Online Survey Among Pregnant Women With Medical Indication Or Wish For Elective Caesarean Section On Second Opinions In Germany: Study Protocol

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Abstract	**Background:** Caesarean section (CS) rates have been continuously rising worldwide over the last decade without being accompanied by significant health benefits. Various approaches are discussed internationally to limit the proportion of caesarean deliveries to the necessary cases. The proposed study aims to assess the perspective of pregnant women with medical indication or wish for elective CS on second opinions The goal is to examine whether they consider a second opinion useful to facilitate their decision-making and/or certainty for the mode of delivery, and under which circumstances they would seek a second opinion. **Methods:** The study population will comprise adult pregnant women (18 years or older) with medical indication or wish for elective CS (both currently pregnant women and persons for whom the indication was given in a past pregnancy). The

	survey will be conducted online and the data will be evaluated using quantitative descriptive analysis. **Discussion:** The survey is an opportunity to get a comprehensive picture from the perspective of pregnant women. In combination with our survey of health professionals it paves the way for following research in this area. The results might be limited by a possible selection bias of the study population. **Ethics:** Ethical approval for the study was obtained by the Medical Ethics Committee of the University of Witten/Herdecke. Results will be published in a relevant scientific journal and communicated to interested participants (when demanded). **Ethical approval date:** 22th December 2022 **Estimated start of the survey: 1**st July 2023
Key words	Second Opinion; Elective Caesarean Sections; Pregnant Women; Germany; Online Survey

Introduction

Background and rationale

When medical indicated, caesarean section (CS) is a surgical procedure that can prevent maternal and newborn mortality (1). CS rates have been continuously rising worldwide over the last decades without being accompanied by significant health benefits (2). In Germany, the CS rate increased from approximately 126 thousand CS in 1991 (15.3% of the deliveries) to 221 thousand in 2020 (29.7%) (3). Even though CS is considered a safe procedure nowadays, little is known about the short- and long-term consequences for pregnant women and their children (4). Therefore, various approaches are discussed internationally to limit the proportion

of CS to the necessary cases. One non-clinical approach to address this problem is the use of independent second opinions (SO) which are the subject of interest in this study.

In Germany, the right of statutory health insured persons to obtain an independent SO for specific indications with a risk for oversupply is anchored by law in section 27b SGB V. Since December 2018, they have the right to obtain such an SO in case of indication for tonsillectomy, tonsillotomy and hysterectomy. The set of included indication was expanded in the following years (5). However, two surveys could show that the need for SO goes far beyond the indications that are included in the SO Directive (6, 7). On February 25, 2021 the Institute for Quality and Efficiency in Health Care (IQWiG) published a rapid report in which several elective medical interventions were examined to determine whether they should be included in the SO Directive (8). One of those interventions was elective CS. Despite critical discussion in the literature and the dynamic development of the rate, the IQWiG did not recommend to include elective CS in the SO Directive at this point. The reason for this were doubts about the feasibility since elective CS often take a dynamic and unpredictable clinical course according to the IQWiG. As a result, we initiated several surveys of both pregnant women and health professionals to generate data on the feasibility of SO in the context of elective CS. Since the care of pregnant women in Germany is provided by both physicians and midwives, we included both in the surveys.

Objectives

The survey will be conducted to close the knowledge gap on the extent to which SO are feasible for elective CS in Germany. The objective of the survey is to investigate whether pregnant women with medical indication or wish for elective CS (both currently pregnant women and persons for whom the indication was given in a past pregnancy) consider an SO useful to facilitate their decision-making and/or certainty for the mode of delivery, and under what circumstances they would seek an SO.

Methods

Rationale for the Methodological Approach

Questionnaire-based research can be used to get a comprehensive picture of a population. Furthermore, it provides a high potential for comparability across populations. Electronic surveys, in particular, provide the possibility to conduct large-scale data collections in a low-threshold way and come with advantages of fast distribution and response cycles (9).

Design

In this study, a standardized online questionnaire will be used to record the preferences and the process of decision-making for the mode of delivery in the course of pregnancy. In addition, items on the circumstances and reasons that led to the planning of a CS will be included. Further, satisfaction with the consultation, experiences and wishes for and against an SO in the context of elective CS as well as socio-demographic characteristics that might have an influence on the mode of delivery (e.g. age and education) will be part of the survey. We will develop the questionnaire for the study and the item selection is based on current scientific literature and expert consultations. Before starting the survey, we will pretest the questionnaire to ensure good comprehensibility and to optimize the reading flow.

Data Collection

We will include adult pregnant women (age 18 or older) with medical indication or wish for elective CS (both currently pregnant women and persons for whom the indication was given in a past pregnancy). An elective cesarean section (also known as primary or planned section) is defined as one that is scheduled before the onset of labor. This specifically means that before the procedure, there has been no premature rupture of membranes nor active labor (10). The survey will be disseminated through different channels. The survey will be distributed in relevant information forums such as Facebook or Instagram and we will contact appropriate patient organizations and ask them to share information on our survey, as well as social media

influencers who are active in the topic area. Furthermore, we will recruit midwife practices and gynecologists who agree to pass on information on study participation to pregnant women. The participants can access the online-survey via a link and complete it anonymously. We will use LimeSurvey as the survey tool. To increase the response rate, participants are offered to receive the results of the survey and to participate in a lottery. The lottery includes 300 €, which will be raffled as vouchers of 100 € each. To ensure anonymity, participants can provide their email address via a separate link for the results and for the lottery. The data from the completed questionnaire will be kept separate from the contact details.

No physical or mental risks must be taken into account since the survey is not expected to cause any stress. The participants are informed about the content and objectives of the survey and agree to participate by filling out the questionnaire. Cancellation or revocation of participation is not possible as soon as the questionnaire is completed, since we receive the results anonymously and no conclusion can be drawn about the identity of the participants.

Data Analysis

We will analyze the data using a quantitative descriptive analysis with Microsoft Excel and SPSS. Sociodemographic characteristics will be taken into account as possible factors influencing the answers. Based on the results of our descriptive analysis we might consider conducting a stepwise regression analysis.

	Methods
Data	Instruments

	Online Questionnaire via LimeSurvey Data collection in Microsoft Excel
Data Analysis	Quantitative Descriptive Analysis
	Quantitative Correlation Analysis via SPSS

Table 1: Instruments, Data Collection and Data Analysis

	2022	**2023**			
Quarter	4	1	2	3	4
Questionnaire development	End 31st Dec.				
Pretest questionnaire		End 1st April			
Revision of questionnaire		End 15th April			
Development of information material			End 30th June		
Survey				Begin 1st July	End 31st Oct.
Analysis					End 31st Dec.

Table 2: Time Schedule

Discussion

The worldwide increasing CS rates are discussed critically in the literature. The IQWiG's recommendation not to include elective CS in the SO Directive at this point, was not based on a questionable relevance but on doubts about the feasibility. The present study offers the possibility to examine criteria for or against the use of SO as a tool to limit elective CS to the

necessary cases. To examine those criteria, it is essential to know whether pregnant women with medical indication or wish for elective CS (both currently pregnant women and persons for whom the indication was given in a past pregnancy) perceive SO as helpful, and if so, under what circumstances. The survey of pregnant women with medical indication or wish for elective CS will be supplemented by a currently conducted but not yet published survey of healthcare professionals to gain insight on their perception on the feasibility of SO for elective CS. All in all, the project is an opportunity to get a comprehensive picture from several perspectives and paves the way for following research in this area.

However, it is also important to have a look on the limitations of the study. Even though we have a comprehensive recruitment strategy in place, it is unclear how many participants we will be able to recruit. Furthermore, there might be a selection bias of the study population. For example, pregnant women, who have a positive attitude towards SO may be more likely to participate in the study than pregnant women with a negative attitude. Furthermore, we cannot exclude recall bias for women who have had an indication or wish for elective CS in a past pregnancy.

Declarations

Research ethics approval

We received approval from the ethics committee of the Witten/Herdecke University.

Protocol amendments

Any changes or modifications to the study protocol can only be authorized by the project leader and will be made transparent as amendments in the study protocol. The ethics committee will be informed of any substantial changes to the study protocol. If necessary, the ethical approval will be updated.

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.

Authors' contributions

Anke Kaulbert and Nadja Könsgen drafted the manuscript. Barbara Prediger is a member of the study team that have contributed to specify the study design. All authors have revised the manuscript critically for important intellectual content.

Competing Interests

The authors declare that they have no competing interests.

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List of Abbreviations

CS	Caesarean Section
SO	Second Opinion
IQWiG	Institute for Quality and Efficiency in Health Care

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