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Second opinion programs in Germany: a mixed methods study protocol

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Second opinion programs in Germany: a mixed methods study protocol

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Second opinion - Health literacy – Patient autonomy – Patient-physician relationship – Decision making
– Patient perspective – Germany – Health services research – Mixed-methods

Abstract

Introduction. Second opinion programs aim to support the patients' decision-making process and to avoid treatments that are unnecessary from a medical perspective. The German Second Opinion Directive, introduced in December 2018, constitutes a new legal framework in statutory health insurance for seeking second opinions for elective procedures and so far includes tonsillectomy, tonsillotomy, hysterectomy and shoulder arthroscopy. The directive mandates physicians who recommend one of the above-mentioned surgeries to inform their patients of their legal right to visit a certified second opinion provider. Since second opinion programs are a recent phenomenon in Germany, no comprehensive data are yet available. We aim to examine the characteristics and the use of second opinion programs as well as the needs and expectations from the perspective of (potential) users in Germany, with focus on the decision-making process, the patient-physician relationship, and the motivation to seek a second opinion, as well as the role of health literacy.

Methods and analysis. Six sub-studies will include the following stakeholders: (1. and 2.) patients with one of the four surgery-indications covered by the directive, (3.) patients who electively sought an online-based second opinion, (4.) patients with oncological diseases, (5.) the general population and (6.) expert-physicians. A mixed methods approach will be used, including questionnaires, interviews and focus groups. The data will be evaluated using quantitative descriptive analysis and qualitative content analysis. The integration of the results will take place in the form of a triangulation protocol.

Ethics and dissemination. The study protocol was approved by the Ethics Committee of the Brandenburg Medical School. The findings will be published in peer-reviewed journals and presented at scientific conferences.

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Article Summary

Strengths and Limitations of this Study

- We address the perspectives of various important stakeholders such as patients and physicians in order to obtain a comprehensive overview of the use of and the need for a second medical opinion.
- Because of the mixed methods approach we are able to provide real-life contextual understandings and multilevel perspectives.
- The mixed methods design allows to reconsider the research question for each sub-study and to develop questionnaires and interview guidelines iteratively.
- Since we survey very specific patient groups in some sub-studies, we are dependent on close cooperation with eligible patients and physicians in order to reach the target number of participants.

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Introduction

Surgical second opinion programs are known worldwide since the 1970s (1, 2). Historically, these programs were introduced in the United States to halt the increasing numbers of surgeries, as a means of limiting rising health care costs (1). Second opinion programs offer patients with a recommendation for an elective surgical procedure the opportunity to obtain a second opinion from another medical professional. The primary aims of these programs are to provide an improved knowledge base, to support the patient in the decision-making process and to avoid treatments that are unnecessary from a medical perspective.

In Germany, many statutory health insurers offer a wide variety of second opinion programs with an increasing volume (3). Moreover, it is fairly common to utilize an informal approach to obtain a second opinion, by seeking medical advice from multiple health care practitioners for the same set of symptoms and diagnostic test results, before the patient makes a final decision on proposed interventions. This "informal" patient-initiated second opinion practice is tolerated by the statutory health insurance and usually reimbursed without clear regulations (4). The second opinion programs on the other hand, are structured and subject to clear regulations.

In December 2018, the Federal Joint Committee (G-BA) published the Second Opinion Directive (5), which introduced the first statutory second opinion program covered by the German statutory health insurance for a specified set of elective surgeries: Initially, the directive included only tonsillectomy, tonsillotomy and hysterectomy. In 2020, shoulder arthroscopy was added. A widening of the selected surgeries in the directive is anticipated in the future. A physician who recommends one of the selected surgeries to patients who are members of the statutory health insurance, is obliged to inform the patient about his/her right to obtain a second opinion. Of note, surgical interventions in oncology are explicitly excluded from the directive in its current form and online-based second opinions are not supposed to be provided yet.

As structural second opinion programs are a fairly recent phenomenon in Germany, there have not been any comprehensive efforts to gather data on second opinion programs, except for a few small-scale evaluations (6). As such, the scientific basis for the design of second opinion programs in general, and the criteria for selection of the relevant (surgical) indications is limited.

Studies show that there is a noticeable interest among German citizens to seek a second opinion (7, 8). Moreover, a population-representative study (7) shows that the need for a second opinion goes beyond the indications included in the Second Opinion Directive: more than half of the respondents consider the possibility of a second opinion to be important not only for surgeries involving bones and joints (56%), and for surgeries on internal organs (56%), but also for other types of medical interventions, such as drug treatments in case of cancer (70%) and for radiotherapy (61%). Although

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3 generally speaking, health information is increasingly sought online, 90% of the study participants
4 prefer personal contact with a specialist when they seek a second opinion. Only 10% preferred medical
5 advice by phone or online (7).
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8 The ZWEIT Project was set-up by the Brandenburg Medical School and the Witten/Herdecke University
9 in cooperation with the Association of Statutory Health Insurance Physicians Brandenburg, the
10 statutory health insurer AOK Nordost and an online-based second opinion provider, Medexo.
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16 Objectives

17 The objective of the ZWEIT Project is to examine the characteristics and the use of second opinion
18 programs as well as the needs and expectations from the perspective of (potential) users and
19 physicians. By revealing and summarizing the experiences and the needs of stakeholders in the health
20 care system, we aim to provide decision-makers with important information to support further
21 tailoring of second opinion programs.
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29 Methods and Analysis

30 Rationale for the Mixed Methods Approach

31 The mixed methods approach combines the strengths of qualitative and quantitative research and is
32 appropriate for research questions that require real-life contextual understandings and multi-level
33 perspectives (9). Our questionnaires aim to interrogate a broad spectrum of (potential) patient
34 populations to obtain a comprehensive and representative overview of the need for and the use of
35 second opinions. Questionnaire-based research is rigid and provides a high potential for comparability
36 across populations. The qualitative investigations enable to formulate additional questions and items
37 for the questionnaires, attending to aspects that have previously not been considered (10). Further,
38 they allow an in depth-analysis of the subjective experiences and attitudes of the study participants
39 (11). Thereby, the results of the questionnaires can be deepened and contextualized by using expert
40 and problem-centred interviews (12), as well as focus groups (13). Owing to this methodological
41 complexity, the research questions to be addressed expand beyond the a priori hypotheses developed
42 by the research team (11).
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Design

The study follows a multi-phase design (9). Quantitative and qualitative methods will be performed in parallel, except for Group 2, for which we chose a sequential order (14). Figure 1 shows a summary of the study design, methods and specific objectives.

[Figure 1. ZWEIT Project: Study design.]

As the focus is on the perspective of the user, we will include specific patient groups and physicians. In addition, we will perform a representative survey of the general population.

GROUP 1 - Patients who received indication for surgery

Specific aims. We will focus on the analysis of the second opinion process and the impact of the Second Opinion Directive on the patient-physician relationship.

Study population. This group will include people who have received an indication for tonsillectomy, tonsillotomy, hysterectomy, or shoulder arthroscopy. Further inclusion criteria will be: insured by the statutory health insurance, sufficient knowledge of the German language, and age ≥ 18 or parent and legal guardian respectively willing to complete the questionnaire.

We will recruit physicians specialized in otolaryngology, gynaecology and orthopaedics in the federal states of Berlin and Brandenburg, based on registries from the Association of Statutory Health Insurance Physicians Brandenburg. We will focus on outpatient settings because these physicians commonly provide the surgical indication for the above-mentioned procedures. In the next step, the physicians will recruit participants by distributing the questionnaires and invitations for interviews to their patients who meet the inclusion criteria. Participating physicians will receive a remuneration of five Euro for each invited patient (regardless of whether the patient participates or not).

Outcomes of interest. We will focus on the knowledge, wishes, attitudes and behaviours in the context of the Second Opinion Directive and their effect on the patient-physician relationship as well as on decision-making. Furthermore, we will analyse the effect of health literacy on obtaining a second opinion.

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3 **GROUP 2 – Patients who have undergone tonsillectomy, tonsillotomy, hysterectomy or**
4 **shoulder arthroscopy**
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6 *Specific aims.* We will evaluate the use of second opinions as well as their relevance for the
7 decision behaviour.
8

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10 *Study population.* We will include patients who have undergone tonsillectomy, tonsillotomy,
11 hysterectomy or shoulder arthroscopy due to non-malignant underlying diseases in the period
12 2018-2019. Initially, a preliminary qualitative interview study will include eligible adults (age
13 >18 years), to identify main themes of interest. We will recruit those from clinics and
14 outpatient physicians. Subsequently, the full study will recruit individuals insured by the AOK
15 Nordost who are either adults, or in case of minors, whose parent or legal guardian are willing
16 to complete the questionnaire. AOK Nordost is a German health insurer in the federal states
17 of Berlin, Brandenburg and Mecklenburg-Western Pomerania covering approximately 1,76
18 million insured citizens. Eligible individuals will receive a postal invitation from AOK Nordost to
19 participate in the questionnaire survey and the interviews. Patients who underwent surgery
20 before the Second Opinion Directive was introduced will receive the same questionnaire with
21 specific additional items. AOK Nordost will send a postcard reminder after two weeks. As the
22 Second Opinion Directive on these indications was enacted in December 2018, this study
23 allows a comparison of patients who had surgery pre- and post-directive.
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34 *Outcomes of interest.* This part of the study will focus on the process of informed decision-
35 making and identify knowledge and needs related to obtaining a second opinion, as well as
36 factors that influence the use. In addition, a model of the decision typology of people who have
37 had surgery will be generated. We will also analyse the impact of health literacy on obtaining
38 a second opinion.
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45 **GROUP 3 - Patients who obtained an online-based second opinion**

46 *Specific aims.* Our aim will be to survey patient experiences with an online-based second
47 opinion program.
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49 *Study population.* We will include clients of an online platform (Medexo). Medexo provides a
50 written, medical record based second opinion to patients.
51

52 Medexo will send out study invitation to all its customers in Germany (1,247) from January
53 2016 to February 2019. Non-responders will receive up to two reminders. Accordingly, a
54 heterogeneous sample will be chosen for the interviews in which the characteristics of the
55 individuals differ as much as possible.
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3 *Outcomes of interest.* This part of the project will focus on the motivation to obtain an online-
4 based second opinion and the experiences made during the second opinion process. The
5 investigation includes potential discrepancies between first and second opinion, the impact of
6 the second opinion on the participants' decision and on the patient-physician relationship. In
7 addition, we will analyse health literacy and the perceived advantages and disadvantages of
8 an online-based second opinion.
9

15 **GROUP 4 - Patients with oncological diseases**

16 *Specific aims.* We will explore the relevance of second opinion program in oncology.
17

18 *Study population.* We will include members of oncological support groups with a sample size
19 of up to 30 subjects for problem-centred interviews or focus groups. Advanced cases and
20 palliative situations will be excluded. We will identify eligible organizations through online
21 research, and contacts with individual oncologists and patient representatives.
22

23 *Outcomes of interest.* This part of the study explores whether cancer patients have previously
24 obtained a second opinion or whether there was a need for it.
25

31 **GROUP 5 – General population**

32 *Specific aims.* We aim to analyse the use of second opinions as well as the needs in the general
33 population and identify possible structural and regional differences.
34

35 *Study population.* We will select a random sample of 9,990 citizens living in the region of Berlin
36 and the state of Brandenburg aged 18 years or older through regional registration offices. For
37 selection of participants, we will use disproportionate stratified sampling with settlement
38 pattern (urban area, area with agglomeration, rural area) as stratification variable. For each
39 settlement pattern, we will contact the same number of citizens. We will randomly select all
40 five municipalities in urban areas, 10 in areas with agglomeration and 10 in rural areas. The
41 five urban municipalities will each select 666 persons of their data randomly. The 20 other
42 municipalities will each select 333 persons of their data randomly. We will send questionnaires
43 to the whole sample with the opportunity to win one of 125 gift cards for Amazon (50€ each)
44 as an incentive. Six weeks later, we will send a reminder.
45

46 *Outcomes of interest.* This part of the study will focus on knowledge, attitudes and wishes
47 towards a second opinion program in the context of general health literacy and the local care
48 situation. In this context, we will also analyse the impact of health literacy on obtaining a
49 second opinion.
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GROUP 6 – Specialists and professional medical associations

Specific aims. We will focus on the process of and attitudes towards second opinions as well as the influence of the Second Opinion Directive on daily practise.

Study population. Eligible practitioners will consist of specialists effected by the Second Opinion Directive as well as other specialist areas identified as significant during the various patient examinations (Group 1-4). In addition, we will conduct expert interviews with representatives of professional associations. 30 specialists and 10 representatives from professional associations will be included.

The sample will consist of already cooperating specialists from group 1 and additionally selected physicians. The sample is balanced between physicians who work in rural and urban regions, as well as whether the physicians offer second opinions or not.

Outcomes of interest. We will examine subjective perspectives on second opinions as well as the implementation of the Second Opinion Directive by medical specialists.

Data Collection

We will collect the data via questionnaires, interviews and focus groups (Table 1).

Questionnaires. We will develop the respective questionnaires in several interdisciplinary meetings. All study questionnaires will be piloted in person or via phone among patients who match the inclusion criteria of each group to ensure good comprehensibility and to optimize the reading flow.

The core of each group-specific questionnaire will consist of validated instruments to match the specific aims and outcomes of the respective sub-studies, as shown in Table 1. We will develop additional items specifically for the sub-studies focusing on experiences and wishes towards second opinions, decisional behaviour and local health care characteristics. The holders of the patient data who collect and store information in conjunction with their main duties (e.g. the AOK Nordost or Medexo) will sent out questionnaires for group 2 and 3. Returning the postal questionnaire to the University Study Team, who have no access to personal identifiers of the invited individuals, will be free of charge for the participants. We will use paper-and-pencil questionnaires except for group 2, where we will provide additional online surveys.

Interviews and Focus Groups. For the patient study, an interview guide will be developed for undertaking problem-centred interviews (12, 15) and focus groups (13). A short questionnaire will be added to collect basic data and personal characteristics (15). In addition, an interview guide for the expert interviews with physicians will be constructed based on a literature search and the results of

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the patient interviews. Expert and problem-centred interviews will be conducted in person or by phone. The interview sample will be selected according to the maximum variation criterion (16). All interviews and focus groups will be transcribed word for word (17).

	Methods	Group						
		1	2	3	4	5	6	
Data Collection	Questionnaires	x	x	x		x*		
	Instruments	Health Literacy Survey Europe short form 16 (18, 19)	x	x	x		x	
		Decisional Conflict Scale short form 16 (20, 21)	x	x	x			
		Decision Regret Scale (22)		x				
		Autonomy Preference Index (23)		x				
	Problem-centred Interview	x	x	x	x			
	Expert Interview						x	
Focus group				x		x		
Data Analysis	Quantitative descriptive analysis	x	x	x		x		
	Qualitative Content Analysis	x	x	x	x		x	

Table 1. Instruments, Data Collection and Data Analysis for Study Group 1-6.

Group 1, Patients who received indication for surgery of tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy; 2, Patients who have undergone tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy; 3, Patients who obtained an online-based second opinion; 4, Patients with oncological diseases; 5, General population; 6, Specialists and professional medical associations.

* Some questions will follow a survey conducted in Germany by Geraedts et al. (7)

Data Analysis

We will use quantitative descriptive analysis for the questionnaires and qualitative content analysis for the interviews and focus groups (Table 1). The integration of the results will take place in the form of a triangulation protocol (24).

Quantitative Descriptive Analysis. We will provide descriptive analysis of patient demographics and reported outcomes to characterize the dataset. If reasonable, a stepwise regression analysis to show potential associations between patient characteristics (such as sociodemographic factors) and outcomes of interest will follow.

Qualitative Content Analysis. The structured qualitative content analysis by Kuckartz (25) enables a rule-driven reduction and systematization of the data. In the first phase, we will create categories

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3 describing the material. The aim is to develop an exhaustive category system. In the second phase, we
4 will apply the developed category system to the entire material. To ensure traceability, we will validate
5 the application of the category system by a member check (26, 27).
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10 Discussion

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13 The Second Opinion Directive has created a systematic offer to obtain second opinions for certain
14 surgical procedures in Germany. The present study aims to examine the use of second opinions prior
15 to and since the introduction of the Second Opinion Directive. Additionally, we will elucidate the
16 benefits and drawbacks of the newly introduced second opinion framework in the context of the
17 associated surgical procedures. Moreover, we will investigate topics that are not yet included in the
18 directive, such as online-based second opinion programs and second opinions regarding cancer
19 treatments (5). In parallel, the project team updated knowledge on the current state of affairs
20 regarding second opinion programs by surveying all health insurers (statutory and private) about their
21 programs. These programs continue to be offered in addition to the Second Opinion Directive. The
22 results of our study, together with the results of the survey among health insurers, will provide useful
23 information and further guidance for decision makers to implement more tailored second opinion
24 programs and to stimulate specific future research addressing the knowledge gaps identified in our
25 endeavour.
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35 The study explores the extent to which individuals require health literacy as a competence for
36 obtaining a second opinion (28). In addition, health literacy is dependent on structural factors and thus
37 represents a societal responsibility (29). Accordingly, organizations that provide health services must
38 provide barrier-free access to health- and health care-related information. Second opinion programs
39 aim to support the patient in making informed decisions. The ZWEIT Project provides empirical
40 evidence the extent to which the current second opinion framework offers the patient valid and
41 complete information for making informed decisions, and, if desired, for obtaining a second opinion.
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47 Our study has various strengths: on the micro and meso level, we address opinions, expectations,
48 experiences and needs of various important stakeholders, including clinicians of a variety of disciplines,
49 patients who are pre- and post-surgery, clients of a commercial second opinion provider, and the
50 general population. The questionnaires will be tailored for each of the stakeholders, yet will also
51 contain selected overlapping items. As such, a comparison of the different stakeholders' views and
52 experiences will be possible across the full spectrum of stakeholders, in particular for the selected
53 validated item-scales. The survey on post-surgery patients (Group 2) will include patients pre and post
54 the commencement of the Second Opinion Directive. We aim to check if and how the directive was
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3 implemented in daily clinical practice. The survey on the general population will consider the local care
4 situation specifically and how second opinion programs are feasible in rural areas.

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6 Limitations should be noted as well. To a certain extent, physicians who have a positive attitude
7 towards second opinions may be more likely to participate in the study and to educate their patients
8 about the right to obtain a second opinion than physicians with a negative attitude. This can lead to a
9 bias in the sample of patients recruited through physicians (Group 1).

10
11 In the Second Opinion Directive, the inclusion of other professional groups such as physiotherapists or
12 psychologists is not prohibited, but is neither encouraged. Assuming that a second opinion on shoulder
13 arthroscopy may lead to a decrease in surgeries, more patients may receive conservative treatment
14 including physiotherapy (30). In further research, other medical professions should also be considered,
15 such as physiotherapist. In addition, the perspective of other stakeholders (such as legal experts and
16 policy makers) should also be taken into account in order to analyse the feasibility and requirements
17 of the directive at the macro level.
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28 Ethics and Dissemination

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30 The study protocol was approved by the Ethics Committee of the Brandenburg Medical School on 13
31 June 2019 (number E-01-20190529). All quantitative research will use data anonymization procedures
32 compliant with the General Data Protection Regulation (GDPR). For the interviews and focus groups,
33 the participants are asked to sign an informed consent form. The transcription of the audiotapes and
34 the analysis will be undertaken using pseudonymisation. The participants in the focus groups and
35 interviews are offered an allowance.
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40 The findings will be published in peer-reviewed journals and presented at scientific conferences. In
41 addition, a symposium will be planned at the end of the project, to enable a wide range of stakeholders
42 to take note of the results, and to provide their professional opinion and critical assessment of the
43 conclusions and the potential impact on the Second Opinion Directive.
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50 Data Statement

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52 The datasets generated during the study are not currently publicly available due to the study being
53 ongoing. Data will be available from the corresponding author on reasonable request once the study
54 is completed. Data generated or analysed during the study will be included in manuscripts to be
55 submitted for publication in peer-reviewed journals.
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Author Contributions

DB, CR, SuM, BP and NK drafted the manuscript. EN, DP, SvP, KV, J-CL and DB are co-applicants on the funded grant and contributed to conceptualisation of the study design. AA, SoM, AF, BC and SL are members of the study team that have contributed to specify the study design. All co-authors have revised the manuscript critically for important intellectual content.

Competing Interests

DB, SuM, BP, NK, AA, SoM, KV, SL, BC, AF, SvP, DP, CR and EN declare that they have no competing interests. J-CL is the CEO of Medexo GmbH, a second opinion provider.

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Patient and Public Involvement Statement

The patients were not involved in the design of the study. However, a patient representative is member of the Scientific Advisory Board of the ZWEIT project.

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Figure Legend

Figure 1: ZWEIT Project Study design

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References

1. Lindsey PA, Newhouse J. The cost and value of second surgical opinion programs: a critical review of the literature. *J Health Polit Policy Law*. 1990;15(3):543-70.
2. Grafe WR, McSherry CK, Finkel ML, McCarthy EG. The Elective Surgery Second Opinion Program. *Ann Surg*. 1978;188(3):323-30.
3. Pieper D, Heß S, Mathes T. Bestandsaufnahme zu Zweitmeinungsverfahren in der Gesetzlichen Krankenversicherung (GKV). *Gesundheitswesen*. 2018;80(10):859-63.
4. GKV-Spitzenverband. Stellungnahme zum Referentenentwurf des GKV-Versorgungsstärkungsgesetzes. 07.11.2014]. Available from: file:///D:/Literatur%20ZWEIT/Stellungnahmen/GKV-Versorgungsstärkungsgesetz/GKV-SV_zu_GKV-VSG.pdf.
5. Gemeinsamer Bundesausschuss. Richtlinie zum Zweitmeinungsverfahren. *Bundesanzeiger*. 2020;B3.
6. Ali J, Pieper D. Kaum aktuelle Daten zu Zweitmeinungsverfahren vorhanden - eine systematische Übersichtsarbeit. *Gesundheitswesen*. 2017;79(10):871-4.
7. Geraedts M, Kraska R. Zweitmeinungen: Inanspruchnahme und Bedarf aus Sicht der Bevölkerung. *Gesundheitsmonitor 2016: Bertelsmann Stiftung*; 2016. p. 160-77.
8. Weyerstrass J, Prediger B, Neugebauer E, Pieper D. First results of a German second opinion program show high patient satisfaction and large discrepancies between initial therapy recommendations and second opinion. *Z Evid Fortbild Qual Gesundhwes*. 2018;133:46-50.
9. Creswell JW, Klassen AC, Plano Clark VL, Smith KC. Best practices for mixed methods research in the health sciences. Bethesda (Maryland): National Institutes of Health. 2011;2013:541-5.
10. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
11. Flick U, Kardorff Ev, Steinke I. Was ist qualitative Forschung? Einleitung und Überblick. In: Flick U, Kardorff Ev, Steinke I, editors. *Qualitative Forschung: Ein Handbuch*. 11. ed. Reinbek: Rowohlt Taschenbuch; 2015. p. 13-29.
12. Mey G, Mruck K. Interviews. In: Mey G, Mruck K, editors. *Handbuch qualitative Forschung in der Psychologie*. Wiesbaden: Springer; 2010. p. 423-35.
13. Krueger RA. *Focus groups: A practical guide for applied research*: Sage publications; 2014.
14. Creswell JW, Hirose M. Mixed methods and survey research in family medicine and community health. *Family Medicine and Community Health*. 2019;7(2):e000086.
15. Witzel A. *Das problemzentrierte Interview*. Beltz; 1985.
16. Patton MQ. *Qualitative research & evaluation methods: Integrating theory and practice*: Sage publications; 2014.
17. Dresing T, Pehl T. *Praxisbuch Interview, Transkription & Analyse Anleitungen und Regelsysteme für qualitativ Forschende*. Marburg: Dr. Dresing & Pehl GmbH; 2012.
18. Pelikan JM, Ganahl K. *Die europäische Gesundheitskompetenz-Studie: Konzept, Instrument und ausgewählte Ergebnisse*. Health Literacy, Forschungsstand und Perspektiven 1st ed Bern: Hogrefe. 2017:93-126.
19. Pelikan JM, Ganahl K. Measuring health literacy in general populations: Primary findings from the HLS-EU Consortium's health literacy assessment effort. *Stud Health Technol Inform*. 2017;240:34-59.
20. Buchholz A, Hölzel L, Kriston L, Simon D, Härter M. Die decisional conflict scale in deutscher sprache (DCS-D)—dimensionale struktur in einer stichprobe von hausarztpatienten. *Klinische Diagnostik und Evaluation*. 2011;4:15-30.
21. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25-30.
22. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. *Med Decis Making*. 2003;23(4):281-92.
23. Simon D, Kriston L, Härter M. Die deutsche modifizierte Fassung des Autonomie-Präferenz-Index (API-Dm). *Klinische Diagnostik und Evaluation*. 2011;4(1):5-14.

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- 3 24. O’Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods
- 4 studies. *BMJ*. 2010;341:c4587.
- 5 25. Kuckartz U. *Qualitative Inhaltsanalyse*. 4. ed. Weinheim: Beltz Juventa; 2018.
- 6 26. Kuper A, Lingard L, Levinson W. Critically appraising qualitative research. *BMJ*.
- 7 2008;337:a1035.
- 8 27. Onwuegbuzie AJ, Leech NL. Validity and qualitative research: An oxymoron? *Quality &*
- 9 *Quantity*. 2007;41(2):233-49.
- 10 28. Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy
- 11 and public health: a systematic review and integration of definitions and models. *BMC Public Health*.
- 12 2012;12:80.
- 13 29. Ernstmann N, Bauer U, Berens E-M, Bitzer E, Bollweg T, Danner M, et al. DNVF Memorandum
- 14 Gesundheitskompetenz (Teil 1) – Hintergrund, Relevanz, Gegenstand und Fragestellungen in der
- 15 Versorgungsforschung. *Das Gesundheitswesen*. 2020;82:e77-e93.
- 16 30. Steuri R, Sattelmayer M, Elsig S, Kolly C, Tal A, Taeymans J, et al. Effectiveness of conservative
- 17 interventions including exercise, manual therapy and medical management in adults with shoulder
- 18 impingement: a systematic review and meta-analysis of RCTs. *Br J Sports Med*. 2017;51(18):1340-7.
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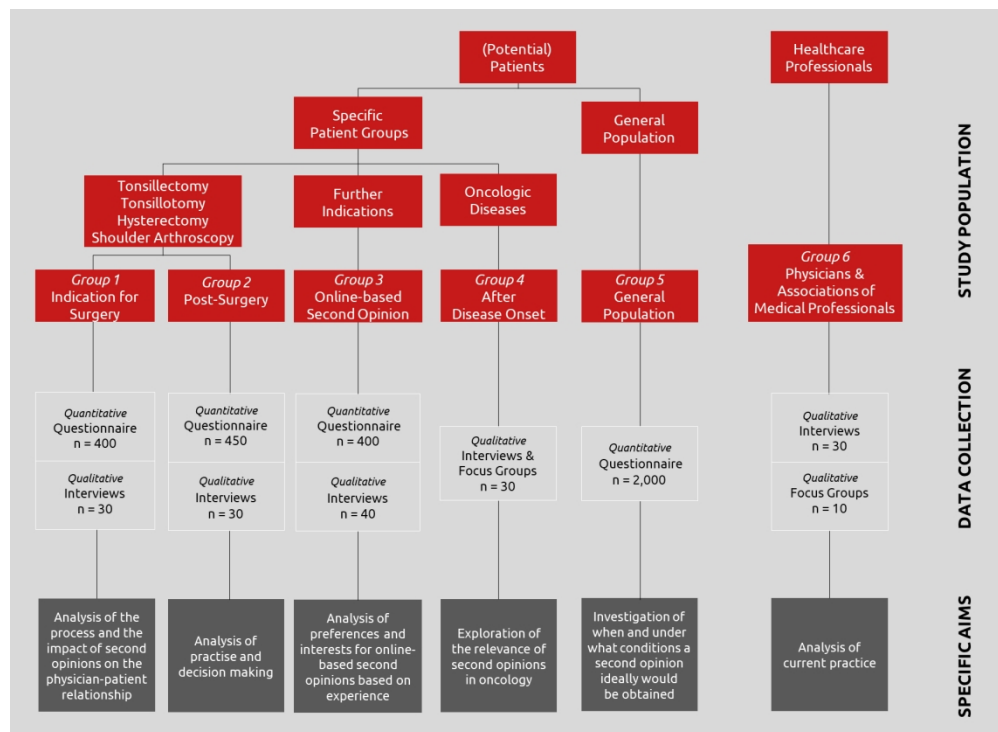


Figure 1. ZWEIT Project: Study design.

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Second opinion programs in Germany: a mixed methods study protocol

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Second opinion programs in Germany: a mixed methods study protocol

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Second opinion - Health literacy – Patient autonomy – Patient-physician relationship – Decision making
– Patient perspective – Germany – Health services research – Mixed-methods

Abstract

Introduction. Second opinion programs aim to support the patients' decision-making process and to avoid treatments that are unnecessary from a medical perspective. The German Second Opinion Directive, introduced in December 2018, constitutes a new legal framework in statutory health insurance for seeking second opinions for elective procedures and so far includes tonsillectomy, tonsillotomy, hysterectomy and shoulder arthroscopy. The directive mandates physicians who recommend one of the above-mentioned surgeries to inform their patients of their legal right to visit a certified second opinion provider. Since second opinion programs are a fairly recent phenomenon in Germany, no comprehensive data are yet available on the degree of implementation, users, potential barriers and their effectiveness. We aim to examine the characteristics and the use of second opinion programs as well as the needs and wishes from the perspective of (potential) users in Germany, with focus on the decision-making process, the patient-physician relationship, and the motivation to seek a second opinion, as well as the role of health literacy.

Methods and analysis. Six sub-studies will include the following stakeholders: (1. and 2.) patients with one of the four surgery-indications covered by the directive, (3.) patients who electively sought an online-based second opinion, (4.) patients with oncological diseases, (5.) the general population and (6.) expert-physicians. A mixed methods approach will be used, including questionnaires, interviews and focus groups. The data will be evaluated using quantitative descriptive analysis and qualitative content analysis. The integration of the results will take place in the form of a triangulation protocol.

Ethics and dissemination. The study protocol was approved by the Ethics Committee of the Brandenburg Medical School. The findings will be published in peer-reviewed journals and presented at scientific conferences.

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Article Summary

Strengths and Limitations of this Study

- We address the perspectives of various important stakeholders such as patients and physicians in order to obtain a comprehensive overview of the use of and the need for a second medical opinion.
- Because of the mixed methods approach we are able to provide real-life contextual understandings and multilevel perspectives.
- The mixed methods design allows to reconsider the research question for each sub-study and to develop questionnaires and interview guidelines iteratively.
- Since we survey very specific patient groups in some sub-studies, we are dependent on close cooperation with eligible patients and physicians in order to reach the target number of participants.

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Introduction

Surgical second opinion programs are known worldwide since the 1970s (1, 2). Historically, these programs were introduced in the United States to halt the increasing numbers of surgeries, as a means of limiting rising health care costs (1). Second opinion programs offer patients with a recommendation for an elective surgical procedure the opportunity to obtain a second opinion from another medical professional. The primary aims of these programs are to provide an improved knowledge base, to support the patient in the decision-making process and to avoid treatments that are unnecessary from a medical perspective.

In Germany, many statutory health insurers offer a wide variety of second opinion programs with an increasing volume (3). Moreover, it is fairly common among patients to utilize an informal approach to obtain a second opinion, by seeking medical advice from multiple health care practitioners for the same set of symptoms and diagnostic test results, before the patient makes a final decision on proposed interventions. This "informal" patient-initiated second opinion practice is tolerated by the statutory health insurance and usually reimbursed without clear regulations (4). The second opinion programs on the other hand, are structured and subject to clear regulations.

In December 2018, the Federal Joint Committee (G-BA) published the Second Opinion Directive (5), which introduced the first statutory second opinion program covered by the German statutory health insurance for a specified set of elective surgeries: Initially, the directive included only tonsillectomy, tonsillotomy and hysterectomy. In 2020, shoulder arthroscopy was added. A widening of the selected surgeries in the directive is anticipated in the future. A physician who recommends one of the selected surgeries to patients who are members of the statutory health insurance, is obliged to inform the patient about his/her right to obtain a second opinion. The physician must also provide further information, for example where the patient can find second-opinion physicians and decision aids. Of note, surgical interventions in oncology are explicitly excluded from the directive in its current form and online-based second opinions are not supposed to be provided yet.

As structural second opinion programs are a fairly recent phenomenon in Germany, there have not been any comprehensive efforts to gather data on the degree of implementation, users, potential barriers, acceptance and benefits of the second opinion programs, e.g. value for informed decision making or reduction of surgeries, except for a few small-scale evaluations (6). As such, the scientific basis for the design of second opinion programs in general, and the criteria for selection of the relevant (surgical) indications is limited.

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3 Studies show that there is a noticeable interest among German citizens to seek a second opinion (7,
4 8). Moreover, a population-representative study (7) shows that the need for a second opinion goes
5 beyond the indications included in the Second Opinion Directive: more than half of the respondents
6 consider the possibility of a second opinion to be important not only for surgeries involving bones and
7 joints (56%), and for surgeries on internal organs (56%), but also for other types of medical
8 interventions, such as drug treatments in case of cancer (70%) and for radiotherapy (61%). Although
9 generally speaking, health information is increasingly sought online, 90% of the study participants
10 prefer personal contact with a specialist when they seek a second opinion. Only 10% preferred medical
11 advice by phone or online (7).
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18 The ZWEIT Project was set-up by the Brandenburg Medical School and the Witten/Herdecke University
19 in cooperation with the Association of Statutory Health Insurance Physicians Brandenburg, the
20 statutory health insurer AOK Nordost and an online-based second opinion provider, Medexo.
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26 Objectives

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28 The study is particularly important right now because the Second Opinion Directive recently created a
29 new legal framework for second opinion programs. This has also an impact on existing second opinion
30 programs in health insurance. For example, health insurers offer online second opinion programs only
31 as long as they do not include the surgeries specified by the directive. As the Second Opinion Directive
32 can replace existing second opinion programs offered by health insurers, it is important that the effects
33 of the directive will be evaluated to what extent they meet the needs of patients and how feasible the
34 directive is for physicians.
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40 The objective of the ZWEIT Project is to examine the characteristics and the use of second opinion
41 programs as well as the needs and wishes from the perspective of (potential) users and physicians. By
42 revealing and summarizing the experiences and the needs of stakeholders in the health care system,
43 we aim to provide decision-makers in health policy with important information to support further
44 tailoring of second opinion programs.
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51 Methods and Analysis

52 Rationale for the Mixed Methods Approach

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54 The mixed methods approach combines the strengths of qualitative and quantitative research and is
55 appropriate for research questions that require real-life contextual understandings and multi-level
56 perspectives (9). Our questionnaires aim to interrogate a broad spectrum of (potential) patient
57 populations to obtain a comprehensive and representative overview of the need for and the use of
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3 second opinions. Questionnaire-based research is rigid and provides a high potential for comparability
4 across populations. The qualitative investigations enable to formulate additional questions and items
5 for the questionnaires, attending to aspects that have previously not been considered (10). Further,
6 they allow an in depth-analysis of the subjective experiences and attitudes of the study participants
7 (11). Thereby, the results of the questionnaires can be deepened and contextualized by using expert
8 and problem-centred interviews (12), as well as focus groups (13). Owing to this methodological
9 complexity, the research questions to be addressed expand beyond the a priori hypotheses developed
10 by the research team (11).

19 Design

20 The study follows a multi-phase design (9). Quantitative and qualitative methods will be performed in
21 parallel, except for group 2, for which we chose a sequential order (14). Figure 1 shows a summary of
22 the study design, methods and specific objectives.

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30 [Figure 1. ZWEIT Project: Study design.]

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34 As the focus is on the perspective of the user, we will include specific patient groups and physicians. In
35 group 1 and 2 we will concentrate on patients whose indications are within the scope of the Second
36 Opinion Directive. We will compare patients with the indication given before and after the introduction
37 of the directive. In group 3 we will survey patients who have obtained a second opinion via an online
38 platform. Online-based second opinion programs are offered by several health insurers. Since the
39 Second Opinion Directive excludes so far online-based second opinions, these programs can only be
40 provided by statutory health insurers for surgeries that are not part of the directive. At the same time,
41 online-based second opinions could compensate for regional differences in health care, such as a lack
42 of medical specialists. The Second Opinion Directive does not apply to oncological diseases. However,
43 it is known from preliminary studies that there is a need for a second opinion in oncology (7) and that
44 many statutory health insurers offer second opinion programs for oncological indications (3). We will
45 continue to explore the need for a second oncological opinion in group 4 so that future second opinion
46 programs can be tailored to the characteristics of specific oncological patient populations. In addition,
47 we will perform a representative survey of the general population in order to analyse the needs in the
48 general population, e.g. with regard to the relevant indications. In order to investigate the experience
49 with the Second Opinion Directive and the requirements for a successful second opinion process from
50 a professional point of view, we will interview physicians.

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GROUP 1 - Patients who received indication for surgery

Specific aims. We will focus on the analysis of the second opinion process and the impact of the Second Opinion Directive on the patient-physician relationship.

Study population. This group will include people who have received an indication for tonsillectomy, tonsillotomy, hysterectomy, or shoulder arthroscopy. Further inclusion criteria will be: insured by the statutory health insurance, sufficient knowledge of the German language, and age ≥ 18 or parent and legal guardian respectively willing to complete the questionnaire.

We will recruit physicians specialized in otolaryngology, gynaecology and orthopaedics in the federal states of Berlin and Brandenburg, based on registries from the Association of Statutory Health Insurance Physicians Brandenburg. We will focus on outpatient settings because these physicians commonly provide the surgical indication for the above-mentioned procedures. In the next step, the physicians will recruit participants by distributing the questionnaires and invitations for interviews to their patients who meet the inclusion criteria. Participating physicians will receive a remuneration of five Euro for each invited patient (regardless of whether the patient participates or not).

Outcomes of interest. We will focus on the implementation of the Second Opinion Directive and the quality of information the physician provides to the patient, e.g. information about which physicians provide a second opinion and where to find decision aids. We will investigate whether a second opinion was required, what reasons exist for or against obtaining a second opinion and what sort of wishes patients have with regard to a second opinion program, e.g. preference for a personal or online-based second opinion or quality demands on the medical specialist. Furthermore, we will analyse the impact of the directive on the patient-physician relationship as well as the effect of health literacy on obtaining a second opinion.

GROUP 2 – Patients who have undergone tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy

Specific aims. We will evaluate the use of second opinions as well as their relevance for the decision behaviour in patients who already decided upon undergoing the surgeries specified by the Second Opinion Directive.

Study population. We will include patients who have undergone tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy due to non-malignant underlying diseases in the period 2018-2019. Initially, a preliminary qualitative interview study will include eligible adults (age

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3 >18 years), to identify main themes of interest. We will recruit those from clinics and
4 outpatient physicians. Subsequently, the full study will recruit individuals insured by the AOK
5 Nordost who are either adults, or in case of minors, whose parent or legal guardian are willing
6 to complete the questionnaire. AOK Nordost is a German health insurer in the federal states
7 of Berlin, Brandenburg and Mecklenburg-Western Pomerania covering approximately 1,76
8 million insured citizens. Eligible individuals will receive a postal invitation from AOK Nordost to
9 participate in the questionnaire survey and the interviews. Patients who underwent surgery
10 before the Second Opinion Directive was introduced will receive the same questionnaire with
11 specific additional items. AOK Nordost will send a postcard reminder after two weeks. As the
12 Second Opinion Directive on these indications was enacted in December 2018, this study
13 allows a comparison of patients who had surgery pre- and post-directive.
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18 *Outcomes of interest.* This part of the study will focus on the patient's informed decision-
19 making process and identify knowledge and needs related to obtaining a second opinion, as
20 well as factors that influence the use. Furthermore, we will compare the impact of the Second
21 Opinion Directives on receiving a second opinion between patients who have undergone
22 surgery before and after the introduction of the directive. In addition, a model of the decision
23 typology of people who have had surgery will be generated. We will also analyse the impact of
24 health literacy on obtaining a second opinion.
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36 **GROUP 3 - Patients who obtained an online-based second opinion**

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38 *Specific aims.* Our aim will be to survey patient experiences with an online-based second
39 opinion program.
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41 *Study population.* We will include clients of an online platform (Medexo). Medexo provides a
42 written, medical record based second opinion to patients.
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45 Medexo will send out study invitation to all its customers in Germany (1,247) from January
46 2016 to February 2019. Non-responders will receive up to two reminders. Accordingly, a
47 heterogeneous sample will be chosen for the interviews in which the characteristics of the
48 individuals differ as much as possible.
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52 *Outcomes of interest.* This part of the project will focus on the motivation to obtain an online-
53 based second opinion and the experiences made during the second opinion process. The
54 investigation includes potential discrepancies between first and second opinion, the impact of
55 the second opinion on the participants' decision and on the patient-physician relationship. In
56 addition, we will analyse health literacy and the perceived advantages and disadvantages of
57 an online-based second opinion.
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GROUP 4 - Patients with oncological diseases

Specific aims. We will explore the relevance of second opinion program in oncology.

Study population. We will include members of oncological support groups with a sample size of up to 30 subjects for problem-centred interviews or focus groups. Advanced cases and palliative situations will be excluded. We will identify eligible organizations through online research, and contacts with individual oncologists and patient representatives.

Outcomes of interest. This part of the study explores whether cancer patients have previously obtained a second opinion or whether there was a need for it.

GROUP 5 – General population

Specific aims. We aim to analyse the use of second opinions as well as the needs in the general population and identify possible structural and regional differences.

Study population. We will select a random sample of 9,990 citizens living in the region of Berlin and the state of Brandenburg aged 18 years or older through regional registration offices. For selection of participants, we will use disproportionate stratified sampling with settlement pattern (urban area, area with agglomeration, rural area) as stratification variable. For each settlement pattern, we will contact the same number of citizens. We will randomly select all five municipalities in urban areas, 10 in areas with agglomeration and 10 in rural areas. The five urban municipalities will each select 666 persons of their data randomly. The 20 other municipalities will each select 333 persons of their data randomly. We will send questionnaires to the whole sample with the opportunity to win one of 125 gift cards for Amazon (50€ each) as an incentive. Six weeks later, we will send a reminder.

Outcomes of interest. This part of the study will focus on knowledge, attitudes and wishes towards a second opinion program in the context of general health literacy and the local care situation. In this context, we will also analyse the impact of health literacy on obtaining a second opinion.

GROUP 6 – Specialists and professional medical associations

Specific aims. We will focus on the process of and attitudes towards second opinions as well as the influence of the Second Opinion Directive on daily practise.

Study population. Eligible practitioners will consist of specialists affected by the Second Opinion Directive. In addition, we will conduct expert interviews with representatives of

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3 professional associations. 30 specialists and 10 representatives from professional associations
4 will be included.
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6 The sample will consist of already cooperating specialists from group 1 and additionally
7 selected physicians. The sample is balanced between physicians who work in rural and urban
8 regions, as well as whether the physicians offer second opinions or not.
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12 *Outcomes of interest.* We will examine subjective perspectives on second opinions as well as
13 the implementation of the Second Opinion Directive by medical specialists.
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16 17 18 Data Collection

19 We will collect the data via questionnaires, interviews and focus groups (Table 1).

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21 *Questionnaires.* We will develop the respective questionnaires in several interdisciplinary meetings. All
22 study questionnaires will be piloted in person or via phone among patients who match the inclusion
23 criteria of each group to ensure good comprehensibility and to optimize the reading flow.
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26 The core of each group-specific questionnaire will consist of validated instruments to match the
27 specific aims and outcomes of the respective sub-studies, as shown in Table 1. We will develop
28 additional items specifically for the sub-studies focusing on experiences and wishes towards second
29 opinions, decisional behaviour and local health care characteristics. Health-related and socio-
30 demographic data will also be included where appropriate in the sub-studies: disease, duration of
31 symptoms and severity, decision preferences, age, gender, marital status, educational level, income
32 and rural versus urban residence.
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39 The holders of the patient data who collect and store information in conjunction with their main duties
40 (e.g. the AOK Nordost or Medexo) will sent out questionnaires for group 2 and 3. Returning the postal
41 questionnaire to the University Study Team, who have no access to personal identifiers of the invited
42 individuals, will be free of charge for the participants. We will use paper-and-pencil questionnaires
43 except for group 2, where we will provide additional online surveys. Since it is optional for the patients
44 to participate in the survey, we will examine sampling bias by comparing the characteristics of the
45 respondents to the non-respondents, e.g. where feasible by age and gender.
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51 *Interviews and Focus Groups.* For the patient study, an interview guide will be developed for
52 undertaking problem-centred interviews (12, 15) and focus groups (13). A short questionnaire will be
53 added to collect basic data and personal characteristics (15). In addition, an interview guide for the
54 expert interviews with physicians will be constructed based on a literature search and the results of
55 the patient interviews. The interview protocol contains a section of questions about experiencing the
56 second opinion process, if applicable. Furthermore, the participants are asked about their preferences
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regarding the development of second opinion offers. Each sub-study contains a topic-specific block: group 1: impact of the second opinion on the patient-physician relationship; group 2: decision-making behaviour; group 3: lack of personal contact due to an online-based second opinion; group 4: social conditions; group 6: impact on daily practice. Expert and problem-centred interviews will be conducted in person or by phone. The interview sample will be selected according to the maximum variation criterion (16). Relevant criteria are age, gender and residence (rural versus urban). All interviews and focus groups will be transcribed word for word (17).

	Methods	Group						
		1	2	3	4	5	6	
Data Collection	Questionnaires	x	x	x		x*		
	Instruments	Health Literacy Survey Europe short form 16 (18, 19)	x	x	x		x	
		Decisional Conflict Scale short form 16 (20, 21)	x	x	x			
		Decision Regret Scale (22)		x				
		Autonomy Preference Index (23)		x				
	Problem-centred Interview	x	x	x	x			
	Expert Interview						x	
Focus group				x		x		
Data Analysis	Quantitative descriptive analysis	x	x	x		x		
	Qualitative Content Analysis	x	x	x	x		x	

Table 1. Instruments, Data Collection and Data Analysis for Study Group 1-6.

Group 1, Patients who received indication for surgery of tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy; 2, Patients who have undergone tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy; 3, Patients who obtained an online-based second opinion; 4, Patients with oncological diseases; 5, General population; 6, Specialists and professional medical associations.

* Some questions will follow a survey conducted in Germany by Geraedts et al. (7)

Data Analysis

We will use quantitative descriptive analysis for the questionnaires and qualitative content analysis for the interviews and focus groups (Table 1).

Quantitative Descriptive Analysis. We will focus on descriptive analyses of patient demographics and reported outcomes to characterize the dataset. Where feasible, we will examine associations of sociodemographic or health-related factors such as age, gender, health literacy, population density of

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1
2
3 residence, decisional conflict and education for each sub-study. Based on this and on univariate
4 analysis we might consider a stepwise regression analysis to be performed.

5
6 *Qualitative Content Analysis.* The structured qualitative content analysis by Kuckartz (24) enables a
7 rule-driven reduction and systematization of the data. In the first phase, we will create categories
8 describing the material. This procedure is inductive and is carried out on the transcript with regard to
9 the question. The aim is to develop an exhaustive category system. The first phase will be performed
10 in parallel for data collection. In the second phase, we will apply the developed category system to the
11 entire material. For the second phase, the data collection must already be completed. To ensure
12 traceability, we will validate the application of the category system by a member check (25, 26).

13
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18 *Integration of the data.* First, the responses to the questions that are unspecific to the involved
19 interventions will be compared descriptively between the sub-studies, such as the participants'
20 preferences towards the type of the second opinion (online-based second opinion on the basis of
21 documents versus personally provided second opinion) or whether they have previously obtained a
22 second opinion. Second, the quantitative and qualitative results will be integrated using a triangulation
23 protocol (27). This means a separated analysis of data and their subsequent presentation side by side
24 in a single document (14, 27). This technique allows to consider where there is agreement, partial
25 agreement, silence or dissonance between findings from different methods (27). Furthermore, the
26 qualitative data will be used to deepen the quantitative findings and, thus, to enable their more
27 complex understanding (14), e.g. the reasons for especially positive or negative attitudes may be
28 understood into more detail or for rejecting of a second opinion program.

37 38 Discussion

39
40 The Second Opinion Directive has created a systematic offer to obtain second opinions for certain
41 surgical procedures in Germany. The present study aims to examine the use of second opinions prior
42 to and since the introduction of the Second Opinion Directive. Additionally, we will elucidate the
43 benefits and drawbacks of the newly introduced second opinion framework in the context of the
44 associated surgical procedures. Moreover, we will investigate topics that are not yet included in the
45 directive, such as online-based second opinion programs and second opinions regarding cancer
46 treatments (5). In parallel, the project team updated knowledge on the current state of affairs
47 regarding second opinion programs by surveying all health insurers (statutory and private) about their
48 programs. These programs continue to be offered in addition to the Second Opinion Directive. The
49 results of our study, together with the results of the survey among health insurers, will provide useful
50 information and further guidance for decision makers to implement more tailored second opinion
51 programs and to stimulate specific future research addressing the knowledge gaps identified in our
52 endeavour.

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3 The study explores the extent to which individuals require health literacy as a competence for
4 obtaining a second opinion (28). In addition, health literacy is dependent on structural factors and thus
5 represents a societal responsibility (29). Accordingly, organizations that provide health services must
6 provide barrier-free access to health- and health care-related information. Second opinion programs
7 aim to support the patient in making informed decisions. The ZWEIT Project provides empirical
8 evidence the extent to which the current second opinion framework offers the patient valid and
9 complete information for making informed decisions, and, if desired, for obtaining a second opinion.

10
11 Our study has various strengths: on the micro and meso level, we address opinions, wishes,
12 experiences and needs of various important stakeholders, including clinicians of a variety of disciplines,
13 patients who are pre- and post-surgery, clients of a commercial second opinion provider, and the
14 general population. The questionnaires will be tailored for each of the stakeholders, yet will also
15 contain selected overlapping items. As such, a comparison of the different stakeholders' views and
16 experiences will be possible across the full spectrum of stakeholders, in particular for the selected
17 validated item-scales. The survey on post-surgery patients (Group 2) will include patients pre and post
18 the commencement of the Second Opinion Directive. We aim to check if and how the directive was
19 implemented in daily clinical practice. The survey on the general population will consider the local care
20 situation specifically and how second opinion programs are feasible in rural areas.

21
22 Limitations should be noted as well. To a certain extent, physicians who have a positive attitude
23 towards second opinions may be more likely to participate in the study and to educate their patients
24 about the right to obtain a second opinion than physicians with a negative attitude. This can lead to a
25 bias in the sample of patients recruited through physicians (Group 1).

26
27 In the Second Opinion Directive, the inclusion of other professional groups such as physiotherapists or
28 psychologists is not prohibited, but is neither encouraged. Assuming that a second opinion on shoulder
29 arthroscopy may lead to a decrease in surgeries, more patients may receive conservative treatment
30 including physiotherapy (30). In further research, other medical professions should also be considered,
31 such as physiotherapist. In addition, the perspective of other stakeholders (such as legal experts and
32 policy makers) should also be taken into account in order to analyse the feasibility and requirements
33 of the directive at the macro level.

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The study protocol was approved by the Ethics Committee of the Brandenburg Medical School on 13
June 2019 (number E-01-20190529). All quantitative research will use data anonymization procedures
compliant with the General Data Protection Regulation (GDPR). For the interviews and focus groups,
the participants are asked to sign an informed consent form. The transcription of the audiotapes and

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the analysis will be undertaken using pseudonymisation. The participants in the focus groups and interviews are offered an allowance.

The findings will be published in peer-reviewed journals and presented at scientific conferences. In addition, a symposium will be planned at the end of the project, to enable a wide range of stakeholders to take note of the results, and to provide their professional opinion and critical assessment of the conclusions and the potential impact on the Second Opinion Directive.

Data Statement

The datasets generated during the study are not currently publicly available due to the study being ongoing. Data will be available from the corresponding author on reasonable request once the study is completed. Data generated or analysed during the study will be included in manuscripts to be submitted for publication in peer-reviewed journals.

Patient and Public Involvement Statement

The patients were not involved in the design of the study. However, a patient representative is member of the Scientific Advisory Board of the ZWEIT project.

Study Status

In table 2 we show the study status for each sub-study and dates for (expected) completion of data collection and analysis.

Group	Data Collection Completed	Status Data collection	Data Analysis Completed
1	31 July 2021	Ongoing	31 October 2021
2	30 June 2021	Ongoing	30 September 2021
3	31 January 2020	Completed	31 March 2021
4	30 June 2021	Not yet initiated	31 August 2021
5	31 October 2020	Completed	30 June 2021
6	30 April 2021	Ongoing	31 June 2021

Table 2. (Expected) Dates for the Completion of Data Collection and Analysis in Group 1-6 and Status for Data Collection at the Time of the First Revision.

Author Contributions

DB, CR, SuM, BP and NK drafted the manuscript. EN, DP, SvP, KV, J-CL and DB are co-applicants on the funded grant and contributed to conceptualisation of the study design. AA, SoM, AF, BC and SL are

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1
2
3 members of the study team that have contributed to specify the study design. All co-authors have
4 revised the manuscript critically for important intellectual content.
5
6

7 8 **Competing Interests**

9 DB, SuM, BP, NK, AA, SoM, KV, SL, BC, AF, SvP, DP, CR and EN declare that they have no competing
10 interests. J-CL is the CEO of Medexo GmbH, a second opinion provider.
11
12
13
14

15 16 **Acknowledgement**

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19 Nothacker). Kristin Schnuppe (Coordinating Center for Clinical Studies, Medical University
20 Brandenburg) provided support with the data protection concept.
21
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30 Fund, grant number 01VSF18014).
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35 36 **Figure Legend**

37 Figure 1: ZWEIT Project Study design
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References

1. Lindsey PA, Newhouse J. The cost and value of second surgical opinion programs: a critical review of the literature. *J Health Polit Policy Law*. 1990;15(3):543-70.
2. Grafe WR, McSherry CK, Finkel ML, McCarthy EG. The Elective Surgery Second Opinion Program. *Ann Surg*. 1978;188(3):323-30.
3. Pieper D, Heß S, Mathes T. Bestandsaufnahme zu Zweitmeinungsverfahren in der Gesetzlichen Krankenversicherung (GKV). *Gesundheitswesen*. 2018;80(10):859-63.
4. GKV-Spitzenverband. Stellungnahme zum Referentenentwurf des GKV-Versorgungsstärkungsgesetzes. 07.11.2014]. Available from: file:///D:/Literatur%20ZWEIT/Stellungnahmen/GKV-Versorgungsstärkungsgesetz/GKV-SV_zu_GKV-VSG.pdf.
5. Gemeinsamer Bundesausschuss. Richtlinie zum Zweitmeinungsverfahren. *Bundesanzeiger*. 2020;B3.
6. Ali J, Pieper D. Kaum aktuelle Daten zu Zweitmeinungsverfahren vorhanden - eine systematische Übersichtsarbeit. *Gesundheitswesen*. 2017;79(10):871-4.
7. Geraedts M, Kraska R. Zweitmeinungen: Inanspruchnahme und Bedarf aus Sicht der Bevölkerung. *Gesundheitsmonitor 2016: Bertelsmann Stiftung*; 2016. p. 160-77.
8. Weyerstrass J, Prediger B, Neugebauer E, Pieper D. First results of a German second opinion program show high patient satisfaction and large discrepancies between initial therapy recommendations and second opinion. *Z Evid Fortbild Qual Gesundhwes*. 2018;133:46-50.
9. Creswell JW, Klassen AC, Plano Clark VL, Smith KC. Best practices for mixed methods research in the health sciences. Bethesda (Maryland): National Institutes of Health. 2011;2013:541-5.
10. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
11. Flick U, Kardorff Ev, Steinke I. Was ist qualitative Forschung? Einleitung und Überblick. In: Flick U, Kardorff Ev, Steinke I, editors. *Qualitative Forschung: Ein Handbuch*. 11. ed. Reinbek: Rowohlt Taschenbuch; 2015. p. 13-29.
12. Mey G, Mruck K. Interviews. In: Mey G, Mruck K, editors. *Handbuch qualitative Forschung in der Psychologie*. Wiesbaden: Springer; 2010. p. 423-35.
13. Krueger RA. *Focus groups: A practical guide for applied research*: Sage publications; 2014.
14. Creswell JW, Hirose M. Mixed methods and survey research in family medicine and community health. *Family Medicine and Community Health*. 2019;7(2):e000086.
15. Witzel A. *Das problemzentrierte Interview*. Beltz; 1985.
16. Patton MQ. *Qualitative research & evaluation methods: Integrating theory and practice*: Sage publications; 2014.
17. Dresing T, Pehl T. *Praxisbuch Interview, Transkription & Analyse Anleitungen und Regelsysteme für qualitativ Forschende*. Marburg: Dr. Dresing & Pehl GmbH; 2012.
18. Pelikan JM, Ganahl K. *Die europäische Gesundheitskompetenz-Studie: Konzept, Instrument und ausgewählte Ergebnisse*. Health Literacy, Forschungsstand und Perspektiven 1st ed Bern: Hogrefe. 2017:93-126.
19. Pelikan JM, Ganahl K. Measuring health literacy in general populations: Primary findings from the HLS-EU Consortium's health literacy assessment effort. *Stud Health Technol Inform*. 2017;240:34-59.
20. Buchholz A, Hölzel L, Kriston L, Simon D, Härter M. Die decisional conflict scale in deutscher sprache (DCS-D)—dimensionale struktur in einer stichprobe von hausarztpatienten. *Klinische Diagnostik und Evaluation*. 2011;4:15-30.
21. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25-30.
22. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. *Med Decis Making*. 2003;23(4):281-92.
23. Simon D, Kriston L, Härter M. Die deutsche modifizierte Fassung des Autonomie-Präferenz-Index (API-Dm). *Klinische Diagnostik und Evaluation*. 2011;4(1):5-14.

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- 2
- 3 24. Kuckartz U. Qualitative Inhaltsanalyse. 4. ed. Weinheim: Beltz Juventa; 2018.
- 4 25. Kuper A, Lingard L, Levinson W. Critically appraising qualitative research. *BMJ*.
- 5 2008;337:a1035.
- 6 26. Onwuegbuzie AJ, Leech NL. Validity and qualitative research: An oxymoron? *Quality &*
- 7 *Quantity*. 2007;41(2):233-49.
- 8 27. O’Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods
- 9 studies. *BMJ*. 2010;341:c4587.
- 10 28. Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy
- 11 and public health: a systematic review and integration of definitions and models. *BMC Public Health*.
- 12 2012;12:80.
- 13 29. Ernstmann N, Bauer U, Berens E-M, Bitzer E, Bollweg T, Danner M, et al. DNVF Memorandum
- 14 Gesundheitskompetenz (Teil 1) – Hintergrund, Relevanz, Gegenstand und Fragestellungen in der
- 15 Versorgungsforschung. *Das Gesundheitswesen*. 2020;82:e77-e93.
- 16 30. Steuri R, Sattelmayer M, Elsig S, Kolly C, Tal A, Taeymans J, et al. Effectiveness of conservative
- 17 interventions including exercise, manual therapy and medical management in adults with shoulder
- 18 impingement: a systematic review and meta-analysis of RCTs. *Br J Sports Med*. 2017;51(18):1340-7.
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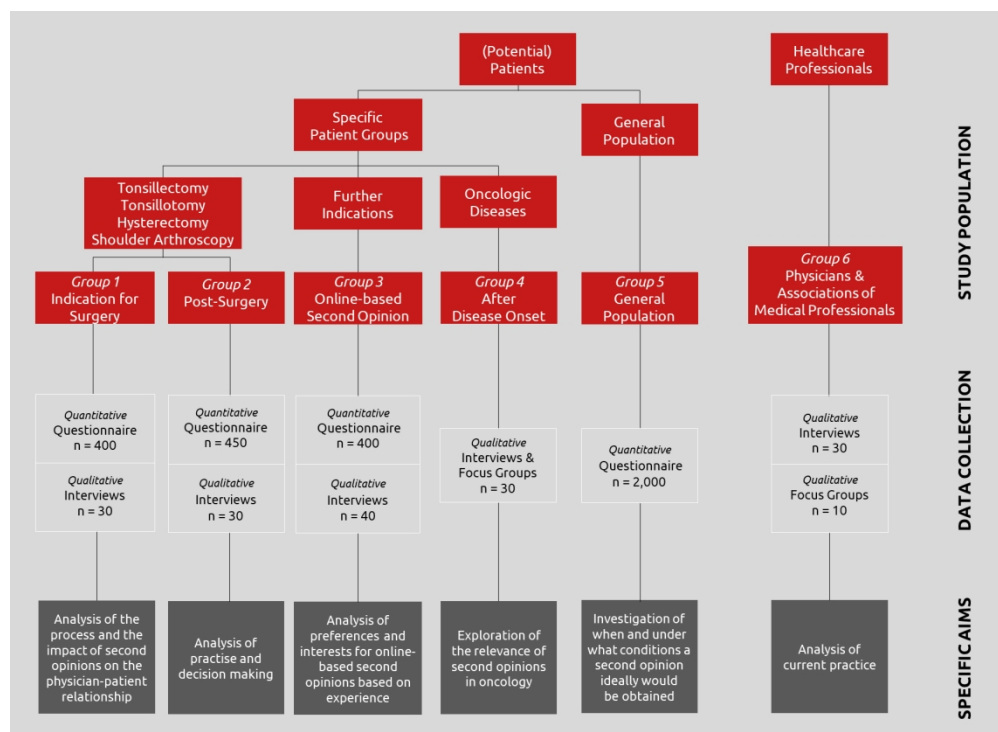


Figure 1. ZWEIT Project: Study design.

BMJ Open

Second opinion programs in Germany: a mixed methods study protocol

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Second opinion programs in Germany: a mixed methods study protocol

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Keywords

Second opinion - Health literacy – Patient autonomy – Patient-physician relationship – Decision making
– Patient perspective – Germany – Health services research – Mixed-methods

Abstract

Introduction. Second opinion programs aim to support the patients' decision-making process and to avoid treatments that are unnecessary from a medical perspective. The German Second Opinion Directive, introduced in December 2018, constitutes a new legal framework in statutory health insurance for seeking second opinions for elective procedures and so far includes tonsillectomy, tonsillotomy, hysterectomy and shoulder arthroscopy. The directive mandates physicians who recommend one of the above-mentioned surgeries to inform their patients of their legal right to visit a certified second opinion provider. Since second opinion programs are a fairly recent phenomenon in Germany, no comprehensive data are yet available on the degree of implementation, users, potential barriers and their effectiveness. We aim to examine the characteristics and the use of second opinion programs as well as the needs and wishes from the perspective of (potential) users in Germany, with focus on the decision-making process, the patient-physician relationship, and the motivation to seek a second opinion, as well as the role of health literacy.

Methods and analysis. Six sub-studies will include the following stakeholders: (1. and 2.) patients with one of the four surgery-indications covered by the directive, (3.) patients who electively sought an online-based second opinion, (4.) patients with oncological diseases, (5.) the general population and (6.) expert-physicians. A mixed methods approach will be used, including questionnaires, interviews and focus groups. The data will be evaluated using quantitative descriptive analysis and qualitative content analysis. The integration of the results will take place in the form of a triangulation protocol.

Ethics and dissemination. The study protocol was approved by the Ethics Committee of the Brandenburg Medical School. The findings will be published in peer-reviewed journals and presented at scientific conferences.

Word Count Abstract: 280 words

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Article Summary

Strengths and Limitations of this Study

- We address the perspectives of various important stakeholders such as patients and physicians in order to obtain a comprehensive overview of the use of and the need for a second medical opinion.
- Because of the mixed methods approach we are able to provide real-life contextual understandings and multilevel perspectives.
- The mixed methods design allows to reconsider the research question for each sub-study and to develop questionnaires and interview guidelines iteratively.
- Since we survey very specific patient groups in some sub-studies, we are dependent on close cooperation with eligible patients and physicians in order to reach the target number of participants.

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Introduction

Surgical second opinion programs are known worldwide since the 1970s (1, 2). Historically, these programs were introduced in the United States to halt the increasing numbers of surgeries, as a means of limiting rising health care costs (1). Second opinion programs offer patients with a recommendation for an elective surgical procedure the opportunity to obtain a second opinion from another medical professional. The primary aims of these programs are to provide an improved knowledge base, to support the patient in the decision-making process and to avoid treatments that are unnecessary from a medical perspective.

In Germany, many statutory health insurers offer a wide variety of second opinion programs with an increasing volume (3). Moreover, it is fairly common among patients to utilize an informal approach to obtain a second opinion, by seeking medical advice from multiple health care practitioners for the same set of symptoms and diagnostic test results, before the patient makes a final decision on proposed interventions. This "informal" patient-initiated second opinion practice is tolerated by the statutory health insurance and usually reimbursed without clear regulations (4). The second opinion programs on the other hand, are structured and subject to clear regulations.

In December 2018, the Federal Joint Committee (G-BA) published the Second Opinion Directive (5), which introduced the first statutory second opinion program covered by the German statutory health insurance for a specified set of elective surgeries: Initially, the directive included only tonsillectomy, tonsillotomy and hysterectomy. In 2020, shoulder arthroscopy was added. A widening of the selected surgeries in the directive is anticipated in the future. A physician who recommends one of the selected surgeries to patients who are members of the statutory health insurance, is obliged to inform the patient about his/her right to obtain a second opinion. The physician must also provide further information, for example where the patient can find second-opinion physicians and decision aids. Of note, surgical interventions in oncology are explicitly excluded from the directive in its current form and online-based second opinions are not supposed to be provided yet according to the Second Opinion Directive.

As structural second opinion programs are a fairly recent phenomenon in Germany, there have not been any comprehensive efforts to gather data on the degree of implementation, users, potential barriers, acceptance and benefits of the second opinion programs, e.g. value for informed decision making or reduction of surgeries, except for a few small-scale evaluations (6). As such, the scientific basis for the design of second opinion programs in general, and the criteria for selection of the relevant (surgical) indications is limited.

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3 Studies show that there is a noticeable interest among German citizens to seek a second opinion (7,
4 8). Moreover, a population-representative study (7) shows that the need for a second opinion goes
5 beyond the indications included in the Second Opinion Directive: more than half of the respondents
6 consider the possibility of a second opinion to be important not only for surgeries involving bones and
7 joints (56%), and for surgeries on internal organs (56%), but also for other types of medical
8 interventions, such as drug treatments in case of cancer (70%) and for radiotherapy (61%). Although
9 generally speaking, health information is increasingly sought online, 90% of the study participants
10 prefer personal contact with a specialist when they seek a second opinion. Only 10% preferred medical
11 advice by phone or online (7).
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18 The ZWEIT Project was set-up by the Brandenburg Medical School and the Witten/Herdecke University
19 in cooperation with the Association of Statutory Health Insurance Physicians Brandenburg, the
20 statutory health insurer AOK Nordost and an online-based second opinion provider, Medexo.
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26 Objectives

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28 The study is particularly important right now because the Second Opinion Directive recently created a
29 new legal framework for second opinion programs. This has also an impact on existing second opinion
30 programs in health insurance. For example, health insurers offer online second opinion programs only
31 as long as they do not include the surgeries specified by the directive. As the Second Opinion Directive
32 can replace existing second opinion programs offered by health insurers, it is important that the effects
33 of the directive will be evaluated to what extent they meet the needs of patients and how feasible the
34 directive is for physicians.
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40 The objective of the ZWEIT Project is to examine the characteristics and the use of second opinion
41 programs as well as the needs and wishes from the perspective of (potential) users and physicians. By
42 revealing and summarizing the experiences and the needs of stakeholders in the health care system,
43 we aim to provide decision-makers in health policy with important information to support further
44 tailoring of second opinion programs.
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51 Methods and Analysis

52 Rationale for the Mixed Methods Approach

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54 The mixed methods approach combines the strengths of qualitative and quantitative research and is
55 appropriate for research questions that require real-life contextual understandings and multi-level
56 perspectives (9). Our questionnaires aim to interrogate a broad spectrum of (potential) patient
57 populations to obtain a comprehensive and representative overview of the need for and the use of
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3 second opinions. Questionnaire-based research is rigid and provides a high potential for comparability
4 across populations. The qualitative investigations enable to formulate additional questions and items
5 for the questionnaires, attending to aspects that have previously not been considered (10). Further,
6 they allow an in depth-analysis of the subjective experiences and attitudes of the study participants
7 (11). Thereby, the results of the questionnaires can be deepened and contextualized by using expert
8 and problem-centred interviews (12), as well as focus groups (13). Owing to this methodological
9 complexity, the research questions to be addressed expand beyond the a priori hypotheses developed
10 by the research team (11).
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19 Design

20 The study follows a multi-phase design (9). Quantitative and qualitative methods will be performed in
21 parallel, except for group 2, for which we chose a sequential order (14). Figure 1 shows a summary of
22 the study design, methods and specific objectives.
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27 *[Figure 1. ZWEIT Project: Study design.]*
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30 As the focus is on the perspective of the user, we will include specific patient groups and physicians. In
31 group 1 and 2 we will concentrate on patients whose indications are within the scope of the Second
32 Opinion Directive. We will compare patients with the indication given before and after the introduction
33 of the directive. In group 3 we will survey patients who have obtained a second opinion via an online
34 platform. Online-based second opinion programs are offered by several health insurers. Since the
35 Second Opinion Directive excludes so far online-based second opinions, these programs can only be
36 provided by statutory health insurers for surgeries that are not part of the directive. At the same time,
37 online-based second opinions could compensate for regional differences in health care, such as a lack
38 of medical specialists. The Second Opinion Directive does not apply to oncological diseases. However,
39 it is known from preliminary studies that there is a need for a second opinion in oncology (7) and that
40 many statutory health insurers offer second opinion programs for oncological indications (3). We will
41 continue to explore the need for a second oncological opinion in group 4 so that future second opinion
42 programs can be tailored to the characteristics of specific oncological patient populations. In addition,
43 we will perform a representative survey of the general population in order to analyse the needs in the
44 general population, e.g. with regard to the relevant indications. In order to investigate the experience
45 with the Second Opinion Directive and the requirements for a successful second opinion process from
46 a professional point of view, we will interview physicians.
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GROUP 1 - Patients who received indication for surgery

Specific aims. We will focus on the analysis of the second opinion process and the impact of the Second Opinion Directive on the patient-physician relationship.

Study population. This group will include people who have received an indication for tonsillectomy, tonsillotomy, hysterectomy, or shoulder arthroscopy. Further inclusion criteria will be: insured by the statutory health insurance, sufficient knowledge of the German language, and age ≥ 18 or parent and legal guardian respectively willing to complete the questionnaire.

We will recruit physicians specialized in otolaryngology, gynaecology and orthopaedics in the federal states of Berlin and Brandenburg, based on registries from the Association of Statutory Health Insurance Physicians Brandenburg. We will focus on outpatient settings because these physicians commonly provide the surgical indication for the above-mentioned procedures. In the next step, the physicians will recruit participants by distributing the questionnaires and invitations for interviews to their patients who meet the inclusion criteria. Participating physicians will receive a remuneration of five Euro for each invited patient (regardless of whether the patient participates or not). According to the total number of tonsillectomies, tonsillotomies and hysterectomies (approx. 157,120, (15)) in relation to the total number of outpatient gynaecologists and ENT physicians (approx. 16,024, (16)) in Germany in 2017, we assume an average of 20 eligible patients per physician within a data collection period of two years. With 65 cooperating physicians we assume 1,300 eligible patients. With a response rate of 30% (17), we expect a sample size of $n = 400$.

Outcomes of interest. We will focus on the implementation of the Second Opinion Directive and the quality of information the physician provides to the patient, e.g. information about which physicians provide a second opinion and where to find decision aids. We will investigate whether a second opinion was required, what reasons exist for or against obtaining a second opinion and what sort of wishes patients have with regard to a second opinion program, e.g. preference for a personal or online-based second opinion or quality demands on the medical specialist. Furthermore, we will analyse the impact of the directive on the patient-physician relationship as well as the effect of health literacy on obtaining a second opinion.

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3 **GROUP 2 – Patients who have undergone tonsillectomy, tonsillotomy, hysterectomy or**
4 **shoulder arthroscopy**
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7 *Specific aims.* We will evaluate the use of second opinions as well as their relevance for the
8 decision behaviour in patients who already decided upon undergoing the surgeries specified
9 by the Second Opinion Directive.
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12 *Study population.* We will include patients who have undergone tonsillectomy, tonsillotomy,
13 hysterectomy or shoulder arthroscopy due to non-malignant underlying diseases in the period
14 2018-2019. Initially, a preliminary qualitative interview study will include eligible adults (age
15 >18 years), to identify main themes of interest. We will recruit those from clinics and
16 outpatient physicians. Subsequently, the full study will recruit individuals insured by the AOK
17 Nordost who are either adults, or in case of minors, whose parent or legal guardian are willing
18 to complete the questionnaire. AOK Nordost is a German health insurer in the federal states
19 of Berlin, Brandenburg and Mecklenburg-Western Pomerania covering approximately 1,76
20 million insured citizens. Eligible individuals will receive a postal invitation from AOK Nordost to
21 participate in the questionnaire survey and the interviews. Patients who underwent surgery
22 before the Second Opinion Directive was introduced will receive the same questionnaire with
23 specific additional items. AOK Nordost will send a postcard reminder after two weeks. Based
24 on the case numbers from previous years (approx. 9,000 per year) and response rates (5-10%)
25 based on the experience of the AOK Nordost from similar surveys, the estimated number of
26 responses is at least 450 in a conservative scenario. As the Second Opinion Directive on these
27 indications was enacted in December 2018, this study allows a comparison of patients who
28 had surgery pre- and post-directive.
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32 *Outcomes of interest.* This part of the study will focus on the patient's informed decision-
33 making process and identify knowledge and needs related to obtaining a second opinion, as
34 well as factors that influence the use. Furthermore, we will compare the impact of the Second
35 Opinion Directives on receiving a second opinion between patients who have undergone
36 surgery before and after the introduction of the directive. In addition, a model of the decision
37 typology of people who have had surgery will be generated. We will also analyse the impact of
38 health literacy on obtaining a second opinion.
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54 **GROUP 3 - Patients who obtained an online-based second opinion**

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56 *Specific aims.* Our aim will be to survey patient experiences with an online-based second
57 opinion program.
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3 *Study population.* We will include clients of an online platform (Medexo). Medexo provides a
4 written, medical record based second opinion to patients.
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6 Medexo will send out study invitation to all its customers in Germany (1,247) from January
7 2016 to February 2019. Non-responders will receive up to two reminders Assuming a
8 conventional response rate for postal surveys of 30% (17), we plan to recruit 400 participants.
9 Accordingly, a heterogeneous sample will be chosen for the interviews in which the
10 characteristics of the individuals differ as much as possible.
11

12 *Outcomes of interest.* This part of the project will focus on the motivation to obtain an online-
13 based second opinion and the experiences made during the second opinion process. The
14 investigation includes potential discrepancies between first and second opinion, the impact of
15 the second opinion on the participants' decision and on the patient-physician relationship. In
16 addition, we will analyse health literacy and the perceived advantages and disadvantages of
17 an online-based second opinion.
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26 **GROUP 4 - Patients with oncological diseases**

27 *Specific aims.* We will explore the relevance of second opinion program in oncology.
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29 *Study population.* We will include members of oncological support groups with a sample size
30 of up to 30 subjects for problem-centred interviews or focus groups. Advanced cases and
31 palliative situations will be excluded. We will identify eligible organizations through online
32 research, and contacts with individual oncologists and patient representatives.
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38 *Outcomes of interest.* This part of the study explores whether cancer patients have previously
39 obtained a second opinion or whether there was a need for it.
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44 **GROUP 5 – General population**

45 *Specific aims.* We aim to analyse the use of second opinions as well as the needs in the general
46 population and identify possible structural and regional differences.
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49 *Study population.* We based the sample size $n = 2,000$ on the last representative survey on the
50 subject of second opinion in Germany by Geraedts and Kraska (7) and also considered an
51 evenly distributed number of cases for rural, urban and agglomeration areas. Assuming a
52 response rate of 20 %, we will select a random sample of 9,990 citizens living in the region of
53 Berlin and the state of Brandenburg aged 18 years or older through regional registration
54 offices. We will select a random sample of 9,990 citizens living in the region of Berlin and the
55 state of Brandenburg aged 18 years or older through regional registration offices. For selection
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3 of participants, we will use disproportionate stratified sampling with settlement pattern (urban
4 area, area with agglomeration, rural area) as stratification variable. For each settlement
5 pattern, we will contact the same number of citizens. We will randomly select all five
6 municipalities in urban areas, 10 in areas with agglomeration and 10 in rural areas. The five
7 urban municipalities will each select 666 persons of their data randomly. The 20 other
8 municipalities will each select 333 persons of their data randomly. We will send questionnaires
9 to the whole sample with the opportunity to win one of 125 gift cards for Amazon (50€ each)
10 as an incentive. Six weeks later, we will send a reminder.

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17 *Outcomes of interest.* This part of the study will focus on knowledge, attitudes and wishes
18 towards a second opinion program in the context of general health literacy and the local care
19 situation. In this context, we will also analyse the impact of health literacy on obtaining a
20 second opinion.
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23 24 25 26 **GROUP 6 – Specialists and professional medical associations**

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28 *Specific aims.* We will focus on the process of and attitudes towards second opinions as well
29 as the influence of the Second Opinion Directive on daily practise.

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32 *Study population.* Eligible practitioners will consist of specialists affected by the Second
33 Opinion Directive. In addition, we will conduct expert interviews with representatives of
34 professional associations. 30 specialists and 10 representatives from professional associations
35 will be included.
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38 The sample will consist of already cooperating specialists from group 1 and additionally
39 selected physicians. The sample is balanced between physicians who work in rural and urban
40 regions, as well as whether the physicians offer second opinions or not.
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44 *Outcomes of interest.* We will examine subjective perspectives on second opinions as well as
45 the implementation of the Second Opinion Directive by medical specialists.
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49 **Data Collection**

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51 We will collect the data via questionnaires, interviews and focus groups (Table 1).

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53 *Questionnaires.* We will develop the respective questionnaires in several interdisciplinary meetings. All
54 study questionnaires will be piloted in person or via phone among patients who match the inclusion
55 criteria of each group to ensure good comprehensibility and to optimize the reading flow.
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58 The core of each group-specific questionnaire will consist of validated instruments to match the
59 specific aims and outcomes of the respective sub-studies, as shown in Table 1. We will develop
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3 additional items specifically for the sub-studies focusing on experiences and wishes towards second
4 opinions, decisional behaviour and local health care characteristics. Health-related and socio-
5 demographic data will also be included where appropriate in the sub-studies: disease, duration of
6 symptoms and severity, decision preferences, age, gender, marital status, educational level, income
7 and rural versus urban residence.
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11 The holders of the patient data who collect and store information in conjunction with their main duties
12 (e.g. the AOK Nordost or Medexo) will sent out questionnaires for group 2 and 3. Returning the postal
13 questionnaire to the University Study Team, who have no access to personal identifiers of the invited
14 individuals, will be free of charge for the participants. We will use paper-and-pencil questionnaires
15 except for group 2, where we will provide additional online surveys. Since it is optional for the patients
16 to participate in the survey, we will examine sampling bias by comparing the characteristics of the
17 respondents to the non-respondents, e.g. where feasible by age and gender.
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21 *Interviews and Focus Groups.* For the patient study, an interview guide will be developed for
22 undertaking problem-centred interviews (12, 18) and focus groups (13). A short questionnaire will be
23 added to collect basic data and personal characteristics (18). In addition, an interview guide for the
24 expert interviews with physicians will be constructed based on a literature search and the results of
25 the patient interviews. The interview protocol contains a section of questions about experiencing the
26 second opinion process, if applicable. Furthermore, the participants are asked about their preferences
27 regarding the development of second opinion offers. Each sub-study contains a topic-specific block:
28 group 1: impact of the second opinion on the patient-physician relationship; group 2: decision-making
29 behaviour; group 3: lack of personal contact due to an online-based second opinion; group 4: social
30 conditions; group 6: impact on daily practice. Expert and problem-centred interviews will be conducted
31 in person or by phone. The interview sample will be selected according to the maximum variation
32 criterion (19). Relevant criteria are age, gender and residence (rural versus urban). All interviews and
33 focus groups will be transcribed word for word (20).
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Methods		Group						
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Data Collection	Questionnaires	x	x	x		x*		
	Instruments	Health Literacy Survey Europe short form 16 (21, 22)	x	x	x		x	
		Decisional Conflict Scale short form 16 (23, 24)	x	x	x			
		Decision Regret Scale (25)		x				
		Autonomy Preference Index (26)		x				
	Problem-centred Interview	x	x	x	x			
	Expert Interview						x	
Focus group				x		x		
Data Analysis	Quantitative descriptive analysis	x	x	x		x		
	Qualitative Content Analysis	x	x	x	x		x	

Table 1. Instruments, Data Collection and Data Analysis for Study Group 1-6.

Group 1, Patients who received indication for surgery of tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy; 2, Patients who have undergone tonsillectomy, tonsillotomy, hysterectomy or shoulder arthroscopy; 3, Patients who obtained an online-based second opinion; 4, Patients with oncological diseases; 5, General population; 6, Specialists and professional medical associations.

* Some questions will follow a survey conducted in Germany by Geraedts et al. (7)

Data Analysis

We will use quantitative descriptive analysis for the questionnaires and qualitative content analysis for the interviews and focus groups (Table 1).

Quantitative Descriptive Analysis. We will focus on descriptive analyses of patient demographics and reported outcomes to characterize the dataset. Where feasible, we will examine associations of sociodemographic or health-related factors such as age, gender, health literacy, population density of residence, decisional conflict and education for each sub-study. Based on this and on univariate analysis we might consider a stepwise regression analysis to be performed.

Qualitative Content Analysis. The structured qualitative content analysis by Kuckartz (27) enables a rule-driven reduction and systematization of the data. In the first phase, we will create categories describing the material. This procedure is inductive and is carried out on the transcript with regard to the question. The aim is to develop an exhaustive category system. The first phase will be performed in parallel for data collection. In the second phase, we will apply the developed category system to the

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3 entire material. For the second phase, the data collection must already be completed. To ensure
4 traceability, we will validate the application of the category system by a member check (28, 29).

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6 *Integration of the data.* First, the responses to the questions that are unspecific to the involved
7 interventions will be compared descriptively between the sub-studies, such as the participants'
8 preferences towards the type of the second opinion (online-based second opinion on the basis of
9 documents versus personally provided second opinion) or whether they have previously obtained a
10 second opinion. Second, the quantitative and qualitative results will be integrated using a triangulation
11 protocol (30). This means a separated analysis of data and their subsequent presentation side by side
12 in a single document (14, 30). This technique allows to consider where there is agreement, partial
13 agreement, silence or dissonance between findings from different methods (30). Furthermore, the
14 qualitative data will be used to deepen the quantitative findings and, thus, to enable their more
15 complex understanding (14), e.g. the reasons for especially positive or negative attitudes may be
16 understood into more detail or for rejecting of a second opinion program.
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26 Discussion

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28 The Second Opinion Directive has created a systematic offer to obtain second opinions for certain
29 surgical procedures in Germany. The present study aims to examine the use of second opinions prior
30 to and since the introduction of the Second Opinion Directive. Additionally, we will elucidate the
31 benefits and drawbacks of the newly introduced second opinion framework in the context of the
32 associated surgical procedures. Moreover, we will investigate topics that are not yet included in the
33 directive, such as online-based second opinion programs and second opinions regarding cancer
34 treatments (5). In parallel, the project team updated knowledge on the current state of affairs
35 regarding second opinion programs by surveying all health insurers (statutory and private) about their
36 programs. These programs continue to be offered in addition to the Second Opinion Directive. The
37 results of our study, together with the results of the survey among health insurers, will provide useful
38 information and further guidance for decision makers to implement more tailored second opinion
39 programs and to stimulate specific future research addressing the knowledge gaps identified in our
40 endeavour.
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50 The study explores the extent to which individuals require health literacy as a competence for
51 obtaining a second opinion (31). In addition, health literacy is dependent on structural factors and thus
52 represents a societal responsibility (32). Accordingly, organizations that provide health services must
53 provide barrier-free access to health- and health care-related information. Second opinion programs
54 aim to support the patient in making informed decisions. The ZWEIT Project provides empirical
55 evidence the extent to which the current second opinion framework offers the patient valid and
56 complete information for making informed decisions, and, if desired, for obtaining a second opinion.
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3 Our study has various strengths: on the micro and meso level, we address opinions, wishes,
4 experiences and needs of various important stakeholders, including clinicians of a variety of disciplines,
5 patients who are pre- and post-surgery, clients of a commercial second opinion provider, and the
6 general population. The questionnaires will be tailored for each of the stakeholders, yet will also
7 contain selected overlapping items. As such, a comparison of the different stakeholders' views and
8 experiences will be possible across the full spectrum of stakeholders, in particular for the selected
9 validated item-scales. The survey on post-surgery patients (Group 2) will include patients pre and post
10 the commencement of the Second Opinion Directive. We aim to check if and how the directive was
11 implemented in daily clinical practice. The survey on the general population will consider the local care
12 situation specifically and how second opinion programs are feasible in rural areas.

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Limitations should be noted as well. To a certain extent, physicians who have a positive attitude
towards second opinions may be more likely to participate in the study and to educate their patients
about the right to obtain a second opinion than physicians with a negative attitude. This can lead to a
bias in the sample of patients recruited through physicians (Group 1).

In the Second Opinion Directive, the inclusion of other professional groups such as physiotherapists or
psychologists is not prohibited, but is neither encouraged. Assuming that a second opinion on shoulder
arthroscopy may lead to a decrease in surgeries, more patients may receive conservative treatment
including physiotherapy (33). In further research, other medical professions should also be considered,
such as physiotherapist. In addition, the perspective of other stakeholders (such as legal experts and
policy makers) should also be taken into account in order to analyse the feasibility and requirements
of the directive at the macro level.

Ethics and Dissemination

The study protocol was approved by the Ethics Committee of the Brandenburg Medical School on 13
June 2019 (number E-01-20190529). All quantitative research will use data anonymization procedures
compliant with the General Data Protection Regulation (GDPR). For the interviews and focus groups,
the participants are asked to sign an informed consent form. The transcription of the audiotapes and
the analysis will be undertaken using pseudonymisation. The participants in the focus groups and
interviews are offered an allowance.

The findings will be published in peer-reviewed journals and presented at scientific conferences. In
addition, a symposium will be planned at the end of the project, to enable a wide range of stakeholders
to take note of the results, and to provide their professional opinion and critical assessment of the
conclusions and the potential impact on the Second Opinion Directive.

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Data Statement

The datasets generated during the study are not currently publicly available due to the study being ongoing. Data will be available from the corresponding author on reasonable request once the study is completed. Data generated or analysed during the study will be included in manuscripts to be submitted for publication in peer-reviewed journals.

Patient and Public Involvement Statement

The patients were not involved in the design of the study. However, a patient representative is member of the Scientific Advisory Board of the ZWEIT project.

Study Status

In table 2 we show the study status for each sub-study and dates for (expected) completion of data collection and analysis.

Group	Data Collection Completed	Status Data collection	Data Analysis Completed
1	31 July 2021	Ongoing	31 October 2021
2	30 June 2021	Ongoing	30 September 2021
3	31 January 2020	Completed	31 March 2021
4	30 June 2021	Not yet initiated	31 August 2021
5	31 October 2020	Completed	30 June 2021
6	30 April 2021	Ongoing	31 June 2021

Table 2. (Expected) Dates for the Completion of Data Collection and Analysis in Group 1-6 and Status for Data Collection at the Time of the First Revision.

Author Contributions

DB, CR, SuM, BP and NK drafted the manuscript. EN, DP, SvP, KV, J-CL and DB are co-applicants on the funded grant and contributed to conceptualisation of the study design. AA, SoM, AF, BC and SL are members of the study team that have contributed to specify the study design. All co-authors have revised the manuscript critically for important intellectual content.

Competing Interests

DB, SuM, BP, NK, AA, SoM, KV, SL, BC, AF, SvP, DP, CR and EN declare that they have no competing interests. J-CL is the CEO of Medexo GmbH, a second opinion provider.

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Figure Legend

Figure 1: ZWEIT Project Study design

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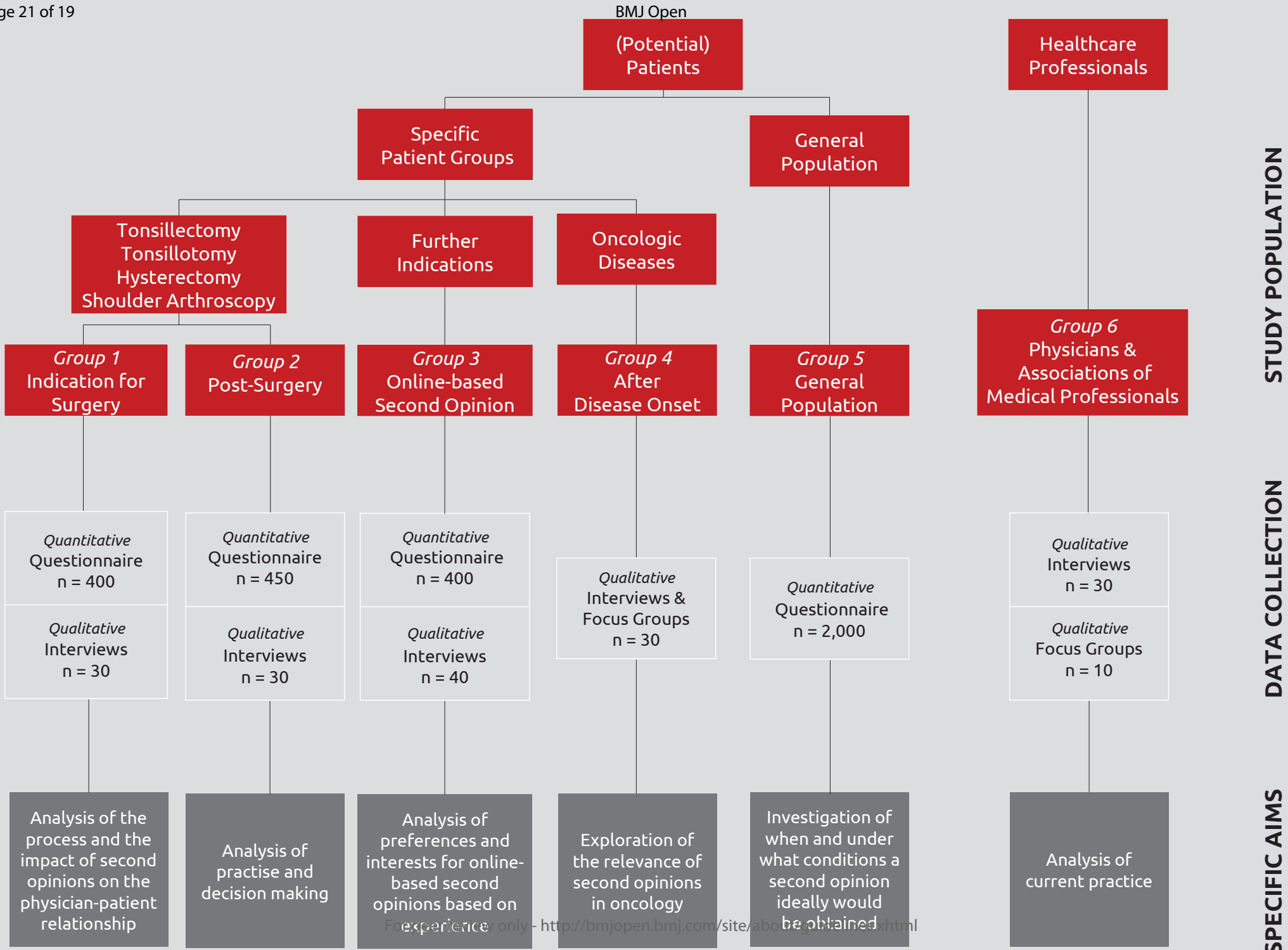
References

1. Lindsey PA, Newhouse J. The cost and value of second surgical opinion programs: a critical review of the literature. *J Health Polit Policy Law*. 1990;15(3):543-70.
2. Grafe WR, McSherry CK, Finkel ML, McCarthy EG. The Elective Surgery Second Opinion Program. *Ann Surg*. 1978;188(3):323-30.
3. Pieper D, Heß S, Mathes T. Bestandsaufnahme zu Zweitmeinungsverfahren in der Gesetzlichen Krankenversicherung (GKV). *Gesundheitswesen*. 2018;80(10):859-63.
4. GKV-Spitzenverband. Stellungnahme zum Referentenentwurf des GKV-Versorgungsstärkungsgesetzes. 07.11.2014]. Available from: file:///D:/Literatur%20ZWEIT/Stellungnahmen/GKV-Versorgungsstärkungsgesetz/GKV-SV_zu_GKV-VSG.pdf.
5. Gemeinsamer Bundesausschuss. Richtlinie zum Zweitmeinungsverfahren. *Bundesanzeiger*. 2020;B3.
6. Ali J, Pieper D. Kaum aktuelle Daten zu Zweitmeinungsverfahren vorhanden - eine systematische Übersichtsarbeit. *Gesundheitswesen*. 2017;79(10):871-4.
7. Geraedts M, Kraska R. Zweitmeinungen: Inanspruchnahme und Bedarf aus Sicht der Bevölkerung. *Gesundheitsmonitor 2016: Bertelsmann Stiftung*; 2016. p. 160-77.
8. Weyerstrass J, Prediger B, Neugebauer E, Pieper D. First results of a German second opinion program show high patient satisfaction and large discrepancies between initial therapy recommendations and second opinion. *Z Evid Fortbild Qual Gesundhwes*. 2018;133:46-50.
9. Creswell JW, Klassen AC, Plano Clark VL, Smith KC. Best practices for mixed methods research in the health sciences. Bethesda (Maryland): National Institutes of Health. 2011;2013:541-5.
10. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
11. Flick U, Kardorff Ev, Steinke I. Was ist qualitative Forschung? Einleitung und Überblick. In: Flick U, Kardorff Ev, Steinke I, editors. *Qualitative Forschung: Ein Handbuch*. 11. ed. Reinbek: Rowohlt Taschenbuch; 2015. p. 13-29.
12. Mey G, Mruck K. Interviews. In: Mey G, Mruck K, editors. *Handbuch qualitative Forschung in der Psychologie*. Wiesbaden: Springer; 2010. p. 423-35.
13. Krueger RA. *Focus groups: A practical guide for applied research*: Sage publications; 2014.
14. Creswell JW, Hirose M. Mixed methods and survey research in family medicine and community health. *Family Medicine and Community Health*. 2019;7(2):e000086.
15. Statistisches Bundesamt. Fallpauschalenbezogene Krankenhausstatistik 2017. Available from: <https://www.destatis.de>.
16. Bundesärztekammer. Ärztestatistik zum 31. Dezember 2017. Available from: https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Statistik2017/Stat17AbbTab.pdf.
17. Clearinghouse for Military Family Readiness. Survey response rates: Rapid literature review. University Park, PA: Clearinghouse for Military Family Readiness; 2019.
18. Witzel A. *Das problemzentrierte Interview*. Beltz; 1985.
19. Patton MQ. *Qualitative research & evaluation methods: Integrating theory and practice*: Sage publications; 2014.
20. Dresing T, Pehl T. *Praxisbuch Interview, Transkription & Analyse Anleitungen und Regelsysteme für qualitativ Forschende*. Marburg: Dr. Dresing & Pehl GmbH; 2012.
21. Pelikan JM, Ganahl K. Die europäische Gesundheitskompetenz-Studie: Konzept, Instrument und ausgewählte Ergebnisse. *Health Literacy, Forschungsstand und Perspektiven 1st ed* Bern: Hogrefe. 2017:93-126.
22. Pelikan JM, Ganahl K. Measuring health literacy in general populations: Primary findings from the HLS-EU Consortium's health literacy assessment effort. *Stud Health Technol Inform*. 2017;240:34-59.

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3 23. Buchholz A, Hölzel L, Kriston L, Simon D, Härter M. Die decisional conflict scale in deutscher
4 sprache (DCS-D)–dimensionale struktur in einer stichprobe von hausarztpatienten. *Klinische*
5 *Diagnostik und Evaluation*. 2011;4:15-30.
6 24. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25-30.
7 25. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a
8 decision regret scale. *Med Decis Making*. 2003;23(4):281-92.
9 26. Simon D, Kriston L, Härter M. Die deutsche modifizierte Fassung des Autonomie-Präferenz-
10 Index (API-Dm). *Klinische Diagnostik und Evaluation*. 2011;4(1):5-14.
11 27. Kuckartz U. *Qualitative Inhaltsanalyse*. 4. ed. Weinheim: Beltz Juventa; 2018.
12 28. Kuper A, Lingard L, Levinson W. Critically appraising qualitative research. *BMJ*.
13 2008;337:a1035.
14 29. Onwuegbuzie AJ, Leech NL. Validity and qualitative research: An oxymoron? *Quality &*
15 *Quantity*. 2007;41(2):233-49.
16 30. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods
17 studies. *BMJ*. 2010;341:c4587.
18 31. Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy
19 and public health: a systematic review and integration of definitions and models. *BMC Public Health*.
20 2012;12:80.
21 32. Ernstmann N, Bauer U, Berens E-M, Bitzer E, Bollweg T, Danner M, et al. DNVF Memorandum
22 Gesundheitskompetenz (Teil 1) – Hintergrund, Relevanz, Gegenstand und Fragestellungen in der
23 Versorgungsforschung. *Das Gesundheitswesen*. 2020;82:e77-e93.
24 33. Steuri R, Sattelmayer M, Elsig S, Kolly C, Tal A, Taeymans J, et al. Effectiveness of conservative
25 interventions including exercise, manual therapy and medical management in adults with shoulder
26 impingement: a systematic review and meta-analysis of RCTs. *Br J Sports Med*. 2017;51(18):1340-7.
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STUDY POPULATION

DATA COLLECTION

SPECIFIC AIMS