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The applicability and implementation of patient versions of guidelines in oncology: a study protocol

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ABSTRACT

Introduction

Clinical practice guidelines (CPGs) are primarily addressing health care providers. However, guideline-based information may be equally helpful for patients when making health decisions. Within the German Guideline Program in Oncology (GGPO) patient versions of CPGs have been mandatory for more than 10 years, though a systematic evaluation of those and their impact on patients is lacking.

The aim of the project is to investigate the role and applicability of patient versions by considering the perspectives of experts, patients and health care providers to develop recommendations for the development, dissemination and implementation of patient versions in Germany.

Methods and analysis

The project comprises two main modules. In module 1, we will first investigate methods and approaches for the development, dissemination and implementation of patient versions by systematically reviewing international literature and conceptual / methods papers. Further, we will conduct interviews with experts in the development of patient versions. We will explore their specific knowledge and experiences in the development, dissemination and implementation of patient versions. In module 2, we will explore patients' and health care providers' perceptions on patient versions in oncology from the perspective of patients and health care providers. Thereby, we will conduct interviews on various patient versions of the GGPO, followed by focus groups for breast cancer, prostate cancer and colon cancer, respectively.

The results of both modules will be used to develop recommendations for enhancing the development, dissemination and implementation of patient versions in Germany by involving the relevant stakeholder groups.

Ethics and dissemination

Ethical approval for the qualitative parts of the project was given by the ethics commission of the Witten/Herdecke University (number 160/2021). The findings of the project will be published in peer-reviewed journals and presented at scientific conferences.

Keywords: Guidelines, Clinical practice guideline, Patient version

Strengths and limitations of this study

- We will address the perspectives of both patients and health care providers in order to evaluate patient versions of guidelines in oncology in Germany.
- To obtain information on the development, dissemination and implementation of patient versions, we will conduct systematic literature searches and explore the perspective of experts in the field of developing patient versions.
- We will develop recommendations for the development, dissemination and implementation of patient versions in Germany by involving the relevant stakeholders.
- Although, will focus on patient versions in oncology, several results might be useful for patient versions in general.
- Some information we will generate may be specific for a particular patient version and may not transfer to all patient versions.

[Word count full text: 3999]

INTRODUCTION

Clinical practice guidelines (CPGs) are systematically developed statements that provide evidence-based recommendations to guide appropriate healthcare [1,2]. Although CPGs are primarily produced for health care providers, guideline-based information may be equally helpful for patients when making health decisions. Furthermore, such information may strengthen the health literacy and may support the communication between patients and health care providers. Therefore, several guideline organisations develop patient versions of CPGs for many years now [3,4]. However, it was shown that patients and members of the public often fail to understand the general concept of CPGs [5,6]. Further, patient and public attitudes to both CPGs and patient versions of CPGs were found to be very heterogeneous [7]. Several patients expressed their concerns that the information may not be applicable to their own situation. In some studies, CPGs were found to be empowering, while in other studies participants were worried that they are rationing care and limiting decision-making. The awareness of CPGs and patient versions of CPGs in public was seen as generally low [7].

Internationally, there is a notable heterogeneity regarding the terminology in the field of patient versions of CPGs [4]. Used terms are for example “patient version“, “patient guideline”, “lay version” or just “patient information”. We will use in the following the term “patient version”.

Patient versions are specific formats of evidence-based patient information. They are subject to various definitions and criteria [8,9]. An essential characteristic of patient versions is, that they are based on CPGs and “translate” guideline recommendations into laypersons‘ plain language to make them accessible for patients and members of the public. However, little is known about to what extent patient versions are helpful for example in informed choice and shared decision-making [6,10]. Although patient versions can be developed for various diseases and health care areas, particularly in oncology there are a number of studies showing that information needs of patients are high but often unmet [11-14]. Patient information can help gain control after a cancer diagnosis [15]. This can result in confidence in treatment decisions and understanding the consequences of the disease and treatment of one’s life [15].

Within the German Guideline Program in Oncology (GGPO) patient versions have been mandatory for more than 10 years. In the development of those, quality criteria on reliable patient information have been considered [16-18]. Currently, the GGPO provides 26 patient versions (state 10/2021). However, these have been criticised for not addressing all informational needs [19]. To date, a systematic evaluation of patient versions and their impact on patients is lacking [20].

We are not aware of studies that consider the different perspectives of patients, health care providers and developers regarding patient versions altogether. Further, to our knowledge, there is lack of information regarding dissemination and implementation strategies of patient versions being used.

Objectives

The aim of the project is to investigate the role and applicability of patient versions by considering the perspectives of experts, patients and health care providers to develop recommendations for the development, dissemination and implementation of patient versions in Germany.

METHODS AND ANALYSIS

The AnImPaLLo project "*Applicability and Implementation of patient versions of guidelines in oncology*" was set up by the Witten/Herdecke University in cooperation with relevant stakeholders in the field of patient versions (further referred to as project partners). Thus, we include patient representatives and organisations that are involved in the development of patient versions in Germany. The project partners are the GGPO, the Association of the Scientific Medical societies in Germany (AWMF), the German Agency for Quality in Medicine (ÄZQ) and two large national patient organisations for prostate cancer and women with cancer (*Bundesverband Prostatakrebs Selbsthilfe e.V., Frauenselbsthilfe Krebs Bundesverband e.V.*).

Study Design

The project comprises two main modules, each main module includes two submodules. In module 1, we will first investigate methods and approaches for the development, dissemination and implementation of patient versions by systematically reviewing international literature and conceptual / methods papers. Further, we will conduct interviews with experts in the development of patient versions. We will explore their specific knowledge and experiences in the development, dissemination and implementation of patient versions. The aspect of development will also comprise information regarding updating of patient versions. In module 2, we will explore patients' and health care providers' perceptions on German patient versions in oncology. Thereby, we will conduct interviews on various patient versions of the GGPO, followed by focus groups for breast, prostate and colon cancer, respectively.

The results of both modules will be used to develop recommendations for enhancing the development, dissemination and implementation of patient versions in Germany by involving an expert panel consisting of persons with expertise in the development of patient versions as well as representatives

of relevant stakeholder groups. Figure 1 provides an overview of the project course and illustrates the modular structure.

Figure 1: Overview of the project course

Module 1a

To obtain information on methods and approaches for development, dissemination and implementation of patient versions, we will search the websites and publications of 17 organisations which are known for developing patient versions (supplemental file A) [4]. In addition, we will try to identify other potentially relevant documents on the websites of further relevant organisations which are listed as members of the Guidelines International Network (GIN) (https://g-i-n.net/organisation/).

Additionally, we will perform a systematic literature search. We will search Medline via PubMed and OVID using the search strategy displayed in supplemental file B. We will search for references published from 2000 until today as the field of patient versions is a rather new one. Our search strategy will take into account the international heterogeneity regarding the terminology of patient versions. References will be eligible for inclusion if they meet all of the following criteria:

- dated from the year 2000 until today
- methodological or empirical reports, commentaries, editorials, or other reports describing, evaluating, or comparing strategies or methods
- addressing the methodology of developing, disseminating and/or implementing patient versions
- published in German or English
- full-text version available.

We will exclude articles addressing the methodology of developing, disseminating and/or implementing related to other forms of patient information tools that are not directly linked to a CPG, such as decision aids or educational material.

We will identify further relevant articles by screening the reference lists of relevant references and snowballing [21]. Additionally, we will ask experts in this field for further literature. Two independent reviewers will screen all identified titles and abstracts for eligibility. The two reviewers will carry out full text screening of the included references independently and will document the reasons for excluding references. Disagreements will be resolved through discussion until reaching consensus.

Data collection

One reviewer will extract the findings in standardized tables and a second reviewer will check these data. To do so, additionally to information on the date of publication, the authors, and their corresponding guideline organization or medical society, we will extract information on development, dissemination and implementation of patient versions in general or regarding a specific patient version. Again, disagreements will be resolved through discussion until reaching consensus.

Data analysis

We will narratively synthesize the information and content generated by the literature search.

Module 1b

To explore the perspective of experts in the field of developing patient versions, we will conduct semi-structured interviews via telephone or video conferencing (e.g. Zoom) with national and international guideline organisations. We will interview representatives of organisations regarding their experience in the development, dissemination and implementation of patient versions.

Study population

A total of up to N = 20 interviews are assumed as being sufficient for data saturation. We plan to conduct 17 interviews with international and three interviews with national experts. We will draw the 17 organisations on international level as described above [4], because they published more than four patient versions and are therefore considered to have expertise in their development. We will include additional organisations frequently working on patient versions by recommendations of experts in the field and personal knowledge. We may also identify relevant organisations through the literature screening conducted in Module 1a.

On the national level, we will interview a representative of the ÄZQ, as this organisation is mainly involved in the development of patient versions in Germany. The ÄZQ has been responsible for the mandatory development of patient versions in the GGPO and the National Program for Disease Management Guidelines (NDMG) for more than 10 years. More recently, other organisations are involved in developing patient versions in the GGPO. Besides, some medical societies in Germany also produce patient versions. Accordingly, it is our aim to conduct at least two more interviews with representatives of other organisations in Germany with experience in this field to ensure that the results do not come from just one national institution. We will identify these by searching the database on patient versions from the AWMF with the filters "Status: Current" and "Document type: Patient Version". We will include medical societies that published the highest number of patient versions since 01.01.2018. Organisations which develop oncological patient versions in Germany will be named by the GGPO.

Recruitment

After the identification of eligible guideline organisations at national and international level, we will contact the organisations through e-mail and request to name a representative willing to participate in an interview. Next to expertise in the development of patient versions, further inclusion criteria of the interview participants are age ≥ 18 and sufficient knowledge of the German or English language.

Interview guide

Literature commonly used and relevant in the field of patient versions will provide thematic support in the preparation of the interview guide for this module. The project team at the Witten/Herdecke University will send a draft of the interview guide to the project partners for review. We will discuss any comments or recommendations from the project partners and, if necessary, make amendments before the final interview guide is translated into English. Both interview guides will be pre tested and subsequently adapted if necessary.

Personal information about gender, age, current position and experience in the development of patient versions will be queried at the beginning of the interview in order to be able to put the statements into context and, if applicable, to identify differences between the interviewees. We will ask questions about aims, formats, topics and ask about the development process of patient versions and challenges occurring alongside. Further, we will ask for information about target groups of patient versions and how they are addressed. We will query facilitators and barriers in the development, dissemination, and implementation of patient versions. We will collect answers on the public availability of methods on patient versions and whether these are presented in a way understandable to laypersons, for example appropriate explanations to different grading of recommendations. Finally, we will request an outlook on the future importance of patient versions, especially with regard to demographic change and digitalization.

Data collection

Persons who will perform the interviews will be trained in advance. They will conduct the interviews by telephone or video conferencing and record them by an audio recording device. Subsequently, the interviews will be transcribed verbatim by an external institution.

Data analysis

We will process sociodemographic data of the interviewees descriptively using Excel 2016.

We will analyse the interview material using qualitative content analysis according to Mayring [22]. We will create a coding guideline and code the transcripts using MAXQDA analysis software. The first interviews will be analysed in order to adapt the interview guides if necessary.

Data will be structured according to a predefined category system. We will develop main categories deductively based on the core topics and questions of the interviews. Then, we will complement and refine the scheme in an inductive manner by further categories or subcategories during the analysis of the material. Results will be discussed in the research team.

Module 2a

To explore the perspective of patients and health care providers, we will conduct semi-structured telephone interviews. First, we will ask questions about experiences with and expectations in patient versions in general and secondly, we will ask the interviewees about their perception on a specific existing oncological patient version. In preparation for the interview, the participants will receive a specific patient version. The participants will be asked to familiarize with the patient version before the interview.

Study population

We will include persons with a diagnosis of cancer in the past. Further inclusion criteria will be: age ≥ 18 years and sufficient knowledge of the German language. As health care providers we will include members of health care professions who are directly involved in the care of patients with cancer (e.g. physicians, psycho-oncologists and nurses). For the group of patients and the group of health care providers we target a number of 25 interviewees each. Depending on the information yield, we will recruit further participants until no more important topics occur [23].

Recruitment

The recruitment of patients and health care providers will primarily be done via a survey with patients and health care providers about the awareness and role of patient versions in oncology. The survey was undertaken under the leadership of the AWMF in the run-up to our project. At the end of the survey, the participants were asked whether they would like to participate in an in-depth interview. The survey with patients was conducted online and by post between November 2020 and May 2021, while the survey with health care providers has run online between April and June 2021. 712 patients and 400 health care providers completed the survey. Overall, about 100 patients and 10 health care providers have expressed interest to participate in our study.

In addition, we recruited participants by distributing a call for participation in our study via the Internet through our project partners (e.g. via websites, newsletters, social media). Furthermore, health care providers will be recruited via a random selection of certified and non-certified oncology centers nationwide. Certified cancer centers are those that are certificated by the German Cancer Society (DKG) (https://www.krebsgesellschaft.de/german-cancer-society.html). Both certified and non-certifies centers will be identified by the German Hospital Directory (https://www.german-hospital-

directory.com). Initially, relevant hospital units (e.g. outpatient clinic, psycho-oncology) will be contacted by telephone in order to identify persons that are directly involved in the care of patients. Subsequently, we will send more detailed information on the project via e-mail if requested.

The selection of participants will be performed according to the principle of maximum variation [24] to reflect a wide range of participant's characteristics. Patient's characteristics are age, socioeconomic status, cancer diagnosis and stages of the disease, member of a self-help organisation and private or statutory health insurance. Participating patients who have completed the interview will receive an incentive of € 20. Health care providers will be selected in particular according to their profession and experience in the treatment of patients with oncological diseases as well as the type of centre (certified or non-certified) and healthcare sector (inpatient or outpatient).

Choice of patient versions

Of the existing oncological patient versions, we will exclude the patient versions addressing early detection of cancer and focus on those that are not older than 5 years as CPG recommendations which are mentioned in patient versions might be outdated after 3 to 5 years [25,26]. Patients will be assigned to patient versions according to their cancer diagnosis. If there is no patient version for their type of diagnosis or if it is outdated, patient versions will be offered on the cross-sectional topics supportive therapy or psycho-oncology. Health care providers will receive a patient version relevant to the patients they care for. The participants may choose a digital (pdf-document) or a brochure of the patient version.

Interview guide

The procedure for developing the interview guides will be in accordance with module 1b. They will be tailored to the particular interview group. Results of the survey of the AWMF mentioned above will be considered in the interview guides. The survey results will be published separately. The interview guide for patients includes questions on the assessment of the relevance and trustworthiness of the content, completeness and importance of the information, reasons for searching for information and for what purposes the information is used. To investigate applicability, questions about how the patient version may support patients in making decisions related to their cancer treatment or in coping with the disease / self-management (communicative effectiveness), based on the concept for evaluations of patient information by Garner et al [27] will be raised. To assess the readability (text and presentation) and the comprehensibility (interaction between text and reader) targeted questions on knowledge and risk perception related to selected statements in the patient versions will be included. The interview guide for health care providers contains similar questions with the exception of aspects relating to comprehensibility. In addition, the guide includes questions on the awareness of the patient versions and whether and how they are made available in the clinical setting. Furthermore, we will ask

questions about the assessment of the influence on the quality of care. The interview guides will be pre tested and subsequently adapted if necessary.

Data collection

The data collection will be performed in accordance with module 1b.

Data analysis

The data analysis will be performed in accordance with module 1b.

Module 2b

On completion of the preceded modules, we will conduct mixed focus groups with patients and health care providers, separately for the most common cancer entities breast, prostate and colon cancer. The aim is to generate additional in-depth information in particular due to the interchange between patients and health care providers. For each indication, we will conduct two focus groups with 8 to 12 participants each. The restriction on three cancer entities is made due to reasons of feasibility. Additional criterion for this choice is the possibility of being able to delineate gender-specific aspects.

We plan to conduct the focus groups in person. If this is not possible due to the pandemic situation, we will conduct online focus group discussions. To date, there are several experiences with online focus groups [28-30]. Accordingly, influencing factors on group interactions and data collection as well as specific requirements for data protection will be considered if this should become relevant.

Study population

We will include patients diagnosed with breast, colorectal or prostate cancer, age ≥18 years and sufficient understanding of the German language. Inclusion criteria for the health care providers are the same as described in module 2a.

Recruitment

We will recruit participants in accordance with Module 2a. In addition, we will also ask interviewees (patients with breast, prostate or colon cancer and health care providers which are involved in the care of these patients) of module 2a if they are willing to participate in a focus group. All participants will receive an incentive of € 50. Further, we will reimburse the travel expenses if necessary.

Guide for the focus group discussions

Informed by the interviews in the other modules, we will develop a guide for the focus group discussions. Again, all members of the project team will be involved in the conception. The guide will take up specific aspects from the interviews and focus on how patient versions could be effectively used in the communication between patients and health care providers and how their application could be encouraged.

Data collection

The data collection will be performed in accordance with module 1b.

Data analysis

The data analysis will be performed in accordance with module 1b and will be done separately for each entity.

Development of recommendations for the development, dissemination and implementation of patient versions

On basis of the results of the preceding modules, we will derive recommendations for the development, dissemination and implementation particularly of oncological patient versions in Germany. For this purpose, we will involve an expert panel consisting of persons with expertise in the development of patient versions as well as representatives of relevant stakeholder groups, e.g. patient representatives, patient organisations, the Federal Joint Committee, the GGPO, the AWMF, the ÄZQ, the Federal Ministry of Health, the German Health Literacy Network (DNGK), German Network for Healthcare Research (DNVF), the German Society for Epidemiology (DGEpi), the Institute for Quality and Efficiency in Health Care (IQWiG), Foundation for Health Knowledge and the German Network for Evidence-based Medicine (DNEbM). We expect that the dissemination and implementation of the recommendations will be supported by involving these stakeholders.

We will invite to a one-day workshop. In preparation for the workshop, the project team at the Witten/Herdecke University will develop drafts for recommendations on the base of results from analyses of the interviews, focus groups and relevant literature and the corresponding identified areas requiring improvement. We will discuss the recommendations with the project partners to agree on a final proposal for recommendations with justification based on the findings for each recommendation. Subsequently, we will send the proposal to the panel.

At the workshop, we will discuss and refine the recommendations with the whole panel. We will come to the final recommendations by using a formal consensus method with at least 75% agreement for each recommendation as threshold. A trained and independent moderator will guide the workshop. We assume that the recommendations will comprise specific aspects related to patient versions in oncology but also aspects that affect patient versions in general.

We will disseminate and promote the recommendations to author groups in Germany, which are engaged in ongoing or forthcoming projects for developing CPGs and / or patient versions.

DISCUSSION

Our study will enable a better understanding of factors that influence the applicability as well as the development, dissemination and implementation of patient versions by direct questioning the relevant stakeholders. Due to the identification of potential for improvement the project can contribute to the advancement of patient versions in Germany. Furthermore, the determination of adequate strategies for dissemination and implementation can support the wide use of patient versions and a more patient-centred care.

To our knowledge, this is the first study on patient versions that will take different perspectives of patients, health care providers and guideline developers into account. We will focus on patient versions in oncology. However, we expect that several results are useful for the development and implementation of patient versions in general as we will likely generate recommendations that will affect also more general aspects of patient versions. Although the recommendations resulting from the project will be related to the German context, they can usefully contribute to the international debate on patient versions.

A limitation of the study is that we will restrict the focus groups to the diseases breast, prostate and colon cancer which are the most common cancer entities in Germany. In patients with other oncological entities, for example those with rare cancers, there may be other information needs and aspects which should be emphasized. However, within the interviews with patients and healthcare providers we will include various entities. Accordingly, we will consider different patient versions. These were developed using the same methods and have some generic sections that are included in all patient versions such as “living with cancer”. However, they were written by various authors, have various length and in part different focuses. Particularly, the patient versions with cross-sectional topics such as supportive therapy or psycho-oncology address patients with cancer in general and give more complementary information. This means that we are on the one hand able to generate information from a broader range of patient versions and cancer entities. On the other hand, some information may be specific for a particular patient version and may not transfer to all patient versions.

ETHICS AND DISSEMINATION

Ethical approval for the qualitative parts of the project was given by the ethics commission of the Witten/Herdecke University (number 160/2021). For the interviews and focus groups, we will ask the participants to sign an informed consent. Although we may present the names of organisations from module 1b, the interview partners and their relationship with the specific guideline organisation will

stay confidential. For the transcription of the audiotapes and the analyses, we will pseudonymise personal data.

The findings of the project will be published in peer-reviewed journals and presented at scientific conferences. To present the findings of qualitative research, we will consider the consolidated criteria for reporting qualitative research (COREQ) [31].

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AUTHORS' CONTRIBUTIONS

MB, SB and NM wrote the first draft of the manuscript. MB revised the manuscript. MB, SB, NM, SB, GC, MF, SF, TL, MN, CS and DP contributed to the conceptualisation of the study design. DP contributed to draft the manuscript and supervised the process. All authors discussed and edited the final document.

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COMPETING INTEREST STATEMENT

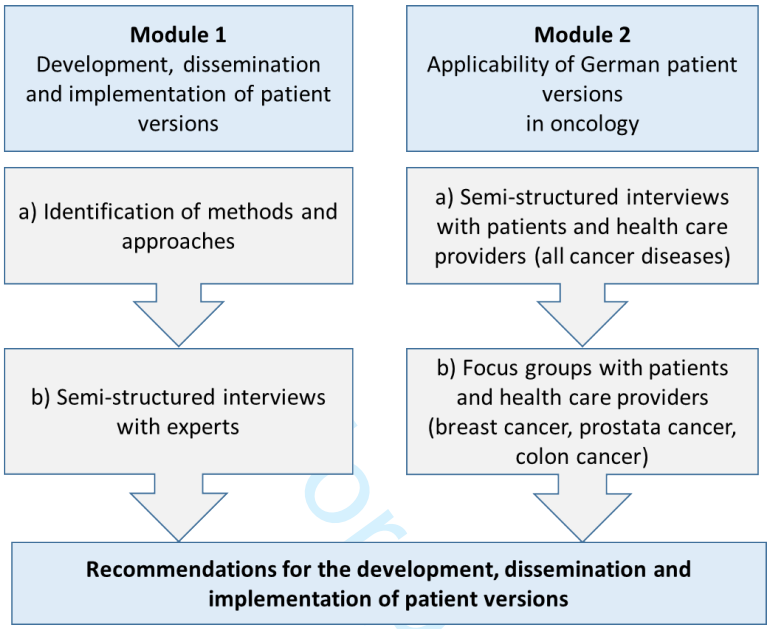
SB, NM, GC, SF, NS and DP declare that they have no competing interests. MB is involved in the development of patient versions in oncology in Germany. SB and MN are representatives of the AWMF which receive constant financial support of the German Cancer Aid to support the GGPO and are involved in the methodological counselling of CPGs in oncology and other CPGs. MF is a representative

of the publisher of the patient versions in oncology in Germany and involved in the methodological counselling of CPGs and patient versions in oncology. TL is a representative of the publisher of the patient versions in oncology in Germany. CS was involved in the development of patient versions in oncology in Germany until 2019 and is responsible for the development of patient versions in the National Program for Disease Management Guidelines (NDMG) and the methodological refinement of those.

PATIENT AND PUBLIC INVOLVEMENT

Patients or the public were involved in the design, or conduct, or reporting, or dissemination plans of our research.

Figure 1: Overview of the project course



Guideline Organisations from Santesso et al. (2016)[1]

Organisation	Location
American Academy of Neurology	United States
American College of Gastroenterology	United States
American College of Physicians	United States
American Society of Clinical Oncology	United States
American Urological Association, Urology Care Foundation	United States
Canadian Diabetes Association	Canada
Canadian Paediatric Society	Canada
Centers for Disease Control and Prevention	United States
European Society for Medical Oncology	Europe
National Comprehensive Cancer Network	United States
National Institute for Health and Care Excellence (NICE)	United Kingdom
Queensland Clinical Guidelines	Australia
Royal College of Obstetricians and Gynaecologists	United Kingdom
Scottish Intercollegiate Guidelines Network	Scotland
University of Michigan Hospital and Health Centers	United States
UpToDate	The Netherlands
US Preventive Services Task Force	United States

[1]Santesso, N. et al. (2016), Dissemination of Clinical Practice Guidelines: A Content Analysis of Patient Versions, DOI: 10.1177/0272989X16644427

Search Strategies for PubMed and OVID (Medline)

PubMed	((("Practice Guidelines as Topic"[Mesh] or guideline*[tiab]) AND (patient version*[tiab] OR public version*[tiab])) OR patient guideline*[tiab] OR "evidence-based patient information*"[tiab]) AND (method[tiab] OR methods[tiab] OR methodolog*[tiab] OR ((methodical[tiab] OR methodological[tiab]) AND (approach[tiab] OR procedure[tiab])) OR proceeding[tiab] OR procedure[tiab] OR creation[tiab] OR developing[tiab] OR development[tiab] OR elaboration[tiab] OR preparation[tiab] OR conducting[tiab] OR implementation[tiab] OR disseminat*[tiab]) AND (english[la] OR german[la]) NOT (comment[pt] OR letter[pt] OR editorial[pt])
OVID (Medline)	1. exp practice guideline/ 2. guideline?.ti,ab,kf. 3. ((patient or public) adj1 version?).ti,ab,kf. 4. (1 or 2) and 3 5. (patient? adj2 guideline?).ti,ab,kf. 6. evidence-based patient information.ti,ab,kf. 7. 4 or 5 or 6 8. (method? or methodolog* or ((methodical or methodological) adj1 (approach or procedure)) or proceeding or procedure or creation or developing or development or elaboration or preparation or conducting or implementation or disseminat*).ti,ab,kf. 9. 7 and 8 10. (english or german).la. 11. 9 and 10 12. (comment or letter or editorial).pt. 13. 11 not 12

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Investigating the role and applicability of patient versions of guidelines in oncology and deriving recommendations for the development, dissemination and implementation of patient versions in Germany: protocol for multi-phase study

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Primary Subject Heading:	Patient-centred medicine
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Investigating the role and applicability of patient versions of guidelines in oncology and deriving recommendations for the development, dissemination and implementation of patient versions in Germany: protocol for multi-phase study

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ABSTRACT

Introduction

The German Guideline Program in Oncology (GGPO) has published patient versions of clinical practice guidelines (CPGs) for more than 10 years. However, a systematic evaluation of these is lacking. The project aims to investigate the role and applicability of patient versions by considering the perspectives of experts, patients and health care providers to derive recommendations for the development, dissemination and implementation of patient versions in Germany.

Methods and analysis

The project comprises two main modules. In module 1, we will first obtain information on methods and approaches for the development, dissemination and implementation of patient versions by conducting systematic searches in Medline and screening the websites of guideline organisations. We will include any articles, such as methodological or empirical reports, published in German or English since 2000, that address methodological aspects related to patient versions. Further, we will conduct 20 interviews with experts from international and German organisations who are involved in the development of patient versions. In module 2, we will first conduct interviews to explore patients' and health care providers' perceptions of patient versions of the GGPO. For the group of patients and the group of health care providers, we aim to conduct 25 interviews each. Second, we will conduct focus groups, separately for breast, prostate and colon cancer. The recruitment of participants for the interviews and focus groups will primarily be done through a previous survey about patient versions in oncology. The results will be used to derive recommendations for enhancing the development, dissemination and implementation of patient versions by involving the relevant stakeholder groups.

Ethics and dissemination

Ethical approval for the qualitative parts of the project was given by the ethics committee of Witten/Herdecke University (number 160/2021). Participants will be required to provide informed consent. The project findings will be published in peer-reviewed journals and presented at scientific conferences.

Keywords: Guidelines, Clinical practice guideline, Patient version

Strengths and limitations of this study

- We will address the perspectives of both patients and health care providers to evaluate patient versions of guidelines in oncology in Germany.
- To obtain information on the development, dissemination and implementation of patient versions, we will conduct systematic literature searches and explore the perspective of experts in the field of developing patient versions.
- We will develop recommendations for the development, dissemination and implementation of patient versions in Germany by involving the relevant stakeholders.
- Although we will focus on patient versions in oncology, several results might be useful for patient versions in general.
- Some information we will generate may be specific for a particular patient version and may not apply to all patient versions.

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INTRODUCTION

Clinical practice guidelines (CPGs) are systematically developed statements that provide evidence-based recommendations to guide appropriate healthcare [1,2]. Although CPGs are primarily produced for health care providers, guideline-based information may be equally helpful for patients when making health decisions. Furthermore, such information may strengthen health literacy and may support the communication between patients and health care providers. Therefore, several guideline organisations develop patient versions of CPGs for many years now [3,4]. However, it was shown that patients and members of the public often fail to understand the general concept of CPGs [5,6]. Further, patient and public attitudes to both CPGs and patient versions of CPGs were found to be very heterogeneous [7]. Several patients expressed their concerns that the information may not apply to their situation. In some studies, CPGs were found to be empowering, while in other studies participants were worried that they are rationing care and limiting decision-making. The awareness of CPGs and patient versions of CPGs in public was seen as generally low [7].

Internationally, there is a notable heterogeneity regarding the terminology in the field of patient versions of CPGs [4]. Used terms are for example “patient version“, “patient guideline”, “lay version” or just “patient information”. In the following, we will use the term “patient version”.

Patient versions are specific formats of evidence-based patient information. They are subject to various definitions and criteria [8,9]. An essential characteristic of patient versions is, that they are based on CPGs and “translate” guideline recommendations into laypersons‘ plain language to make them accessible for patients and members of the public. However, little is known about to what extent patient versions are helpful for example in informed choice and shared decision-making [6,10]. Although patient versions can be developed for various diseases and health care areas, particularly in oncology several studies show that information needs of patients are high but often unmet [11-14]. Patient information can help to gain control after a cancer diagnosis , which can result in confidence in treatment decisions and understanding the consequences of the disease and treatment of one’s life [15].

Within the German Guideline Program in Oncology (GGPO) patient versions have been mandatory for more than 10 years. In the development of those, quality criteria on reliable patient information have been considered [16-18]. Currently, the GGPO provides 26 patient versions (state 10/2021). However, these have been criticised for not addressing all informational needs [19]. To date, a systematic evaluation of patient versions and their impact on patients is lacking [20].

We are not aware of studies that consider the different perspectives of patients, health care providers and developers regarding patient versions altogether. Further, to our knowledge, there is a lack of information regarding dissemination and implementation strategies of patient versions being used.

Objectives

The project aims to investigate the role and applicability of patient versions by considering the perspectives of experts, patients and health care providers to derive recommendations for the development, dissemination and implementation of patient versions in Germany.

METHODS AND ANALYSIS

The AnImPaLLo project "*Applicability and Implementation of patient versions of guidelines in oncology*" was set up by the Witten/Herdecke University in cooperation with relevant stakeholders in the field of patient versions (further referred to as project partners). Thus, we include patient representatives and organisations that are involved in the development of patient versions in Germany. The project partners are the GGPO, the Association of the Scientific Medical Societies in Germany - Institute for Medical Knowledge Management (AWMF-IMWI), the German Agency for Quality in Medicine (ÄZQ) and two large national patient organisations for prostate cancer and women with cancer (*Bundesverband Prostatakrebs Selbsthilfe e.V., Frauenselbsthilfe Krebs Bundesverband e.V.*).

Study Design

The project comprises two main modules, each main module includes two submodules. In module 1, we will first investigate methods and approaches for the development, dissemination and implementation of patient versions by systematically reviewing international literature and conceptual / methods papers. Further, we will conduct interviews with experts in the development of patient versions. We will explore their specific knowledge and experiences in the development, dissemination and implementation of patient versions. The aspect of development will also comprise information regarding updating of patient versions. In module 2, we will explore patients' and health care providers' perceptions of German patient versions in oncology. Thereby, we will conduct interviews on various patient versions of the GGPO, followed by focus groups for breast, prostate and colon cancer, respectively.

The results of both modules will be used to derive recommendations for enhancing the development, dissemination and implementation of patient versions in Germany by involving an expert panel consisting of persons with expertise in the development of patient versions as well as representatives

of relevant stakeholder groups. Figure 1 provides an overview of the project course and illustrates the modular structure.

Figure 1: Overview of the project course

Module 1a

The protocol for module 1 adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis-Protocols (PRISMA-P)[21]. As PRISMA-P aims to guide the development of protocols for systematic reviews evaluating healthcare interventions, we deviated from the original checklist by omitting items (e.g., outcomes and prioritization) due to the methodological focus of our planned systematic review.

To obtain information on methods and approaches for the development, dissemination and implementation of patient versions, we will search the websites and publications of 17 organisations known for developing patient versions (appendix A) [4]. Moreover, we try to identify other potentially relevant documents on the websites of further organisations listed as members of the Guidelines International Network (GIN) (https://g-i-n.net/organisation/).

Additionally, we will perform a systematic literature search. We will search Medline via PubMed and OVID (see appendix B for full search strategy). We will search for references published from 2000 until the date of the search as the field of patient versions fairly new. Our search strategy will consider the international heterogeneity regarding the terminology of patient versions. References will be eligible for inclusion if they meet all of the following criteria:

- dated from the year 2000 onwards
- methodological or empirical reports, commentaries, editorials, or other reports describing, evaluating, or comparing strategies or methods
- addressing the methodology of developing, disseminating and/or implementing patient versions
- published in German or English
- full-text version available.

We will exclude articles related to other forms of patient information tools that are not directly linked to a CPG, such as decision aids or educational material.

We will identify further relevant articles by screening the reference lists of relevant references and snowballing [22]. Additionally, we will ask experts in this field for further literature. Two independent reviewers will screen all identified titles and abstracts for eligibility. The two reviewers will carry out full-text screening of the included references independently and will document the reasons for excluding references. Disagreements will be resolved through discussion until reaching consensus.

Data collection

One reviewer will extract the findings in standardized tables and a second reviewer will check these data. To do so, additionally to information on the date of publication, the authors, and their corresponding guideline organization or medical society, we will extract information on the development, dissemination and implementation of patient versions in general or regarding a specific patient version. Again, disagreements will be resolved through discussion until reaching consensus.

Data analysis

We will narratively synthesize the information and content generated by the literature search.

Module 1b

To explore the perspective of experts in the field of developing patient versions, we will conduct semi-structured interviews via telephone or video conferencing (e.g., Zoom) with national and international guideline organisations. We will interview representatives of organisations regarding their experience in the development, dissemination and implementation of patient versions.

Study population

A total of up to N = 20 interviews are assumed as being sufficient for data saturation. We plan to conduct 17 interviews with international and three interviews with national experts. We will draw the 17 organisations on the international level as described above [4] because they published more than four patient versions and are hence considered to have expertise in their development. We will include additional organisations frequently working on patient versions by recommendations of experts in the field and personal knowledge. We may also identify relevant organisations through the literature screening conducted in Module 1a.

On the national level, we will interview a representative of the ÄZQ, as this organisation is mainly involved in the development of patient versions in Germany. The ÄZQ has been responsible for the mandatory development of patient versions in the GGPO and the National Program for Disease Management Guidelines (NDMG) for more than 10 years. More recently, other organisations are involved in developing patient versions in the GGPO. Besides, some medical societies in Germany also produce patient versions. Accordingly, we aim to conduct at least two more interviews with

representatives of other organisations in Germany with experience in this field to ensure that the results do not come from just one national institution. We will identify these by searching the database on patient versions from the AWMF with the filters "Status: Current" and "Document type: Patient Version". We will include medical societies that published the highest number of patient versions since 01.01.2018. Organisations developing oncological patient versions in Germany will be named by the GGPO.

Recruitment

After the identification of eligible guideline organisations at the national and international level, we will contact the organisations through e-mail and request to name a representative willing to participate in an interview. Next to expertise in the development of patient versions, further inclusion criteria of the interview participants are age ≥ 18 and sufficient knowledge of the German or English language.

Interview guide

Literature commonly used and relevant in the field of patient versions will provide thematic support in the preparation of the interview guide for this module. The project team at Witten/Herdecke University will send a draft of the interview guide to the project partners for review. We will discuss any comments or recommendations from the project partners and, if necessary, make amendments before the final interview guide is translated into English. Both interview guides will be pre-tested and subsequently adapted if necessary. We will use the first two interviews as a pretest.

Personal information about gender, age, occupation and experience in the development of patient versions will be queried at the beginning of the interview to be able to put the statements into context and, if applicable, to identify differences between the interviewees. We will ask questions about aims, formats, topics and ask about the development process of patient versions and challenges occurring alongside. Further, we will ask for information about target groups of patient versions and how they are addressed. We will query facilitators and barriers in the development, dissemination, and implementation of patient versions. We will collect responses on the public availability of methods on patient versions and whether these are presented in a way understandable to laypersons, e.g., adequate explanations on different grades of recommendations. Finally, we will request an outlook on the future importance of patient versions, especially regarding demographic change and digitalization.

Data collection

Persons who will perform the interviews will be trained in advance. They will conduct the interviews by telephone or video conferencing and record them using an audio recording device. Subsequently, the interviews will be transcribed verbatim by an external institution.

Data analysis

We will process sociodemographic data of the interviewees descriptively using Excel 2016.

We will analyse the interview material using qualitative content analysis according to Mayring [23]. We will create a coding guideline and code the transcripts using MAXQDA analysis software. The first interviews will be analysed towards possible necessary adaptions of the interview guide..

Data will be structured according to a predefined category system. We will develop main categories deductively based on the core topics and questions of the interviews. During the analysis of the material, we will inductively complement and refine the scheme with further categories or subcategories. The results will be discussed in the research team.

Module 2a

To explore the perspective of patients and health care providers, we will conduct semi-structured telephone interviews. First, we will ask questions about experiences with and expectations of patient versions in general and second, we will ask the interviewees about their perception of a specific existing oncological patient version. In preparation for the interview, the participants will receive a specific patient version and will be asked to familiarise with it prior to the interview.

Study population

We will include persons with a diagnosis of cancer in the past. Further inclusion criteria will be age ≥ 18 years and sufficient knowledge of the German language. As health care providers, we will include health professionals who are directly involved in the care of cancer patients (e.g., physicians, psycho-oncologists and nurses). For the group of patients and the group of health care providers, we target 25 interviewees each. Depending on the information yield, we will recruit further participants until no more important topics occur [24].

Recruitment

The recruitment of patients and health care providers will primarily be done via an online survey with patients and health care providers about the awareness and role of patient versions in oncology. The survey was undertaken under the leadership of the AWMF in the run-up to our project. At the end of the survey, the participants were asked whether they would like to participate in an in-depth interview. The survey with patients was conducted between November 2020 and May 2021, while the survey with health care providers has run between April and June 2021. 712 patients and 400 health care providers completed the survey. Overall, about 100 patients and 10 health care providers have expressed interest to participate in our study.

In addition, we will recruit participants by distributing a call for participation in our study via the internet through our project partners (e.g. via websites, newsletters, social media). Moreover, health care providers will be recruited via a random selection of certified and non-certified oncology centres nationwide. Certified cancer centres are those that are certificated by the German Cancer Society (DKG) (https://www.krebsgesellschaft.de/german-cancer-society.html). Both certified and non-certified centres will be identified by the German Hospital Directory (https://www.german-hospital-directory.com). Initially, relevant hospital units (e.g., outpatient clinic, psycho-oncology) will be contacted by telephone to identify persons that are directly involved in the care of patients. Subsequently, we will send more detailed information on the project via e-mail if requested.

The selection of participants will be performed according to the principle of maximum variation [25] to reflect a wide range of participants' characteristics. The patient's characteristics are age, socioeconomic status, cancer diagnosis and stages of the disease, member of a self-help organisation and private or statutory health insurance. Participating patients who have completed the interview will receive an incentive of € 20. Health care providers will be selected according to their profession and experience in the treatment of patients with oncological diseases as well as the type of centre (certified or non-certified) and healthcare sector (inpatient or outpatient).

Choice of patient versions

Of the existing oncological patient versions, we will exclude the patient versions addressing early detection of cancer and focus on those that are not older than 5 years as CPG recommendations which are mentioned in patient versions might be outdated after 3 to 5 years [26,27]. Patients will be assigned to patient versions according to their cancer diagnosis. If there is no patient version for their type of diagnosis or if it is outdated, patient versions on the cross-sectional topics of supportive therapy or psycho-oncology will be offered. Health care providers will receive a patient version relevant to the patients they care for. The participants may choose a digital (pdf-document) or a brochure of the patient version.

Interview guide

The procedure for developing the interview guides will be in accordance with module 1b. They will be tailored to the respective interview group. Results of the survey of the AWMF mentioned above will be considered in the interview guides. The survey results will be published separately. The interview guide for patients includes questions on the assessment of the relevance and trustworthiness of the content, completeness and importance of the information, reasons for searching for information and for what purposes the information is used. To investigate applicability, questions about how the patient version may support patients in making decisions related to their cancer treatment or in coping with the disease / self-management (communicative effectiveness), based on the concept for

evaluations of patient information by Garner et al [28] will be raised. To assess the readability (text and presentation) and the comprehensibility (interaction between text and reader) targeted questions on knowledge and risk perception related to selected statements in the patient versions will be included. The interview guide for health care providers contains similar questions apart from aspects relating to comprehensibility. In addition, the guide includes questions on the awareness of the patient versions and whether and how they are made available in the clinical setting. Furthermore, we will ask questions about the assessment of the influence on the quality of care. Both interview guides will be pre-tested and subsequently adapted if necessary. We will use the first two interviews as a pretest.

Data collection

The data collection will be performed in accordance with module 1b.

Data analysis

The data analysis will be performed in accordance with module 1b.

Module 2b

On completion of the preceded modules, we will conduct mixed focus groups with patients and health care providers, separately for the most common cancer entities breast, prostate and colon cancer. The aim is to obtain additional, in-depth information especially through the dialogue between patients and health care providers. For each entity, we will conduct two focus groups with 8 to 12 participants each. The restriction on three cancer entities is made due to reasons of feasibility. An additional criterion for this choice is the possibility of being able to delineate gender-specific aspects.

We plan to conduct the focus groups in person. If this is not possible due to the pandemic situation, we will conduct online focus group discussions. To date, there are several experiences with online focus groups [29-31]. Accordingly, influencing factors on group interactions and data collection as well as specific requirements for data protection will be considered if this should become relevant.

Study population

We will include patients diagnosed with breast, colorectal or prostate cancer, age ≥18 years and sufficient understanding of the German language. Inclusion criteria for the health care providers are the same as described in module 2a.

Recruitment

We will recruit participants in accordance with Module 2a. In addition, we will also ask interviewees (patients with breast, prostate or colon cancer and health care providers which are involved in the care of these patients) of module 2a if they are willing to participate in a focus group. All participants will receive an incentive of € 50. Further, we will reimburse the travel expenses if necessary.

Guide for the focus group discussions

Informed by the interviews in the other modules, we will develop a guide for the focus group discussions. Again, all members of the project team will be involved in the conception. The guide will take up specific aspects from the interviews and focus on how patient versions could be effectively used in the communication between patients and health care providers and how their application could be encouraged.

Data collection

The data collection will be performed in accordance with module 1b.

Data analysis

The data analysis will be performed in accordance with module 1b and will be done separately for each entity.

Development of recommendations for the development, dissemination and implementation of patient versions

On basis of the results of the preceding modules, we will derive recommendations for the development, dissemination and implementation particularly of oncological patient versions in Germany. For this purpose, we will involve an expert panel consisting of persons with expertise in the development of patient versions as well as representatives of relevant stakeholder groups, e.g. patient representatives, patient organisations, the Federal Joint Committee, the GGPO, the AWMF, the ÄZQ, the Federal Ministry of Health, the German Health Literacy Network (DNGK), German Network for Healthcare Research (DNVF), the German Society for Epidemiology (DGEpi), the Institute for Quality and Efficiency in Health Care (IQWiG), Foundation for Health Knowledge and the German Network for Evidence-based Medicine (DNEbM). We expect that the dissemination and implementation of the recommendations will be supported by involving these stakeholders.

We will invite to a one-day workshop. In preparation for the workshop, the project team at Witten/Herdecke University will develop drafts for recommendations based on results from analyses of the interviews, focus groups and relevant literature and the corresponding identified areas requiring improvement. We will discuss the recommendations with the project partners to agree on a final proposal for recommendations with justification based on the findings for each recommendation. Subsequently, we will send the proposal to the panel.

During the workshop, we will discuss and refine the recommendations with the whole panel. We will develop the final recommendations through a formal consensus process, with each recommendation requiring over 75% agreement. A trained and independent moderator will guide the workshop. We

assume that the recommendations will comprise specific aspects related to patient versions in oncology but also aspects that affect patient versions in general.

We will disseminate and promote the recommendations to author groups in Germany, which are engaged in ongoing or forthcoming projects for developing CPGs and/or patient versions.

Patient and Public Involvement

Patients or the public were involved in the design, conduct, reporting, dissemination plans of our research.

ETHICS AND DISSEMINATION

Ethical approval for the qualitative parts of the project was given by the ethics committee of Witten/Herdecke University (number 160/2021). For the interviews and focus groups, we will ask the participants to sign an informed consent and data protection form. Although we may present the names of organisations from module 1b, the interview partners and their relationship with the specific guideline organisation will stay confidential. For the transcription of the audiotapes and the analyses, we will pseudonymise personal data.

The findings of the project will be published in peer-reviewed journals and presented at scientific conferences. To present the findings of qualitative research, we will use the consolidated criteria for reporting qualitative research (COREQ) [32]. For the presentation of the findings of the literature review, we will adhere to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) reporting criteria, where applicable [33].

DISCUSSION

Our study will enable a better understanding of factors influencing the applicability as well as the development, dissemination and implementation of patient versions by direct questioning the relevant stakeholders. By identifying potential for improvement, the project can contribute to the further advancement of patient versions in Germany. Furthermore, the determination of adequate strategies for dissemination and implementation can support the wide use of patient versions and more patient-centred care.

To our knowledge, this is the first study on patient versions that will take different perspectives of patients, health care providers and guideline developers into account. We will focus on patient versions in oncology. However, we expect that several results are useful for the development and implementation of patient versions in general as we will likely generate recommendations that will

affect also more general aspects of patient versions. Although the recommendations resulting from the project will be related to the German context, they can usefully contribute to the international debate on patient versions.

A limitation of the study is that we will restrict the focus groups to the diseases breast, prostate and colon cancer which are the most common cancer entities in Germany. For patients with other oncological entities, e.g., rare cancers, there may be other information needs and aspects that should be emphasized. However, within the interviews with patients and healthcare providers, we will include various entities. Accordingly, we will consider different patient versions. These were developed using the same methods and have some generic sections that are included in all patient versions such as "living with cancer". However, they were written by various authors, have various lengths and in part different focuses. Particularly, the patient versions with cross-sectional topics such as supportive therapy or psycho-oncology address patients with cancer in general and give more complementary information. This means that we are on the one hand able to generate information from a broader range of patient versions and cancer entities. On the other hand, some information may be specific for a particular patient version and may not transfer to all patient versions.

In our project, we will focus on oncological patient versions that are not older than 5 years. However, particularly in the often rapidly changing field of oncology, CPGs and patient versions might comprise recommendations that are already outdated after a much shorter time. Although oncological CPGs within the GGPO are updated at regular intervals, there might be recommendations that are no more valid shortly after publication. There is the option of preparing an amendment, both for CPGs and patient versions. However, keeping all recommendations up-to-date is difficult due to a lack of resources. We expect the aspect of up-to-dateness of CPGs and patient versions and how to handle that issue will be discussed, for example when it comes to the trustworthiness of the content. Although outside the scope of our project, it will be interesting to follow the implications from patient versions that arise from living guidelines.

CONTRIBUTORSHIP STATEMENT

MB, SB and NM wrote the first draft of the manuscript. MB revised the manuscript. MB, SB, NM, SB, GC, MF, SF, TL, MN, CS and DP contributed to the conceptualisation of the study design. DP contributed to drafting the manuscript and supervised the process. All authors discussed and edited the final document.

COMPETING INTERESTs

SB, NM, GC, SF, NS and DP declare that they have no competing interests. MB is involved in the development of patient versions in oncology in Germany. SB and MN are representatives of the AWMF which receive constant financial support from the German Cancer Aid to support the GGPO and are involved in the methodological counselling of CPGs in oncology and other CPGs. MF is a representative of the publisher of the patient versions in oncology in Germany and is involved in the methodological counselling of CPGs and patient versions in oncology. TL is a representative of the publisher of the patient versions in oncology in Germany. CS was involved in the development of patient versions in oncology in Germany until 2019 and is responsible for the development of patient versions in the National Program for Disease Management Guidelines (NDMG) and the methodological refinement of those.

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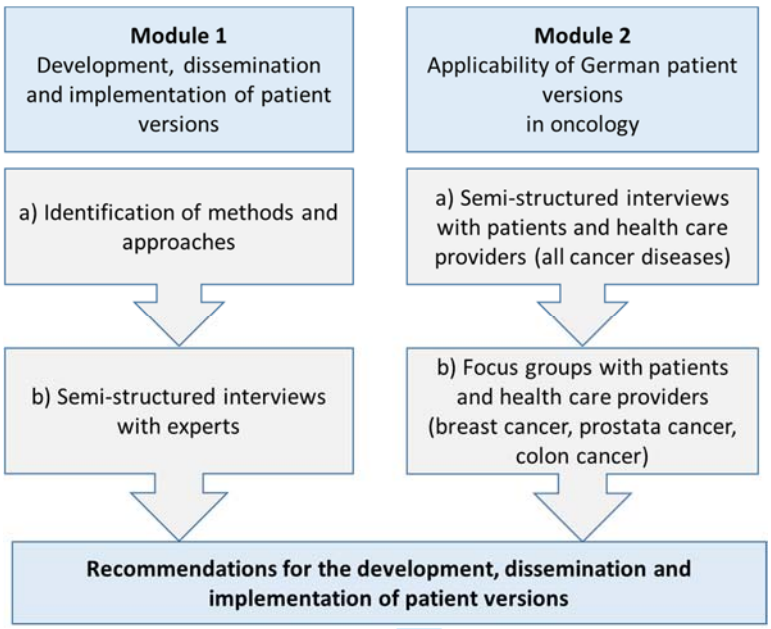
Figure 1: Overview of the project course



Appendix A: Guideline Organisations from Santesso et al. (2016)[1]

Organisation	Location
American Academy of Neurology	United States
American College of Gastroenterology	United States
American College of Physicians	United States
American Society of Clinical Oncology	United States
American Urological Association, Urology Care Foundation	United States
Canadian Diabetes Association	Canada
Canadian Paediatric Society	Canada
Centers for Disease Control and Prevention	United States
European Society for Medical Oncology	Europe
National Comprehensive Cancer Network	United States
National Institute for Health and Care Excellence (NICE)	United Kingdom
Queensland Clinical Guidelines	Australia
Royal College of Obstetricians and Gynaecologists	United Kingdom
Scottish Intercollegiate Guidelines Network	Scotland
University of Michigan Hospital and Health Centers	United States
UpToDate	The Netherlands
US Preventive Services Task Force	United States

[1]Santesso, N. et al. (2016), Dissemination of Clinical Practice Guidelines: A Content Analysis of Patient Versions, DOI: 10.1177/0272989X16644427

Appendix B: Search Strategies for PubMed and OVID (Medline)

PubMed	((("Practice Guidelines as Topic"[Mesh] or guideline*[tiab]) AND (patient version*[tiab] OR public version*[tiab])) OR patient guideline*[tiab] OR "evidence-based patient information*"[tiab]) AND (method[tiab] OR methods[tiab] OR methodolog*[tiab] OR ((methodical[tiab] OR methodological[tiab]) AND (approach[tiab] OR procedure[tiab])) OR proceeding[tiab] OR procedure[tiab] OR creation[tiab] OR developing[tiab] OR development[tiab] OR elaboration[tiab] OR preparation[tiab] OR conducting[tiab] OR implementation[tiab] OR disseminat*[tiab]) AND (english[la] OR german[la]) NOT (comment[pt] OR letter[pt] OR editorial[pt])
OVID (Medline)	1. exp practice guideline/ 2. guideline?.ti,ab,kf. 3. ((patient or public) adj1 version?).ti,ab,kf. 4. (1 or 2) and 3 5. (patient? adj2 guideline?).ti,ab,kf. 6. evidence-based patient information.ti,ab,kf. 7. 4 or 5 or 6 8. (method? or methodolog* or ((methodical or methodological) adj1 (approach or procedure)) or proceeding or procedure or creation or developing or development or elaboration or preparation or conducting or implementation or disseminat*).ti,ab,kf. 9. 7 and 8 10. (english or german).la. 11. 9 and 10 12. (comment or letter or editorial).pt. 13. 11 not 12