

The ICHOM Standard Set for Pregnancy and Childbirth – Translation and Linguistic Adaptation for Germany

Das ICHOM-Standardset für Schwangerschaft und Geburt – Übersetzung und sprachliche Anpassung für Deutschland



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ABSTRACT

Introduction The gathering of health and quality-of-life issues that matter most to patients over so-called patient-reported outcomes (PROs) is a key aspect of patient-centered healthcare. In obstetrics, this approach has the potential to expand the current understanding of what quality entails by including patient perspectives. The International Consortium for Health Outcome Measures (ICHOM), founded in 2012, is a global organization which aims to standardise the collection of PROs and make the results comparable worldwide. A PRO Set for obstetrics, “Pregnancy and Childbirth”, was published in 2018. The aim of our work was to translate the instruments of this set that are not yet available in German into German.

Methods The instruments were translated from English into German using the Functional Assessment of Chronic Illness Therapy (FACIT) translation method. The translated instruments consisted of the Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF), the Mother-to-Infant Bonding Scale (MIBS), and the Birth Satisfaction Scale – Revised (BSS-R) as well as a number of individual questions (items).

Results The final version of the German translations were found to be easily comprehensible by the target group. During the cognitive debriefing, it became clear that pregnant women and women who had just given birth often used a number of medically incorrect terms to refer to their symptoms or complaints. In the translations great care was taken to ensure that the wording was as close as possible to the general usage of the language while at the same time the terminology was medically correct. To achieve a precise but comprehensible translation, the response structure of the BSES-SF also had to be adapted.

Conclusions The instruments of the ICHOM Standard Set “Pregnancy and Childbirth”, which were not previously available in German, were successfully translated into German. This meant dealing with a few challenges such as adapting questions or response structures. The cultural and linguistic comprehensibility of the German translations were confirmed during the subsequent cognitive debriefing. The translations offer the possibility of implementing the complete ICHOM

Set for Pregnancy and Childbirth. This would provide an opportunity to expand the existing understanding of quality by including the subjective experience of women during and after childbirth and, in future, to compare outcomes with those of other hospitals across the world.

ZUSAMMENFASSUNG

Einleitung Die Erhebung von patient*innenberichteter Gesundheit und Lebensqualität über sogenannte Patient-Reported Outcomes (PROs) – sind ein zentraler Bestandteil patient*innenzentrierter Gesundheitsversorgung. Auch in der Geburtsmedizin haben sie das Potenzial, das aktuelle Qualitätsverständnis um die Patientinnenperspektive zu erweitern. Mit dem International Consortium for Health Outcome Measures (ICHOM) gibt es seit 2012 eine globale Organisation, welche die Erhebung von PROs standardisieren und Ergebnisse weltweit vergleichbar machen möchte. Für den Bereich Geburtsmedizin wurde 2018 das PRO-Set „Pregnancy and Childbirth“ veröffentlicht. Ziel dieser Arbeit ist die Übersetzung der noch nicht im Deutschen verfügbaren Instrumente dieses Sets ins Deutsche.

Methoden Die Übersetzung der Instrumente vom Englischen ins Deutsche erfolgte nach der Functional Assessment of Chronic Illness Therapy-(FACIT-)Übersetzungsmethode. Die übersetzten Instrumente umfassen die Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF), die Mother-to-Infant

Bonding Scale (MIBS), die Birth Satisfaction Scale – Revised (BSS-R) sowie mehrere Einzelfragen (Items).

Ergebnisse Die Endfassung der deutschen Übersetzungen ergaben ein hohes Maß an Verständlichkeit in der Zielgruppe. Bei der Durchführung des Cognitive Debriefings zeigte sich, dass im Sprachgebrauch der Schwangeren und Wöchnerinnen häufig medizinisch inkorrekte Formulierungen für Symptome oder Beschwerden genutzt werden. In den Übersetzungen wurde daher darauf geachtet, die Formulierungen möglichst dem allgemeinen Sprachgebrauch bei gleichzeitig medizinisch korrekter Ausdrucksweise anzupassen. Des Weiteren musste, um eine präzise und verständliche Übersetzung zu erreichen, die Antwortstruktur des BSES-SF adaptiert werden.

Schlussfolgerungen Die bisher nicht in deutscher Sprache verfügbaren Instrumente des ICHOM-Sets „Pregnancy and Childbirth“ konnten mit einigen wenigen Herausforderungen, wie z. B. Anpassung der Frage- oder Antwortstruktur, erfolgreich ins Deutsche übersetzt werden. Die kulturelle und sprachliche Verständlichkeit der deutschen Übersetzung konnte im Rahmen des Cognitive Debriefings bestätigt werden. Die Übersetzung bietet die Möglichkeit, dass vollständige ICHOM-Set für Schwangerschaft und Geburt zu implementieren. Daraus ergibt sich die Chance, das bisherige Qualitätsverständnis um das subjektive Erleben der Frauen rund um die Geburt zu erweitern sowie Ergebnisse zukünftig mit Kliniken international zu vergleichen.

Introduction

“A good birth goes beyond having a healthy baby.” [1]. Based on growing scientific knowledge, it has been possible to increasingly standardise the care of pregnant women and the peripartum somatic care of women in recent decades. This is reflected by the increase in both the quality and quantity of international and national guidelines, such as those issued by the German Society of Gynecology and Obstetrics (DGGG) [2]. Currently, procedural and physical data about the course of a birth and the state of health of the mother and the newborn are primarily collected and evaluated to monitor the quality of established guidelines. The focus is first and foremost on ensuring low morbidity and mortality rates. A more in-depth analysis of the data provides additional insight into current trends, e.g., the percentage of cesarean sections, the number of medically induced births, or treatment effects following the use of new or amended methods. Taken together, the data provide some insight into the quality and extent of care provided. But these physical and procedural data do not shed much light on either the birth as such or on how the convalescence process was experienced from the perspective of the women; which medium to long-term impact did the birth have on their body image, their physical and social activities, their continence, their breastfeeding and the relationship between mother and child. Including the patients’ perspective is therefore fundamental, particularly in the context of a holistic, future-oriented medicine [3].

In recent years, the standardized collection of patient-reported outcomes (PROs) to evaluate the current state of health and the quality of treatment received from the patients’ perspective has become increasingly important in many countries and in all areas of medical care. In the United Kingdom, PROs have been used systematically since 2009 as indicators for the quality of care given to patients who receive hip or knee replacements [4]. In the Netherlands, the use of PROs was stipulated in the government’s coalition agreement of 2017, and the Ministry of Health has submitted a concept for the gradual introduction of PROs [5].

PROs include all characteristics or manifestations that relate to a patient’s state of health as reported by the patient herself or himself, without these data being altered or interpreted by someone else (in particular, by medically trained staff) [6]. In addition to concrete symptoms, this also encompasses quality-of-life factors, including physical as well as psychological and social factors [7]. PROs are measured with the help of Patient Reported Outcome Measures (PROMs), generally referred to as questionnaires or instruments. For example, the Edinburgh Postnatal Depression Scale (EPDS = PROM) can be used to measure postpartum depression in women (= PRO). A number of instruments are currently available to measure depression, but they use different scales to present their results. In order to enable future exchange and comparison of results collected with different instruments in hospitals worldwide, it is necessary that the instruments are either collected with the same metric (unit) or all use the same questionnaire.

Internationally there are two leading cross-disease initiatives which aim to create a way of standardizing and comparing such patient-related data. One of them is PROMIS (Patient Reported Outcomes Measurement Information System) and the other is the International Consortium for Health Outcomes Measurement. In addition to providing their own instruments to survey disease-independent health factors, PROMIS aims to standardize the evaluation of outcomes and results by establishing a standard set of metrics, with “50” corresponding to the average of the general population, and a standard deviation of “10” (T-scores) [8].

ICHOM is an initiative which compiles sets of questions taken from previously validated instruments for various clinical pictures across a number of medical areas (including interdisciplinary areas). The aim is to use the same instruments to standardize and compare both national and international outcomes. As part of the development process to design an ICHOM Standard Set, an international working group composed of clinicians, researchers and patient representatives define a minimum number and standard of questionnaires and corresponding case-mix factors, which should be administered before the start of treatment and during convalescence. These sets may partly include PROMIS instruments.

In 2018, a 21-member international panel of experts composed of midwives, obstetricians/gynecologists and patient representatives from a total of 8 different countries developed a Standard Set for surveys to be administered during pregnancy and childbirth. The relevant domains (factors), case-mix parameters, questionnaires and time points when the survey instruments should be administered were decided in 11 sessions, using a modified Delphi method to establish consensus. In addition to a systematic literature analysis, this method includes the compilation of expert opinions and interviews with pregnant women and

mothers. Particularly interviews with affected women aim to ensure that patients’ perspectives are taken sufficiently into account when evaluating care [9].

Methods

Instruments

► **Table 1** shows the health and quality-of-life factors which are surveyed with the ICHOM Set for Pregnancy and Childbirth. In addition to patient demographics and patient history, the surveys focus on the dimensions “incontinence”, “breastfeeding”, “change of role”, “birth experience”, “general health” and “mental health” as well as “pain during sexual intercourse”. The eight instruments and 19 individual questions resulted in a list of 82 items. Five of the instruments (31 items in total) and 3 individual questions were already available in German in the form of validated translations [10–14]. The Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF), the Mother-to-Infant Bonding Scale (MIBS), the Birth Satisfaction Scale – Revised (BSS-R) and several individual questions had not yet been translated. The design of the ICHOM Standard Set envisages a total of five different time points when a survey should be administered (► **Fig. 1**), starting with the first prepartum examination before the third month of pregnancy and concluding with a survey carried out at six months postpartum.

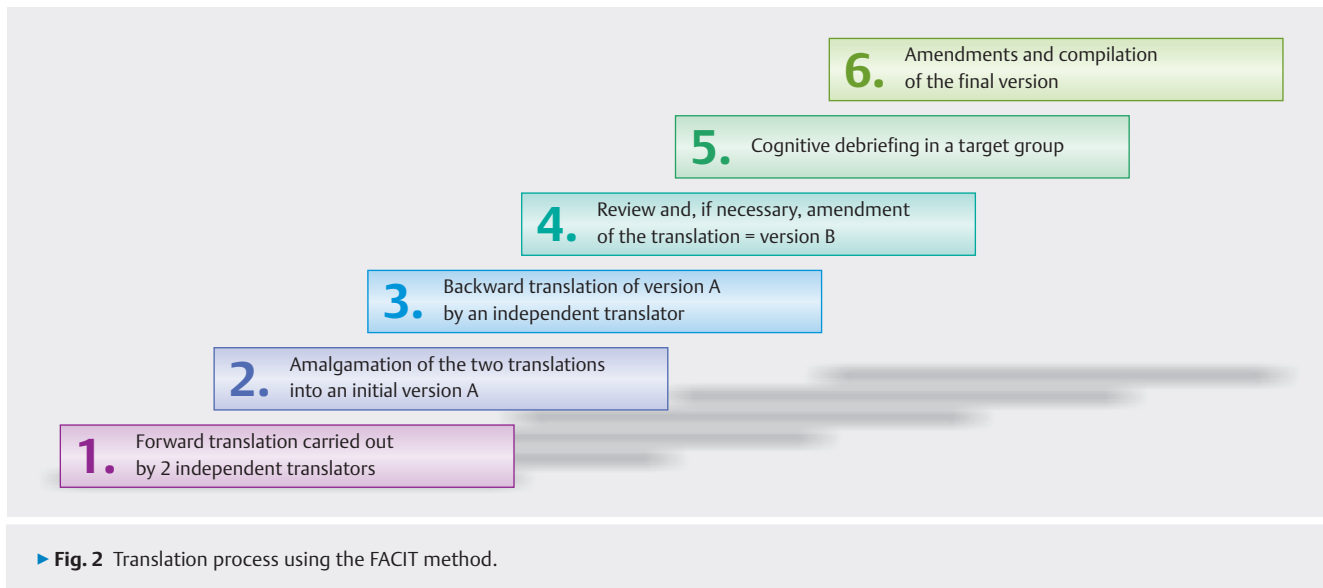
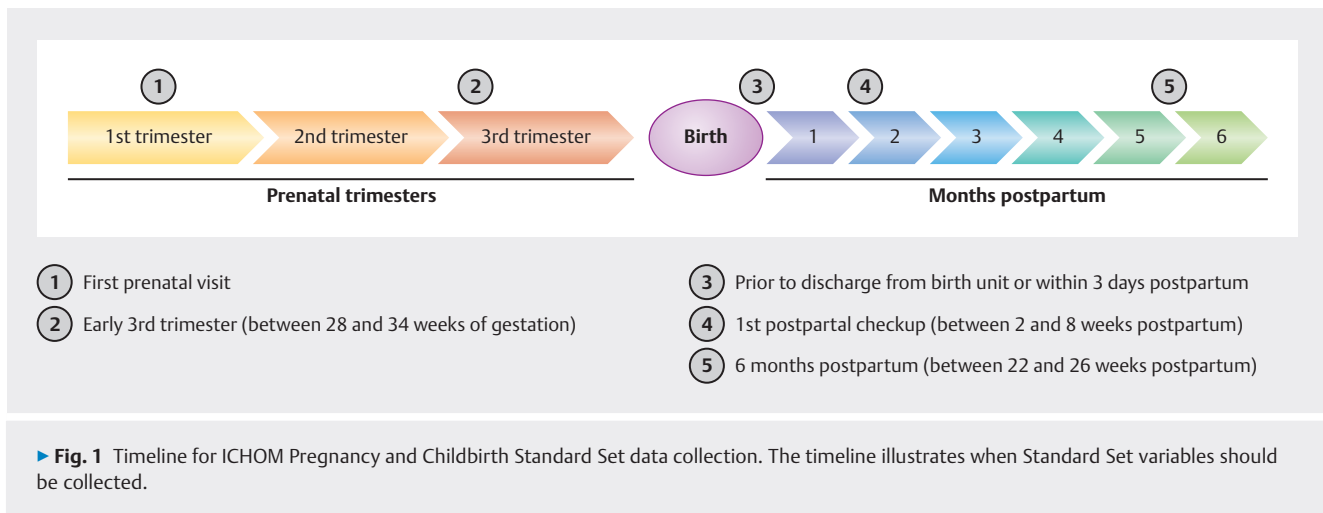
Translation

The three instruments BSES-SF, MIBS and BSS-R, which were not yet available in German (a total of 32 items), and 16 individual questions were translated using the Functional Assessment of Chronic Illness Therapy (FACIT) translation method (► **Fig. 2**). The

► **Table 1** Overview of the ICHOM Standard Set for Pregnancy and Childbirth.

Factors	Instruments and items	German translation	Time points to administer a survey*
Patient demographics and history	Individual questions (8)	✓	1
Incontinence	Jorge-Wexner Incontinence Score or ICIQ-UI-SF	✓ [10] ✓ [11]	1, 2, 4, 5
	+ Individual questions: incontinence screening (1)	–	1, 2, 4, 5
Breastfeeding	Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF)	–	2, 3, 4
	+ individual questions: “successful breastfeeding” (3)	–	3, 4, 5
Role transition	Mother-to-Infant Bonding Scale (MIBS)	–	3, 4
	+ individual question: confidence in role as mother (1)	–	4, 5
Birth experience and satisfaction with care received	Birth Satisfaction Scale – Revised (BSS-R)	–	4
	+ individual questions: satisfaction with care received (5)	–	2, 4, 5
General health and quality of life	PROMIS Global-10	✓ [12]	1, 2, 4, 5
Mental health	PHQ-2	✓ [13]	1, 2, 4, 5
	+ Edinburgh Postnatal Depression Scale (EPDS)	✓ [14]	
Pain with intercourse	PROMIS Sexual Function (single item)	–	1, 4, 5

PHQ = Patient Health Questionnaire, PROMIS = Patient Reported Outcomes Measurement Information System, * cf. ► **Fig. 1**.



FACIT method is a translation process which ensures the semantic and technical equivalence of translations to the original texts [15]. The permission of the respective instrument developers was sought before starting to translate the instruments BSES-SF, MIBS and BSS-R.

In accordance with the FACIT method, the first step consisted of a forward translation into German by two independent translators. Both translations were subsequently merged together to create a first German-language version. In the next step, this version was translated back into English, again by two independent translators. Any discrepancies between the English back translation and the original English text were discussed by the research team and, if considered sufficiently important, the German wording was changed or amended.

Linguistic validation

Cognitive debriefing is a linguistic validation process in which possible problems of comprehension relating to individual items are tested in different target groups [16]. The 48 items requiring validation were divided into two groups according to the time point at which the questions were administered, with 29 items tested in a target group of pregnant women and 20 items tested in a target group of women who have given birth. The question about “Confidence with role as a mother” was validated in both groups, as there were differences in the wording used for the prenatal and postpartum surveys. Because of the large number of items (29 items) requiring validation by the group of pregnant women, this group of items was subdivided. The items were ultimately tested in three different groups:

1. pregnant women = 10 items,
2. pregnant women = 19 items, and
3. new mothers = 20 items.

A total of 15 women were recruited for the validation, with five women in each of the three groups. All of the women were currently receiving care in the Charité, Department of Obstetrics (prepartum care or mother-and-child ward). The participants were requested to read the entire item aloud, reproduce the contents of the item in their own words and subsequently “think aloud” about the item. As they were thinking aloud, they were requested to address anything they stumbled over while reading aloud or which appeared unclear to them [17]. Considerations and comments made during the cognitive debriefing were subsequently discussed and incorporated in the translation.

Results

Translation process

The majority of items could be translated forwards and backwards without difficulty. A direct translation could not be used for one of the items of the BSS-R nor for the response categories of the BSES-SF.

BSS-R

There was no difficulty in translating the question “I came through childbirth virtually unscathed” in the BSS-R literally into German as “*Ich habe die Geburt unbeschadet überstanden*”, and the backward translation of the question was found to closely match the original. However, when the translations were reviewed and merged by obstetricians, it was noted that women interpreted this phrase in a number of very different ways. The same issue had previously been raised by the experts reviewing the Italian translation of this item. They had noted that the word “unscathed” could be understood psychologically, physically or emotionally [18]. Following this analysis, the German word “*unbeschadet*” was replaced by the phrase “*ohne körperliche oder psychische Komplikationen*” (which translates literally as “without physical or mental complications”).

BSES-SF

The possible response categories were given as a scale which ranged from “Not at all confident” to “Very confident”, although the translation of “confident” into German is ambiguous as the word can also be translated as self-assured/self-confident, certain or optimistic. After talking to the development team of the BSES-SF and the team of the Erasmus Clinic Rotterdam which had previously translated the instrument into Dutch, the phrase “*Ich bin zuversichtlich, dass*” (which equates to “I am confident that”) was added at the beginning of every item in a deviation from the original text.

Cognitive debriefing

During the cognitive debriefing of the 15 women, a number of terms were identified which had to be reformulated due to comprehension problems arising from the translation.

Incontinence

The question which screens for incontinence also asks about involuntary flatulence. During the interviews it was found that the

majority of respondents were not familiar with the word *Flatulenzen*. The phrase “*Abgang von Winden*” (= passing wind), which is used in the Jorge-Wexner Incontinence Score, was also not understood. After the term was paraphrased and respondents were asked to say what it meant in their own words, test persons repeatedly used the word “*Blähung*”. After further discussions with the participants in the study, the term “*Abgang von Luft*” (= passing gas) was identified as medically correct as well as generally intelligible.

Pain during sexual intercourse

In response to the question whether pain had an impact on the respondent’s sexual life, the participants in the study noted that the range of possible responses for persons who had no sexual activity was insufficient (“0 = In the past 30 days I did not experience pain”, “1 = Not at all” to “5 = Very much”). As the question was a validated item from the PROMIS Sexual Function item bank, a new item (“In the past 30 days, how satisfied were you with your sex life?”) was developed, based on item SFSAT201 of PROMIS, and prepended to the original item, with possible responses ranging from “0 = In the last 30 days I did not have an active sex life” to “1 = Not at all” and “5 = Very much”. The question about any impairments to the respondent’s sex life due to pain was subsequently only asked if the respondent had previously stated that she had an active sex life.

An overview of all amendments undertaken following the cognitive debriefing is given in ► **Table 2**.

Discussion

The ICHOM Set for Pregnancy and Childbirth covers a range of dimensions which are relevant for women during pregnancy and birth [9]. Because the three instruments BSES-SF, MIBS and BSS-R had not yet been translated into German, full use of the ICHOM Set was not possible in German speaking countries. As part of this study these three instruments have been translated into German, the comprehensibility of the translations was verified using a cohort of 15 pregnant women and women who had just given birth. Some of the wording was amended following their input.

The FACIT method was used for the translation process to ensure that the translation would be valid. The FACIT method is a qualitative method which is used to ascertain that the meaning of a translation corresponds to the meaning of the original text. It does not provide any information about the measurement capabilities of translated instruments, which is why an additional quantitative examination based on this study will be necessary.

Part of the qualitative validation consisted of the cognitive debriefing of 15 pregnant women and women who had just given birth, who were surveyed using the new translation. The women were initially sceptical about such a survey, which is regularly planned as part of clinical routine, but this turned into great interest and broad openness in the course of the survey. The women felt that the issues covered during the cognitive debriefing, such as expectations about breastfeeding, mother-child bonding and birth experience, were relevant. To successfully implement this instrument in future, it appears to be important to counter initially

► **Table 2** List of adaptations made to the translation after the validation process with comments.

Item and instrument in the original	Formulation of the question in German after the first translation	Changes made following debriefing	Comments
I can always breastfeed my baby without using formula as a supplement. (BSES03)	<i>Ich bin zuversichtlich, mein Kind immer stillen zu können und keine Ergänzung mit Milchpulver/ Formulanahrung (industriell hergestellte Anfangsnahrung) zu benötigen.</i>	<i>Ich bin zuversichtlich, mein Kind immer stillen zu können und keine Ergänzung mit industriell hergestellter Anfangsnahrung (Milchpulver) zu benötigen.</i>	The term <i>Formulanahrung</i> (= formula food) was not clear. <i>Industriell hergestellter Anfangsnahrung in Kombination mit Milchpulver</i> (= industrially produced infant formula) was understood.
I can always keep wanting to breastfeed. (BSES07)	<i>Ich bin zuversichtlich, dass ich auch weiterhin stillen möchte.</i> and <i>Ich bin zuversichtlich, so lange wie möglich stillen zu wollen.</i>	<i>Ich bin zuversichtlich, so lange wie möglich stillen zu wollen.</i>	A decision/vote was taken during cognitive debriefing about which wording was understood better.
I can always deal with the fact that breastfeeding can be time-consuming. (BSES10)	<i>Ich bin zuversichtlich, dass ich immer damit umgehen kann, dass das Stillen sehr zeitaufwendig ist.</i> and <i>Ich bin zuversichtlich, dass ich immer mit der Tatsache umgehen kann, dass das Stillen sehr zeitaufwendig ist.</i>	<i>Ich bin zuversichtlich, dass ich immer damit umgehen kann, dass das Stillen sehr zeitaufwendig ist.</i>	A decision/vote was taken during cognitive debriefing. The second sentence generated negative emotions in the study participants, the thought of work.
I can always continue to breastfeed my baby for every feeding. (BSES12)	<i>Ich bin zuversichtlich, mein Kind stets bei jeder Mahlzeit zu stillen.</i>	<i>Ich bin zuversichtlich, mein Kind stets bei jeder Mahlzeit (bei jeder Nahrungsaufnahme) stillen zu können.</i>	Question was amended as the term <i>Mahlzeit</i> was understood to refer to breakfast, lunch and dinner.
Obstetric history Bleeding so much during pregnancy, birth, or after giving birth that you needed to be given blood.	<i>Blutungen während der Schwangerschaft, Geburt oder nach der Geburt, die so stark waren, dass Sie Fremdblut bekommen mussten.</i>	<i>Blutungen während der Schwangerschaft, Geburt oder nach der Geburt, die so stark waren, dass Sie eine Bluttransfusion bekommen mussten.</i>	All of the women were much more familiar with the term <i>Bluttransfusion</i> (= blood transfusion) rather than <i>Fremdblut</i> (= allogeneic blood).
In the past month, have you leaked urine, leaked stool or passed gas by accident?	<i>Hatten Sie im letzten Monat ungewollt Verlust von Urin oder Abgang von Stuhl oder Winden?</i>	<i>Hatten Sie im letzten Monat ungewollt Verlust von Urin oder Abgang von Luft oder Stuhl?</i>	The term <i>Winden</i> was often not understood. Alternative suggestions included: <i>Abgang von Blähungen, unkontrollierte Blähung</i> ; most patients were unfamiliar with the medical term <i>Flatulenzen</i> .
In the past 30 days, how much has pain affected your satisfaction with your sex life?	<i>In den letzten 30 Tagen, wie stark hat Schmerz Ihre Zufriedenheit mit Ihrem Sexualleben beeinflusst?</i>	<i>In den letzten 30 Tagen, wie stark haben Schmerz in irgendeinem Teil Ihres Körpers Ihre Zufriedenheit mit Ihrem Sexualleben beeinflusst?</i>	For many affected women, it was not clear which pain was being referred to. The sentence was therefore amended to include "in irgendeinem Teil Ihres Körpers" (= in any part of your body).

expected skepticism through targeted communication about the aims and benefits of the survey.

The use of PROs in obstetrics should facilitate more personal doctor–patient communication which takes account of women’s medical issues and insecurities. They also provide a quality assessment of the care received, which may lead to a new definition of the need for treatment once the patient’s perspective has also been taken into account. The Birth Satisfaction Scale – Revised (BSS-R) is used to measure the satisfaction of a woman with the birth experience and her perception of the birth experience [19]. Contrary to longstanding assumptions, birth experience did not correlate with the pain experienced during the birth. Factors such

as the extent of support provided by medical staff and the involvement of the women giving birth in decision-making during the course of the birth appear to be significantly more relevant [20]. A woman’s birth experience has a significant impact on her subjective perception of health and health-related quality of life [21] and thus also has an impact on the development of the mother and child relationship [22]. A healthy and secure bond between mother and child is important for the psychological and physiological development of the child [23]. The MIBS focuses particularly on the early emotional bond between mother and newborn; because of its short structure and its focus on just eight emotion-laden adjectives, it can also be administered to women with lower

language skills [24,25]. Early identification of an attachment disorder between mother and child can reduce the risk of physical and mental abuse [26].

The translation of the Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF) also offers the opportunity to improve care as it allows risk factors which hamper breastfeeding to be identified early on. According to the recommendations of the World Health Organization (WHO), infants should be exclusively breastfed for the first six months of life and breastfeeding on demand should continue at least until the age of two years [27]. With an initial breastfeeding rate of 82% just after birth, Germany is at the lower end of the scale in international comparisons [28]. Data from the 2018 Nutrition Report by the German Nutrition Society showed that 56% of infants in Germany are exclusively breastfed up to their 4th month of life and that this figure drops to just 8% by their 6th month of life [29]. There are many risk factors which may lead to women not breastfeeding their infants. In addition to socio-demographic factors, risk factors include lack of the intention to breastfeed or a limited wish to breastfeed, lack of a positive attitude to breastfeeding as well as the giving of supplementary liquids to the neonate in the first 2 weeks of life. These specific factors are measured by the BSES-SF, and the information obtained provides medical staff with the opportunity to offer targeted breastfeeding advice to pregnant women at an early stage.

As the instruments BSES-SF, MIBS and BSS-R have been translated into German, German hospitals now have the option to implement the complete ICHOM Set for Pregnancy and Childbirth and compare PRO results with those of other hospitals worldwide. To do this, it will be necessary to adapt the time points at which the surveys are administered. In Germany, the surveys at the time points “early 3rd trimester” and “within 3 days postpartum” can usually be carried out by the institution where the woman gives birth, the surveys at the time points “1st postpartum checkup” and “6 months postpartum” can be initiated and evaluated digitally by the hospital where the woman gives birth. To be able to administer the initial survey in the 1st trimester of pregnancy, a cross-sectoral survey, which would require the participation of non-hospital-based doctors, is conceivable in future and would be desirable. The ICHOM Standard Set for Pregnancy and Childbirth provides the opportunity to obtain a cross-sectional view of the health and quality of life of women, from their first trimester of pregnancy up until 6 months postpartum, and to record the quality of care across a number of care sectors.

Conflict of Interest

The authors declare that they have no conflict of interest.

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ERRATUM

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