistent with our underlying SDM construct and reflects a finding from our earlier qualitative study. Specifically, in SDM in oncology it seems of minor importance who makes the final call, as long as the process was shared.[11] Such an approach to SDM has been described by others. That is, patients were aware of and benefited from an SDM process, regardless of who they believed made the treatment decision.[31] Second, the iSHARE questionnaires focus on an SDM process that can extend beyond a consultation. The iSHARE questionnaires therefore can be administered at various time points during the decision-making process.

We started out with the assumption that the assessment of SDM should be based on a formative measurement model, as did the developers of the CollaboRATE[32] and the OPTION-5.[12] Assuming a formative measurement model implicates the use of less regular methods to inform item reduction, one of which is rating the importance of items during field-testing.[1] In our study this method proved a feasible and valuable approach, but it would have been helpful to have specific, evidence-based criteria to apply to the results when narrowing down the item pool. Measuring a construct based on a formative measurement model also implies that the calculation of a total score may not be appropriate, since the dimensions can be independent. Scores are therefore calculated per dimension. Clearly, a total score may sometimes be preferred because it can be a useful summary score. For the present questionnaires, we have no theoretical indication that one or more dimensions should be weighted differently from the others to calculate the total score.[1, 33]

Current measurement instruments assessing SDM from different viewpoints use the same items, formulated from different viewpoints, but agreement has nevertheless been found to

be poor. We also used the same items for the iSHARE questionnaires, but let both patients' and physicians' views inform the SDM model which we used as input to our SDM construct. Further, both patients and physicians were involved in selecting the domains and items. With these questionnaires we further ask participants about behaviour, and responses should therefore provide a view on what actually happened during decision making processes. We therefore expect that the iSHAREpatient and iSHAREphysician questionnaires will show at least a somewhat better agreement than has been found before.[14, 15, 19] Nonetheless, interpretation of specific behaviours may still differ between patients and physicians, leading to different views on the extent to which SDM occurred.

We are currently undertaking a validation study to determine whether the iSHAREpatient and iSHAREphysician assess the construct as intended and assess SDM in similar ways from the two different viewpoints. Further assessment of psychometric properties of the questionnaires is necessary before recommending the use of the iSHARE questionnaires.
Study limitations

Although we used the original COSMIN checklist as a guideline throughout the development process,[28] our findings should be considered in light of two main limitations. First, physicians only assessed content validity on domain level and not on item level, for pragmatic reasons. Second, although we aimed to include patients representing a range of different education levels, most included patients were highly educated, resulting in potential biases towards domains and items that may be less important to or less comprehensible for other patients.

## 5. CONCLUSION

This study provides a patient and a physician questionnaire to assess SDM in oncology, based on a clearly defined construct and a thorough development process. The iSHARE questionnaires are short, assess both patient and physician behaviours, focus on the SDM process during all consultations relevant to making the decision, on the SDM process occurring outside consultations, and may be administered before or after the final decision has been made. Results obtained by using these questionnaires provide starting points to support the SDM process in ways tailored to actual behaviours and to both participants in the process.

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# Appendix A.

## Measuring shared decision making: Choice of response scale matters

Oral abstract presented at the 2019 International Shared Decision Making Conference, Quebec City, Canada.

Bomhof-Roordink H, Gärtner FR, Stiggelbout AM, Pieterse AH. Measuring shared decision making: Choice of response scale matters. Abstract presented at the International Shared Decision Making Conference, Quebec City, Canada (2019). Available from: *https://fourwaves-sots.s3.amazonaws.com/static/media/uploads/2019/06/28/isdm2019-oralsessionsbooklet-2019-06-28.pdf.*

### Aim

To determine which response scale shows greatest variation, fewest ceiling effects, and seems most feasible, for a patient questionnaire developed to assess patient and oncologist shared decision making behaviours in oncology.

### Methods

We drafted four different response scales: 1) a five-point 'agree' scale ranging from 'Totally disagree' to 'Totally agree'; 2) a five-point 'done' scale ranging from 'Not done at all' to 'Done completely'; 3) a five-point 'positively unbalanced done' scale ranging from 'Not done at all' to 'Done completely', with 'neutral' as second response option; and 4) a 100-point 'VAS done' scale, with ends labelled as 'Not done at all' and 'Done completely'. We approached members of an online cancer patient panel by email and asked them to complete the 16-item draft questionnaire; panel members were randomized to one of the scales. We calculated the sum score (range, 16-80) and mean for each randomized group. We considered the coefficient of variation (CV) and the range of total scores as indicators of variation, and inspected the score distributions to detect ceiling effects. Based on these results, we selected response scales to determine comprehensibility in cognitive interviews.

### Results

Forty-one to 54 panel members responded in each randomization group (total N=191). The groups did not significantly differ regarding age, gender, education, diagnosis, or treatment. In order of magnitude, means were: 61.5 (SD 16.5, CV 0.27, range 27-80), 'done' scale; 59.9 (SD 16.4, CV 0.27, range 23- 80), 'agree' scale; 58.5 (SD 17.5, CV 0.30, range 21-80), 'positively unbalanced done' scale; and 52.5 (SD 16.5, CV 0.31, range 22.0-75.7), 'VAS done' scale. The latter mean was significantly lower compared to the 'done' and 'agree' scales. The 'agree' and 'done' scales showed the highest ceiling effects, and these were abandoned. Cognitive interviews showed that the 'VAS done' scale was sometimes interpreted as a dichotomous scale. The 'positively unbalanced done' scale turned out to be most feasible.

### Conclusions

This study provides clear evidence that the choice of response scale can substantially influence the findings. Questionnaire developers should consider which response scale seems most appropriate, particularly when ceiling effects can be expected.

## Appendix B.

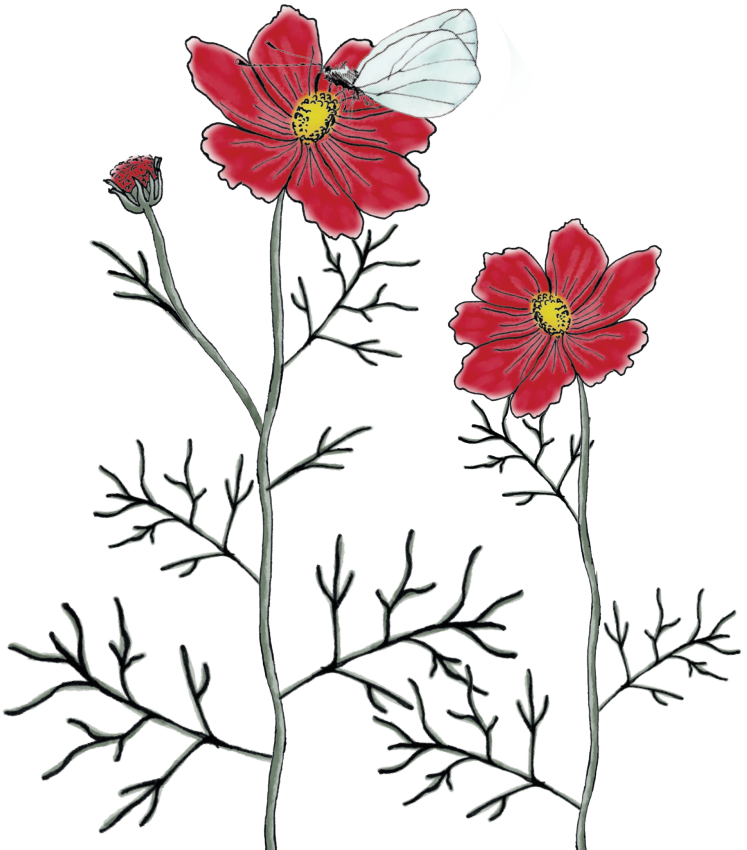
### The construct of SDM in oncology; selection of clustered domains during the development process. Clustering is indicated by shading.

| First selection informed by a model of SDM in oncology and a review of SDM models (§3.2) | Selection after receiving feedback from SDM experts (§3.2) | Selection after content validity testing in cancer patients (§3.3) | Selection after content validity testing in physicians and field-testing in cancer patients (§3.4) | Final selection after cognitive interviews in cancer patients and physicians (§3.6, Box 1) |
|---|---|---|---|---|
| The physician establishes (creates or checks) choice awareness | The physician establishes (creates or checks) choice awareness | The physician establishes (creates or checks) choice awareness | The physician establishes (creates or checks) choice awareness | The physician establishes (creates or checks) choice awareness |
| The physician expresses that patient's opinion is important in process | The physician expresses that patient's opinion is important in process | The physician expresses that patient's opinion is important in process | The physician expresses that patient's opinion is important in process | The physician expresses that patient's opinion is important in process |
| The physician invites the patient to share decisions | | | | |
| The physician decides on the agenda for the consultation | | | | |
| | The physicians lists the treatment options | The physicians lists the treatment options | The physicians lists the treatment options† | |
| The physician provides information on the benefits/risks of the treatment options | The physician provides information on the benefits/risks of the treatment options | The physician provides information on the benefits/risks of the treatment options | The physician provides information on the benefits/risks of the treatment options | The physician provides information on the benefits/risks of the treatment options |
| The physician informs the patient that more than one option is medically acceptable | | | | |
| The physician provides balanced information | The physician provides balanced information | The physician provides balanced information | The physician provides balanced information | The physician provides balanced information |
| | The physician checks patient's understanding | The physician checks patient's understanding | The physician checks patient's understanding | The physician checks patient's understanding |

| | | | | |
|---|---|---|---|---|
| | The patient asks about (other) management options | The patient asks about (other) management options | | |
| | The patient asks for clarification | The patient asks for clarification | The patient asks for clarification | The patient asks for clarification |
| The physician learns about the patient's values, goals of care, concerns and/or preferences in the context of the treatment options | The physician learns about the patient's values, goals of care, concerns and/or preferences in the context of the treatment options | The physician learns about the patient's values, goals of care, concerns and/or preferences in the context of the treatment options | The physician learns about the patient's values, goals of care, concerns and/or preferences in the context of the treatment options† | |
| | The physician checks own understanding of patient's values, goals of care, concerns and/or preferences in the context of the treatment options | The physician checks own understanding of patient's values, goals of care, concerns and/or preferences in the context of the treatment options | | The physician checks own understanding of patient's values, goals of care, concerns and/or preferences in the context of the treatment options |
| The patient expresses values, feelings, concerns, thoughts and preferences in the context of the treatment options | The patient expresses values, feelings, concerns, thoughts and preferences in the context of the treatment options | The patient expresses values, feelings, concerns, thoughts and preferences in the context of the treatment options | The patient expresses values, feelings, concerns, thoughts and preferences in the context of the treatment options | The patient expresses values, feelings, concerns, thoughts and preferences in the context of the treatment options |
| Physician supports with considering options | The physician supports the patient in deliberation | The physician supports the patient in deliberation | The physician supports the patient in deliberation | The physician supports the patient in deliberation |
| Physician deliberates | | | | |
| The patient considers what is most important to him/her in the context of the treatment options | The patient considers what is most important to him/her in the context of the treatment options | The patient considers what is most important to him/her in the context of the treatment options, during the consultation | The patient considers what is most important to him/her in the context of the treatment options† | The patient considers what is most important to him/her in the context of the treatment options |
| | | The patient considers what is most important to him/her in the context of the treatment options, before or after the consultation | | |

| | | | | |
|---|---|---|---|---|
| The physician gives a treatment recommendation that is a function of patient's preferences | The physician gives a treatment recommendation that is a function of patient's preferences | The physician gives a treatment recommendation that is a function of patient's preferences | | |
| The patient offers his/her opinion regarding the treatment options | The patient offers his/her opinion regarding the treatment options | The patient offers his/her opinion regarding the treatment options | | |
| Make or explicitly postpone decision that is based on patient's preferences / values / goals | Make or explicitly postpone decision that is based on patient's preferences / values / goals | Make or explicitly postpone decision that is based on patient's preferences / values / goals | Make or explicitly postpone decision that is based on patient's preferences / values / goals | Make or explicitly postpone decision that is based on patient's preferences / values / goals |
| | The physician assesses what the patient needs to make a decision | The physician assesses what the patient needs to make a decision | The physician assesses what the patient needs to make a decision | The physician assesses what the patient needs to make a decision |
| | | The physician gives the patient room to contribute to SDM | The physician gives the patient room to contribute to SDM | The physician gives the patient room to contribute to SDM |

†These domains were not selected for the draft physician questionnaire that was used as input to the cognitive interviews.



# 6

# PATIENT AND PHYSICIAN SHARED DECISION-MAKING BEHAVIOURS IN ONCOLOGY: EVIDENCE ON ADEQUATE MEASUREMENT PROPERTIES OF THE iSHARE QUESTIONNAIRES

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## ABSTRACT

### Objectives

We have developed two Dutch questionnaires to assess the shared decision-making (SDM) process in oncology; the iSHAREpatient and iSHAREphysician. In this study, we aimed to determine: scores, construct validity, test-retest agreement (iSHAREpatient), and inter-rater (iSHAREpatient-iSHAREphysician) agreement.

### Methods

Physicians from seven Dutch hospitals recruited cancer patients, and completed the iSHAREphysician and SDM-Questionnaire-physician version. Their patients completed the: iSHAREpatient, nine-item SDM-Questionnaire, Decisional Conflict Scale, Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness, and five-item Perceived Efficacy in Patient-Physician Interactions. We formulated, respectively, one (iSHAREphysician) and 10 (iSHAREpatient) a priori hypotheses regarding correlations between the iSHARE questionnaires and questionnaires assessing related constructs. To assess test-retest agreement patients completed the iSHAREpatient again 1-2 weeks later.

### Results

In total, 151 treatment decision-making processes with unique patients were rated. Dimension and total iSHARE scores were high both in patients and physicians. The hypothesis on the iSHAREphysician and 9/10 hypotheses on the iSHAREpatient were confirmed. Test-retest and inter-rater agreement were >.60 for most items.

### Conclusions

The iSHARE questionnaires show high scores, have good construct validity, substantial test-retest agreement, and moderate inter-rater agreement.

### Practice implications

Results from the iSHARE questionnaires can inform both physician- and patient-directed efforts to improve SDM in clinical practice.

# 1. INTRODUCTION

*Those who have not experienced the intricacies of clinical practice demand measures that are easy, precise, and complete—as if a sack of potatoes was being weighed. True, some elements in the quality of care are easy to define and measure, but there are also profundities that still elude us. We must not allow anyone to belittle or ignore them; they are the secret and glory of our art.*

*Avedis Donabedian*[1]

Measurement of shared decision making (SDM) remains a challenge.[2-4] The SDM process in which patients, their loved ones and healthcare professionals together arrive at treatment decisions incorporating patients' values and preferences is not easy to capture in a measurement instrument. SDM happens both during and outside consultations,[5] involves both observable (e.g., information-giving) and covert (e.g., thinking about the options) behaviours, and includes behaviours of both patients and healthcare professionals.[6, 7] Current SDM measurement instruments do not cover all of these aspects, and substantially differ in which SDM elements are assessed.[8, 9] Many often-used measurement instruments assess only healthcare professionals' behaviour (e.g., OPTION,[10] CollaboRATE)[11] or do not assess patient behaviour independently of physician behaviour (e.g., nine-item SDM-Questionnaire (SDM-Q-9),[12] SDM-Questionnaire-physician version (SDM-Q-Doc),[13] impeding the assessment of patients' role.

We developed the Dutch iSHARE questionnaires to assess SDM in oncology, from both a patient (iSHAREpatient) and physician (iSHAREphysician) viewpoint.[14] We chose the oncology setting since cancer patients often face preference-sensitive decisions.[15, 16] The SDM construct was informed by an SDM model in oncology based on stakeholders' views, and by a review of SDM models across healthcare settings published until June 2016. The iSHARE questionnaires include both patient and physician behaviours. Cancer patients and physicians were extensively involved during the development process, in line with quality criteria for the development of health-related measurement instruments.[17]

We aimed to a) describe scores obtained by the iSHARE questionnaires in an oncology setting, and determine b) construct validity of the iSHARE questionnaires, c) test-retest agreement of the iSHAREpatient, and d) agreement between scores on the iSHAREpatient and iSHAREphysician.

# 2. METHODS

## 2.1 Study design

In this multicentre study, we asked physicians from seven Dutch hospitals to complete a questionnaire after each consultation with a unique eligible patient, between June 2018 and December 2019. Participating patients were asked to complete a questionnaire after the consultation, and again 1-2 weeks later. We aimed for 50 physicians, each including at least two patients, based on the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist.[18-20] The Medical Ethical Committee of the Leiden University Medical Centre (LUMC) approved the study (NL50551.058.14, P14.207), which was conducted according to the Dutch Medical Research Involving Human Subjects Act.

## 2.2 Participant recruitment

We approached physicians treating cancer patients for participation, and asked consenting physicians to recruit consecutive unique eligible patients. Patients were eligible if they had been diagnosed with cancer, were ≥18 years old, able to speak and write Dutch, had a consultation in which a decision to start, stop, change or forgo treatment with curative or palliative intent was discussed, and had a life expectancy of over three months. We aimed to assess the measurement properties of the iSHARE questionnaires in a sample representing the heterogeneity of cancer treatment decisions, and therefore asked physicians from a range of cancer specialties to approach patients.

The physicians provided patients with an information letter, an informed consent form, and a post-consultation questionnaire, and asked them if they agreed to being called by the researchers. If so, we contacted them to ask if they had questions and if they were willing to participate. Consenting patients sent us their signed informed consent form and the completed questionnaire. We only used the physician's questionnaire if the patient had provided informed consent.

## 2.3 Data collection

Physicians reported their birth year, gender, year of start of specialization, working place, and specialty. They completed the iSHAREphysician[14] and the SDM-Q-Doc[13] post-consultation on paper or online. They also reported the patient's primary tumour type and curative/palliative intent of the treatment discussed. Patients completed the: iSHAREpatient,[14] SDM-Q-9,[12] Decisional Conflict Scale (DCS),[21] Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness (COMRADE),[22] five-item Perceived Efficacy in Patient-Physician Interactions (PEPPI-5),[23] and birth date, gender, education, month and year of most recent cancer diagnosis, and number of consultations they had in mind while completing the questionnaire, on paper or online. We sent consenting patients the iSHAREpatient again on paper or via email, whichever they preferred, within a few days after we had received the initial questionnaire. To match patients and physicians, the paper version of the questionnaire included a study code that was unique for each unique decision-making process. In case patients or physicians completed the questionnaires online, they used a link to the online database questionnaire system Qualtrics, and entered the study code. We entered the data from the paper questionnaires in Qualtrics.

## 2.4 iSHAREpatient and iSHAREphysician

The iSHAREpatient (Box 1) and iSHAREphysician (Box 2) have the same, but mirrored 15 items,[14] with a six-point unbalanced scale, ranging from 'not at all' (0) to 'completely' (5).[24] They encompass the same construct, consisting of six dimensions (i.e., Choice awareness, Medical information, Preferences, Deliberation, Time for deliberation, Decision). The items relate to these six dimensions, which we do not assume to be necessarily correlated,[2, 25, 26] leading us to adopt a formative measurement model (i.e., the items form the construct).[14] The dimensions aim to assess the complete SDM process both during and outside consultations, and include both patient and physician behaviours. Depending on whether a decision has already been made or not, either the score on item 15 or item 16 is relevant to compute the

score on dimension six.[14] If a patient or physician had indicated that a decision had been made, or if the response to that item was missing, we report the score on item 15; otherwise, we report the score on item 16.

We calculated dimension scores (range, 0-5) and a total score (the sum of the dimension scores; range, 0-30) for both iSHARE questionnaires. We applied a linear transformation to obtain a 0 to 100 total score ((score/30)*100). Higher dimension and total scores indicate higher levels of SDM. We only report dimension and total scores if all the respective items had been completed; the formative nature of the construct makes imputation of missing values inappropriate.

## 2.5 Construct validity of the iSHAREpatient and iSHAREphysician

We determined construct validity by testing hypotheses about correlations between the iSHARE questionnaires and questionnaires measuring related constructs. We formulated a priori hypotheses based on the content of the respective scales, subscales and items and/or on the construct they aim to assess. For example, we expected the COMRADE subscale 'satisfaction with communication' to correlate positively with the iSHAREpatient, based on the content of the items. We tested hypotheses on total score level for both iSHARE questionnaires and on dimension level for the iSHAREpatient (Table 5). We further expected the three iSHAREpatient items on patient-initiated behaviour (items 7, 13, 14) each to correlate with the PEPPI-5. We expected a correlation of >.30 or <-.30 for each hypothesis. We did not formulate hypotheses at the dimension level for the iSHAREphysician or the iSHAREpatient dimensions Choice Awareness, Deliberation, and Time for Deliberation, since we could not find questionnaires measuring related constructs from the same viewpoint.

### 2.5.1 SDM-Q-9 and SDM-Q-Doc

The SDM-Q-9[12] and SDM-Q-Doc[13] assess SDM from respectively patient and physician perspective. They each include nine items that are scored on a six-point scale from 'completely disagree' (0) to 'completely agree' (5). The raw score ranges from 0 to 45 and is multiplied by 20/9, resulting in a score from 0 to 100. Higher scores indicate higher levels of SDM.[12, 13] Both questionnaires have been validated in the oncology setting,[27-29] and have been translated and validated in Dutch.[30] Cronbach's α's were .90 (SDM-Q-9) and .85 (SDM-Q-Doc).

### 2.5.2 COMRADE

The COMRADE aims to measure effectiveness of risk communication and treatment decision making in consultations, and consists of two subscales: satisfaction with communication (10 items) and confidence in decision (10 items). The response scale ranges from 'strongly disagree' (1) to 'strongly agree' (5).[22] We calculated subscale scores based on the original factor analysis that was provided by the developer. Both subscale scores range from 0 to 100, with higher scores indicating more satisfaction or confidence, respectively. The COMRADE has been translated in Dutch.[31] Cronbach's α's were .91 (satisfaction with communication) and .90 (confidence in decision).

### 2.5.3 DCS

The DCS is a 16-item questionnaire assessing the level of decisional conflict; the five-point scale items range from 'strongly agree' (0) to 'strongly disagree' (4).[21] The scale consists of five subscales: feeling uncertain (3 items), feeling uninformed (3 items), feeling unclear about values (3 items), feeling unsupported (3 items), and ineffective decision making (4 items).[32] To calculate the subscale scores, item scores are summed, divided by the number of items in the subscales and multiplied by 25, with scores ranging from 0 to 100. The total score ranges from 0 to 64, is multiplied by 25/16, resulting in a standardized score from 0 to 100. Higher scores indicate higher decisional conflict. The DCS has been translated and validated in Dutch, in an oncology setting.[33] Cronbach's α's were .69 (feeling uncertain), .73 (feeling uninformed), .58 (feeling unclear about values), .32 (feeling unsupported) and .82 (ineffective decision making).

### 2.5.4 PEPPI-5

The PEPPI-5 aims to measure patients' perceived self-efficacy in obtaining medical information and attention to their medical concerns from physicians. The response scale ranges from 'not at all confident' (1) to 'very confident' (5) and the total score ranges from 5 to 25, with higher scores representing higher perceived self-efficacy in patient-physician interactions.[23] The PEPPI-5 has been translated and validated in Dutch, in patients with osteoarthritis.[34] Cronbach's α was .91.

## 2.6 Test-retest agreement of the iSHAREpatient

We assessed test-retest agreement of the iSHAREpatient, that is, the extent to which item scores for patients with a stable perception of the SDM process were the same for repeated measurements over time.[35] The COSMIN study design checklist[20] requires participants to be stable during the chosen interval, and the interval to be long enough to avoid them recalling their scores at first administration; we expected a time window of 1-2 weeks to be appropriate between test and retest. We excluded patients who answered affirmatively to one or both of the following questions at retest: 'Please think back to the time you filled in the questionnaire for the first time. Do you have different thoughts regarding the decision-making process now, compared to the thoughts you had back then?' and 'Have you had another conversation with the physician in the meantime?'.

We did not consider it feasible to assess test-retest agreement for the iSHAREphysician. We did not expect physicians to be able to recall the treatment decision-making process for a particular patient well enough over a period of 1-2 weeks to complete the iSHAREphysician again for that patient.

## 2.7 Inter-rater agreement between the iSHAREpatient and iSHAREphysician

In accordance with the COSMIN study design checklist[20] we determined agreement (not correlation) between the scores on the iSHAREpatient and iSHAREphysician.

**Box 1.** iSHAREpatient†[14]

**iSHARE: Deciding together on the treatment of cancer**

When completing this questionnaire, please think of the last time you spoke to your doctor in the hospital about the treatment options. This may have been in one or multiple conversations. When you are completing the questionnaire, please think about all these conversations.

The statements are about the doctor and about yourself. Some statements may look similar, but ask about something different.

For each statement, tick the answer that fits best. There are no right or wrong answers, it is your opinion that matters. Your answers will remain anonymous, so the doctor will not see them.

This questionnaire is not about how satisfied you are with your doctor. It is about what your doctor said or did during the conversation.

Do you find the information mentioned above clear?

☐ Yes

☐ No. Please state what is not clear to you: .....

1. The doctor explained what the advantages of the treatment options are

| not at all | hardly | a little | for a large part | almost completely | completely |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

2. The doctor explained what the disadvantages of the treatment options are
3. The doctor explained the advantages and disadvantages of each treatment option equally well
4. The doctor checked whether I understood the advantages of the treatment options
5. The doctor checked whether I understood the disadvantages of the treatment options
6. The doctor told me how the treatment options differ from each other
7. I asked questions about the treatment options
8. At the beginning of the conversation, the doctor said that there was a choice with regard to my treatment*
9. The doctor said that it matters what I think is important*
10. The doctor checked whether he/she understood what was important to me
11. The doctor helped me to weigh up the advantages and disadvantages of the treatment options
12. The doctor gave me time to weigh up the advantages and disadvantages of the treatment options (during or after the conversation)
13. I told the doctor what was important to me
14. I weighed up the advantages and disadvantages of the treatment options (before, during or after the conversation)

*Has a decision about treatment been made?*

☐ *Yes, the decision has been made* → *please fill in question 15 below*

☐ *No, the decision has not been made* → *please fill in question 16 below*

15. The decision takes into account what I consider to be important
16. The doctor has discussed with me what I need in order to weigh up the advantages and disadvantages of the treatment options

† This is an English translation of the original Dutch iSHAREpatient. A translation agency translated the iSHAREpatient using a forward-backward approach.

*Items 8 and 9 of the iSHARE questionnaires assess whether the physician created choice awareness. Theoretically, we consider this as the first step of the SDM process. We decided against putting the items at the start of the questionnaires because patients did not seem to critically reflect on what was asked if they were presented first. We recommend future users to adopt the same approach.

**Box 2.** iSHAREphysician†[14]

**iSHARE: Deciding together on the treatment of cancer**

When completing this questionnaire, please think about the consultation in which you discussed the decision about the treatment with the patient. You may have had several consultations with the patient about this decision. When you are completing the questionnaire, please think about all these consultations.

The statements are about the patient and about yourself. There are no right or wrong answers.

1. I explained what the advantages of the treatment options are

| not at all | hardly | a little | for a large part | almost completely | completely |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

2. I explained what the disadvantages of the treatment options are
3. I explained the advantages and disadvantages of each treatment option equally well
4. I checked whether the patient understood the advantages of the treatment options
5. I checked whether the patient understood the disadvantages of the treatment options
6. I told the patient how the treatment options differ from each other
7. The patient asked questions about the treatment options
8. At the beginning of the conversation, I said that there was a choice with regard to the patient's treatment*
9. I said that it matters what the patient thinks is important*
10. I checked whether I understood what was important to the patient
11. I helped the patient to weigh up the advantages and disadvantages of the treatment options
12. I gave the patient time to weigh up the advantages and disadvantages of the treatment options (during or after the conversation)
13. The patient told me what was important to him/her
14. The patient weighed up the advantages and disadvantages of the treatment options (before, during or after the conversation)

*Has a decision about treatment been made?*

☐ *Yes, the decision has been made* → *please fill in question 15 below*

☐ *No, the decision has not been made* → *please fill in question 16 below*

15. The decision takes into account what the patient considers to be important
16. I discussed with the patient what he/she needs in order to weigh up the advantages and disadvantages of the treatment options

†This is an English translation of the original Dutch iSHAREphysician. The translation is based on the translation of the iSHAREpatient.

*Items 8 and 9 of the iSHARE questionnaires assess whether the physician created choice awareness. Theoretically, we consider this as the first step of the SDM process. We decided against putting the items at the start of the questionnaires because patients did not seem to critically reflect on what was asked if they were presented first. We recommend future users to adopt the same approach.

## 2.8 Statistical analyses

### 2.8.1 Selection and missing values

We excluded test and/or retest patient questionnaires if they had been completed >30 days post-consultation, and physician questionnaires if they had been completed >7 days post-consultation (Figure 1). We assumed that a longer period would be detrimental to participants' recollection of the decision-making process.

We handled missing values according to authors' recommendations, if provided in the original or Dutch validation paper (see section 2.5).[12, 13, 34] For the other questionnaires and the iSHARE questionnaires (see section 2.4), we only report scores when all respective items had been completed. We report sample sizes per analysis, since these may differ due to missing values.

### 2.8.2 Analyses

Descriptive statistics were used to report scores on all questionnaires. Hypotheses were tested by calculating Spearman correlation coefficients between the scores on the iSHARE questionnaires and the respective comparison questionnaires, as the data were non-normally distributed on all scales. We determined test-retest agreement and inter-rater agreement by calculating agreement and the corresponding 95% confidence intervals (CIs).[36, 37] Due to the non-normally distributed data it was not possible to calculate weighted kappa's. For test-retest agreement we defined agreement as the same item score obtained both at test and retest: (X00+X11+X22+X33+X44+X55)/(X01+X02+X03+X04 +X05+X10+X12+…+X54), where e.g., X33 means that for both test and retest the item score was 3. For inter-rater agreement, we allowed the item scores to differ one point, since we considered it acceptable if scores from the respective viewpoints somewhat differed. To illustrate, a score of 5 on an iSHAREpatient item and a score of 4 on the same iSHAREphysician item (i.e., X54), was considered as agreement. Consequently, proportion agreement (P) was defined as: (X00+X01+X10+X11+X12+X21+X22+X23+X32+X33+X34+X43+X44+X45+X54+X55) /(X02+X03+X04+X05+X13+X14+…+X53). The corresponding CIs were calculated as follows:

$$P_{low} = P - c_{\frac{\alpha}{2}}\sqrt{\frac{\mathrm{P}(1-\mathrm{P})}{\mathrm{n}} - \frac{1}{2n}} \qquad P_{high} = P + c_{\frac{\alpha}{2}}\sqrt{\frac{\mathrm{P}(1-\mathrm{P})}{\mathrm{n}} + \frac{1}{2n}}$$

When agreement was close to 0 or 1 (i.e. ≤.3 or ≥.7), we applied the Fleiss correction to the corresponding CIs. These CIs were calculated as follows:[36]

$$P_{low} = \left(2nP + {c_{\frac{\alpha}{2}}}^2 - 1\right) - c_{\frac{\alpha}{2}}\sqrt{\frac{{c_{\frac{\alpha}{2}}}^2 - \left(2 + \frac{1}{\mathrm{n}}\right) + 4\mathrm{P}(\mathrm{n}(1-\mathrm{P}) + 1)}{2(\mathrm{n} + {c_{\frac{\alpha}{2}}}^2)}}$$

$$P_{high} = \left(2nP + {c_{\frac{\alpha}{2}}}^2 - 1\right) + c_{\frac{\alpha}{2}}\sqrt{\frac{{c_{\frac{\alpha}{2}}}^2 + \left(2 + \frac{1}{\mathrm{n}}\right) + 4\mathrm{P}(\mathrm{n}(1-\mathrm{P}) - 1)}{2(\mathrm{n} + {c_{\frac{\alpha}{2}}}^2)}}$$

where $n$ is the sample size and $c_{\frac{\alpha}{2}}$ the percentile cut-off for the standard normal distribution (i.e., 1.96 for the 95% CI). CIs for agreement were calculated in Excel version 2010. We used SPSS version 25 to perform all other analyses. A p-value <.05 was considered statistically significant.

## 3. RESULTS

### 3.1 Participants

In total, 156 patients and 51 physicians participated in the study (Table 1). Fifty-seven eligible patients who had been approached for participation by their treating physician and took the study information home, did not provide consent. We do not know how many eligible patients have been approached and declined immediately. In total, 151 treatment decision-making processes were rated by both patients and physicians, with a range of one to seven per physician. Five decision processes were only rated by patients and eleven only by physicians (Figure 1). Patients completed the initial questionnaire 6.0+6.0 (range, 0-29) days post-consultation and physicians 0.2+0.8 (range, 0-7) days post-consultation. Eighty-five patients thought about more than one consultation while completing the questionnaire.

### 3.2 Responses on the iSHAREpatient and iSHAREphysician

Both the iSHAREpatient and iSHAREphysician showed few missing values (Table 2). The iSHAREpatient and iSHAREphysician dimension scores showed a distribution skewed toward higher scores (Figure 2). Median total scores (interquartile range (IQR)) were 95.0 (77.1-99.5) (iSHAREpatient) and 75.0 (61.1-90.7) (iSHAREphysician) (Table 3). In total, 35 (23%) patients and for 15 (10%) treatment decision-making processes physicians gave the highest possible total score (100).

### 3.3 Construct validity of the iSHARE questionnaires

Table 3 displays the median total and subscale scores on the comparison questionnaires used for hypotheses testing. The hypothesis formulated for the iSHAREphysician was confirmed. Nine out of ten hypotheses formulated for the iSHAREpatient were also confirmed (Table 5).

### 3.4 Test-retest agreement iSHAREpatient

In total, 112 patients completed the iSHAREpatient for the second time within 30 days post-consultation, of which 45 were excluded for various reasons (Figure 1). Mean time between test and retest was 11.1+3.7 (range, 4-24) days. Agreement at item level ranged from .55 (item 11) to .84 (item 15) (Table 4). Three patients had reported that no decision had been made at both test and retest and completed item 16 twice; agreement was .00. A post-hoc analysis in which we allowed item scores to differ one point, showed agreement ranging from .79 (item 7) to .97 (item 15) (Table 4).

### 3.5 Inter-rater agreement between the iSHAREpatient and iSHAREphysician

Inter-rater agreement between the iSHARE questionnaires ranged from .55 (item 12) to .79 (item 1 and 15). Seven patients and physicians both had reported that no decision had been made and completed item 16; agreement was .43 (Table 2).

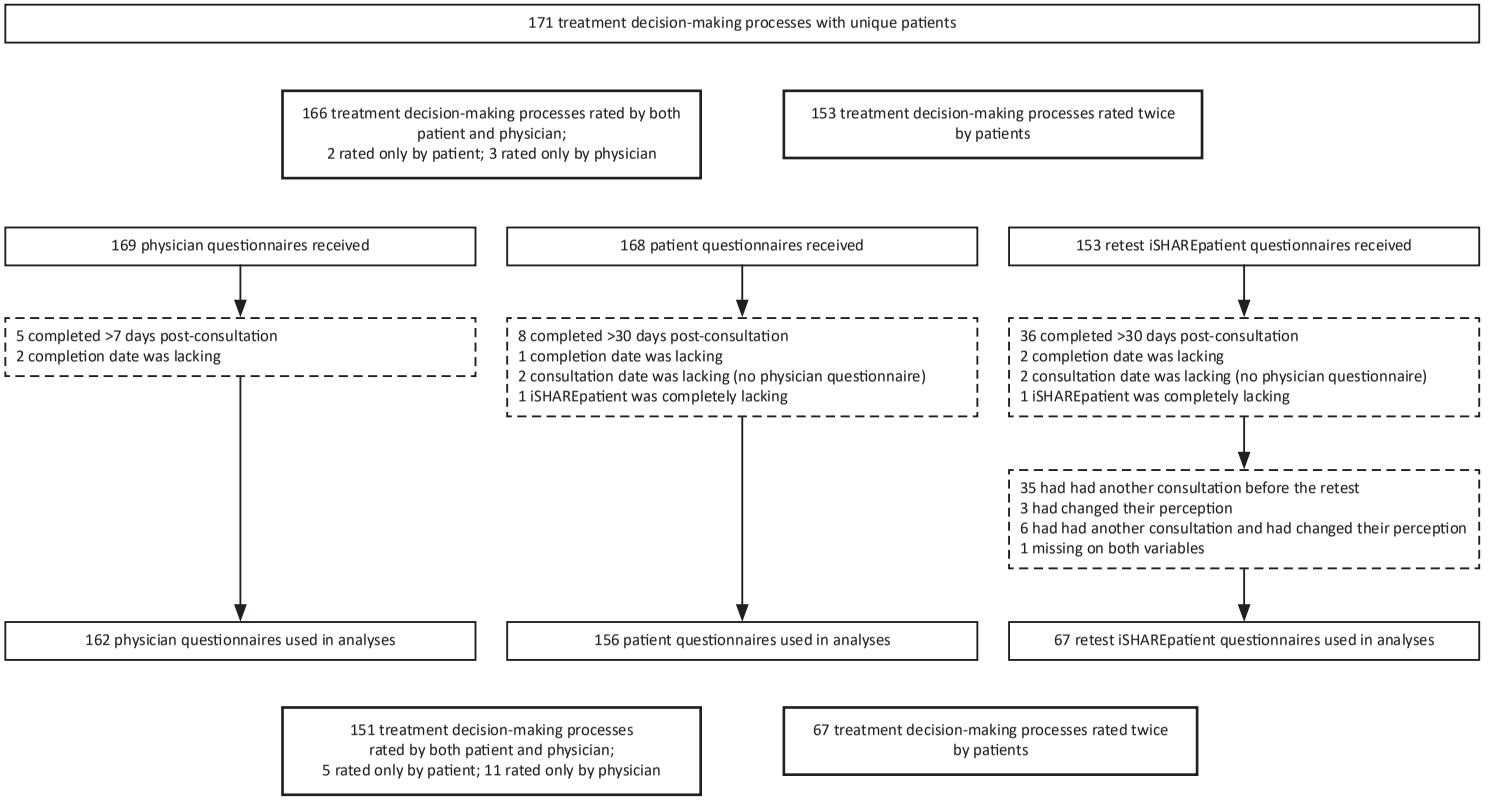


**Figure 1.** Flow diagram of participants

**Table 1.** Patient (n=156) and physician (n=51, who rated 162 treatment decision-making processes) socio-demographic, and disease- or work-related characteristics

| | N* | Percentage or mean ± SD |
|---|---|---|
| **Patients** | | |
| Sex, female | 67 | 43% |
| Age, years | 156 | 67.5 ± 12.5 |
| Education level | 153 | |
| *Low* | 46 | 30% |
| *Intermediate* | 43 | 28% |
| *High* | 64 | 42% |
| Primary tumour type | 156 | |
| *Gastro-intestinal* | 42 | 27% |
| *Urological* | 36 | 23% |
| *Breast* | 22 | 14% |
| *Lung* | 17 | 11% |
| *Haematological* | 13 | 8% |
| *Gynaecological* | 10 | 6% |
| *Other* | 16 | 11% |
| Treatment intent | 154 | |
| *Curative* | 90 | 58% |
| *Palliative* | 59 | 38% |
| *Other* | 5 | 3% |
| Months since most recent cancer diagnosis | 143 | |
| *0-3* | 66 | 46% |
| *4-12* | 34 | 24% |
| *>12* | 43 | 30% |
| | | |
| **Physicians** | | |
| Sex, female | 24 | 47% |
| Age, years | 51 | 44.4 ± 9.6 |
| Years since start specialist training | 51 | 15.8 ± 8.4 |
| Hospital | 52 | |
| *Academic (n=2)* | 33 | 65% |
| *Non-academic (n=5)* | 18 | 35% |
| Specialty | 51 | |
| *Radiotherapy* | 17 | 33% |
| *Medical Oncology* | 11 | 22% |
| *Urology* | 6 | 12% |
| *Surgery* | 4 | 8% |
| *Gynaecology* | 3 | 6% |
| *Pulmonology* | 4 | 8% |
| *Other* | 6 | 12% |

*Numbers do not always add up to the total sample size, due to missing values.
SD=standard deviation

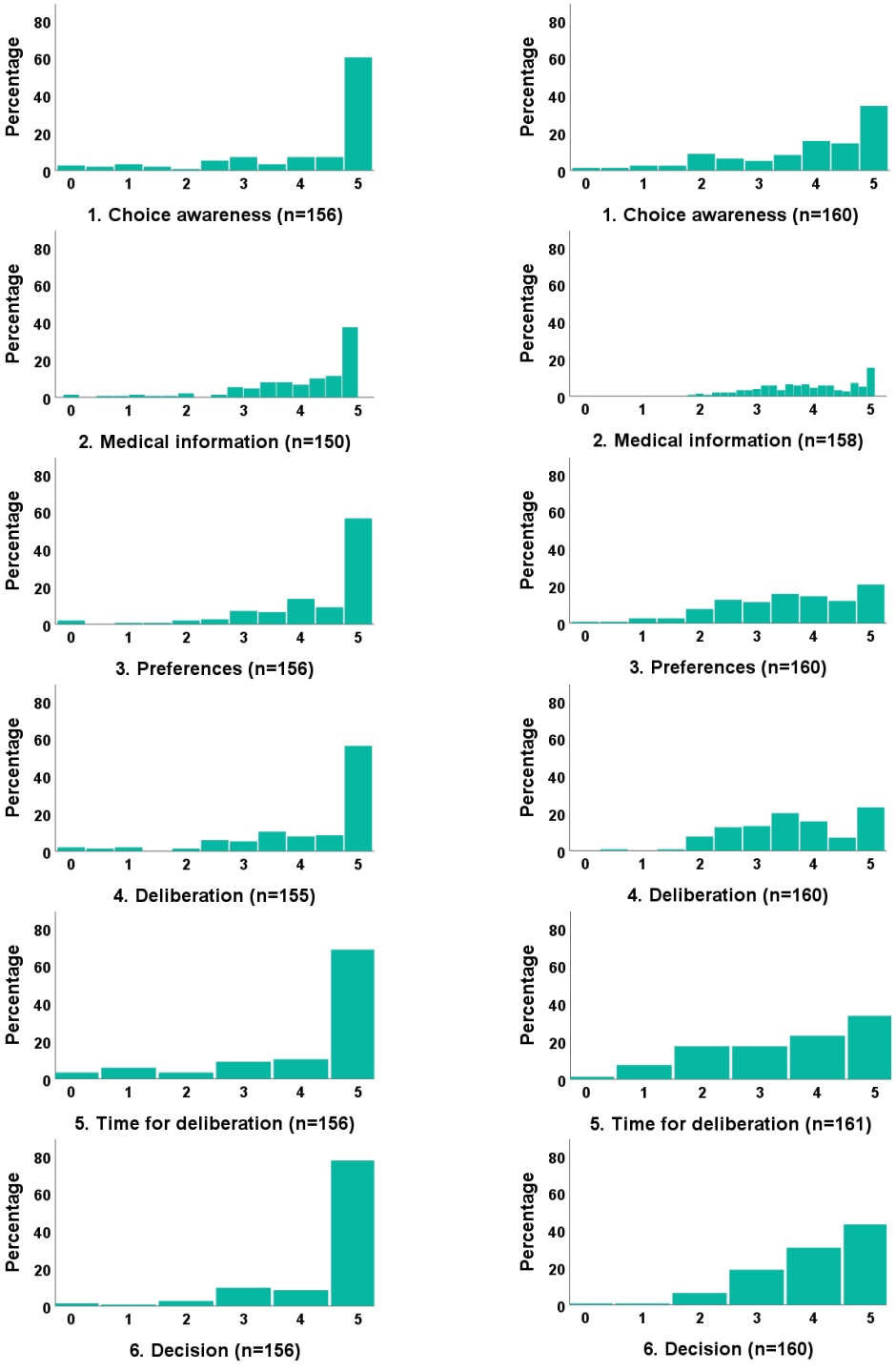


**Figure 2.** Dimension scores on the iSHARE questionnaires

**Table 2.** Median, interquartile range, range, and agreement on item level for the iSHAREpatient (n=156 treatment decision-making processes) and iSHAREphysician (n=162 treatment decision-making processes)

| | **iSHAREpatient** | | **iSHAREphysician** | | **Agreement¯** | |
|---|---|---|---|---|---|---|
| | N | Median (IQR), range | N | Median (IQR), range | N | P (95%CI) |
| *Item score (0-5)* | | | | | | |
| 1. Physician explained advantages of treatment options | 155 | 5.0 (4.0-5.0), 0-5 | 162 | 4.0 (4.0-5.0), 0-5 | 150 | .79 (.71* - .84*) |
| 2. Physician explained disadvantages of treatment options | 156 | 5.0 (3.0-5.0), 0-5 | 162 | 4.0 (4.0-5.0), 2-5 | 151 | .72 (.64* - .78*) |
| 3. Physician explained (dis)advantages equally well | 154 | 5.0 (3.0-5.0), 0-5 | 161 | 4.0 (3.0-5.0), 0-5 | 148 | .68 (.60 - .76) |
| 4. Physician checked patient's understanding of advantages | 155 | 5.0 (4.0-5.0), 0-5 | 162 | 4.0 (3.0-5.0), 1-5 | 150 | .67 (.59 - .75) |
| 5. Physician checked patient's understanding of disadvantages | 154 | 5.0 (4.0-5.0), 0-5 | 162 | 4.0 (3.0-5.0), 1-5 | 149 | .65 (.57 - .73) |
| 6. Physician told how treatment options differ | 155 | 5.0 (3.0-5.0), 0-5 | 158 | 4.0 (3.0-5.0), 0-5 | 146 | .63 (.55 - .71) |
| 7. Patient asked for clarification | 155 | 5.0 (3.0-5.0), 0-5 | 161 | 4.0 (2.0-5.0), 0-5 | 149 | .60 (.52 - .68) |
| 8. Physician said there is a choice | 156 | 5.0 (3.0-5.0), 0-5 | 160 | 4.0 (3.0-5.0), 0-5 | 149 | .65 (.57 - .73) |
| 9. Physician said patient's opinion is important | 156 | 5.0 (4.0-5.0), 0-5 | 161 | 4.0 (3.0-5.0), 0-5 | 150 | .67 (.59 - .75) |
| 10. Physician checked if he/she understood what is important for patient | 156 | 5.0 (4.0-5.0), 0-5 | 160 | 4.0 (3.0-5.0), 0-5 | 149 | .61 (.53 - .69) |
| 11. Physician helped patient weighing (dis)advantages | 156 | 5.0 (3.0-5.0), 0-5 | 161 | 4.0 (3.0-5.0), 0-5 | 150 | .63 (.55 - .71) |
| 12. Physician gave patient time for weighing (dis)advantages | 156 | 5.0 (4.0-5.0), 0-5 | 161 | 4.0 (2.0-5.0), 0-5 | 150 | .55 (.47 - .64) |
| 13. Patient told physician what is important to him/her | 156 | 5.0 (4.0-5.0), 0-5 | 161 | 4.0 (3.0-5.0), 0-5 | 150 | .59 (.50 - .67) |
| 14. Patient weighed (dis)advantages[#] | 155 | 5.0 (4.0-5.0), 0-5 | 160 | 4.0 (3.0-5.0), 0-5 | 148 | .59 (.51 - .68) |
| 15. Decision takes into account what is important for patient[^] | 140 | 5.0 (5.0-5.0), 0-5 | 141 | 4.0 (4.0-5.0), 0-5 | 124[¯] | .79 (.71* - .85*) |
| 16. Physician discussed what patient needs for weighing options[^] | 16 | 4.0 (3.0-5.0), 0-5 | 19 | 4.0 (2.0-4.0), 1-5 | 7[¯] | .43 (-.01 - .87) |

[¯]Agreement was defined as the same item score or one point difference obtained by the iSHAREpatient and iSHAREphysician, since we considered it acceptable if scores from the respective viewpoints differed somewhat.

[#]In our development article[14] we recommend researchers to split this item if they would like to determine whether weighing the options happened during or outside the consultation. In this study we presented these items at the end of the patient questionnaire: I weighed up the advantages and disadvantages of the treatment options during the conversation. Median (IQR): 4.0 (3.0-5.0) I weighed up the advantages and disadvantages of the treatment options before or after the conversation. Median (IQR): 4.0 (2.0-5.0).

[¯]We only report agreement if both patient and physician agreed on whether a decision had been made; a treatment decision was made according to both patient and physician for 124 decision-making processes, while no treatment decision was made according to both patient and physician for seven decision-making processes. For 10 decision-making processes the patient indicated that a decision had been made, while no decision had been made according to the physician; it was the other way around for eight decision-making processes.

^We report item 15 if a patient/physician had reported that a decision had been made or if the response to that item was missing; we report item 16 if a patient/physician had reported that no decision had been made.
*Fleiss correction applied
CI = Confidence interval; IQR = interquartile range; P = proportion agreement

**Table 3.** Median and interquartile range for dimension and total scale scores of the iSHAREpatient (n=156 treatment decision-making processes) and iSHAREphysician (n=162 treatment decision-making processes), and for total and subscale scores of the comparison questionnaires

| | | **Patient** | | **Physician** | |
|---|---|---|---|---|---|
| | Item | N* | Median (IQR) | N* | Median (IQR) |
| iSHARE dimension scores | | | **iSHAREpatient** | | **iSHAREphysician** |
| *1. Choice awareness (0-5)* | 8,9 | 156 | 5.0 (3.5-5.0) | 160 | 4.0 (3.0-5.0) |
| *2. Medical information (0-5)* | 1-7 | 150 | 4.4 (3.6-5.0) | 158 | 3.9 (3.3-4.7) |
| *3. Preferences (0-5)* | 10,13 | 156 | 5.0 (4.0-5.0) | 160 | 3.5 (2.5-4.5) |
| *4. Deliberation (0-5)* | 11,14 | 155 | 5.0 (3.5-5.0) | 160 | 3.5 (3.0-4.5) |
| *5. Time for deliberation (0-5)* | 12 | 156 | 5.0 (4.0-5.0) | 161 | 4.0 (2.0-5.0) |
| *6. Decision (0-5)* | 15 or 16 | 156 | 5.0 (5.0-5.0) | 160 | 4.0 (3.0-5.0) |
| iSHARE total score (0-100) | | 149 | 95.0 (77.1-99.5) | 155 | 75.0 (61.1-90.7) |
| | | | **SDM-Q-9** | | **SDM-Q-Doc** |
| SDM-Q (0-100) | | 151 | 88.9 (71.1-97.8) | 161 | 77.8 (69.4-88.9) |
| COMRADE | | | | | |
| *Satisfaction with communication (0-100)* | | 130 | 72.0 (63.1-78.2) | | |
| *Confidence in decision# (0-100)* | | 130 | 78.7 (71.0-79.3) | | |
| DCS# (0-100) | | 149 | 15.6 (5.5-25.8) | | |
| *Feeling uncertain# (0-100)* | | 153 | 16.7 (0.0-41.7) | | |
| *Feeling uninformed (0-100)* | | 152 | 16.7 (0.0-25.0) | | |
| *Feeling unclear about values (0-100)* | | 151 | 25.0 (0.0-33.3) | | |
| *Feeling unsupported (0-100)* | | 152 | 8.3 (0.0-25.0) | | |
| *Ineffective decision making (0-100)* | | 153 | 0.0 (0.0-12.5) | | |
| PEPPI-5 (5-25) | | 155 | 24.0 (20.0-25.0) | | |

*Numbers do not always add up to the total sample size, due to missing values.

#No a priori hypothesis was formulated regarding the correlation between this total or subscale score and either of the iSHARE questionnaires (Table 5); scores are reported for sake of information.

COMRADE = Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness; DCS = Decisional Conflict Scale; IQR = interquartile range; PEPPI-5 = five-item Perceived Efficacy in Patient-Physician Interactions; SDM-Q-9 = nine-item SDM-Questionnaire; SDM-Q-Doc = SDM-Questionnaire-physician version

**Table 4.** Test-retest agreement on item level for the iSHAREpatient (n=67 treatment decision-making processes)

| | **Agreement¯** | | **Agreement¯** |
|---|---|---|---|
| | N | P (95%CI) | P (95%CI) |
| 1. Physician explained advantages of treatment options | 67 | .64 (.52 - .76) | .85 (.74* - .91*) |
| 2. Physician explained disadvantages of treatment options | 67 | .60 (.47 - .72) | .88 (.77* - .93*) |
| 3. Physician explained (dis)advantages equally well | 67 | .64 (.52 - .76) | .84 (.72* - .90*) |
| 4. Physician checked patient's understanding of advantages | 67 | .70 (.58* - .79*) | .91 (.81* - .95*) |
| 5. Physician checked patient's understanding of disadvantages | 66 | .61 (.48 - .73) | .85 (.73* - .91*) |
| 6. Physician told how treatment options differ | 67 | .64 (.52 - .76) | .84 (.72* - .90*) |
| 7. Patient asked for clarification | 67 | .60 (.47 - .72) | .79 (.67* - .86*) |
| 8. Physician said there is a choice | 67 | .72 (.59* - .80*) | .87 (.76* - .92*) |
| 9. Physician said patient's opinion is important | 67 | .79 (.67* - .86*) | .93 (.83* - .96*) |
| 10. Physician checked if he/she understood what is important for patient | 67 | .69 (.57 - .81) | .91 (.81* - .95*) |
| 11. Physician helped patient weighing (dis)advantages | 67 | .55 (.43 - .68) | .85 (.74* - .91*) |
| 12. Physician gave patient time for weighing (dis)advantages | 67 | .64 (.52 - .76) | .91 (.81* - .95*) |
| 13. Patient told physician what is important to him/her | 67 | .76 (.64* - .84*) | .94 (.85* - .97*) |
| 14. Patient weighed (dis)advantages | 67 | .70 (.58* - .79*) | .91 (.81* - .95*) |
| 15. Decision takes into account what is important for patient^ | 61 | .84 (.71* - .90*) | .97 (.88* - .98*) |
| 16. Physician discussed what patient needs for weighing options^ | 3 | .00 (.03* - .56*) | .33 (-.37 - 1.03) |

¯Agreement was defined as the same item score obtained both at test and retest.

¯Agreement was defined as the same item score obtained both at test and retest, or one point difference as post-hoc analysis.

^We report item 15 if a patient had reported that a decision had been made or if the response to that item was missing; we report item 16 if a patient had reported that no decision had been made.

*Fleiss correction applied

CI = confidence interval; P = proportion agreement

**Table 5.** Correlations between the iSHARE and other questionnaires

| iSHARE questionnaire | Comparison scale - subscale | | |
|---|---|---|---|
| | | N | Spearman Rho* |
| iSHAREphysician | SDM-Q-Doc | 155 | .84⁻ |
| iSHAREpatient | SDM-Q-9 | 144 | .77⁻ |
| | COMRADE – Satisfaction with communication | 125 | .68⁻ |
| iSHAREpatient dimension (item) | | | |
| 2. Medical information (1-7) | DCS – Feeling uninformed | 146 | -.44⁻ |
| 2. Medical information (7)[a] | PEPPI-5 | 154 | .31⁻ |
| 3. Preferences (10,13) | DCS – Feeling unclear about values | 151 | -.43⁻ |
| 3. Preferences (13)[a] | PEPPI-5 | 155 | .40⁻ |
| 4. Deliberation (14)[a] | PEPPI-5 | 154 | .27 |
| 6. Decision (15)[^] | DCS – Ineffective decision making | 138 | -.46⁻ |
| 6. Decision (16)[^] | DCS – Feeling unsupported | 15 | -.66⁻ |

Note. The expected correlation was >.30 for the SDM-Q-9, SDM-Q-Doc, COMRADE and PEPPI-5, and <-.30 for the DCS.
[^]We report item 15 if a patient had reported that a decision had been made or if the response to that item was missing; we report item 16 if a patient had reported that no decision had been made.
*p<.01
[a] Items measuring patient behaviour
⁻Hypothesis was confirmed
COMRADE = Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness; DCS = Decisional Conflict Scale; IQR = interquartile range; PEPPI-5 = five-item Perceived Efficacy in Patient-Physician Interactions; SDM-Q-9 = nine-item SDM-Questionnaire; SDM-Q-Doc = SDM-Questionnaire – physician version

## 4. DISCUSSION AND CONCLUSION

### 4.1. Discussion

In this study, we determined the measurement properties of the iSHAREpatient and the iSHAREphysician designed to assess SDM in oncology. As opposed to many existing questionnaires, the iSHARE questionnaires are based on a clear definition of the construct, provide a comprehensive assessment of the SDM process in- and outside consultations, and allow the assessment of both patient and physician behaviours.[2, 14] We have conducted a large-scale study, including patients and physicians from academic and non-academic hospitals, physicians from different specialties, patients with a variety of cancer diagnoses, and with treatment intents being either curative or palliative. The current analyses have shown high dimension and total scores on both iSHARE questionnaires, and good construct validity of the iSHARE questionnaires. The iSHAREpatient showed substantial test-retest agreement. Further, the iSHARE questionnaires show moderate inter-rater agreement.

The iSHARE questionnaires, and especially the iSHAREpatient, showed high scores. More than 15% of the patients reported the highest possible score, which may be considered as a moderate ceiling effect.[38] Patient SDM questionnaires are known for ceiling effects.

These may be caused by the so-called halo effect, leading people to unconsciously alter their judgment of others' attributes based on their judgment of unrelated attributes.[39] To illustrate, if physicians are perceived to be friendly, the halo effect leads patients to evaluate their information-giving behaviours favourably instead of critically assessing them. Methods to reduce these effects, such as reflecting (stop-and-think) before rating the SDM process, have not been shown successful in patients.[3] We aimed to avoid ceiling effects by using an unbalanced response scale, that is, using a scale with more positively-labelled than negatively-labelled response options, thereby enabling more differentiation.[24] We further explicitly stated in the introduction of the iSHAREpatient that the questionnaire is not about satisfaction with the physician (Box 1).[14] However, these precautions do not seem to have adequately addressed the problem. The high scores may have resulted from recruiting physicians from our network (i.e., researcher selection bias), some of whom had been trained in SDM and whose patients may actually have experienced high levels of SDM. Moreover, physicians may have, consciously or unconsciously, selectively approached patients with whom the decision-making process was, or was expected to be, shared (i.e., physician selection bias). In addition, patients who declined participation may have been less involved in decision making (i.e., patient selection bias). A clear indication that our sample suffered from selection bias were the remarkably high scores on the other questionnaires too. Two recent studies in Dutch cancer patients[40, 41] showed substantially lower SDM-Q-9 scores and higher decisional conflict scores. In addition, two recent studies in Dutch cancer patients[42] and Dutch cancer survivors[43] showed somewhat lower patients' perceived self-efficacy compared to our sample. It is therefore important to await the scores in other samples before drawing definitive conclusions about the high scores. Of note, treatment decision making is often distributed across consultations and time[44] and half of the patients indeed thought about more than one consultation while completing the questionnaire.

The iSHARE questionnaires showed only very small numbers of missing values and no specific patterns, implicating acceptability of the items for both patients and physicians, and no systematic bias. Regardless, more research is needed on how to deal with missing values for instruments assessing formative constructs.

Our results demonstrated good construct validity (i.e., >75% of the results confirm our hypotheses)[45] of the iSHARE questionnaires. The iSHAREpatient and iSHAREphysician correlated highly (>.50) with the SDM-Q-9 and SDM-Q-Doc, indicating that the questionnaires measure the same construct.[46] The iSHARE questionnaires offer a more valid assessment of the SDM process since they cover both patient and physician behaviours. Hypotheses with regard to correlations with the COMRADE and DCS subscales were confirmed, adding to the proof for construct validity. Internal consistency of the DCS subscales seemed sub-optimal, a problem identified previously.[47] Further, two of three hypotheses regarding the PEPPI-5 were confirmed. To our knowledge no appropriate questionnaires were available at the time of designing the study for construct validity testing of any of the iSHAREphysician dimensions, nor for the Choice Awareness, Deliberation and Time for Deliberation dimensions of the iSHAREpatient. We recommend hypotheses testing for the other iSHARE dimensions once appropriate measurement instruments become available.

We determined test-retest agreement for the iSHAREpatient. This is a strength of the study, as this has not frequently been established for patient SDM questionnaires.[2] While several guidelines are available for kappa and intraclass correlations,[45, 48] we are not aware of any criteria to label the proportion agreement. Using the labels proposed for the kappa,[49] we propose that a proportion agreement of ≤.30 is 'slight'; >.30 'fair'; >.50 'moderate'; >.70 'substantial', and >.90 'almost perfect'. This results in substantial agreement for four, moderate for eleven, and slight for one of the iSHAREpatient items. Higher agreement may be found if the period between the two assessments is even shorter. The time period should be long enough, so that participants will not remember their previous answers; yet patients risk forgetting about their and their physician's behaviours if the period is too long. In addition, test-retest agreement of a questionnaire evaluating a decision-making process may be different from one evaluating, e.g., a state such as quality of life, or an attitude. Consequently, we did a post-hoc analysis in which we allowed the item scores to differ one point; agreement was almost perfect for seven items, substantial for eight items and fair for one item. All in all, the results demonstrate substantial test-retest agreement.

We applied the same criteria to the agreement between the iSHAREpatient and iSHAREphysician scores, allowing one point difference; agreement was substantial for three, moderate for 12 and fair for one item, demonstrating moderate inter-rater agreement overall. As noted, some physicians had been trained in SDM and may have reflected more critically on the decision process than their patients. Patients' and physicians' ratings of communication, including SDM in oncology[27, 28] are known to correlate poorly, but it should be noted that correlations are not the appropriate measure for agreement.[50, 51] Only few studies calculated the kappa and proportion agreement.[50] To the best of our knowledge, we are the first to have calculated proportion agreement for patient and physician SDM scores in oncology, which makes it hard to compare results. We aimed to achieve good inter-rater agreement by using the same underlying construct for both questionnaires, using the same items and most importantly, extensively involving both patients and physicians throughout the development process of the questionnaires.[14] We recommend future users of the iSHARE questionnaires to consider which perspective is most feasible to determine or to use both, bearing in mind that they represent different perspectives.

The iSHARE questionnaires contain two versions of the last item; for the majority of decision-making processes a decision had been made, so item 15 (The decision takes into account what is important for the patient) was reported. As a consequence there were not enough data to determine agreement for item 16 (The physician discussed what the patient needs to weigh the options). The iSHARE questionnaires may be applicable to healthcare settings outside of oncology, but we advise content validity testing first. We also recommend to determine cross-cultural validity when using the iSHARE questionnaires in languages other than Dutch. Finally, the findings should be considered in light of several limitations. As discussed, different forms of selection bias might have been present. Further, we aimed to include a broad range of patients, including in terms of education. Forty percent were highly educated, which may limit the representativeness of the sample for the patient population.

### 4.2. Conclusion

The iSHAREpatient and iSHAREphysician demonstrate good construct validity, substantial test-retest agreement (iSHAREpatient), and moderate inter-rater agreement. The dimension and total scores were high, which may have largely been caused by selection bias.

### 4.3 Practice Implications

Results obtained using the iSHARE questionnaires provide information about the entire SDM process, about both patient and physician behaviours, from the perspective of patient and/or physician, and may be administered before or after the final decision has been made. The results may inform both physician- and patient-directed efforts to improve SDM in clinical practice, and dimension scores can be used to determine the impact of interventions or training on specific aspects of the SDM process.

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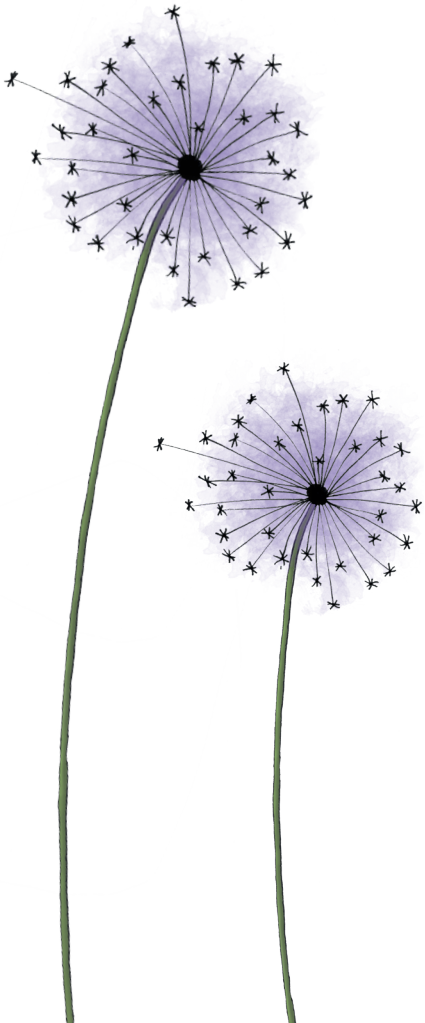

# 7

# GENERAL DISCUSSION

Extensive research into shared decision making (SDM) between patient and healthcare professionals started in the 21th century, after the first models had been published in 1997[1] and 1999.[2] Research activities in the SDM field may be categorized in four different domains; *'(i) definition of SDM and development of frameworks, (ii) development and psychometric testing of measurement scales, (iii) development and evaluation of SDM interventions and (iv) implementation [of SDM] in routine practice.'*[3] While SDM interventions have been developed and campaigns to foster SDM implementation have been started, we noted that there were still measurement difficulties, and that SDM measurement was often limited to physician behaviour, while patient responsibilities were described in the first SDM models. Therefore, we set out to address the first two domains: we aimed to answer the following two fundamental questions in this thesis; *What is SDM and How can the SDM process be measured, specifically for oncology?*

We critically appraised the then available SDM measurement instruments, thereby informing researchers on their strengths and weaknesses. There was an overall lack of evidence on the quality of measurement instruments (Chapter 2). We showed both the variety and the consensus in components present in forty SDM models, what roles healthcare professionals and patients are described to have according to these models, and how the presence of certain components has varied over time. We presented an SDM map displaying the components seen as key per healthcare setting Chapter 3). In a qualitative study, we showed that SDM in oncology extends to time outside consultations and includes both patient and physician behaviours according to the relevant stakeholders (Chapter 4).

Informed by all these data and by using the original COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist,[4, 5] we developed the iSHARE questionnaires. The iSHAREpatient and ISHAREphysician assess the SDM process from different viewpoints, include both patient and physician behaviours, are aimed to assess the full SDM process, and may also be administered before a final decision has been made (Chapter 5). Finally, we validated the iSHARE questionnaires in a sample of patients and physicians, including patients with different cancer diagnoses and treated with varying intents, and physicians from differently specialties. The iSHARE questionnaires have adequate measurement properties and are fit to assess specific parts of the SDM process (Chapter 6).

In this chapter, we will discuss our main findings, reflect on the methods we have used and propose implications for research and clinical practice.

## Actors in SDM

Early SDM models already identified patient behaviour to be part of this decision-making process, next to healthcare professional behaviour.[1, 2] In our review of SDM models, we found that patient and healthcare professionals are identified as actors in the majority of the models published until September 2019 (Chapter 3). Still, it might feel uncomfortable for healthcare professionals to give patients some responsibility, or to at least expect something from them, to achieve SDM. We know from qualitative research and from studies using the Control Preferences Scale (CPS) that patients want to participate in decision making and see

specific roles for themselves, both in- and outside oncology.[6-12] Indeed, in our qualitative study about SDM in oncology (Chapter 4) it became clear that patients have specific roles in SDM. Patients and members of the general population emphasized the importance of patients communicating openly, as was found before.[6, 13] This may help physicians in getting to know their patients, and patients need to feel 'known' to actively participate in SDM.[14] Healthcare professionals should see patients as a person, not as just a patient.[14, 15]

Healthcare professionals and developers of SDM interventions should be aware of the essence of time for patients' role in SDM. Time in which the patient can reflect on the decision, sleep on it, and discuss it with significant others if they wish to do so (Chapter 4). Also in an oncology setting there is often time to take a few days before making the final decision. This might implicate a different organization of healthcare, where time would be routinely scheduled between the consultation in which a diagnosis, or a change in the status of the disease, is communicated and possible treatment options are discussed, and the consultation in which treatment decisions are made. First having time to process and accept the diagnosis and thereafter considering the treatment options is expected to facilitate patient involvement.[16, 17]

Next to the patient and physician, also others may have a role in the SDM process, such as nurses,[18, 19] general practitioners,[20] caregivers,[21] family members, and significant others.[22] Roles of others have only recently been described and may receive more attention in future studies on defining and measuring SDM, but also when designing SDM interventions. A few existing examples are a scale measuring role competency of oncology nurses[23] and SDM interventions aiming at nurses, both in oncology[24] and in primary care.[25] Specifically for the oncology setting, we found that treatment options are often discussed with relatives or the general practitioner outside of the consultation with the specialist (Chapter 4).

While patient behaviour is part of the SDM process, existing SDM measurement instruments most often only assess healthcare professional behaviour (e.g., OPTION,[26] CollaboRATE[27]), or include both patient and physician behaviour in one item (e.g., nine-item SDM-Questionnaire (SDM-Q-9)[28] and SDM-Questionnaire-physician-version (SDM-Q-Doc)[29]). We urge researchers who develop SDM measurement instruments to include items dedicated to patient behaviours. In the iSHARE questionnaires, we included items on either physician or patient roles. The iSHARE questionnaires therefore can also be used to assess the effects of campaigns and interventions aiming at patient behaviour. Note that we deliberately chose to include only patient and physician behaviours. Others may be involved, but if they are not, SDM is no less.

## Development and validation of the iSHARE questionnaires

We used the original version of the COSMIN checklist[4, 5] to rate the development and validation studies included in our systematic review (Chapter 2). We further used the checklist as a guideline during the development and validation process of the iSHARE questionnaires, although it had been developed to rate the methodological quality of studies on measurement properties. In recent years, many different COSMIN checklists and tools have been published: the risk of bias checklist[30] (which substitutes the original checklist)

and guideline,[31] both for systematic reviews of patient-reported outcome measures (PROM); the study design checklist;[32] the methodology for evaluating the content validity of PROMS;[33] the risk of bias tool to assess the quality of studies on reliability or measurement error of outcome measurement instruments;[34] and the reporting guideline for studies on measurement properties.[35] We recommend researchers to use the appropriate COSMIN tools and to report on this, and especially to use the reporting guideline,[35] to make sure all necessary information is reported for future users of the measurement instrument.
To date, the guidelines available are relevant to the development and the validation of measurement instruments based on a reflective measurement model, and to a lesser extent when a formative measurement model is assumed. The former is more common. However, to us, such guidelines would have been useful, given that we assumed a formative measurement model for the iSHARE questionnaires. The COSMIN group might develop a guideline on how to deal with item selection and validation of a measurement instrument when a formative measurement model is assumed.

During all the phases of the development and the validation of the iSHARE questionnaires, we asked patients and physicians for their opinions and incorporated their feedback. Their involvement contributed to the design of questionnaires that turned out to be feasible during the cognitive interviews (Chapter 5). We also aimed to reach acceptable agreement between the scores on the iSHAREpatient and iSHAREphysician, by using this approach. The low number of missing values in the validation study (Chapter 6) suggested acceptability of both the iSHAREpatient and the iSHAREphysician.

We tested content validity quantitatively in a sample of 12 cancer patients and 11 physicians. The then available original COSMIN checklist did not make a difference between quantitative and qualitative data collection for content validity testing, and ≥10 was considered to be an adequate sample size.[4, 5] The more recent COSMIN study design checklist[32] (and the COSMIN risk of bias checklist[30, 36]) now recommends content validity testing using a sample size of >50 for quantitative studies. We performed content validity testing of the iSHAREphysician at the level of the domains (note, the 13 iSHARE domains are clustered in six dimensions), while the original COSMIN checklist (and the more recent COSMIN risk of bias checklist[30, 36] and COSMIN study design checklist[32]) states it should be done on the item level.[4, 5] We indeed asked patients to assess each item but decided against asking this from physicians, due to the time investment it would require. Somehow, it is strange though that we were hesitant to ask additional time investment of healthcare professionals to test the items while at the same time asking so much more time and effort of patients. We, as researchers, should consider the time we ask from both patient and healthcare professionals in the development and validation of measurement instruments. A measurement instrument is not directly beneficial to either patients or healthcare professionals, other than for example, a decision aid. For future development and validation studies it might be smart to reduce the individual burden by only presenting half of the items that should be assessed to one group and the other half to another group, thereby doubling the required sample.

We tested hypotheses about the correlation between the scores on the iSHAREpatient (dimensions) and the scores on several measurement instruments from the patient viewpoint

(the SDM-Q-9, the Decisional Conflict Scale (DCS), the Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness, and the five-item Perceived Efficacy in Patient-Physician Interactions (PEPPI-5)) to determine construct validity. We were only able to determine construct validity of the iSHAREphysician by formulating a hypothesis about the correlation between the scores on the iSHAREphysician and the scores on the SDM-Q-Doc. At the start of the validation study, no other measurement instrument was available to assess the SDM process from the viewpoint of the physician that had been validated in Dutch. This is still true today. Also, no questionnaires measuring related constructs from the physician viewpoint are available, on which to base hypotheses for validation. When these will become available, it will be valuable to formulate hypotheses on the dimension level to further validate the iSHAREphysician.

We decided to not compare the iSHARE questionnaires to a measurement instrument assessing the SDM process from an observer viewpoint (e.g., to the OPTION-12 or the OPTION-5) for two reasons. First and foremost, poor correlations have been found between scores on self- versus observer-based SDM measurement instruments.[3, 37, 38] The different perspectives on the SDM process may be due to differences in the construct underlying the respective measurement instruments, as well as to an inherently different view on the extent to which SDM occurred from these different perspectives. If the correlation between the scores on the iSHARE questionnaires and an observer-based coding scheme was low, we should doubt whether this informs us about the validity of the iSHARE questionnaires. Second, we would have faced logistic challenges which we could not solve in a pragmatically enough manner to be able to collect the necessary data.

In the field, Pearson[39, 40] and Spearman[38] correlations have been reported as parameters of test-retest, inter- and intra-rater reliability (Chapter 2). However, the COSMIN group recommends to calculate intraclass correlation coefficients for continuous scores and (weighted) Kappa's for dichotomous, nominal, and ordinal scores as reliability parameters.[32, 34] We were not able to calculate weighted Kappa's because the data were not distributed normally (Chapter 6) and therefore calculated agreement, which is considered to be a parameter of measurement error for dichotomous, nominal, and ordinal scores. To determine measurement error for continuous scores, calculation of the Standard Error of Measurement, Smallest Detectable Change, Limits of Agreement or Coefficient of Variation is recommended.[32, 34] We call upon the field to calculate and report both on reliability and measurement error, if possible.

### Response scales

In a side-study, we tested four different response scales to determine the most appropriate one for the iSHARE questionnaires (Chapter 5). We were in particular interested in possible ceiling effects, as SDM measurement instruments from the patient viewpoint have shown to be prone to them.[41-43] We compared the scores obtained with the different response scales, using the draft version of the iSHAREpatient questionnaire. We had anticipated that a five-point scale ranging from 'not done at all' to 'done completely' would show fewer ceiling effects compared to a five-point scale ranging from 'totally disagree' to 'totally agree', due to the focus on actual behaviour in the response options. Further, respondents tend to agree

with questionnaire items regardless of their content, referred to as acquiescence bias.[44] We also tested a five-point positively unbalanced scale, ranging from 'not done at all' to 'done completely', i.e., with more labels on the positive end of the scale. The scale provided more choice and detail if someone would like to rate the item positively. This unbalanced format is known to reduce ceiling effects, when compared to a balanced scale in patient satisfaction measurement.[45] Finally, we included a visual analogue scale (VAS) with the ends labelled as 'not done at all' and 'done completely', as the VAS is known to show fewer ceiling effects compared to a Likert scale.[46]

The results obtained by the VAS scale showed fine results for the mean, standard deviation, range, and the coefficient of variation. Upon further inspection, the histogram showed a bimodal distribution (i.e., two distant peaks in the distribution), which can indicate inconsistent use of response options.[47] This underscores the importance of visual inspection of collected data. During the cognitive interviews we also saw problems with the completion of the VAS, and we decided against the use of the VAS scale based on these observations.

The five-point unbalanced 'done' scale showed favourable results as well. Informed by these findings, and in combination with the results of the cognitive interviews, we decided to use a six-point scale with two negative response options ('not at all' [helemaal niet gedaan] and 'hardly' [bijna niet gedaan]), and four positive response options ('a little' [een beetje gedaan], 'for a large part' [voor een groot deel gedaan], 'almost completely' [bijna helemaal gedaan], and 'completely' [helemaal gedaan]). Despite our attempts to limit ceiling effects, they were undeniably present in our validation study and scores were even higher (the SDM-Q-9[48, 49] and the PEPPI-5[48, 50, 51]) and lower (the DCS[48, 49]) than in other Dutch oncology samples. We have discussed the possibility of researcher, physician, and patient bias (Chapter 6). Another explanation might be that patients and physicians did not closely read the labels and may have in fact used it as a 'balanced' scale. A different approach, in which the response options are presented as words that should be circled instead of boxes that should be checked[52] might result in patients and physician closely reading the labels.

We encourage researchers in the SDM field to test different response scales when developing a measurement instrument. This enables them to choose the one with the largest range, the most variation, and fewest ceiling or floor effects. Next to these quantitative parameters, the focus of research on response scales should also be on their interpretability and feasibility for respondents.

### Using the iSHARE questionnaires

The iSHARE questionnaires were developed and tested in Dutch, implying exclusion of cancer patients who do not speak or read Dutch. We involved patients throughout the development process and made efforts to formulate clear items, but the samples in which we tested feasibility and acceptability were highly educated (Chapters 4, 5 and 6). We therefore do not know whether low literate patients may experience difficulties in understanding the items. We did not explicitly test the iSHAREpatient in low literate patients and recommend developers of SDM instruments to do so. Users of the iSHARE questionnaire and other measurement instruments may perform additional testing in patients with various levels of education and

health literacy, especially when translating existing measurement instruments.

The iSHARE questionnaires may be used to establish baseline levels of SDM in a particular setting, or a change in the SDM level due to an intervention or training. We expect that the iSHARE questionnaires show fewer ceiling effects in a new sample compared to the effects demonstrated in our validation study (Chapter 6), allowing the detection of improvement. Of course, responsiveness of the iSHARE questionnaires should be assessed first. Responsiveness is a measurement property that is seldom assessed; it was only done for the CollaboRATE (Chapter 2). Responsiveness needs to be assessed in a longitudinal design in which a measurement instrument is administered twice and a change should be expected between the two assessments, e.g., as a result of an intervention. A priori hypotheses on the change scores need to be formulated. A feasible option to assess responsiveness, is to include the questionnaire under study (e.g., the iSHAREpatient) next to another questionnaire (e.g., the SDM-Q-9) which is used to evaluate the effect of an intervention to foster SDM. The construct approach may then be used,[32, 53] in which hypotheses are formulated about the expected direction and magnitude of correlations between change scores on the SDM-Q-9 and the iSHAREpatient. Note that in this case, the data collected for the iSHAREpatient should only be used to determine responsiveness of the iSHAREpatient and not to draw conclusions about the effect of the intervention. Apart from the possibility of the iSHARE questionnaires and other questionnaires to measure change over time, it might be valuable to discuss what change is clinically relevant in what context, compared to being statistically significant. We call upon the field to determine the minimal important change values in future research, and anchor-based methods may be used to that end.[54, 55] Future users of the iSHARE questionnaires who aim to use the questionnaires to assess the effect of an intervention, may critically review its dimensions and individual items, to determine in advance on which of them their intervention might have an effect. If only relevant dimensions or items are included in a questionnaire, study load for both patients and healthcare professional decreases. For example, items 9 and 10 (i.e., 9. The doctor said that it matters what I think is important and 10. The doctor checked whether he/she understood what was important to me) may show higher scores when a patient has completed a PROM and patient and healthcare professional have discussed it during the consultation. Although PROMs are increasingly linked to SDM,[56, 57] their impact on SDM has not yet been assessed. In the future, specific dimensions of the iSHARE questionnaires might be used to do so. We also encourage future users to critically assess whose viewpoint should be measured. Since the agreement between the iSHARE questionnaires is moderate, it might be enough to assess only one viewpoint, thereby reducing study burden.

Our validation study (Chapter 6) indicates that for the majority of decision-making processes (131/149), patients and physicians agree on whether a decision has been made. This is higher than was found previously in an oncology setting.[58] We cannot be sure whether this agreement was specific for our sample, and therefore ask future users of both iSHARE questionnaires to report their findings.

We described how to calculate a total score on both iSHARE questionnaires (Chapter 5) and reported this in our validation study (Chapter 6) to inform future users. We urge them to

carefully consider the use of total versus dimensions scores, since dimension scores are more informative for a formative construct. We do not explicitly describe weighing of the dimensions to arrive at a total score (Chapter 5), but we did so by combining dimension scores into a total score, instead of computing a total score based on individual items. Combining dimension scores results in proportionally giving more weight to dimensions with fewer items. If we would have computed total scores based on individual items, the total score would largely be determined by the seven of 15 items that refer to asking for and providing medical information. The information component makes up a large part of SDM measurement instruments e.g.,[59] and therefore has a major impact on the obtained SDM scores. We consider all dimensions to be of equal importance and call on future users to follow this approach.

## Measuring SDM in future research

In 2017, we identified 40 SDM measurement instruments, including 21 original versions, four revised versions, and 15 translated versions (Chapter 2). In subsequent years, adapted (e.g., CollaboRATE$^{pediatric60}$) and translated versions (e.g., the Japanese versions of the SDM-Q-9 and SDM-Q-Doc[61, 62] and an Arabic version of the SDM-Q-9[63]) have been published, as well as papers on the development and validation of a patient questionnaire; the SDM Process Scale.[64-66] The SureScore[67] and the Alberta Shared decision-maKing Measurement Instrument (ASK-MI)[68] questionnaires have recently been developed to assess SDM, with both a patient and a clinician version. Also, a new observer measurement instrument has been developed, the 4SDM.[49] Both the 4SDM and the OPTION[12] were able to detect change as a result of an SDM training for oncologists, and we therefore recommend to further validate the 4SDM (e.g., content validity, construct validity, intra-rater and inter-rater agreement) and to publish about its development and validation process.

We recommend further validation and reliability testing of existing instruments, including the iSHARE questionnaires. In addition to further validation, we call authors to always describe their construct when developing or validating a measurement instrument, or to explicitly refer to a source in which the construct is described. It will help future users to determine whether the construct matches their SDM model, and thus whether the measurement instrument is useful to assess SDM in their study.

If one assumes a somewhat different underlying SDM construct than the ones underlying any of the already existing measurement instruments, one may edit an existing measurement instrument to meet one's purposes. However, authors should not simply edit items or remove or add items and refer to the original questionnaire without mentioning the changes. The known measurement properties do not longer apply to an adapted version. One solution is to explicitly describe the changes and the reason for them in the Methods section of an article, or to include the adapted version in an Appendix. Another approach is to present it as an officially adapted version of an existing measurement instrument and to give it a new name. An example of adapting an already existing and validated measurement instrument to match another SDM model, is the adaptation of the OPTION-5 into OPTION$^{MCC}$.[69] The same may apply if SDM needs to be measured from another viewpoint. CollaboRATE, a patient questionnaire, was adapted into the CollaboRATE$^{pediatric}$ in German to assess SDM from the

patient, parent, and parent-proxy viewpoint.[60] The SDM-Q-9 and SDM-Q-doc have been adapted into the Care SDM-Questionnaire for care receivers (SDM-C-patient) and the Care SDM-Questionnaire for care providers (SDM-C-provider), to measure SDM between patient and healthcare professionals other than physicians.[70] We strongly recommend to determine the measurement properties of these instruments. Adaptations of existing measurement instruments may also include adding an assessment of behaviour of others, next to that of the patient and the physician.

It might be valuable to set up an international item bank for SDM, given the many measurement instruments available (Chapter 2). Especially if a formative measurement model is assumed and given that many different SDM models exist, researchers might benefit from the opportunity to create their own SDM measurement instrument based on the SDM model that fits their setting best. Researchers then do not have to formulate new, unvalidated items, and can compose a fitting combination of validated dimensions or items, which matches their specific construct. For this reason, we need more data on measurement properties on both the dimension and item levels, over and above information on a total scale level. We provide evidence on agreement on the item level for the iSHARE questionnaires, and for some iSHAREpatient items hypothesis testing was done on the item level (Chapter 6). Item scores for the SDM-Q-9 have also been published.[42] To the extent that such evidence is available for other SDM measurement instruments, it may be included in the item bank to inform future users. The dimensions and items should have a clear description and all information available on measurement properties in different settings should be reported. Validated versions of the items in other languages may also be included. Note that item response theory (IRT) only applies to reflective, and not formative measurement models. If one assumes a reflective measurement model, IRT is normally used to determine the item characteristic curves (i.e., a plot that shows the association between a patient's underlying ability and the probability of a particular response to the item) of the items. Item difficulty and patient ability are linked to each other in an IRT model,[71] and may inform researchers on which items to select from the item bank, but this approach is not applicable to an SDM item bank. SDM items do not by definition differ in difficulty, other than for example items on walking ability (a unidimensional construct). Someone who cannot walk will by definition not be able to run either and will answer items accordingly. Researchers should instead select items from the item bank based on their content.

We studied the SDM process, which includes time during and outside consultations. These consultations were face-to-face consultations. This thesis started with a comparison between the complex behaviours needed for this decision-making process, in comparison to the more easy-to-implement behaviours recommended to slow the spread of COVID-19. COVID-19 has changed much in the main SDM playing field: the consultation room. Patients have been requested to come alone, not to shake hands, to wear a mask, and to keep physical distance whenever possible. They have increasingly been invited to digital appointments instead of in-person ones. Some of these and other effects of the pandemic on healthcare delivery most probably will stay in the coming years. We do not yet know how this may affect communication, and more specifically SDM between patients and healthcare professionals. Attention should be paid to what different behaviours it may potentially require from the

participants. The literature on remote SDM focusses on technological features and less on how conducting consultations remotely affects collaboration between patients and healthcare professionals.[72] A study with simulated consultations showed that perceived SDM did not differ significantly between face-to-face and screen-to-screen consultation,[73] which is promising. However, to draw firm conclusions on how remote consultations impacts the interaction between patients and healthcare professionals and SDM, more research in real-life clinical practice is needed.

## SDM as the norm

SDM between patients and healthcare professionals should become the norm, especially when the patient wishes to be involved. Indeed, even in a more acute situation SDM is the preferred approach to be used when there is clinical equipoise or uncertainty about the best approach for this patient, when the patient can be involved, and when there is sufficient time to do so.[74] If a patient prefers to be involved but is not yet ready to be, due to e.g., patient-related characteristics, healthcare professionals' directed efforts to help make the patient ready may enable participatione.[75] The given that SDM slowly becomes the norm is reflected in its establishment by Dutch law[76] and its promotion by healthcare professional organisations, patient organisations, and the government.[77] As a consequence, there might be the tendency to formulate norms regarding the required level of SDM in a certain setting. In Italy for example, the level of SDM was proposed as a quality indicator for breast cancer care.[78] However, it is questionable if making SDM a requirement for organizational accreditation would benefit SDM implementation.[79] In fact, we call insurers and policy makers to refrain from benchmarking for SDM. The SDM field has still work to do to guarantee valid and meaningful measurement instruments for different contexts, to ensure that those in charge of SDM implementation and reimbursement know wat they should measure.[80] When the level of SDM is used as a quality indicator or is used for accreditation, one should be aware that the way it is measured may have a major impact on what behaviour is actually promoted. It may result in rewarding easy to measure healthcare professional behaviour, such as the use of decision aids, instead of promoting the awareness of all that is needed to truly involve patients in making decisions about their care.[81, 82]

## Conclusion

Healthcare professionals and researchers should be aware of the role that patients have in SDM and enable their participation. To that end, healthcare professionals should get to know their patients and see them as a person with a condition, and not only as a patient. Providing time to consider options outside of the consultation may be an important facilitator of patient involvement. Intervention developers should design them in such a way that the interventions support patients in their unique role, which may differ depending on the setting.

The iSHARE questionnaires assess both patient and physician behaviours and cover the entire SDM process. Both patients and physicians were involved in all steps of the development and validation and they show adequate measurement properties. We recommend use of the iSHARE questionnaires in an oncology setting.

The variety of existing SDM models and measurement instruments is not necessarily a problem and may be a natural result of the formative nature of the SDM construct. The SDM map may be used to determine which SDM components are relevant in specific setting. Both SDM models and SDM measurement instruments benefit from a clear description, as this enables future users to apply them in appropriate ways. For SDM measurement instruments, including the iSHARE questionnaires, further high-quality validation studies are needed, and especially responsiveness should be assessed. We recommend using existing measurement instruments, by adapting and renaming them if needed, or by building an item bank, enabling researchers to compose a fitting combination of items or dimensions. Instrument developers should consider the assessment of patients' role and the formative measurement model. Finally, we recommend to always involve patients and healthcare professionals in the development and validation of SDM measurement instruments. While this work continues, more knowledge on SDM measurement will become available. This will help finding answers to challenges still present in the field.

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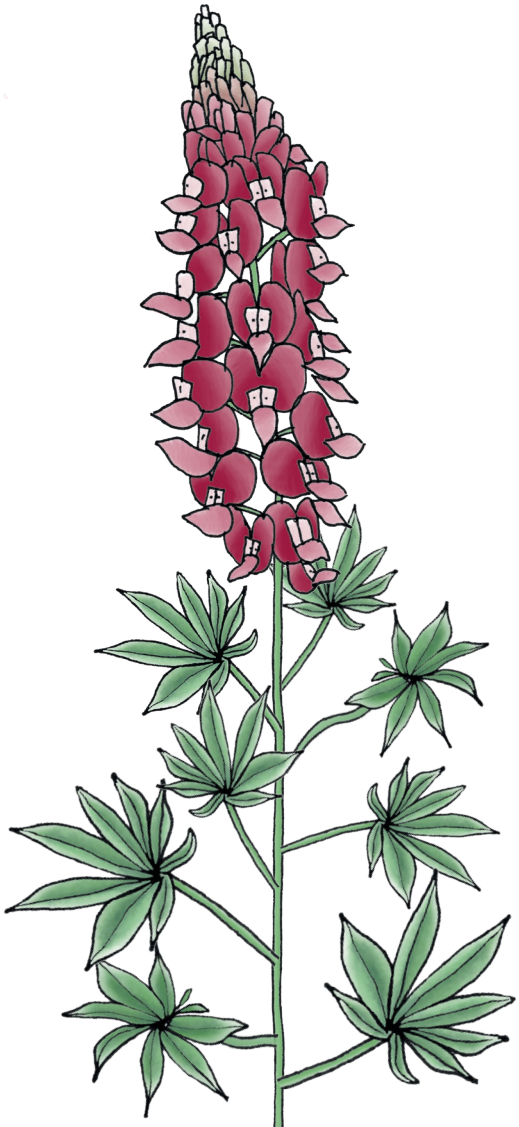

# 8

SUMMARY

SAMENVATTING

DE iSHARE VRAGENLIJSTEN

LIST OF PUBLICATIONS

CURRICULUM VITAE

DANKWOORD

## Summary

### Chapter 1

In this thesis, we aimed to develop and validate a patient and physician questionnaire to measure the shared decision making (SDM) process in oncology. In Chapter 1, we described the history of SDM models and provided an overview of implementation activities in The Netherlands. We identified SDM measurement challenges: there is limited evidence on measurement properties, patients' role is not assessed while it is present in SDM models, patients and healthcare professionals have been involved only to a limited extent in the development of SDM measurement instruments, and a reflective measurement model is often assumed, while a formative might be more appropriate. The aim of this thesis was therefore to develop and validate questionnaires to assess the SDM process in oncology from both the patient and the physician viewpoints. We chose the oncology setting because it is a setting in which patients often face preference-sensitive decisions, and in which most patients prefer an active or collaborative role in treatment decision making. To inform the development and validation process of our questionnaires, we used the original COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist and we wrote two reviews: one on existing SDM measurement instruments and one on existing SDM models.

### Chapter 2

In Chapter 2, we systematically inventoried instruments assessing the SDM process and appraised their measurement quality, taking into account the quality of the methods used. To this end, we searched seven bibliographic databases for studies investigating instruments measuring the SDM process. Per instrument identified, we assessed the level of evidence separately for 10 measurement properties following a three-step procedure: 1) appraisal of the quality of the methods used using the COSMIN checklist, 2) appraisal of the psychometric quality of the measurement property using three possible quality scores, and 3) best-evidence synthesis based on the number of studies, the methodological and psychometric quality, and the direction and consistency of the results. In total, we included 51 articles describing the development and/or evaluation of 40 SDM process instruments: 16 patient questionnaires, four provider questionnaires, 18 coding schemes and two instruments measuring multiple perspectives. Our analysis showed an overall lack of evidence for their measurement quality, because either validation was missing or methods were poor. The best-evidence synthesis indicated positive results for a major part of instruments regarding content validity (50%) and structural validity (53%) if these had been evaluated, but negative results for a major part of instruments when inter-rater reliability (47%) and hypotheses testing (59%) had been evaluated. We therefore concluded that the choice of the most appropriate instrument can best be based on the instrument's content and characteristics such as the perspective from which the SDM process is assessed.

### Chapter 3

In Chapter 3, we provided a systematic overview of SDM models, gave insight in the prominence of components present in SDM models, described who was identified as responsible within the components (patient, healthcare professional, both, none), showed the occurrence of

SDM components over time, and, finally, presented an SDM map, by healthcare setting, to identify SDM components seen as key. We searched the same seven databases for articles. We included peer-reviewed articles in English presenting a new or adapted model of SDM. In total, we included 40 articles, and each described a unique SDM model. Twelve models were generic, the others were specific to a healthcare setting. Fourteen were based on empirical data, and 26 primarily on analytical thinking. We identified 53 different elements and clustered them into 24 components. Overall, *'Describe treatment options'* was the most prominent component across models. Components present in >50% of models were: *'Make the decision'* (75%), *'Patient preferences'* (65%), *'Tailor information'* (65%), *'Deliberate'* (58%), *'Create choice awareness'* (55%), and '*Learn about the patient*' (53%). In the majority of the models (27/40), both the healthcare professional and the patient were identified as actors. *'Describe treatment options'* and '*Make the decision*' were the two components which were present in most models in any time period. *'Create choice awareness'* stood out for being present in a markedly larger proportion of models over time. In conclusion, our review showed that SDM models quite consistently share some components but that there is no unified view on what SDM *is*.

## Chapter 4

In Chapter 4, we constructed a model of SDM about cancer treatment by conducting an extensive consultation of stakeholders, informed by the literature. We interviewed 76 stakeholders: cancer patients, potential future patients, oncologists, nurses, and SDM researchers. We asked, "If I say 'Doctors and patients making decisions together about cancer treatment,' what does this make you think about?" Ideas were further solicited by presenting 19 cards each describing a possible SDM element. Interviews were inductively coded and analysed, and the emerging themes were integrated into a model. The resulting model assigns specific roles in SDM to both oncologists and patients. Oncologists determine possible treatments, emphasise the importance of patients' opinion, explain treatment options, get to know patients, guide patients, and provide treatment recommendations. Patients ask questions, express thoughts and feelings, consider options, offer opinions, and decide or delegate decisions to oncologists. Outside consultations, patients search for information, prepare questions, and consider options. In short, next to oncologists' role, cancer patients also have a clear role in SDM about cancer treatment, during and outside consultations.

## Chapter 5

In Chapter 5, we developed a patient and a physician questionnaire to measure SDM in oncology and determined their content validity and comprehensibility. The domains of the SDM construct were informed by our systematic review of SDM models and our oncology-specific SDM model. We formulated items for each SDM domain. Cancer patients and physicians rated content validity in an online questionnaire. We assumed a formative measurement model and performed online field-testing in cancer patients to inform further item reduction. We tested item comprehension in cognitive interviews with cancer patients and physicians. First, we identified 17 domains and formulated 132 items. Then, twelve cancer patients rated content validity at the item level, and 11 physicians rated content validity at the domain level. Finally, we field-tested the items among 131 cancer patients

and conducted cognitive interviews with eight cancer patients and five physicians. These phases resulted in the 15-item iSHAREpatient and 15-item iSHAREphysician questionnaires, covering 13 domains, clustered in six dimensions. The iSHARE questionnaires both assess patient and physician behaviours and cover the entire SDM process rather than a single consultation.

## Chapter 6

In Chapter 6, we determined: scores, construct validity, test-retest agreement of the iSHAREpatient, and inter-rater agreement between the iSHAREpatient and the iSHAREphysician. Physicians from seven Dutch hospitals recruited cancer patients, and completed the iSHAREphysician and SDM-Questionnaire-physician version. Their patients completed the: iSHAREpatient, nine-item SDM-Questionnaire, Decisional Conflict Scale, Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness, and five-item Perceived Efficacy in Patient-Physician Interactions. We formulated, respectively, one (iSHAREphysician) and 10 (iSHAREpatient) a priori hypotheses regarding correlations between the iSHARE questionnaires and questionnaires assessing related constructs. To assess test-retest agreement, patients completed the iSHAREpatient again 1-2 weeks later. In total, 151 treatment decision-making processes with unique patients were rated. Dimension and total iSHARE scores were high both in patients and physicians. The hypothesis on the iSHAREphysician and nine out of ten hypotheses on the iSHAREpatient were confirmed. Test-retest and inter-rater agreement were >.60 for most items. We concluded that the iSHARE questionnaires show high scores, have good construct validity, substantial test-retest agreement, and moderate inter-rater agreement.

## Chapter 7

In Chapter 7, we discussed the findings, including strengths and limitations and recommendations for clinical practice and future research. Patients have their own roles in SDM, and healthcare professionals should support them in their roles. Appropriate interventions may further assist patients. Both SDM models and SDM measurement instruments need a comprehensive description to inform future users. Further validation of existing SDM measurement instruments is needed and we recommend the use of the COSMIN tools. Both during the development and the validation of SDM measurement instruments, researchers need to consider the formative nature of the SDM construct, and should involve the end-users. Adapting existing SDM measurement instruments or building items banks might reduce study burden for patients, healthcare professionals and researchers. We recommend the use of the iSHARE questionnaires in an oncology setting, as they assess both patient and physician behaviours, cover the entire SDM process, are based on a thorough development process, and have adequate measurement properties.

# Samenvatting

## Hoofdstuk 1

In dit proefschrift hebben we een arts en een patiënt vragenlijst om samen beslissen ('shared decision making, SDM') in de oncologie te meten, ontwikkeld en gevalideerd. In hoofdstuk 1 hebben we de historie geschetst van de wijze waarop samen beslissen in het verleden gedefinieerd is. Ook hebben we een overzicht gegeven van de activiteiten om samen beslissen te implementeren in Nederland. We identificeerden de volgende uitdagingen op het gebied van het meten van samen beslissen: er is beperkt bewijs over de meeteigenschappen van bestaande vragenlijsten, de rol van patiënten wordt niet beoordeeld terwijl deze wel aanwezig is in definities van samen beslissen en patiënten en zorgverleners zijn slechts in beperkte mate betrokken bij de ontwikkeling van deze meetinstrumenten. Verder wordt er vaak uitgegaan van een reflectief meetmodel waarin de vragen een afspiegeling zijn van het construct, terwijl een formatieve benadering waarin de vragen samen het construct vormen wellicht passender is. Het doel van dit proefschrift was daarom het ontwikkelen en valideren van vragenlijsten om samen beslissen in de oncologie te beoordelen vanuit het oogpunt van zowel de patiënt als de arts. We kozen voor de oncologische setting omdat er vaak sprake is van voorkeursgevoelige beslissingen en de meeste patiënten met kanker de voorkeur geven aan een actieve rol bij het nemen van beslissingen over de behandeling, of graag samen met de arts willen beslissen. Voor de ontwikkeling en validatie van onze vragenlijsten hebben we de originele COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist gebruikt. We hebben ook twee systematische literatuuroverzichten geschreven: één over bestaande instrumenten die samen beslissen meten en één over modellen die samen beslissen definiëren.

## Hoofdstuk 2

In hoofdstuk 2 hebben we de zelfrapportage en observatie instrumenten die het proces van samen beslissen meten systematisch geïnventariseerd en hun meetkwaliteit beoordeeld. Daarbij hebben we rekening gehouden met de kwaliteit van de gebruikte methoden. We hebben in zeven bibliografische databases gezocht naar studies over instrumenten die het proces van samen beslissen meten. Per geïdentificeerd instrument hebben we in 3 stappen het niveau van bewijs beoordeeld voor 10 meeteigenschappen: 1) beoordeling van de kwaliteit van de gebruikte methoden met behulp van de COSMIN checklist, 2) beoordeling van de psychometrische kwaliteit van de meeteigenschap met behulp van drie kwaliteitsscores en 3) best-evidence synthese op basis van het aantal studies, de methodologische kwaliteit en meetkwaliteit, en de richting en consistentie van de resultaten. In totaal hebben we 51 artikelen geïncludeerd die de ontwikkeling en/of evaluatie van 40 instrumenten die samen beslissen meten beschrijven: 16 vragenlijsten voor patiënten, vier vragenlijsten voor zorgverleners, 18 codeerschema's en twee instrumenten die meerdere perspectieven meten. Onze analyse liet zien dat er over het algemeen een gebrek aan bewijs is voor hun meetkwaliteit, omdat ofwel de validatie ontbrak of de gebruikte methoden van onvoldoende kwaliteit waren. De best-evidence synthese gaf positieve resultaten voor de helft van de instrumenten met betrekking tot inhoudsvaliditeit (50%) en structurele validiteit (53%) en negatieve resultaten voor inter-beoordelaars betrouwbaarheid (47%) of het testen van hypothesen (59%) wanneer deze eigenschappen waren geëvalueerd. We concludeerden

daarom dat de keuze voor het meest geschikte instrument vooralsnog het beste kan worden gebaseerd op de inhoud en kenmerken van het instrument, zoals het perspectief van waaruit het proces van samen beslissen wordt beoordeeld.

## Hoofdstuk 3

In Hoofdstuk 3 hebben we een systematisch overzicht gegeven van modellen waarin samen beslissen wordt gedefinieerd, inzicht gegeven in het voorkomen van componenten in die modellen, beschreven wie als verantwoordelijke werd geïdentificeerd binnen de componenten (patiënt, zorgverlener, beiden, geen) en het vóórkomen van de componenten in de loop van de tijd getoond. Ten slotte presenteerden we een overzicht waarin per zorgsetting componenten van samen beslissen zijn weergegeven die als essentieel worden beschouwd. We hebben in dezelfde zeven databases gezocht naar artikelen. We hebben Engelse peer-reviewed artikelen geïncludeerd die een nieuw of aangepast model van samen beslissen presenteren. In totaal hebben we 40 artikelen opgenomen en elk beschreven ze een uniek model. Twaalf modellen waren generiek, de andere waren specifiek voor een zorgsetting. Veertien waren gebaseerd op empirische gegevens en 26 voornamelijk op analytisch denken. We hebben 53 verschillende elementen geïdentificeerd en deze geclusterd in 24 componenten. Over het algemeen was 'Beschrijf behandelmogelijkheden' de meest prominente component in alle modellen. De volgende componenten waren aanwezig in meer dan 50% van de modellen: 'Beslissing nemen' (75%), 'Voorkeuren van de patiënt' (65%), 'Informatie op maat' (65%), 'Wikken en wegen' (58%), 'Keuzebewustzijn creëren' (55%) en 'Leren over de patiënt' (53%). In de meeste modellen (27/40) werden zowel de zorgverlener als de patiënt als actor geïdentificeerd. 'Beschrijf behandelmogelijkheden' en 'Beslissing nemen' waren de twee componenten die in de meeste modellen aanwezig waren ongeacht het moment van publicatie. 'Keuzebewustzijn creëren' viel op doordat het in de loop van de tijd in een aanzienlijk groter deel van de modellen aanwezig was. Concluderend toonde ons literatuuroverzicht aan dat modellen waarin samen beslissen gedefinieerd wordt vrij consistent bepaalde componenten delen en ook dat er geen uniform beeld is van wat samen beslissen precies is.

## Hoofdstuk 4

In Hoofdstuk 4 hebben we een model van samen beslissen over de behandeling van kanker geconstrueerd op basis van een uitgebreide raadpleging van betrokkenen, die mede geïnformeerd werd door de literatuur. We interviewden 76 betrokkenen: patiënten met kanker, potentiële toekomstige patiënten, oncologen, verpleegkundigen en SDM onderzoekers. We vroegen: "Als ik zeg 'Artsen en patiënten die samen beslissen over de behandeling van kanker', waar denkt u dan aan?" We vroegen verder naar gedachten hierover door 19 kaartjes te presenteren die elk een mogelijk element van samen beslissen beschrijven. We hebben interviews inductief gecodeerd en geanalyseerd en de gevonden thema's geïntegreerd in een model. Het model beschrijft specifieke rollen in samen beslissen van zowel oncologen als patiënten. Oncologen bepalen mogelijke behandelingen, benadrukken het belang van de mening van patiënten, leggen behandelmogelijkheden uit, leren patiënten kennen, begeleiden patiënten en geven behandeladviezen. Patiënten stellen vragen, uiten gedachten en gevoelens, overwegen behandelmogelijkheden, geven meningen en beslissen of delegeren de beslissing aan hun oncoloog. Buiten de consulten om zoeken

patiënten naar informatie, bereiden vragen voor en overwegen opties. Kortom, naast de rol van oncologen hebben ook patiënten een duidelijke rol in samen beslissen over de behandeling van kanker, tijdens en buiten consulten.

## Hoofdstuk 5

In Hoofdstuk 5 hebben we een vragenlijst voor patiënten en een vragenlijst voor artsen ontwikkeld om samen beslissen tussen arts en patiënt over de behandeling in de oncologie te meten. Daarvan hebben we de inhoudsvaliditeit en de begrijpelijkheid bepaald. De domeinen van het SDM construct hebben we gebaseerd op ons systematische literatuuroverzicht van SDM modellen en ons oncologie-specifieke SDM model. Voor elk SDM domein hebben we mogelijke vragen geformuleerd. Patiënten met kanker en artsen beoordeelden de inhoudsvaliditeit in een online vragenlijst. We gingen uit van een formatief meetmodel en hebben een online veldtest onder patiënten met kanker uitgevoerd om het aantal vragen te verkleinen. We hebben de begrijpelijkheid van de vragenlijst getest in cognitieve interviews met patiënten met kanker en artsen. Bij aanvang hebben we 17 domeinen geïdentificeerd en 132 vragen geformuleerd. Vervolgens beoordeelden twaalf patiënten met kanker de inhoudsvaliditeit van de vragen en 11 artsen de inhoudsvaliditeit van clusters van vragen, de zogenaamde domeinen. Ten slotte hebben we de vragenlijst online getest onder 131 patiënten met kanker. Vervolgens hebben acht patiënten met kanker en vijf artsen deelgenomen aan cognitieve interviews. Deze verschillende fases resulteerden in de iSHAREpatient en iSHAREphysician vragenlijsten, beiden bestaand uit 15 vragen die 13 domeinen beslaan en geclusterd zijn in 6 dimensies. De iSHARE vragenlijsten beoordelen het gedrag van zowel de patiënt als de arts en omvatten het gehele proces van samen beslissen, ook buiten consulten om.

## Hoofdstuk 6

In Hoofdstuk 6 evalueerden we de meetkwaliteit van de iSHARE vragenlijsten. We bepaalden de scores, construct validiteit, test-hertest overeenkomst van de iSHAREpatient en inter-beoordelaars overeenkomst tussen de iSHAREpatient en de iSHAREphysician vragenlijsten. Artsen uit zeven Nederlandse ziekenhuizen includeerden patiënten met kanker en vulden de iSHAREphysician en de SDM-Questionnaire-physician version in. Hun patiënten vulden naast de iSHAREpatient ook de volgende vragenlijsten in, die gerelateerde constructen meten: de nine-item SDM-Questionnaire, de Decisional Conflict Scale, de Combined Outcome Measure for Risk communication And treatment Decision-making Effectiveness en de five-item Perceived Efficacy in Patient-Physician Interactions. We formuleerden respectievelijk 1 (iSHAREphysician) en 10 (iSHAREpatient) a priori hypothesen met betrekking tot samenhang tussen de iSHARE vragenlijsten en vragenlijsten die gerelateerde constructen beoordelen. Om de test-hertest overeenkomst te beoordelen, vulden patiënten de iSHAREpatient 1-2 weken later opnieuw in. In totaal werden 151 besluitvormingsprocessen met unieke patiënten over de behandeling beoordeeld. Dimensie scores en totale iSHARE scores waren hoog, zowel bij patiënten als bij artsen. De hypothese over de iSHAREphysician en negen van de tien hypothesen over de iSHAREpatient werden bevestigd. Test-hertest overeenkomst en inter-beoordelaars overeenkomst waren >.60 voor de meeste vragen. We concludeerden dat de iSHARE vragenlijsten hoge scores laten zien, goede construct validiteit hebben en een substantiële test-hertest en matige inter-beoordelaars overeenkomst hebben.

## Hoofdstuk 7

In Hoofdstuk 7 bespraken we de bevindingen, inclusief sterke punten en beperkingen van ons onderzoek, en aanbevelingen voor de klinische praktijk en toekomstig onderzoek. Patiënten hebben hun eigen rol in samen beslissen en zorgprofessionals zouden hen in deze rol moeten ondersteunen. Passende interventies kunnen patiënten verder helpen. Verdere validatie van bestaande meetinstrumenten is nodig en we raden het gebruik van de COSMIN richtlijnen daarbij aan. Zowel tijdens de ontwikkeling als de validatie van instrumenten die samen beslissen meten moeten onderzoekers rekening houden met het formatieve karakter van het construct. Ook is het van belang om de eindgebruikers bij de ontwikkeling en validatie te betrekken. Het aanpassen van bestaande instrumenten die samen beslissen meten of het opzetten van een databank van vragen kan de studielast voor patiënten, zorgprofessionals en onderzoekers verminderen. We raden het gebruik van de iSHARE vragenlijsten aan in een oncologische setting, omdat ze zowel het gedrag van de patiënt als van de arts beoordelen, het hele besluitvormingsproces bestrijken, gebaseerd zijn op een grondig ontwikkelproces en adequate meeteigenschappen hebben.

*iSHAREpatient*

## i-SHARE: samen beslissen over de behandeling van kanker

Wilt u bij het invullen van deze vragenlijst denken aan de laatste keer dat u met uw arts in het ziekenhuis gesproken heeft over de behandelmogelijkheden? Dit kan in één of meerdere gesprekken gedaan zijn. Wilt u bij het invullen denken aan al deze gesprekken?

De uitspraken gaan over de arts en over uzelf. Sommige uitspraken lijken op elkaar, maar vragen iets anders.

Kruis bij elke uitspraak het antwoord aan dat het beste past. Er zijn geen goede of foute antwoorden, het gaat om uw mening. Uw antwoorden blijven anoniem, dus de arts krijgt ze niet te zien.

Deze vragenlijst gaat niet om hoe tevreden u bent met uw arts. Het gaat er om wat uw arts gezegd of gedaan heeft tijdens het gesprek.

Vindt u bovenstaande informatie duidelijk?

□ ja

□ nee, wilt u aangeven wat u niet duidelijk vindt:.....

**1. De arts heeft uitgelegd wat de voordelen van de behandelmogelijkheden zijn**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**2. De arts heeft uitgelegd wat de nadelen van de behandelmogelijkheden zijn**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**3. De arts heeft de voordelen en de nadelen van elke behandelmogelijkheid even goed uitgelegd**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**4. De arts is nagegaan of ik de voordelen van de behandelmogelijkheden begreep**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**5. De arts is nagegaan of ik de nadelen van de behandelmogelijkheden begreep**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**6. De arts heeft verteld waarin de behandelmogelijkheden van elkaar verschillen**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**7. Ik heb vragen gesteld over de behandelmogelijkheden**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**8. Aan het begin van het gesprek heeft de arts gezegd dat er een keuze is met betrekking tot mijn behandeling**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**9. De arts heeft gezegd dat het ertoe doet wat ik zelf belangrijk vind**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**10. De arts is nagegaan of hij/zij goed begreep wat voor mij belangrijk is**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**11. De arts heeft mij geholpen om de voordelen en de nadelen van de behandelmogelijkheden af te wegen**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**12. De arts heeft mij tijd gegeven om de voordelen en de nadelen van de behandelmogelijkheden af te wegen (tijdens of na het gesprek)**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**13. Ik heb tegen de arts gezegd wat voor mij belangrijk is**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**14. Ik heb de voordelen en de nadelen van de behandelmogelijkheden afgewogen (voor, tijdens of na het gesprek)**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**Is er een beslissing genomen over de behandeling?**

☐ Ja, de beslissing is genomen → vul hieronder vraag 15 in

☐ Nee, er is geen beslissing genomen → vul hieronder vraag 16 in

**15. Bij de beslissing is rekening gehouden met wat ik belangrijk vind**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**16. De arts heeft met mij besproken wat ik nodig heb om de voordelen en de nadelen van de behandelmogelijkheden af te kunnen wegen**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

*iSHAREphysician*

# i-SHARE: samen beslissen over de behandeling van kanker

Wilt u bij het invullen van deze vragenlijst denken aan het consult waarin u de beslissing over de behandeling met de patiënt besproken heeft. Over deze beslissing heeft u mogelijk meerdere consulten gehad met de patiënt. Wilt u bij het invullen denken aan al deze consulten?

De uitspraken gaan over de patiënt en over uzelf. Er zijn geen goede of foute antwoorden.

**1. Ik heb uitgelegd wat de voordelen van de behandelmogelijkheden zijn**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**2. Ik heb uitgelegd wat de nadelen van de behandelmogelijkheden zijn**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**3. Ik heb de voordelen en de nadelen van elke behandelmogelijkheid even goed uitgelegd**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**4. Ik ben nagegaan of de patiënt de voordelen van de behandelmogelijkheden begreep**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**5. Ik ben nagegaan of de patiënt de nadelen van de behandelmogelijkheden begreep**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**6. Ik heb verteld waarin de behandelmogelijkheden van elkaar verschillen**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**7. De patiënt heeft vragen gesteld over de behandelmogelijkheden**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**8. Aan het begin van het gesprek heb ik gezegd dat er een keuze is met betrekking tot de behandeling**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**9. Ik heb gezegd dat het ertoe doet wat de patiënt zelf belangrijk vindt**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**10. Ik ben nagegaan of ik goed begreep wat voor de patiënt belangrijk is**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**11. Ik heb de patiënt geholpen om de voordelen en de nadelen van de behandelmogelijkheden af te wegen**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**12. Ik heb de patiënt tijd gegeven om de voordelen en de nadelen van de behandelmogelijkheden af te wegen (tijdens of na het gesprek)**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**13. De patiënt heeft tegen mij gezegd wat voor hem/haar belangrijk is**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**14. De patiënt heeft de voordelen en de nadelen van de behandelmogelijkheden afgewogen (voor, tijdens of na het gesprek)**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**Is er een beslissing genomen over de behandeling?**

☐ Ja, de beslissing is genomen → vul hieronder vraag 15 in

☐ Nee, er is geen beslissing genomen → vul hieronder vraag 16 in

**15. Bij de beslissing is rekening gehouden met wat de patiënt belangrijk vindt**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**16. Ik heb met de patiënt besproken wat hij/zij nodig heeft om de voordelen en de nadelen van de behandelmogelijkheden af te kunnen wegen**

| helemaal niet gedaan | bijna niet gedaan | een beetje gedaan | voor een groot deel gedaan | bijna helemaal gedaan | helemaal gedaan |
|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

## List of publications

*This thesis*

1. Bomhof-Roordink H, Stiggelbout AM, Gärtner FR, Portielje JEA, de Kroon CD, Peeters K, et al. Patient and physician shared decision-making behaviors in oncology: Evidence on adequate measurement properties of the iSHARE questionnaires. Patient Educ Couns. 2021. doi: 10.1016/j.pec.2021.08.034. *Online ahead of print.*

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## Curriculum Vitae

Hanna Bomhof-Roordink was born in Putten, on the 11th of March, 1985. In 2006 she obtained her high school degree from Landstede, Harderwijk, after attending Johannes Fontanus College, Barneveld till 2003. She completed the bachelor Health and Life Sciences at the Vrije Universiteit (VU) in Amsterdam, in 2009. She completed the research master Lifestyle and Chronic Disorders at the VU in Amsterdam, in 2012. Both her bachelor internship (Isala, Zwolle) and her two master internships (Amsterdam UMC, location VU medical center (VUmc), Amsterdam and University Medical Center Utrecht, Utrecht) resulted in publications. During her study she worked as an assistant in the Data Intelligence team of SmartAgent, Amersfoort. From August 2012 till October 2013 she worked at Amsterdam UMC, location VUmc, to start the TES trial. In February 2014 she started her PhD on 'Measurement of shared decision making in oncology' at Leiden University Medical Center, under supervision of prof. dr. Anne Stiggelbout, prof. dr. Trudy van der Weijden, and dr. Arwen Pieterse. Since May 2019, she has been working as a post-doc researcher on the development and validation of a questionnaire to measure informed decision making regarding participation in cancer screening at Amsterdam UMC, location VUmc and is in involved in the education of medical students.

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