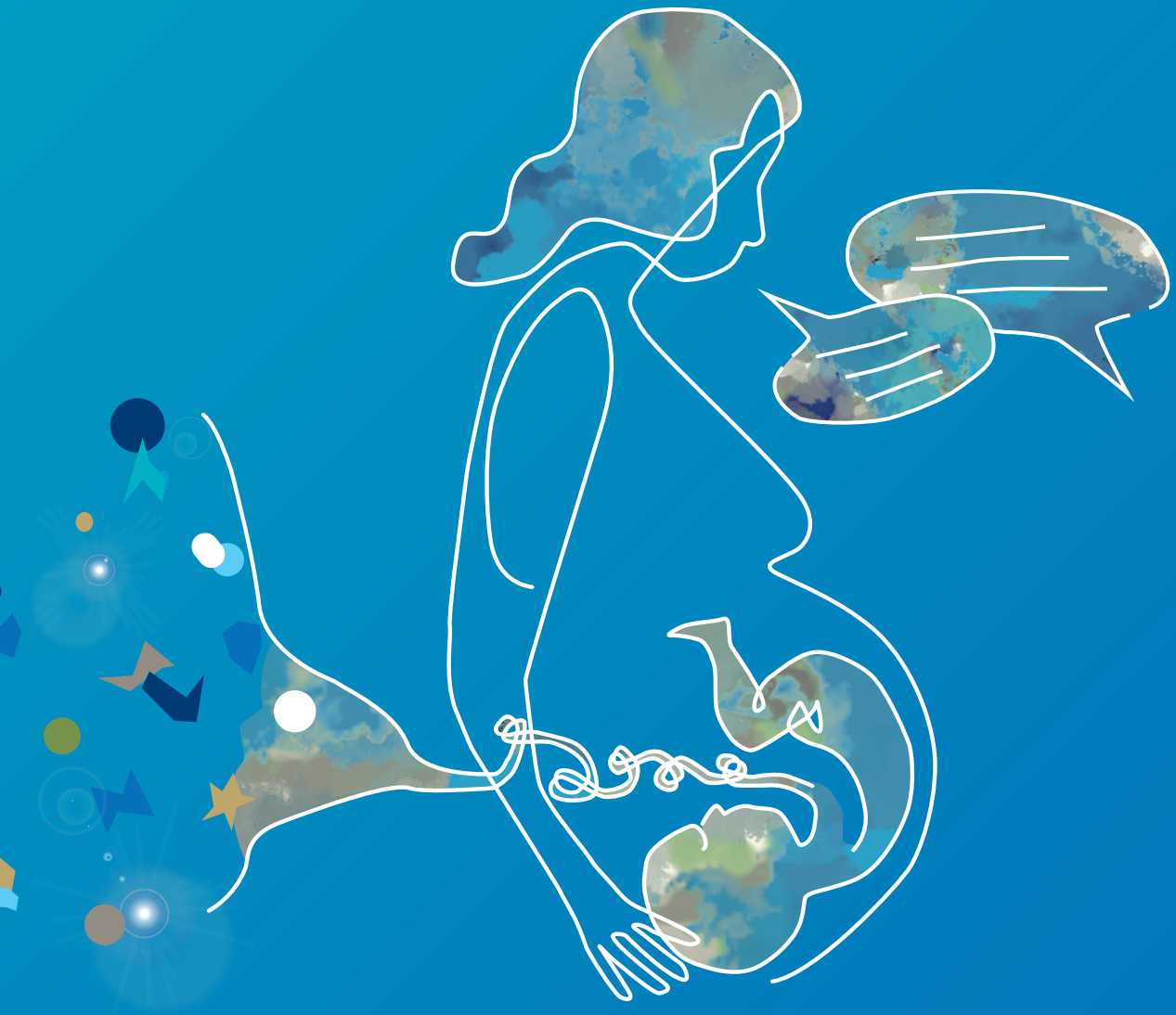
PERSONALIZING PERINATAL CARE FOR WOMEN IN VULNERABLE CIRCUMSTANCES



Lyzette T. Laureij

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Copromotor:	Dr. J. Lagendijk

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Chapter 1

General Introduction

INTRODUCTION

During the phases of pregnancy, childbirth, and the postpartum period, women embark on a transformative journey that brings new life into the world. This significant period represents a crucial time in women's lives, often serving as their first significant encounter with healthcare. Within this context, perinatal care assumes a pivotal role in safeguarding the immediate and lifelong health and well-being of both mothers and infants. It is essential that perinatal care is adapted to personal needs, preferences and values of pregnant women, to achieve the best outcomes for all mothers and infants, regardless of their background.

Perinatal care in the Netherlands

The Dutch perinatal care system traditionally has had a strong emphasis on midwifery-led care and a holistic, preventive approach that considers pregnancy and childbirth as primarily physiological processes with low risks of complications. Community midwives, as primary care providers, play a central role in the delivery of perinatal care in the Netherlands. They work in collaboration with gynecologists and other healthcare professionals when obstetric problems arise or when risk factors are present that may lead to such problems.[1] As such, formal risk stratification directs routing of care during pregnancy and delivery. Shared care is common in Dutch perinatal care, as approximately 70% of pregnant women are referred to a gynecologist during pregnancy.[2] Increasingly, collaboration across the various tiers of care involved during pregnancy and childbirth is formalized via integral organizations at the local level, albeit with substantial regional variation. Additionally, within the Dutch perinatal care system there is a great emphasis on the postpartum period, recognizing it as a critical time for maternal recovery, newborn care, and family bonding. Postpartum care is provided by maternity care assistants (MCA), who support the family at home in the first week following childbirth.[3,4] While MCAs deliver care using a structured protocol, there is flexibility to tailor the amount of hours of care and focus of care according to the specific needs of individual families.[5] This postpartum care aims to contribute to the well-being of mothers and infants, facilitating the transition to parenthood and providing crucial guidance on aspects such as breastfeeding, infant care, and maternal mental health.[6,7]

Adverse perinatal outcomes can have a significant impact on the well-being of women and the health and development of their children.[8-10] Risks of adverse

perinatal outcomes are not distributed evenly across the population. Groups that face a higher risk of experiencing poor health outcomes include those with a low socio-economic status (SES). Additionally, numerous medical and non-medical risk factors, commonly referred to as "social" risk factors, may contribute to adverse health outcomes. Furthermore, women with a lower SES more commonly have less adequate coping skills, health literacy, and self-efficacy.[11-14] Consequently, they are referred to as a "women in vulnerable circumstances". Their vulnerability is further exacerbated by their underutilization of preventive and general healthcare services, perpetuating and exacerbating their risks for adverse health outcomes.[8,13,15-17] The recognition of this perinatal health inequity has inspired multiple projects to improve perinatal care and outcomes.[18-21] Most of these projects focussed their alterations on women in vulnerable circumstances in the Netherlands, aiming to reduce adverse clinical outcomes, such as intrauterine growth restriction (IUGR) or perinatal deaths. There is, however, an increasing recognition that such outcomes may not fully capture the specific impacts and changes in quality of care experienced by individuals in vulnerable circumstances. Therefore, it is important to also take into account those outcomes that consider the perspectives and experiences of women. Such insights can provide valuable information about the quality of healthcare services and may shed light on previously unnoticed areas in need of improvement. Collection of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) provides a unique opportunity to inform the reorganization of care with a focus on quality of life and patients' social participation, in order to obtain insights on outcomes that matter most to the individual receiving care.

Healthcare in the 21th century: personalized healthcare

PROMs and PREMs are outcomes directly reported by patients without interference of healthcare professionals about topics they think are important, providing insights into their symptoms, physical functioning, emotional well-being, and overall satisfaction with their healthcare experiences.[22,23] PROMs and PREMs are typically collected via self-administered questionnaires.[24] PROMs aim to collect information about social participation and quality of life. PREMs reflect patients' experiences with the received care, for example regarding information provision on treatment options or experiences with healthcare providers. When routinely collected during the whole care process, PROMs and PREMs provide healthcare professionals with unique information on the impact of the patient's conditions and the care process.[25,26] By incorporating patients' ex-

periences and perspectives, healthcare providers can obtain a comprehensive understanding of treatment outcomes and tailor care accordingly.[27-29] The ultimate goal is to improve quality of care and health outcomes accordingly. Quality of care encompasses a multifaceted concept that extends beyond merely the provision of healthcare. Recognizing the need for a comprehensive framework to assess and improve healthcare quality, the Institute of Medicine, now known as the National Academy of Medicine, published a report defining six domains of quality to guide efforts in improving healthcare delivery and outcomes.[30] These domains are: effectiveness, patient-centeredness, safety, timeliness, efficiency, and equity of care. Patient-centeredness emphasizes the importance of incorporating the patients' voice in healthcare decision-making. Value-based healthcare (VBHC) is such a patient-centered approach that incorporates both clinician-reported outcomes (CROs) and PROMs and PREMs in order to improve quality of care. The VBHC theory is rooted in the concept of 'value' of the health outcomes achieved related to the energy and costs incurred.[31] It entails measuring and optimizing healthcare outcomes that matter most to patients, such as improved health status, reduced complications, enhanced functional abilities, and increased quality of life.[31,32] By focusing on patient outcomes and experiences, VBHC aims to provide care that aligns with patients' needs, preferences and values, which ultimately may lead to improved health outcomes and increased patient satisfaction. VBHC can be implemented on three different levels. These levels represent different scopes and approaches to achieving value in healthcare:

- Micro-level: the use of individual outcomes for the individual patient and their specific care experience. It emphasizes patient-centered care and shared decision-making between patients and their healthcare providers during consultation.[33]
- Meso-level: this level focuses on specific healthcare organizations or providers within the larger healthcare system. It involves implementing VBHC practices at the organizational or provider level to optimize care delivery and outcomes for specific conditions or diseases.
- Macro-level: using group-level outcomes to benchmark at the level of overall healthcare system and population health. It involves application of health outcomes in policy changes and strategic initiatives aimed at improving the entire healthcare system, for example as a guidance for the buy-in of healthcare by health insurers.

In perinatal care, VBHC principles may help optimize capturing the crucial aspects of this care that may not be observable or easily measurable by healthcare professionals. There is a growing interest in the application of VBHC in perinatal care, and accordingly, an opportunity arises to center care around women, aligning with the current strategy of the Dutch government. This strategy is outlined in the 'Integral Care Agreement' ('Integraal Zorgakkoord' in Dutch,

ICA). The ICA aims to ensure that future healthcare remains effective, accessible, and affordable.[34] To achieve this goal, agreements have been established between the Ministry of Health, Welfare and Sport and numerous healthcare stakeholders, including obstetric care providers. The ICA places particular emphasis on addressing the needs of patients with low SES and limited health literacy. Moreover, the ICA aligns with the Dutch Healthcare Institute's 'framework appropriate care' ('kader passende zorg' in Dutch) which emphasizes four principles that are crucial for ensuring sustainable healthcare: 1) value-based care, 2) patient-centered care facilitated by information tailored to the patient's health literacy, 3) appropriate care is care in the right place, where care should be close to home, and may be replaced by new forms of care such as eHealth, and 4) a focus on health rather than disease.[35] Additionally, the ICA introduces a fifth principle: ensuring a pleasant and conducive work environment for healthcare professionals.[34] The ICA specifically highlights the importance of using PROMs and PREMs to facilitate shared care and shared decision-making with patients. To promote standardized and patient-centered care in perinatal care, several standard outcome sets are available, including the International Consortium for Health Outcomes Measurement (ICHOM) Pregnancy and Childbirth Set (PCB set).[36] Such standard sets aim to provide a comprehensive collection of outcome measures designed to assess and improve the quality of perinatal care provided according to the VBHC principle.
Whereas at the population level, VBHC can be a powerful tool to improve the perinatal care process, there is a risk that it may primarily benefit the most articulate patients, which may in turn aggravate existing health inequalities. When designing and implementing VBHC in perinatal care, it is therefore essential to prioritize the needs of women in vulnerable circumstances. By pursuing this approach, a pathway is established towards fostering a more equitable healthcare system that benefits all individuals. This endeavor aligns with the overarching goals of the ICA and the framework 'appropriate care'.[34,35]

Personalizing perinatal care for women in vulnerable circumstances

The Institute of Medicine underscores the importance of providing equitable care that does not vary in quality according to personal characteristics such as gender, ethnicity, geographic location, and SES.[30] Disparities in health outcomes continue to exist among different socioeconomic groups, such as differences in perinatal mortality, premature birth and small for gestational age babies.[37] Equitable access to healthcare and socioeconomic resources alone is insufficient to eliminate health inequalities.[13] This emphasizes the need for a comprehensive approach

that addresses not only structural determinants of health but also individual and social influence and individual needs.[38] Previous research has demonstrated that preventive strategies aimed at delivering equitable care for pregnant women in vulnerable circumstances may not have an immediate impact on (short-term) clinical outcomes, such as preterm birth.[39,40] A Dutch study has shown that early risk selection and personalized care from pregnancy onwards, while not directly improving clinical outcomes, can benefit maternal self-efficacy, a crucial PROM.[19] From a woman's perspective, maternal self-efficacy is an important outcome of perinatal care.[41] This suggests that care can be further personalized for pregnant women women in vulnerable circumstances, leading to better PROMs and PREMs in the short term. In the long run, an optimized perinatal care system that tailors care based on PROMs and PREMs for these women in vulnerable circumstances may result in improved overall health outcomes.

Aim

The overarching aim of this thesis is to develop and test new strategies to personalize perinatal care with a special focus on women in vulnerable circumstances, based on insights in their current needs and preferences.

Objectives

- To gain insight into the needs and preferences of women in vulnerable circumstances regarding postpartum care (chapter 2).
- To explore whether digital information provision helps new parents in their needs and preferences in the postpartum period (chapter 3).
- To provide healthcare professionals guidance for building professional relationships with pregnant women in vulnerable circumstances (chapter 4).
- To explore the applicability of the ICHOM PCB set,[36] which contains PROMs and PREMs for personalized perinatal care among pregnant and postpartum women, healthcare professionals, and administrators of healthcare organizations in the Netherlands (chapter 5).
- To explore outcomes, experiences, and practice insights following implementation of the PCB set in clinical practice (chapter 6).
- To evaluate women's experiences of routinely collecting and discussing PROMs and PREMs as a regular part of personalized perinatal care (chapter 7).
- To provide an outline for quality improvement at the meso-level based on

Shewhart control charts to monitor different outcomes such as PROMs and PREMs in perinatal care (chapter 8).
- To gain insight in facilitators and barriers regarding the implementation of personalized postpartum care among women in vulnerable circumstances (chapter 9).

Outline of the thesis

Chapter 2 provides an extensive framework for the motivation, experience, and reflection of the usage of postpartum care among women in vulnerable circumstances based on semi-structured interviews. It provides insight into important themes for personalizing postpartum care for this particular subgroup of women. **Chapter 3** explores whether new parents feel they might benefit from digital information provision via an online platform in addition to extensive postpartum care. We elaborate on how parents may be guided towards this platform, its content and the preferences regarding an online platform for new parents and perinatal care professionals. **Chapter 4** provides practical tools for healthcare providers to optimally connect with pregnant women in vulnerable circumstances, in order to improve their healthcare access and health outcomes. In **Chapter 5** we explore the applicability of the ICHOM PCB set for perinatal care in the Netherlands. This set contains CROs, PROMs, and PREMs. Women, administrators of healthcare organizations, and healthcare professionals were asked for their opinions on the applicability of this set during a survey. The survey findings were further deepened by the conduction of focus groups. Following this, **Chapter 6** reports the first outcomes, and practice insights of the use of this outcome set for perinatal care in several regions of the Netherlands. **Chapter 7** evaluates women's experiences with the implementation of routinely collecting and discussing PROMs and PREMs as part of regular perinatal care, and provides insights in their experiences with personalized care during their pregnancy and the postpartum period. In **Chapter 8** an outline is provided for quality improvement of perinatal care based on PROMs and PREMs. Statistical process control charts are used to visualize different outcomes in perinatal care over time, as an important part of Plan Do Study Act cycles at the meso-level. **Chapter 9** summarizes a process evaluation on implementation of personalized care based on PROMs, PREMs, and risk factors. Important barriers and facilitators for acquiring personalized postpartum care among women in vulnerable circumstances are provided. **Chapter 10** summarizes the main findings of this thesis, followed by the implications and recommendations for future research and healthcare.

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Chapter 2

Insight into the process of postpartum care utilisation and in-home support among vulnerable women in the Netherlands: an in-depth qualitative exploration

Lyzette T Laureij
Marije van der Hulst
Jacqueline Lagendijk
Jasper V Been
Hiske E Ernst-Smelt
Arie Franx
Marjolein Lugtenberg
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ABSTRACT

Objective: To gain insight into the process of postpartum care utilisation and in-home support among vulnerable women.

Design, method, participants and setting: A qualitative interview study was conducted among 23 pregnant and postpartum vulnerable women in the Netherlands, following a grounded theory approach. Women were determined as vulnerable by their healthcare providers. Theoretical sampling of participants was applied and was alternated by data analysis to include information-rich cases until saturation was achieved.

Results: A conceptual framework of postpartum care utilisation was generated consisting of three phases: pregnancy, early postpartum period and late postpartum period. Within these phases, information provision, parenting self-efficacy and social network were identified as overarching themes. Perceived inadequate information on content of postpartum care posed a major barrier to forming realistic expectations during pregnancy and hindered its utilisation. Low self-efficacy facilitated postpartum care utilisation. All women experienced increased self-efficacy during and after postpartum care. Support from a social network influenced expectations regarding the added value of postpartum care during pregnancy, and lowered actual utilisation during the postpartum period. The costs of postpartum care and the role of the maternity care assistant acted as general barriers or facilitators influencing the three overarching themes and therefore postpartum care utilisation indirectly.

Conclusions: Our findings suggest that postpartum care utilisation among vulnerable women may be improved by considering the particular phase and relevant themes applying to individual women, and adapt care accordingly. We recommend to provide comprehensive, understandable information and to emphasise the gains of postpartum care in improving self-efficacy for vulnerable women. Moreover, involving a woman's social network in postpartum care may add value to this care for this population.

Strengths and limitations of this study:

- This study focusses on vulnerable women, a group which is often under-represented in research while having a higher risk of adverse health outcomes.
- We were able to obtain a theoretical sample of vulnerable women needed to conduct a proper qualitative study, resulting in rich and complex data.
- By applying a grounded theory approach, a framework was generated that provides insight into the complex process of postpartum care utilisation.
- Limitations of this study are that views of women who did not use any postpartum care were limited and opinions of certain ethnic minority women may have been missed

INTRODUCTION

Women with a low socioeconomic status tend to underuse healthcare services, have an increased risk of adverse health outcomes and are generally less empowered.[1–3] Where women have multiple medical and non-medical risk factors for adverse outcomes and a lack of adequate support or coping skills, they are designated as vulnerable.[4–6] Vulnerability in mothers and their families affects the health and development of their children, which can aggravate inequalities in following generations.[7–9] Breaking this cycle of inequality by improving healthcare utilisation among vulnerable women might therefore be beneficial for improving health outcomes for next generations.

The early postpartum period is highly suitable for improving health outcomes among mothers and their newborns.[10] In the Netherlands, postpartum care is provided at home by maternity care assistants (MCAs) during the early postpartum period. MCAs closely monitor the well-being of the mother, the newborn and the family, and offer opportunities for prevention of health problems (see box 1). Additionally, MCAs provide women with reliable information about caring for their newborn and provide breastfeeding support.[10,11] Dutch postpartum care is easily accessible and extensive in duration. It is partly covered by obligatory health insurances.[12,13] Whereas approximately 95% of all postpartum women use at least some amount of postpartum care, utilisation among vulnerable women is lower than among non-vulnerable women.[13,14] This underuse of postpartum care among vulnerable women is undesirable particularly as these women may benefit most from this preventive and supportive care.[15]

An in-depth understanding of the underlying reasons for the lower utilisation of postpartum care among vulnerable women is currently lacking. By performing a qualitative study, we aimed to gain insight into the process of postpartum care utilisation among vulnerable women, including perceived barriers and facilitators. The results of this study may be used to tailor postpartum care to the needs of vulnerable women, which may subsequently lead to improved utilisation and better health outcomes.

METHODS

Design

We used a qualitative design to gain an in-depth understanding of the process of postpartum care utilisation among vulnerable women. A grounded theory

Textbox 1 Provision and content of postpartum care in the Netherlands

Postpartum care is a unique form of primary care with a focus on prevention of health problems during the postpartum period, provided at home. This care is provided by skilled nurses with a lower secondary education degree, so-called maternity care assistants (MCAs), who are supervised by community midwives.

During pregnancy, every woman may register herself at a chosen maternity care organisation (MCO) in order to receive postpartum care. MCOs are independent enterprises. Their care starts during the third trimester of pregnancy with a home visit by an MCA. This visit is used to explain the content of postpartum care, and to determine the recommended amount of hours of postpartum care during the early postpartum period. This recommendation is based on the Dutch national indication protocol, and is re-evaluated during the first week postpartum by MCAs and midwives. The generally recommended amount of postpartum care is 49 hours (minimal amount is 24 hours, the maximum is 80 hours) spread out over 8–10 consecutive days.

Postpartum care usually starts directly after birth or after discharge from the hospital or birth centre. The provided care from MCAs focusses on information provision, and prevention and identification of healthcare problems, which includes medical check-ups. The information provision is manifold: teaching parents how to take care for their newborn, supporting breast feeding, providing information on what to do when problems occur et cetera. MCAs support parents of newborns with reassurance and positive feedback. During postpartum care, this care is personalised based on the individual needs of the parents. As such, the MCA reduces support as the parents gain confidence in care taking skills. In contrast to obstetric care, postpartum care is only partly covered by a woman's mandatory healthcare insurance. An out-of-pocket payment is required for every hour (€4.50 per hour in 2020), resulting in an average payment of €220.50 for the whole period. Some MCOs compensate (a part of) the total out-of-pocket payments for women with a poor financial situation, although there are no protocols for these situations.

approach was deployed, of which the key elements of the alternating process of data collection and analysis, constant comparison and theoretical sampling were applied (see the Selection of participants, Data collection and Data analysis sections for details of this process). This enabled the generation of a conceptual framework grounded in the data.[16,17]

Patient and public involvement statement

This study aimed to gain insight into the process of postpartum care utilisation among vulnerable women by conducting individual interviews. The study was designed in close collaboration with a council of mothers, healthcare providers and maternity care organisations (MCOs). The study was conducted in collaboration with healthcare providers and MCOs to ensure that outcomes of the study would be relevant for them. All participants were sent their transcript of the interview for member checking. Afterwards, a summary of findings and practical improvements for healthcare providers was communicated in leaflets and symposia.

Research team and reflexivity

LTL is an experienced qualitative researcher, who previously worked as a physician at an obstetric ward. MvdH is a behavioural scientist with a focus on vulnerable mother–child dyads. ML is an experienced qualitative researcher and psychologist. The analysis of the data was primarily conducted by this multidisciplinary team. In addition, the results of the analysis were discussed with additional members of the research team, being JL (gynaecologist in training), JVB (neonatologist), HEE-S (manager in perinatal care research) and AF (professor in obstetrics and gynaecologist). By involving researchers from different backgrounds, the data were illuminated from different angles.

Selection of participants

Eligible vulnerable pregnant and postpartum women were approached by different types of healthcare providers during regular care processes: gynaecologists, midwives, MCAs and social workers. Healthcare providers affiliated with the regional consortium 'Pregnancy and Childbirth in the Southwest of the Netherlands' were approached for the inclusion of participants. Women were classified as vulnerable by their healthcare providers based on having a combination of medical and non-medical risk factors for adverse pregnancy outcomes, and a lack of adequate support or coping skills.[4–6] Examples of medical risk factors are a depression during pregnancy or previous psychiatric diseases. Non-medical risk factors are very broad and may, for example, refer to single motherhood, no fixed abode or financial problems. In addition, women had to be either in their third trimester of pregnancy, to ensure that the home visit of the MCA had taken place, or less than 12 weeks postpartum to prevent recall bias. Women had to be 16 years

Table 1. Characteristics of participants.

Participant's number for quotes	Parity	Age (years)	Status at time of interview	Ethnicity	Living situation[1]	Education level[2]	Amount of postpartum care utilisation by participants[3]
1	1	32	postpartum	Dutch	single	higher	recommended amount
2	1	21	postpartum	other	with supportive adult	lower	less than recommended
3	2	31	postpartum	other	with partner	higher	recommended amount
4	3	41	postpartum	other	with partner	lower	less than recommended
5	3	25	pregnant	Dutch	single, in temporary housing	lower	recommended amount
6	1	28	postpartum	other	single	intermediate	less than recommended
7	1	34	postpartum	Dutch	with partner	intermediate	recommended amount
8	1	22	postpartum	Dutch	with supportive adult	intermediate	less than recommended
9	2	32	postpartum	other	with partner	intermediate	recommended amount
10	1	20	postpartum	Dutch	with partner	intermediate	less than recommended
11	4	29	postpartum	other	single, in women's shelter	intermediate	recommended amount
12	2	38	postpartum	other	with partner	higher	less than recommended
13	0	35	pregnant	Dutch	with partner	higher	less than recommended
14	4	35	pregnant	Dutch	with partner	lower	less than recommended

Table 1 – Continued. Characteristics of participants.

Participant's number for quotes	Parity	Age (years)	Status at time of interview	Ethnicity	Living situation[1]	Education level[2]	Amount of postpartum care utilisation by participants[3]
15	2	26	postpartum	other	with partner	intermediate	recommended amount
16	3	37	postpartum	other	with partner	lower	less than recommended
17	1	20	postpartum	other	with supportive adult	intermediate	recommended amount
18	2	34	postpartum	other	single, living with child	lower	recommended amount
19	0	23	pregnant	Dutch	with partner	intermediate	less than recommended
20	2	29	pregnant	other	with partner	intermediate	recommended amount
21	1	30	postpartum	Dutch	with supportive adult	higher	recommended amount
22	0	36	pregnant	Dutch	with partner	higher	recommended amount
23	0	32	pregnant	other	single, in women's shelter	intermediate	less than recommended

[1] Based on living in a fixed abobe, unless indicated otherwise.
[2] Based on participants' highest successfully completed level of education, classification based on International Standard Classification of Education (ISCED) 2011; lower education corresponds with ISCED levels 0, 1, and 2, intermediate with ISCED levels 3,4 and 5, and higher with ISCED levels [6, 7, 8.42]
[3] For pregnant participants: this represents their intended utilisation of care compared to the recommended amount of hours of postpartum care by their maternity care organisation (MCO). For postpartum participants: this represents their actual use of care compared to the recommended amount of hours postpartum care by their MCO.

or older at inclusion, and needed to have a sufficient understanding of the Dutch or English language. Eligible women who were interested in participating, received an informational leaflet including an informed consent form from their healthcare provider.

Theoretical sampling of participants was applied to include information-rich cases until saturation was achieved. In the beginning of the study, all eligible women were invited to participate. Since we interviewed several postpartum women with a Dutch cultural background, we applied deviant case sampling with a shift towards selecting pregnant women. Finally, we specifically selected women based on their lower (intended) use of postpartum care, and women with a non-Dutch cultural background. Single interviews were scheduled with 26 women. Three postpartum women cancelled the interview without giving a reason, and thus seven pregnant and 16 postpartum women were interviewed (table 1). Despite an extensive search, we did not find any women who did not use any postpartum care at all while also meeting our inclusion criteria. After these 23 interviews, 'functional' theoretical saturation was reached (see also the Data analysis) and sampling of interviewees ended.

Data collection

The interviews were held between January 2018 and November 2018. Interviews were conducted at the participant's home by a trained researcher (LTL) along with a female observer. All interviews started with a short, unrecorded conversation to enable the women to become acquainted with the interviewer and observer. Furthermore, women were reassured that interviews would be handled confidentially. Special consideration was given to simple language use, informal clothing and seating arrangements to encourage women to speak freely and to avoid socially desirable answers.[18] Women received a 25 euro gift voucher after the interview.

We used an interview guide that was developed based on expert opinions gathered in exploratory meetings with different healthcare providers (ie, MCAs, managers of MCOs and other healthcare providers). Adjustments to the interview guide were made after analysing the first four interviews. The adjusted version focused more on women's experiences regarding postpartum care instead of the providers' opinions (see online supplemental figure S1).

Interviews lasted 27–68 min were audiotaped and transcribed verbatim. All transcripts were checked for accuracy by one of the researchers (LTL or MvdH). The verbatim transcript was sent back to each woman to verify the accuracy and completeness of the text (ie, member check).

Data analysis

All transcripts were independently analysed by two researchers (LTL and MvdH) using NVivo V.12. The first phase of analysis consisted of open coding of the first

twelve transcripts. A preliminary coding scheme was developed and discussed between LTL, MvdH and ML. We selected deviant cases of additional participants based on this coding scheme. Next, axial coding was applied; the data were coded deeper and at a more abstract level and relationships between codes were identified. Codes were grouped together and categories were created. Thereafter, selective coding was applied. Core categories were identified and concepts were created. Overarching themes based on the emergent categories were placed in a conceptual framework grounded in the data and these overarching themes acted as facilitators, barriers or both. In addition, two general facilitators and barriers were identified influencing the three overarching themes and therefore postpartum care utilisation indirectly. The terms facilitators and barriers were applied rather strictly in order to gain insights into the underlying reasons for lower postpartum care utilisation among vulnerable women: further utilisation of postpartum care is stimulated by facilitators independently from the result of this further utilisation, whereas a reason to reduce postpartum care utilisation was defined as a barrier also independently from the result of this reduction of postpartum care utilisation. Constant comparison was applied throughout the whole process of data analysis, by comparing the concepts and emerging framework with new data. 'Functional' theoretical saturation was reached after no new insights for the conceptual framework were identified from the data.[19]
Reporting followed the Standards for Reporting Qualitative Research.[20]

RESULTS

Conceptual framework

Women experienced postpartum care as a chronological process started in pregnancy to the postpartum period. This process was divided into three different phases, in which opinions regarding postpartum care were formed and decisions regarding utilisation were made. The first phase was during pregnancy, when women registered at a MCO and the home visit took place. Expectations with respect to the value and decisions regarding utilisation of postpartum care were formed in this phase. The second phase was during the early postpartum period, when women actually experienced postpartum care at home and made decisions about their continued utilisation. The third phase was the late postpartum period. In this phase, reflections of postpartum care were formed regarding the whole postpartum care process. This last phase may ultimately influence decisions about utilisation in a next pregnancy (see figure 1).
We identified three overarching themes influencing the use of postpartum care.

These themes are based on what women expressed during the interviews. All themes may act as a facilitator, barrier or both, within each of the three different phases.

1. Information provision: defined as a woman's perception of the provided written and oral information from healthcare providers (including MCAs) regarding the concept and content of postpartum care, and information on newborn caretaking competences provided by MCAs.
2. Parenting self-efficacy: defined as a woman's belief in her own competences to handle difficult situations, such as caring for her newborn. This self-efficacy may differ between the different phases.
3. Social network: defined as a woman's perceived network of persons who may provide practical or emotional support during the postpartum period. This network consisted of a combination of their partner (if present), friends and family (eg, mother, mother in law and sister).

Two general facilitators and barriers were identified:

1. Costs of postpartum care: different aspects of costs were identified to be a facilitator or barrier to postpartum care utilisation in the three phases. These different aspects were the concept of the out-of-pocket payments, unawareness of the costs and the total amount of the costs, and the payment of these costs by MCOs in some individual cases.
2. Role of the MCA: different aspects of the role of the MCA acted as a facilitator or barrier to postpartum care utilisation in the three phases. These different aspects were the surveillance, the provision of emotional support, the provision of practical support, the connection with the new parents and the perceived appropriateness of the postpartum care by the new parents. These general facilitators and barriers were integrated into the description of the different overarching themes per phase.

Below, the framework regarding the use of postpartum care among vulnerable women is described per phase. The different phases, including the perceived barriers and facilitators for the use of postpartum care and the general facilitators and barriers, are set out. Illustrative quotes are provided per theme in the different phases.

Additional supportive quotes can be found in online supplemental table S1.

Expectations of postpartum care during pregnancy

Women indicated that their expectations regarding the value and utilisation of postpartum care were primarily formed based on information received during pregnancy or during their previous pregnancy and postpartum period (in case of a previous pregnancy). Expectations were furthermore influenced by women's self-efficacy, and their social network.

Information on content of care was provided via leaflets during pregnancy by

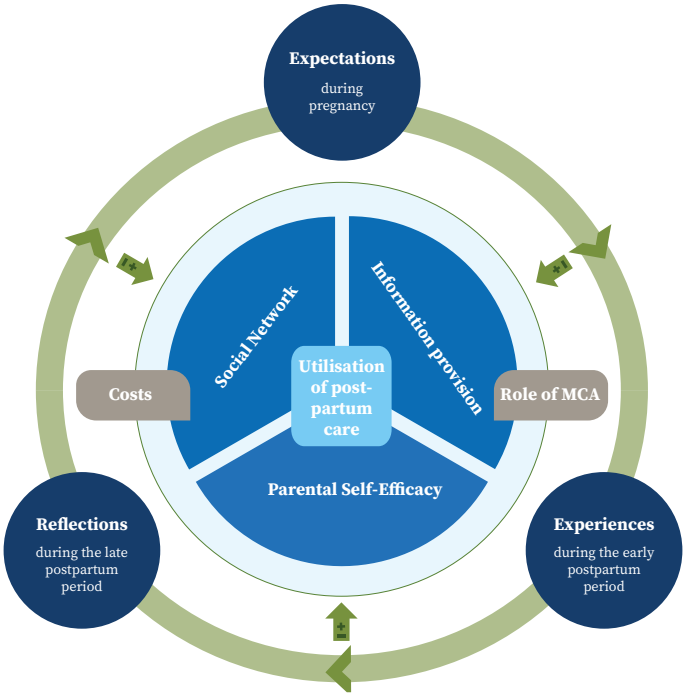

Figure 1.
The process of postpartum care utilisation among vulnerable women during pregnancy and the postpartum period. The three phases (outer circle) and three overarching themes (inner circle) influence postpartum care utilisation. Two general facilitators and barriers in the middle circle were also identified to be facilitators or barriers influencing the three overarching themes and therefore postpartum care utilisation indirectly. MCA, maternity care assistants, skilled nurses that provide the postpartum care at home.

community midwives or gynaecologists. Although this information provision was perceived as essential for the formation of realistic expectations, information provision via leaflets did not fit women's needs. Additional information was provided during the home visit. Women indicated that they appreciated this visit for getting familiar with their MCO, but did not perceive this as adequate information provision on content of care. Pregnant women stated that lack of adequate information negatively influenced their expectations regarding postpartum care and in some cases resulted in misconceptions; the majority of the women thought that postpartum care was mandatory and some thought that MCAs would place them under surveillance regarding their newborn caretaking competences. Some women also stated that they had no clue as to what MCAs would do all day, and how MCAs would support them:

R: "I just want to, what I need help with, tips so to say, but not 8 hours per day or

something... something like that? That is not necessary for me."
I: "And that is because you think that's too much or...?"
R: "Yes, I don't know what they are going to do for eight hours in my house..."
(Respondent #23, pregnant)

Women with perceived low parenting self-efficacy had high expectations of the benefits of postpartum care during pregnancy, which acted as facilitator for intended utilisation. Especially primiparous women stated that they felt very insecure during pregnancy regarding their skills at newborn care tasks, and therefore expected MCAs to help them with caring for their newborn:

"Well, I wanted to have help anyway, and it seemed useful to me as well. I also have to learn a lot about the baby and that [by using postpartum care] is the best way to do it."
(Respondent #8, postpartum)

Also, the anticipation of not being able to care for their newborn themselves due to complications or fatigue, acted as a facilitator to signing up for postpartum care and forming positive expectations. Women with high levels of parenting self-efficacy generally expected to be able to manage the care for their newborn themselves, and wanted MCAs to support them with the household and medical check-ups. Some women with high levels of self-efficacy expected to receive essential and up-to-date information from MCAs, and that this would enhance their self-efficacy even more. Women indicated they wanted to receive all the recommended care if their social network held positive views on it. Some women explained that they were strongly advised by their female friends or relatives to sign up for postpartum care, and followed this advice even though they initially did not want to sign up for postpartum care. Women expected to need less care when they anticipated that their network, including their partner, could help them during the postpartum period:

"But that I immediately was like "Expectations?" Don't think about running my household, because that is just my cup of tea and I have my own people for that, so they [MCAs] don't have to come for that."
(Respondent #14, pregnant)

Women without an extensive social network mostly expected to depend on postpartum care, regardless of having a partner, resulting in a higher intended care utilisation.

Experiences with postpartum care during the early postpartum period

Experiences with postpartum care were primarily gained during the first week postpartum, and were influenced by the perceived quality of care. In contrast to the expectation of being under surveillance of MCAs, nearly all women felt pampered by their MCAs, and felt positively connected with them. Experiences were again influenced by information provision, self-efficacy and social network which, in turn, acted as barriers or facilitators to care utilisation.

Information was mostly provided orally by MCAs during the early postpartum period. Both primiparous and multiparous women perceived this information as important and felt it was adequately tailored to their individual needs. Hence, adequate information provision acted as a facilitator to continued use of postpartum care. Several women were unaware that out-of-pocket-payments were required for using postpartum care, and decided to reduce the hours of care to what they perceived as necessary, after they gained this information. Others valued postpartum care more than the associated costs and were not deterred by the out-of-pocket-payments into account in their decisions regarding utilisation. A few women considered their own medical status as very complex and felt that MCAs were unable to provide them with the information they needed, and consequently lowered their utilisation. Some women with a non-Dutch cultural background indicated that they followed the advice of their MCA while she was present and that they applied more traditional caretaking techniques with their newborns when the MCA left. This did not affect their care utilisation:

> *"We are used to other things, like uhm, we let the baby sleep in prone position so to say, and yes, here they say like "No, [...] it is not allowed", so uhm, you hear that from other people [...] haha. So yes, I will just, yes I just did that what they told me and then I did what we are used to [after the MCA left]."*
> *(Respondent #11, postpartum)*

Experienced low parenting self-efficacy generally positively influenced women's experiences and use of postpartum care. Most women felt insecure during the first days postpartum, and stated they needed all the indicated hours of postpartum care to gain a higher level of self-efficacy. A few women did not like their MCA, but felt too insecure to indicate this to the MCO. Instead of asking for another MCA, they reduced the utilisation of postpartum care. Others stated that they felt secure in caring for their newborn after a few hours of care, and subsequently lowered their postpartum care utilisation because of this increased self-efficacy. All women, including those with high baseline levels of self-efficacy, experienced an increase in self-efficacy due to receiving postpartum care:

"And the baby is still small, you can't hold properly, there is something, you miss something. But they also give you the confidence to do that."
(Respondent #3, postpartum)

Women who received more support from their social network often asked the MCA to focus solely on the care for the newborn and themselves, while their network supported them in running the household. In some cases this led to a reduction of care utilisation. In contrast, absence of support from a social network facilitated the use of postpartum care, as women felt more dependent on their MCAs:

"A sort of, yes, they are your helping hand during such a postpartum period, uhm, but also your support and anchor."
(Respondent #12, postpartum)

Reflections on postpartum care in the late postpartum period

In this phase, experiences were transformed into reflections regarding postpartum care while looking back on the received care. When reflecting on postpartum care after the early postpartum period, the appraisal of MCAs among women appeared to differ greatly. Whereas most women indicated that they saw MCAs as healthcare providers who provide essential care and support, some felt that MCAs were merely a support in running the household. Similar to the previous two phases, reflections were influenced by women's perception of information provision and their perceived self-efficacy, and social network.
Most women missed information during pregnancy on the fact that MCAs also performed medical check-ups, especially since these medical check-ups were highly appreciated. Women felt that the tailored information provided by MCAs postpartum was a huge facilitator for postpartum care utilisation, also for a next postpartum period. Many women did not understand why they needed to pay an out-of-pocket payment for postpartum care at all. However, they generally stressed that they valued the gains of postpartum care over the costs:

R: "Obligatory deductible excess is very common, you know. That will not change. So yes, if you want the baby to stay healthy and yourself as well, I would definitely recommend it. I don't care about the money, I care more about the uhh…"*
I: "The baby? That is important."
R: "The baby."
(Respondent #16, postpartum)
**There is an obligatory deductible excess for healthcare utilisation in the Netherlands for regular care.*

Health care insurance covers costs above this obligatory deductible excess. However, this does not apply to primary care such as care from a general practi-

tioner, midwife or postpartum care. Obligatory deductible excess is not the same as out-of-pocket payments. Out-of-pocket payments only apply to postpartum care and is independent of the obligatory deductible excess.
Women for whom the out-of-pocket payment was compensated by their MCO stated that this did not affect their postpartum care utilisation.
Most women experienced their increased parenting self-efficacy as one of the most important gains of postpartum care. This increased self-efficacy positively influenced their reflections, and as such affected their intended use of postpartum care following a next postpartum period. Women who already experienced high self-efficacy prior to receiving postpartum care, underlined that they still would use postpartum care in future postpartum periods. They believed this care to be important to monitor the health of their newborn and themselves, and this increased their self-efficacy even more:

> *"...How do I do that? In fact you know how to do it, but you want that extra reassurance that she [maternity care assistant] says like "you are doing great, you just have to do it like this, you can do it.", I just really needed that. And see, she is gone and you need to do it by yourself and you just manage, but I was really insecure like "I can't do it the right way, I might hurt him", or whatever. So she really helped with that."*
> *(Respondent #9, postpartum)*

According to the women, the positive connection that most women experienced with their MCAs contributed to this improved self-efficacy. Postpartum women with a low self-efficacy indicated that they, in hindsight, needed more care than they received but did not dare to express this to their MCA.
Several women specified that they regarded MCAs as essential for providing medical care. They indicated that their social network was not equipped to adequately provide this care. Others indicated that having a sufficient social network during their possible next postpartum period would likely decrease their care utilisation, although they stated that their network could never fully replace MCAs.
All women appreciated the provided advice by MCAs regarding caring for their newborns for themselves and their network. Women with a non-Dutch cultural background additionally indicated that MCAs could teach them the newest insights regarding the care for their newborn, as opposed to the traditional way of caring as advised by their mothers and grandmothers:

> *"So I was like... what is really really important to me... uh... in my opinion so to say... in postpartum care is the medical thing for me for example and for the baby as well. Because family is absolutely not capable of doing that [laughs]... you understand?"*
> *(Respondent #4, postpartum)*

DISCUSSION

This qualitative study shows that postpartum care utilisation among vulnerable women is a three-phase process which is mainly influenced by women's perception of the provided information regarding the content of care and actual provided oral information during the provided care, their perceived parenting self-efficacy and perceived support from their social network. During pregnancy, the provided information was perceived as inadequate and posed a major barrier in forming realistic expectations of postpartum care. The information provision during the early postpartum period was found to be essential and this promoted utilisation of postpartum care in a following pregnancy. Low self-efficacy facilitated increased use of postpartum care, which in turn generally improved women's self-efficacy. Women's social network primarily influenced their expectations regarding the added value of postpartum care during pregnancy, and thus influenced actual utilisation during the postpartum period. Furthermore, costs of postpartum care and the role of the MCA indirectly influenced postpartum care utilisation. Overall, vulnerable women recognised the value of postpartum care after experiencing it, and viewed it as essential care for improving their own and their newborns' health.
A strength of this study is that we focused on vulnerable women; a group often under-represented in research.[21–23] Despite the recruitment challenges, it is important to involve vulnerable populations in research to improve care and outcomes for this group, particularly as they have a higher risk of adverse health outcomes.[2,3] Additionally, we showed that it is possible to obtain a theoretical sample of vulnerable women needed to conduct a proper qualitative study. By applying a grounded theory approach, the generation of a conceptual framework grounded in the data was possible. Instead of searching for answers in predefined directions, analyses were largely inductive, allowing meaning to emerge from the data.[24] Theoretical sampling and constant comparisons between the emerging themes and data contributed strongly to the robustness of our results.[19] Validity of our results was further strengthened by using a multidisciplinary research team with backgrounds in different specialisms.
Despite efforts undertaken, we were unable to include women who did not use any postpartum care (ie, less than 5% of the total population), limiting our insights into the considerations of this specific subgroup of women.[13,14] We did interview one woman who gave birth to her second child and did not use postpartum care in the previous postpartum period because she thought it was not useful. Also, we offered interviews in Dutch and English only. We therefore may have missed the opinions of certain ethnic minority women who did not speak these languages.
Our provided conceptual framework regarding postpartum care utilisation is supported by the qualitative systematic review by Walker et al.[25] They determined

necessities for a successful transition to motherhood in the early postpartum period, and identified four themes: connection between women and midwives, identification of women's individual needs, family and cultural influences, and education and support. Our framework builds on this review by focussing on the practical part of the care that is necessary for this transition, and by indicating that this care may be provided by others than midwives. In addition, our theme 'social network' may be an important addition to this review for prevention of serious adverse health outcomes. Cutrona et al provided an mediational model of postpartum depressions, in which social support positively influences parenting self-efficacy, which has a preventive effect on development of a postpartum depression.[26] This indicates that healthcare providers, and MCAs in particular, may recognise the role of the social network and parental self-efficacy even more as important themes in postpartum care utilisation.

Using the terms facilitators and barriers regarding utilisation or further utilisation of postpartum care may suggest that utilisation is the ultimate goal. The terms facilitators and barriers were applied rather strictly in our study; when participants reduced their hours of postpartum care, the contributing factor was defined as a barrier, even when it was of a positive nature. For example, women reduced the amount of hours due to increased self-efficacy, strictly this posed a barrier to further utilisation. However, the contributing factor, that is, increased self-efficacy, may be positive. In practice, optimal circumstances should be created to facilitate informed decision making regarding postpartum care utilisation. Reduced or increased number of hours of postpartum care can be desirable, as long as they fit the needs and requirements of the individual woman and her family.

Women perceived the provided information on content of care during pregnancy as inadequate, even after the home visit. This posed an unexpected major barrier in forming realistic expectations regarding postpartum care and affected (intended) utilisation. Especially the supportive nature of postpartum care was unclear from the information provided. The feeling of surveillance instead of support was found to be a barrier for care utilisation among vulnerable women.[27] Regardless of their social background, women may find it hard to navigate the overwhelming amount of information available.[12,28–30] Health illiteracy may aggravate this experienced lack of adequate information received during pregnancy, and may negatively affect utilisation of postpartum care among vulnerable women.[25,31,32] The highly appreciated, tailored oral information provided by MCAs during the early postpartum period indeed signals the possible influence of health illiteracy.[33,34] Also, the requirement for out-of-pocket payments made some women decide to reduce postpartum care utilisation. This indicates a substantial need for MCOs and healthcare providers to properly inform this vulnerable population about the value of postpartum care already during pregnancy.

The experienced support of MCAs focussing on newborn care competences increased all women's self-efficacy, and as such improved further utilisation of care. In accordance with previous research,[35] we found that multiparous women and women who already experienced high levels of self-efficacy still said to have benefitted from the confirmation and support given by MCAs. Previous studies showed that connections with healthcare providers were often problematic among vulnerable populations.[27,36,37] However, we found that most of our participants had a good connection with their MCAs, possibly contributing to the experienced increased self-efficacy.[38,39] This good connection may be grounded in the nature of this care: easily accessible care at home, leading to continuity of care in a turbulent phase.[29] Nevertheless, some women did not dare to stand up for themselves when postpartum care did not match their needs. This posed an important barrier to utilisation, as these women rather abstained themselves from care than to ask for changes. Emphasising the potential role of postpartum care in increasing women's self-efficacy, and tailored care based on a woman's self-efficacy may be used to improve care utilisation.

Finally, we found that women in absence of a supportive network perceived MCAs as their anchor during the early postpartum period. This may be related to the finding that women in general need companionship, and continuity of care in this period.[29] Also, women with a supportive network highly appreciated the expertise of the MCAs. Providing women and their social network with up-to-date professional knowledge by MCAs might be beneficial for optimising support for women, particularly in the late postpartum period.[34,35] The assessment of a woman's social network and collaboration with this network by MCAs may lead to improved women-centred care and better care utilisation.[11,40,41]

The results of our study indicate that information provision during pregnancy must be improved and tailored to vulnerable populations. This information should highlight the supportive and medical tasks of MCAs, outline the need for out-of-pocket payments and emphasise the potential gains such as improved self-efficacy. For example, this could be done by sending a video to women during pregnancy with an explanation of postpartum care and the gains. Addressing these aspects during pregnancy may lead to increased utilisation of postpartum care, which impacts subsequent healthcare expenditure.[14] Moreover, the provided care should be tailored to a woman's individual needs, with extra attention for women with low self-efficacy. Finally, a woman's social network could be involved in the care for the newborn to maximise support and continuity in support in the late postpartum period. This could be initiated by involving the partner or another relative (eg, mother or aunt) from the home visit onwards and by emphasising his or her importance in the early postpartum period. In the absence of a woman's social network, it is important for MCAs to realise they play an important role in providing support. In countries where there is no extensive postpartum

care, this support can also be provided by community midwives or general practitioners. They may use videos with information provision on how to take care of a newborn, and try to involve persons in the mother's network who can support the mother. Future research among vulnerable women should focus on the role of postpartum care in improving self-efficacy, and on the effects of eliminating out-of-pocket payments on the utilisation of this care.[14] Additionally, this study was performed in a developed country. The issue of underutilisation of postpartum care services in low and middle income countries deserves further exploration in these countries, since women interviewed in this study may have a better support network to overcome problems than others who live in less favoured countries.

CONCLUSION

Our study shows that postpartum care utilisation among vulnerable women is a three-phase process in which information provision, perceived self-efficacy and social network act as either barriers or facilitators to postpartum care utilisation. Individual assessment of these themes and their influence during pregnancy and the whole postpartum period is therefore essential in order to tailor care to vulnerable women's needs and improve utilisation. In general, providing understandable information highlighting the supportive and medical tasks of MCAs, possible gains in improving self-efficacy and involving a woman's social network in postpartum care may add value to care for this population. In addition, by addressing a woman's self-efficacy and social network in the different phases of the process of postpartum care, care utilisation can potentially be improved. The conceptual framework generated in this study may also be used as a basis to optimise care utilisation for vulnerable pregnant and postpartum women outside the Netherlands.

ACKNOWLEDGMENTS

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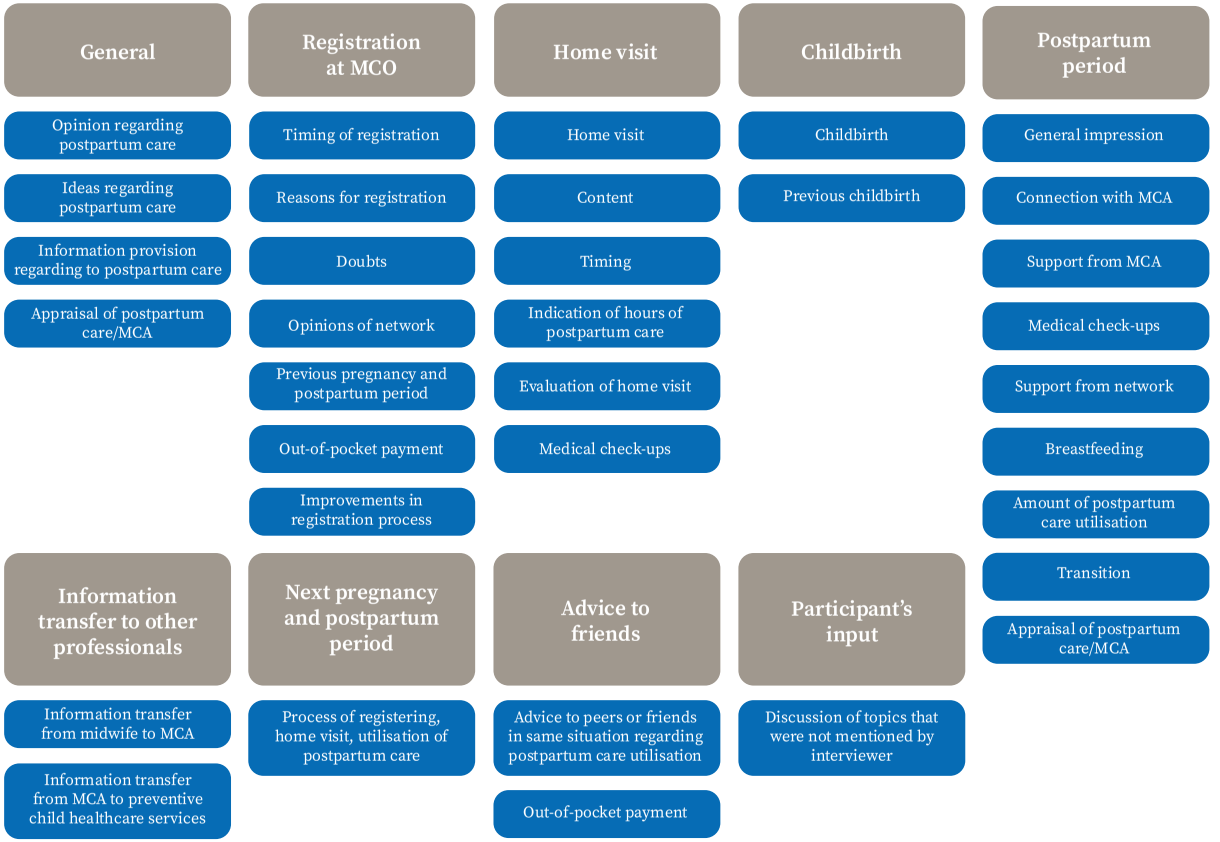

Supporting information Figure S1. Topic List used during the interviews.
MCA: maternity care assistant
MCO: maternity care organisation

Supporting information Table S1. Additional illustrative quotes arranged in phases and themes.

	Expectations	Experiences	Reflections
General quote	"Yes, I know that somebody comes to your home, yes, to help you so to say, but what they are doing exactly and that they are going to teach you everything, wasn't very clear to me. So." Respondent #1 (postpartum)	R: "well, because is often like "yes, if there is no connection, you can always call the organisation for someone else" and I actually don't do that at all, because I have not done that this time. Yes, I find it a bit harsh, and then I think "yes…". I won't do that." I: "So you thought like "then I'd rather not have postpartum care"? R: "Yes, yes" Respondent #15 (postpartum)	R: "And maybe, I don't know, maybe I expected too much from postpartum care, from the maternity care assistant, then you might actually expect her to do the technical stuff, huh. The household part so to say, but also the medical part. Yes, maybe that is too much to ask, but…" I: "Because you did not think she did that enough? Because you say "it is too much to ask?" R: "too much to ask to the maternity care assistant, so to say. That, yes, such a person cannot, of course, err, do everything, at the same time. Yes, it is not without reason that you have eh, healthcare providers and people who support running the household. But yeah, if it sticks to a certain level, that is fine. So it doesn't have to be in detail [the medical check-ups], but…' Respondent #12 (postpartum)
		R: "The maternity care assistant was great. I had a very nice girl. […] so really, yes…" I: "So you liked it, it was just a good…" R: "Yes, it is eh, fortunately I had a maternity care assistant who does not oblige you to do anything. She just let you do your own thing, like hey "See what you can handle, and if you feel tired, just stop. And if you feel OK, then you just go on." But it wasn't a person that forces you to lie on your bed, because that is not who I am at all." Respondent #7 (postpartum)	"yes for me… yes I'm just really satisfied. […][laughs]. Some people may not like that, but for me I'm really fine so far. Yes. And the nurses were just sweet also, and they did their best I think. I'm really satisfied." Respondent #4 (postpartum)
			R: "She [maternity care assistant] [is] just really like me, easy and free and not really going to impose things. Look, I do understand that she needs to help you with things, needs to explain and really need to interpret like "hey, you really have to do it like this, because…." But that are essential tips for your baby and to raise it healthy. But besides that, I really had the best maternity care assistant in the world, really." Respondent #7 (postpartum)

Supporting information Table S1 – Continued. Additional illustrative quotes arranged in phases and themes.

	Expectations	Experiences	Reflections
			"uhm, chaotic, it was very chaotic. Uhmm, when I gave birth, it was in the middle of the night and we had to call them [maternity care organisation] right away, that I had given birth, and the next day at 5 o'clock I still did not have a maternity care assistant… So that was a bit chaotic and at some point I had a maternity care assistant that cared for two families [at the same time], so she could only come for three hours a day, while I should have had 49 hours. And at one point this became 24 hours for eight days, because she had two families." Respondent #10 (postpartum) (The minimum amount of postpartum care that is provided to women is 24 hours, spread out in eight days. This results in three hours of care per day.)
Information provision	"Yes I got a book [leaflet], but I did not read it, no." Respondent #18 (postpartum)	"You just notice that you just forget certain things very quickly [after previous postpartum period]. And then it is very nice to, at least if you have several children so to say, get a refresher course." Respondent #12 (postpartum)	"Because you actually expect that she cares for the baby, because that is wat postpartum care is known for. As you say, they also do medical things and you don't realise that very easily. Measuring temperature, checking your wounds: they all do that too. And that is not really written down [in leaflets] or they don't tell you much about [during the home visit]." Respondent #5 (pregnant)
	"Oh I was like "you have to". […] after the delivery everybody needs to go to a maternity care assistant or to a primary care birth centre or something." Respondent #11 (postpartum) (instead of receiving postpartum care at home, one may choose to receive it (partly) in a primary care birth centre)		"No I think eh… the amount [of the out-of-pocket payment] is not high. And eh, I don't mind that very much. Only yes, I think it is quite absurd that they, that we need to pay for it actually. Because it seems logical to me that you get extra help after your delivery? And if only it is 24 hours so to speak and not the 49 hours: I think that everyone should be able to get postpartum care and that someone can afford the four-euros-something and others just can't." Respondent #10 (postpartum)

Supporting information Table S1 – Continued. Additional illustrative quotes arranged in phases and themes.

	Expectations	Experiences	Reflections
	I: "And what information did you receive about postpartum care during pregnancy?" R: "uhmm, yes quite a lot actually. [During the home visit] That it is really about mother and child, what they can do for you, what they can teach you. [...] they leave the choice to you. Like do you want it, or don't you want it, what do you want, what don't you want... It was enough, yes, they are very clear. [...] they recommend why you better do it. So actually, you get more good advice and it is up to you what you do with it." Respondent #9 (postpartum)		I: "and what did you find most important or the best thing about postpartum care?" R: "first of all, what I'm saying now is really medical, because family cannot do that, sorry. Cleaning the house and other things is up to the woman... I don't know. If my husband cannot take a holiday leave than I just asked a lot of hours of care, and it is still about the money, really, because the more you get the more you have to pay is my opinion." I: "So it is a trade-off?" R: "yes a bit, because we are not sure how much we have to pay. And you know, my husband doesn't earn that much etcetera, so we decided... made an agreement my husband and I... that if he takes a holiday leave, than he will do other things [cleaning the house, cooking]." Respondent #4 (postpartum)
Parenting self-efficacy	I: "And what do think is the most important task of the maternity care assistant?" R: "Well, to meet the wish list of a woman." Respondent #15 (postpartum)	R: '[support with] uhm, really with groceries, and running the household, and also just bathing the baby, because at first I didn't dare to do that because she was really small." Respondent #6 (postpartum)	"Insecurity, and that remains the same, whether you became a mother at the beginning of it [just became a mother], or after four children: it is the same." Respondent #5 (pregnant)
	"No, well I was always like "Guys, give me the minimum amount of postpartum care", purely for the check-ups and stuff like that, I like that, and for all the other things "Go home" you know. I will do my own stuff." Respondent #14 (pregnant)	"It is my second child, but I was just as insecure as with my first." Respondent #12 (postpartum)	R: "Because she also comes from other work [at another family] and then she is going to work for three hours and then maybe she goes to another place [family]..." I: "So maybe you did not dare to ask that [for more postpartum care]?" R: "No I thought than we are going to screw things up or something like that...[laughs]. I thought never mind. But actually I wanted to add two more hours. I still thought that three hours went by too fast..." I: "so actually you would have preferred some more [postpartum care]?" R: "Yes, if only I had done that... but okay too bad." Respondent #4 (postpartum)

Supporting information Table S1 – Continued. Additional illustrative quotes arranged in phases and themes.

Expectations	Experiences	Reflections
"I have, I have the feeling that I will only need help with running the household." Respondent #23 (pregnant)	"And I'm quite scared if…, I'd rather not hold newborns, but yes, your own child will be [put] in your arms… You have to. And uh yes, I'm very clumsy. So I needed it [postpartum care]. And also, this is a boy, I [already] had a girl, so I really was like "Uhm?". Respondent #9 (postpartum)	
"Actually you want to do it yourself, but then I understand them [maternity care assistants] to come to you because yes, they have to care for you, they have to do medical check-ups: I don't know anything about that. So yes… That is why I used it, only for the medical thing and to check if I did anything wrong with the baby." Respondent #16 (postpartum)	"Yes, no correct. No, you really need those hours [of postpartum care]. You just really need that time, and you will take that." Respondent #6 (postpartum)	
"Yes, if you experience your pregnancy as complicated, you take that into account as well a little, you know, it will be stuck in your head a little. And then uhm it makes you doubt yourself, you know, if you are doing it the right way or not." Respondent #16 (postpartum)	"Yes, Yes, I think so. Uhm, it is very important to get again as many tips and tricks as possible of how to deal with a baby and to get that fingerspitzengefühl [instinctive feeling] so to say." Respondent #12 (postpartum)	
"The help with the little one. And the tips, especially for your first [baby]. Yes, there are still, you notice, a lot of things, despite having experienced more children around you, that you just don't know. You get so much information during that first week, that I said halfway through that week like 'Uhm what have you told me already?" haha. Luckily she also writes it down, but…" Respondent #7 (postpartum)		

Supporting information Table S1 – Continued. Additional illustrative quotes arranged in phases and themes.

	Expectations	Experiences	Reflections
	"Yes, well, [help from social network] with cleaning I thought, you know, but not with the baby. I needed to learn a lot and I really wanted to ask somebody [maternity care assistant] that understands it." Respondent #8 (postpartum)		
Social network	"Yes well I don't know. I uhm… My mother told me to do it anyway [utilise postpartum care]. And according to them [health care providers] it would be handy, so…" Respondent #17 (postpartum)	R: "yes she [midwife] completely agreed with me. She also said like "yes you don't have to errr…" I have my daughter [teenager], and I have him [partner] here, you know, I have my neighbours here." I: "Enough hands to help you?" R: "Yes, enough hands, you know, so I thought… and my parents and my sisters. So yes. In principle, I have a large network and that is why I am, I also said like "yes…" you know, to use so many hours of postpartum care is to bite off more than you can chew. That wasn't really an option, for me." Respondent #16 (postpartum)	R: yeah it is [postpartum care] really something essential in my… opinion. Because here in the Netherlands [it is] multicultural you know, you see many people without a family. For example my situation… And even if she has family, there are many things that are culture specific, and that goes wrong. Incorrect upbringing of the baby or something. That is why I think it is really important that every mother knows what is the right way and also to let her rest enough." I: "yes, so what you actually are saying is very important, that culture, that sometimes it is not a regular thing, to have postpartum care." R: "We [refers to own non-Dutch culture] really do weird things and that harms the baby and sometimes mother." I: "Yes, so would you actually recommend everyone to use postpartum care?" R: "Yes, definitely." Respondent #3 (postpartum) R: "I also expressed like "Guys, well, fine, the maternity care assistant visits me for the check-ups" […] "Guys, can you do things better with a newborn? Eh, is the temperature correct, and the defaecation, is everything as it should be?" Respondent #14 (pregnant)

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Chapter 3

Identifying the needs for a web-based postpartum platform among parents of newborns and health care professionals: qualitative focus group study

Lyzette T Laureij
Leonieke J Breunis
Regine P M Steegers-Theunissen
Ageeth N Rosman
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ABSTRACT

Background: During the turbulent postpartum period, there is an urgent need by parents for support and information regarding the care for their infant. In the Netherlands, professional support is provided during the first 8 days postpartum and for a maximum of 8 hours a day. This care is delivered by maternity care assistants (MCAs). Despite the availability of this extensive care, a majority of women prefer to make use of a lesser amount of postpartum care. After this period, access to care is less obvious. Where parents are automatically offered care in the first 8 days after birth, they must request care in the period thereafter. To compensate for a possible gap in information transfer, electronic health (eHealth) can be a valuable, easily accessible addition to regular care.

Objective: We explored the needs and preferred content by new parents and health care professionals of a web-based platform dedicated to the postpartum period and identified barriers and facilitators for using such a platform.

Methods: We conducted 3 semistructured focus groups among (1) parents of newborns, (2) MCAs, and (3) clinicians and administrators in maternity care. A topic list based on a framework designed for innovation processes was used. Thematic content analysis was applied.

Results: In the focus group for parents, 5 mothers and 1 male partner participated. A total of 6 MCAs participated in the second focus group. A total of 5 clinicians and 2 administrators — a member of a stakeholder party and a manager of a maternity care organization — participated in the third focus group. All user groups underlined that a platform focusing on the postpartum period was missing in current care, especially by parents experiencing a gap following the intensive care ending after the first week of childbirth. Parents indicated that they would perceive a postpartum platform as a proper source of reliable information on topics regarding breastfeeding, growth, and developmental milestones, but also as a tool to support them in seeking care with appropriate professionals. They also emphasized the need to receive personalized information and the opportunity to ask questions via the platform. MCAs acknowledged added value of providing additional information on topics that they address during the early postpartum period. MCAs as well as clinicians and administrators would guide parents to such a platform for additional support. All user groups experienced disadvantages of using an authentication procedure and filling out extra questionnaires to receive tailored information.

Conclusions: Our research shows that parents of newborns, MCAs, and clinicians and administrators foresee the additional value of a web-based postpartum platform for at least the whole postpartum period. The platform should be easily accessible and personalized. Content on the platform should contain information

regarding breastfeeding, growth, and developmental milestones. A chat function with professionals could be considered as an option.

INTRODUCTION

Pregnancy, delivery, and taking care of the infant during the postpartum period are large life events. In many countries, the postpartum period (ie, the first 42 days after childbirth) is a largely underestimated period of care for parents.[1,2] It is known that they are in enormous need for information, especially regarding breastfeeding, sleeping patterns, and physical recovery after childbirth.[3] To support maternal and infant health and to prevent morbidity and mortality at the earliest moment during the life course, it is essential that this information is available and accessible.[3-5]

In the Netherlands, postpartum care in the first days after birth is provided by trained professionals, so-called maternity care assistants (MCAs), supervised by community midwives (see Textbox 1 for more information). An MCA provides care for an average of 8 consecutive days, 3-8 hours a day, at the home of the parents of the newborn. All women are offered this extensive postpartum care. However, the majority of women choose to receive fewer hours or days of care than recommended.[6-8]

After these first 8 days, care is less extensive and less regularly scheduled at well-baby clinics for the newborn, which are free of charge and are organized by preventive child health care (PCHC) services. The mother has only one regular postpartum checkup with the midwife at 6 weeks postpartum. This less-extensive care requires women to actively ask for support and guidance. Electronic health (eHealth), for example, a web-based platform, has the potential to support continuity of care for both parents and professionals. It is already widely used in supporting disease management, promoting healthy lifestyles, prevention, and making care more effective.[9,10] There are more eHealth tools focusing on pregnancy than in any other medical field.[11,12] Nevertheless, there is a lack of any eHealth program focusing on the postpartum period. This is a missed opportunity, because it is known that women are willing to use eHealth applications for reliable information during this new phase in life.[13,14]

In countries other than the Netherlands, postpartum care is less extensive. However, independently taking care of an infant at home after early discharge from a maternity ward, without the help of a professional, is experienced as very difficult and stressful.[15-17] Parents of newborns also need compassion and companionship, as loneliness and psychological problems are main issues in the postpartum period.[18] In addition, there is a need for continuity of professional care during

transition of the prenatal to postpartum period.[18,22] eHealth, in its broadest sense, can be a useful additional technique to provide tools for support in this period for parents.[13,23-25] Additionally, health care professionals recognize problems with handover of information in this period, leading to suboptimal care.[26]

Textbox 1. Maternity care in the Netherlands

Care During Pregnancy

In the Netherlands, maternity care is a complex care system. Pregnant women are allocated to three strata of care: primary, secondary, or tertiary care. Allocation is based on division of low-, medium-, or high-risk pregnancy during the first prenatal visit. Primary care is provided by the community midwife to women who have a low-risk pregnancy. Women may give birth at home or at a primary care birth center, supervised by the community midwife.

Secondary care during pregnancy and childbirth takes place at general hospitals by gynecologists or clinical midwives. Women with high-risk pregnancies (eg, severe preeclampsia prior to 32 weeks of gestation) are referred to tertiary care, provided by 12 perinatal centers in the Netherlands. During the third trimester, maternity care assistants (MCAs) visit every woman at home for an assessment of the recommended amount of postpartum care. Postpartum care is provided by MCAs working at maternity care organizations. These are independent enterprises.

Care During the Postpartum Period

Regardless of the strata of care, women are offered postpartum care by MCAs. This care is supervised by the community midwife. Most women choose to receive postpartum care at home, but this is also possible at primary care birth centers. If there are maternal or neonatal complications, part of this postpartum care can take place at the maternity ward (eg, 48 hours of stay at the maternity ward is recommended after a cesarean section). Care by MCAs is provided during the first 8-10 succeeding days. This care includes coping with the new situation and increasing parents' confidence in the care for the infant.[6] They also promote a healthy lifestyle, such as preventing use or reuse of tobacco, and educate parents in the prevention of child abuse.[4] Most of the information and advice is transmitted orally, and information leaflets are used for further support.[6]

The mother herself decides the amount of postpartum care, up to a maximum recommended by the MCA. The minimum amount is 24 hours and the recommended amount in a standard situation is 49 hours (eg, when a mother

breastfeeds her baby and no problems occur during childbirth or the early postpartum period). During the first few days, postpartum care covers 6-8 hours a day. During the following days, this number of hours is reduced. On the last day, the care for the newborn is transferred to well-baby clinics of preventive child health care (PCHC) services. The woman remains under the supervision of the community midwife until 6 weeks postpartum.
Care by midwives, both community and clinical and during both pregnancy and the postpartum period; gynecologists; and PCHC services is covered by a compulsory health insurance. Postpartum care by the MCAs is partly covered by health insurance and women are required to pay an out-of-pocket amount of €4.40 ($4.77 US) per hour, as of 2019, of receipt of this form of postpartum care.

It is unclear whether women who already receive extensive postpartum care would also appreciate a web-based postpartum platform and what the content should be. Also, health care professionals, especially in postpartum care, are not familiar with using eHealth to support their work. Therefore, the aim of this study was to explore the needs and preferred content by new parents and health care professionals of a web-based platform dedicated to the postpartum period and to identify barriers and facilitators for using such a platform.

METHODS

Overview

Textbox 2 details the concept of the proposed web-based postpartum platform to support continuity of care for both parents and health care professionals.

Textbox 2. Concept of the web-based postpartum platform

Background

Women tend to have a need for easily accessible information and support during the preconception period and pregnancy. Electronic health (eHealth) has proven its potential to support women and their partners, such as in achieving a healthier lifestyle and gaining information about pregnancy and healthy lifestyle.[10,25] A web-based platform focused on the postpartum

period could be an additional support for women and their partners during the postpartum period. When this web-based platform is also available for obstetric professionals and maternity care assistants (MCAs), women who have a low postpartum care uptake may be reached more easily. A web-based platform has some advantages above other forms of eHealth, such as lower development costs, less instability caused by upgrades, and easier access for all involved health care professionals.

Aim of the Web-Based Platform

The web-based platform must be an addition to regular postpartum care by MCAs for parents of the newborn. The platform focuses on information provision and prevention.

Target Group

The platform should target parents of newborns and health care professionals, including maternity care professionals, MCAs, and preventive child health care (PCHC) service professionals. Parents will look for reliable information on the web-based platform and professionals will provide this reliable information.

Study Participants

Overview

Two types of users of this web-based postpartum platform were identified: (1) parents of newborns and (2) health care professionals. Parents with a child younger than 12 months were asked to participate as a target group of future users of the platform (ie, parents of newborns), hereafter referred to as parents. Several health care professionals are involved in the care during pregnancy, childbirth, and the postpartum period. We decided to split the health care professionals into two groups: MCAs and all other professionals, hereafter referred to as clinicians. MCAs were approached to participate as potential ambassadors but also as future users of the platform during their working routine. MCAs fulfil a different role in the care for new parents than the other maternity care professionals. Their role is of a more caring nature, as they are specialized nurses. Midwives, obstetricians, and PCHC physicians have less-intensive contact with parents of newborns and are more at a distance. Additionally, MCAs work under supervision of community midwives and may feel that they cannot express themselves freely in the presence of the other maternity care professionals.

Finally, clinicians such as gynecologists, midwives, and PCHC physicians were invited to participate because of their potential contribution to the content of the platform. Also, administrators involved in perinatal care, such as managers of maternity care organizations and the Dutch Patient Federation, were invited because of their potential role in the dissemination of the platform. This group will be referred to as clinicians and administrators.

To increase objectivity and prevent barriers in expressing subjective opinions and experiences, we arranged separate focus groups. All participants were recruited by email and telephone via existing networks from other studies in the Erasmus MC - Sophia Children's Hospital, such as the Rotterdam periconception cohort (Predict Study) and the Healthy Pregnancy 4 All-2 (HP4All-2) study.[27,28] We aimed to recruit 6-10 participants per focus group. In advance of the meeting, all participants received information regarding participation in a focus group, web links to existing pregnancy-related platforms, and statements on the subject.

Parents

Inclusion criteria for parents were (1) having a child born in the past 12 months before the focus group meeting took place, (2) being 18 years of age or older, and (3) having a sufficient understanding of the Dutch language. After women gave consent to participate, a member of the research team called them to ask whether their partner also wanted to join the focus group.

Maternity Care Assistants

MCAs were recruited via managers of maternity care organizations. They met inclusion criteria if they (1) had a sufficient understanding of the Dutch language and (2) worked as an MCA.

Clinicians and Administrators

Clinicians were eligible to participate if they worked in PCHC services or obstetric care. Also, managers of maternity care organizations and the Dutch Patient Federation were asked to participate.

Data Collection

Before the start of the focus groups, each participant was asked to fill out a questionnaire on baseline characteristics. An experienced and trained researcher (ANR) guided all three focus groups and two research assistants took notes. Each focus group was audiotaped and started with a short introduction explaining the aim of the study. Participants were reassured of confidentiality and encouraged to speak freely.

The focus groups were semistructured and based on a topic list grounded in a framework developed by Fleuren et al.[29] This theoretical framework was

developed to explain determinants of innovation within health care and recognizes four main stages of innovation processes: dissemination, adoption, implementation, and continuation. In this study, we especially focused on the first two stages: dissemination and adoption. Transition from one stage to the next can be affected positively or negatively by four different factors: the end user, the innovation itself, the sociopolitical environment, and characteristics of the organization. In order to obtain a complete overview of potential barriers and facilitators, these factors were the main themes of the topic list. Subthemes were based on literature research[12,23,30-32] and divided among the corresponding main themes.
The first part of the focus groups entailed a discussion about the needs for a postpartum platform and wishes for the content of the platform (ie, general information, specific topics, and sources). Secondly, the look and feel of the platform was discussed by showing different existing platforms regarding pregnancy or older children (see Multimedia Appendix 1 for the topic list).

Data Analysis

All transcripts were transcribed verbatim and were anonymized. The verbatim transcriptions were checked with the original audiotapes for accuracy by LTL and returned for member checking to the participants. We used the qualitative software program NVivo 11 (QSR International) to support data analysis. We intended to analyze the results according to the theoretical framework based on the model of Fleuren et al.[29] However, this framework appeared to be inefficient due to too much overlap in coding. Thematic analysis was then applied. The three different transcripts were independently coded by two researchers (LTL and LJB) to create a set of preliminary codes. These preliminary codes were discussed with a third researcher (ANR) and consensus was reached on the codes per transcript. Thereafter, these codes were arranged into different main themes and subthemes for each of the transcripts. The themes, subthemes, and codes were compared between the three groups to check for similarities and differences. Themes and subthemes corresponded between the different groups, although there were differences in preferences. Therefore, the codes in the main themes and subthemes were divided into facilitators and barriers by LTL and LJB. Finally, consensus was reached on the subdivision by the three researchers (LTL, LJB, and ANR).

Ethical Considerations

The Medical Ethics Committee of Erasmus MC declared that the rules laid down in the Medical Research Involving Human Subjects Act, also known as its Dutch abbreviation WMO, do not apply to the study protocol (NL/s/MEC-2017-1134). All parents provided written informed consent; the need for written informed consent from the MCAs as well as clinicians and administrators was waived.

RESULTS

Participants

A total of 5 mothers and 1 male partner joined the focus group for parents (see Table 1). All mothers received postpartum care for at least 24 hours.
In the MCA focus group, 6 MCAs participated (see Table 2). They worked at different maternity care organizations and their work experience varied from 3 to 26 years.
The third focus group (ie, clinicians and administrators) consisted of 5 clinicians working in perinatal care, 1 manager of a maternity care organization, and 1 employee of the patient federation (see Table 3).

Emerging Themes

We identified three different main themes regarding the need and content of a postpartum period platform: (1) information on platform, (2) additional facilities, and (3) accessibility. These three main themes were divided into various subthemes, and facilitators and barriers within these subthemes were identified (see Table 4). The main themes and various subthemes are described in detail in the Results section.

Information on Platform

General

All user groups indicated that a platform dedicated to the postpartum period should be an all-around platform with a wide range of information, dedicated to and classified by period of pregnancy, childbirth, and the postpartum period. All parents ensured that there is a need for general information brought to them passively (eg, not in periodic emails). MCAs stated that the platform would be a good support for parents during the postpartum period. The involvement of different professionals in the whole postpartum period, such as the community midwife, MCA, general practitioner, and PCHC service, leads to a feeling of discontinuity of care among parents, according to all user groups. Parents added to this statement that they often heard different advice from different maternity professionals and PCHC services.
Both parents and MCAs acknowledged the added value of a platform that provided the same information as MCAs, offering parents a possibility to reread orally given information.
Parents also expressed the need for a platform that collected all existing reliable information of other websites. Clinicians and administrators agreed on this. All user groups stressed the existence of several platforms about pregnancy, focused

Table 1. Characteristics of participants: parents of newborns

Sex	Age (years)	Marital status	Education level	Ethnicity	Parity	Age of youngest child (months)	Complicated pregnancy or childbirth	Place of most recent delivery	Amount of postpartum care
Female	32	Married	High	Caucasian	1	7	No	General hospital	Recommended amount
Female	27	Married	High	Caucasian	1	3	Yes	General hospital	Less than recommended amount
Male	26	Married	High	Caucasian	N/A*	7	N/A	N/A	N/A
Female	34	Together, but living apart	Moderate	Caucasian	2	9	No	General hospital	Less than recommended amount
Female	33	Married	High	Caucasian	1	8	No	General hospital	Recommended amount
Female	31	Cohabiting	High	Non-Caucasian	1	9	Yes	General hospital	Recommended amount

*N/A: not applicable

Table 2. Characteristics of participants: maternity care assistants (MCAs)

Sex	Age (years)	Ethnicity	Work experience (years)
Female	48	Caucasian	26
Female	54	Caucasian	8
Female	35	Caucasian	3
Female	53	Non-Caucasian	14
Female	50	Caucasian	3
Female	31	Caucasian	6

Table 3. Characteristics of participants: clinicians and administrators

Sex	Age (years)	Ethnicity	Profession	Work experience (years)
Female	24	Caucasian	Manager at maternity care organization	6
Female	38	Caucasian	Community midwife	15
Female	46	Caucasian	Gynecologist	6
Female	40	Caucasian	Clinical midwife	17
Female	65	Caucasian	Preventive child health care physician	40
Female	32	Caucasian	Policy officer at Dutch Patient Federation	3
Female	37	Caucasian	Community midwife	15

Table 4. Main themes, subthemes, facilitators, and barriers

Main themes and subthemes	Facilitators	Barriers
Information on platform		
General	Need for a postpartum platform[a,b,c] Providing general information[a,b,c] Categorized by period[a,b,c] Uniformity among information given by health care providers[a,b] Statistics on outcomes[a]	For general population[a,b,c] Superficial information[a,b] Registration or extra questions[a,b]
Care guidance	Advice on when to contact professional[a,b,c] Care guidance for domestic abuse[b]	N/A[d]
Information topics	Psychosocial support, sleeping, crying, breastfeeding and bottle feeding, food, birth control and fertility postpartum, and older children[a,b,c] Healthy food and diet-specific information[a,b,c] Prevention[a,b,c]	No moderator[a] Recipes[a,b]
Sources	Reliable sources[a,b,c] Visibility of the sources[a,b]	Funded by industry[c]
Additional facilities		
Communication	Chat function and consultation of professional[a,c]	Fixed amount of push messages[a,b]
Findability of information on the platform	Frequently asked questions on general topics[a] Search option[a,c]	N/A
Accessibility		
Language use	N/A	Complicated language[a,b,c] Mandatory tone[c]
Look and feel	Images and footage[b,c]	Too much text[c] Formal layout[c] Shabby layout[a,b,c]
User group	Vulnerable population[b,c,e]	N/A
Findability and guidance	Easily findable[a] Guidance to platform by obstetric professionals[a,b,c]	Unreliable forums are easy to find[a] Maternity care assistants (MCAs) not trained in electronic health (eHealth)[c]
Timing	Preconception to 6 months postpartum[a,b,c] Filling gap between MCA and preventive child health care (PCHC) service[a,b]	Starting during pregnancy or postpartum period[a]
Authentication	Access without authentication[a,c] Anonymous[a,b,c]	Obligation to create an account and authentication[a,b,c]
Costs	N/A	Paywall[a,b,c]
Device	App[a,b,c]	Email[a,b,c]

[a] Facilitators and barriers applicable to parents.
[b] Facilitators and barriers applicable to maternity care assistants (MCAs).
[c] Facilitators and barriers applicable to clinicians and administrators.
[d] N/A: not applicable.
[e] Vulnerable populations include underserved populations with multifactorial problems, including health illiteracy.

on information for a general population, and that they missed personalized information; for example, specific information on how to address certain problems with the infant (eg, sleeping problems) or psychological problems as a new mother. Filling out extra questions in order to receive personalized information was, however, perceived as bothersome. This was supported by MCAs. In contrast, all groups indicated that filling out extra questions on diet and receiving personalized advice to improve their diet would be desirable. Parents and MCAs feared that generalized information could lead to anxiety among parents if their infant did not reach a developmental milestone. A solution for this was brought up by parents: providing statistics on the incidence of certain preconditions or milestones could be helpful.

> *"Err what I... for example, the statistics say 10 percent of [postpartum] women gets a postpartum depression. Well, if you hear that then you think, "All right, it's not that unlikely that I don't feel well occasionally"."*
> *[Parent focus group, female]*

Care Guidance

All groups experienced barriers among parents to contact the appropriate professional when problems occurred. Clear information on the platform on when to contact which professional was suggested. One of the aspects MCAs are responsible for is sharing specified information on topics regarding domestic abuse and violence. MCAs often share their private telephone numbers—although officially not allowed—with women suspected of being a victim of domestic violence. MCAs thought that providing lists of institutions and telephone numbers in different languages on the platform might be helpful and safer for themselves.

Also, MCAs felt that sometimes they had to provide information on prevention (eg, shaken baby syndrome and postpartum depression) too early, and if they could refer to the platform, new parents could read the information again and use the information when needed.

> *"And it also applies to me personally, that if I would search for something [on the web-based platform] and the advice on the platform would be "consult a health care professional," then I would be more encouraged to eventually call [the professional]."*
> *[Parent focus group, male]*

Information Topics

Parents stated that a platform dedicated to the postpartum period should contain specific information on several main topics regarding the mother and the infant.

They felt that information on psychosocial support, physical recovery, and birth control was important. Regarding the infant, sleeping patterns, crying, and breastfeeding or artificial milk were key topics.
Clinicians and administrators mainly recognized the physical recovery as an important topic, while MCAs named breastfeeding. All user groups also suggested that the platform should contain specific information on healthy food for both mother and infant. Extra information on diet-specific information (eg, vegetarian lifestyle) was desired. Providing healthy recipes was perceived as a barrier by parents and MCAs, because this was found to be culture specific. Parents suggested that they would prefer specific information on healthy food for their infant, such as which vegetables should be introduced first. All user groups stated that coaching by periodic emails containing messages, questions, tips, and facts on a healthy lifestyle and maintaining a healthy lifestyle may be less well-placed during the postpartum period.
Both clinicians and administrators as well as parents emphasized the added value of the possibility to share experiences with other new parents. Parents commented that posting about experiences online often leads to negative comments by other parents. They thought it would scare people off if the experiences and replies were not moderated by a professional.

Sources

The information on a platform must be reliable and must be composed by decent sources, such as professionals from a hospital or professional organizations. These sources should be visible on the platform to increase the sense of reliability. This was stated by clinicians and administrators, as well as by MCAs. Parents confirmed this, and also emphasized that commercial sources reduced the perceived reliability of the platform.

> *"No, those websites where you can see "this text is revised by a certain lung specialist so-and-so, from such-and-such hospital." Then I acknowledge that written text more than Parents From Now [a commercial magazine with a website, focused on young parents: Ouders van Nu, in Dutch], which is sponsored by Zwitsal [Dutch baby products brand]..."*
> *[Parent focus group, female]*

Additional Facilities

Communication

Provision of information via the platform was also discussed. MCAs and parents mentioned the possibility of push messages. Parents felt that push messages regarding healthy lifestyle were too demanding and too paternalistic. They

suggested the possibility to adjust the frequency of messages. Clinicians and administrators added that push messages following a parent's question on the platform would be more convenient, and MCAs stated that messages should have a positive tone.
Both parents as well as clinicians and administrators advised to provide a chat function with a professional on the platform that would be focused on acute problems. This could be used to reassure parents regarding topics such as crying, but also to guide parents to the right professional. The clinicians and administrators remarked that the responder needed to be a trained professional. They suggested 24-hour coverage, as they experienced parents calling them during the night with problems, while parents preferred a chat function during the daytime until early in the evening.

Findability of Information on the Platform

MCAs suggested reserving a part of the platform for frequently asked questions (FAQ). Parents proposed that the questions asked most frequently during a chat conversation could be collected and added to a FAQ topic on the platform.
In order to increase the findability of information on the platform, the platform should have a search option. This was experienced as essential by parents as well as clinicians and administrators, so that the platform becomes more personalized.

> *"Because at the moment you have a chat function [on the web-based portal], you will notice which questions are asked more. And then a commonly asked subject, for example, I would really like to have that [collected] in a question-and-answer database. So, accordingly, one can search for questions or complaints."*
> *[Parent focus group, male]*

Accessibility

User Group and Language Use

All user groups agreed on the use of accessible language. Clinicians and administrators perceived the use of patronizing language as a potential barrier for parents. All user groups underlined that the use of scientific words scared off potential users. MCAs as well as clinicians and administrators stated that a platform was particularly desirable for a vulnerable population with low health literacy. They agreed that the language had to be adjusted to that population accordingly, even though clinicians and administrators doubted whether this vulnerable population could be reached by a platform, as illustrated in the following quotes.

> *"I think [use of] language is also very important." [Respondent #1, clinician and administrator focus group]*

"Yes, just basic language." [Respondent #2]
"Yes, that you will not be patronized." [Respondent #1]
"Yes, [language level] B1, everything as much as possible in B1, yes. And explain difficult words by, for example, clicking on it. A lot of images." [Respondent #3]

Look and Feel of the Platform

The look and feel of the platform was found to be very important by all user groups. This influenced the degree of attractiveness for the users. Clinicians and administrators as well as parents underlined the importance of a neat layout. Shabby look and feel as well as a too-formal layout were considered to be barriers for parents to visit the platform. Clinicians and administrators, especially, emphasized the use of images and footage instead of large amounts of text, in order to reach parents with lower health literacy skills.

Findability and Guidance to the Platform

In order to reach different populations, parents underlined that the platform must be easily found on online search engines. They said that unreliable forums pop up more often in search engines, and this might result in fewer people finding the platform.
Parents also indicated that if their obstetric professionals would advise them to visit the platform, that would increase the findability and value of the platform. They missed the guidance to additional information such as eHealth during regular care, especially when they were transferred multiple times between the strata in maternity care.
Clinicians and administrators as well as MCAs also stated that guiding parents to an approved platform would be better than letting parents find information on the internet themselves. Also, MCAs perceived that some of their colleagues were not able to work with a platform.

"If my doctor would have said or something that I should do it [visiting the web-based platform], then I think I would have... if you get the advice to do it, then I would make the effort to do so."
[Parent focus group, female]

Timing

Parents indicated that they were more likely to change their lifestyle prior to pregnancy. They stated that they would more often use the platform for obtaining information during their pregnancy and postpartum period if they already used it before pregnancy. They also felt that the platform should provide information until 6 months after childbirth.
MCAs as well as clinicians and administrators saw the regular checkups during

pregnancy as an important moment to refer to such a platform. MCAs underlined that parents need more guidance, particularly in the gap between the first week postpartum after the MCA has left and the start of more intensive guidance by the PCHC service.

> *"And I notice that the gap, so to say, from the end of the postpartum care by MCAs until [the start of] the PCHC services, those four weeks, that is actually too long." [Respondent #1, MCA focus group]*
> *"Yes." [Several other respondents]*

Authentication

A perceived barrier among all user groups regarding the accessibility of the platform was the obligation to create an account and log on (ie, authentication). The possibility to ask questions anonymously on the platform was preferred by all user groups. MCAs as well as clinicians and administrators experienced problems with other platforms when they had to create an account and thought that would be a problem for parents also.

> *"The moment I have to log on and create an account with a password, it puts me off."*
> *[Parent focus group, female]*

Costs

The same barrier was perceived regarding paying for using the platform. Parents said that a free platform would be preferred, but if it was really useful, they would consider paying a small amount of money to gain access. Both clinicians and administrators as well as MCAs feared a paywall; they thought that, in particular, the population they wanted to reach with the platform—the vulnerable population—would not be reached if they had to pay.

> *"Look, I work with very different families [during the first week postpartum], I work with families that, so to say, can't even buy a half bread, and with well-off families. Yes, you know, the communication lines [with health care professionals] are shorter, especially compared to those who have money problems." [Respondent #1, MCA focus group]*
> *"Yes, and especially for those people—" [Respondent #2]*
> *"—you need... you need this [web-based postpartum platform]." [Respondent #1]*
> *"You really need this." [Respondent #3]*

Device

Finally, it was discussed in all three focus groups that the platform should be mo-

bile-phone friendly. Parents said that during breastfeeding they often check their mobile phones and that this would be a great moment to search for information. MCAs as well as clinicians and administrators pointed out that even among the poor families, almost everybody has a mobile phone with internet access and that sending messages to their phones would be more convenient than emailing.

DISCUSSION

Principal Findings

In order to develop an eHealth platform to be used by new parents but also by maternity care professionals, we aimed to explore the need for and content of a web-based platform to be used during the postpartum period. Our research showed that there is a need for such a platform, preferably until 6 months after childbirth in addition to regular postpartum care. The platform and the information on the platform should be easy to find. Also, platform developers should pay special attention to the look and feel of a platform in order to increase the usability. Topics on the platform should focus on general information about pregnancy, childbirth, and the postpartum period, but also on more personalized information. A difficulty with this is that parents emphasized the need for personalized information, but they also have a problem with authentication and filling in additional questions about their personal situation; therefore, personalization of information was limited.

Strengths and Limitations

One of the strengths of this study was the safe environment created by arranging three separate focus groups guided by an experienced moderator. Additionally, all participants were given the opportunity to express their opinions and experiences equally. Another strength was the proper qualitative health method that was used for the focus groups and analysis of the data. Furthermore, by using a framework approach, a clear topic list was used to guide the discussions in which all facets of innovation were covered. The transcripts were independently coded by two researchers, resulting in a high level of intercoder agreement.

In addition, all potential user groups of a postpartum period platform were represented. By including not only parents, MCAs, and midwives but also PCHC professionals and administrators, we had the opportunity to consider the need for a postpartum platform and the content from all perspectives. This contributed strongly to the usability and robustness of our results.

In terms of limitations, there is a possible selection bias. The participants in

the parent focus group were generally of Caucasian origin and highly educated. Despite intensive attempts, only one partner, who was male, participated. This may influence the external validity of the results. On the other hand, the MCAs added rich descriptions of their experiences with clients with low socioeconomic status that were in line with the opinions expressed by the parents. Therefore, the overall influence of selection bias on the results may be limited. Another limitation of this study is that some topics were only briefly discussed due to time limitations and, therefore, depth is lacking on some topics. However, by using this approach we were able to cover a wide range of topics. This enabled us to investigate the preconditions for such a platform from a broad perspective.

Comparison With Prior Work

All user groups stated that there is a need for a platform dedicated to the postpartum period because continuity of care is missed and parents hear different advice from different professionals. Problems with handover of information and care among professionals in maternity care has gained more awareness, but was not discussed in our focus groups.[26] The feeling of a lack of continuity of care and receiving conflicting advice among parents is also supported by Baas et al.[33]

Furthermore, it is well known that women experience stress, loneliness, insecurity, and feelings of isolation after childbirth.[1,31] eHealth could provide a partial solution to this problem.[13,18,23,34] However, parents in our focus group felt that eHealth is more important for access to fast and reliable information than to solve feelings of loneliness. A possible explanation can be the presence of the MCA during the postpartum period. Additionally, parents would like to use a platform dedicated to the postpartum period up to several months after childbirth.

The needs for the content of the platform were in line with the findings of Slomian et al.[23] General topics, such as information regarding breastfeeding, physical recovery after childbirth, postpartum depression, among others, were mentioned.[23] Accordingly, the underlying need for reassurance and empowerment was also mentioned and this is recognized among other postpartum women around the world.[2] All user groups acknowledged the added value of care guidance to the appropriate professional and it is known that eHealth can contribute to this process.[9] Push messages were experienced as essential in order to receive important information but also as irritating by parents if the content does not match topics that are important to them and could lead to extra stress. This equilibrium has been recognized in previous research.[35,36] In addition to Slomian et al, we showed that even women who receive extensive postpartum care prefer the use of a platform during the postpartum period.[23,34]

Parents find it stressful if they cannot contact a professional directly.[36] A chat function is required and this may reduce the stress. This chat function does not require 24-hour coverage according to the parents, in contrast to the findings of

Danbjørg.[36] The intensive presence of an MCA during the first week postpartum in the Netherlands may be an explanation for this difference.
In general, the knowledge on the importance of a healthy lifestyle before conception and during pregnancy for both mother and infant is increasing.[37-39] eHealth has the potential to support women to achieve a healthy lifestyle during the preconception period and pregnancy.[12,40] However, parents in our focus group study rejected the idea of achieving a healthy lifestyle with the use of eHealth specifically during the postpartum period and would rather see a platform with information about factors other than lifestyle, such as physical recovery and sleeping patterns of an infant. A combination of both might strengthen the platform.
To ensure the usage of the platform, maternity care professionals should guide women and their partners toward this platform, especially vulnerable women and their partners. Commercial companies already use online websites to inform pregnant and postpartum women about their products and are very experienced with this concept. Collaboration with these commercial companies may increase the knowledge on proper ways of attracting parents to the platform.
Future research should focus on cost-effectiveness and improvement of quality of care of such a platform, since it is an addition to regular postpartum care. Also, the needs and accessibility of a postpartum platform for vulnerable parents or parents with low health literacy should be taken into account in further research. For example, separate interviews with these parents could be undertaken, especially to adapt the content of the platform to their needs and preferences. A randomized controlled trial could be undertaken, targeted to a vulnerable population, in order to investigate the relationship between reliable information via a platform and maternal empowerment.

CONCLUSIONS

Parents and involved maternity care professionals foresee a need for a web-based postpartum period platform, despite the presence of MCAs during the first week after childbirth. This web-based platform ideally connects to preconception and pregnancy platforms and is accessible until 6 months after childbirth, and parents should be referred to this platform by professionals working in perinatal care. There is a need for information provision that is both easily accessible and reliable. Information on the platform should focus on general topics, such as breastfeeding, psychological support, and physical recovery after childbirth. However, the web-based platform should also be tailored to the individual needs of the parents and a chat function is advised. eHealth in the form of a web-based platform may be a suitable solution to this.

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Chapter 4

Building a relationship with the vulnerable pregnant woman: how should this be done and what is the role of the partner and the social environment?

Translated from: "Het opbouwen van een relatie met de kwetsbare zwangere vrouw: hoe doe je dat en wat is de rol van de partner en de omgeving?"

Leonieke J Breunis
Lyzette T Laureij
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CASE STUDY

Bouchra is 37 years old and is married to Patrick. They both have a strong desire to have children. Bouchra has a university degree and is now a housewife. Patrick, aged 32, has been working full-time since gaining his professional qualifications. They are referred to a gynaecologist by their general practitioner after Bouchra had three miscarriages. They both appear well groomed and claim not to smoke or drink alcohol. Bouchra and Patrick always attend the consultation together and Patrick is very involved. On one occasion the couple arrives late for their appointment, which is annoying for the gynaecologist as theirs was the first appointment of the day.

Lisanne is 21 years old, has had no further education after completing her vocational secondary school and occasionally has a minimum wage job. She lives with her mother most of the time, though she sometimes stays with friends or her friends' parents. She is overweight and she smokes. She stopped taking birth control pills after a friend told her that they make you gain weight. Lisanne is now 13 weeks pregnant and the father of the child is not in the picture. She has decided to continue the pregnancy. She does not show up for her first midwife appointment and is late for her second appointment. Her social situation is identified as follows: she is single and unemployed, her pregnancy was unplanned, and she appears to have debts, a housing problem, and an unhealthy lifestyle. Lisanne stopped smoking marihuana once she found out that she was pregnant, but as a result she started smoking more cigarettes.

At first glance, the above situations seem completely different, so both women are approached differently. In the case of Bouchra and Patrick, everything seems to be in order. When asking about alcohol use, the midwife phrases the question as, "You no longer drink alcohol, right?" and the couple's social situation is hardly discussed. In Lisanne's case, the midwife thoroughly inquires into a variety of potential problem areas ("Have you continued to drink alcohol since becoming pregnant?") and because of her earlier use of *marihuana*, it is agreed that her urine will be checked regularly for drugs.

Bouchra becomes pregnant again, but this pregnancy also ends in a miscarriage. Bouchra's general practitioner begins to feel uneasy about the situation. Bouchra becomes more and more withdrawn, Patrick tends to dominate the discussion during appointments, and when Bouchra's general practitioner paid an impromptu visit one morning, Bouchra smells strongly of alcohol. The general practitioner discusses her concerns about Patrick's role and Bouchra's potential alcohol use. It turns out that Patrick has been physically and mentally abusing Bouchra. To numb her pain and grief, Bouchra drinks a lot. She is unable to stop drinking alcohol, despite being pregnant. However, she does not want to

leave Patrick because she has no income of her own and because she badly wants a child.

Lisanne's baby is not growing well during her pregnancy, but Lisanne does not want to stop smoking. She will not accept help and regularly shows up late to appointments or skips them altogether. When the midwife addresses the subject, quarrel arises and Lisanne abruptly stops coming to appointments and refuses to answer her phone.

The above situations show the complexity of social obstetrics. It can be difficult for women to trust their healthcare providers, and women have their own opinions about their personal situations and how to deal with these. As a result, help initiated by healthcare providers does not always have the intended effect and may even backfire, as in Lisanne's situation. In the following sections, we will discuss this in more detail using aspects of the trauma-sensitive approach, presence theory and a method known as 'therapeutic alliance' (see Box 1). Building strong, secure relationships based on mutual trust and adapting care to women's individual needs and perspectives are the cornerstones of this approach. In this way, the stress level drops and scope for behavioural change is created. How can we help women like Bouchra and Lisanne?

Box 1: Theories referenced in this chapter

Trauma-sensitive approach

In this approach you assume that someone has already experienced many distressing events in life and has therefore suffered prolonged stress. This prolonged stress disrupts the stress system, making the person continuously alert to possible danger. The person may also find it difficult to relax and may have never learnt how to cope with emotions. A trauma-sensitive approach provides safety and reassurance by working in an environment that is physically safe (no protruding objects, for example) and by creating a safe atmosphere through the use of clear structure and predictability. The person is encouraged to establish relationships with others. By naming the emotions you observe, affirming that emotions are normal, and by defining what inappropriate emotions and behaviour are, healthcare providers can work together with those under their care to find better ways of coping with emotions.

Presence theory

In this working method, the relationship between healthcare provider and patient/client is on equal footing. The healthcare provider is present for the person, consults with him or her on their care and tailors the care they provide to the person's individual situation. The care provided is seen as a

whole, rather than a collection of separate elements. The perspective of the person receiving the care is the guiding factor.

Therapeutic alliance
In this working method, the healthcare provider facilitates care but is not an authority. The care focuses on the patient/ client, who is encouraged to take an active role. Treatment goals and procedures are determined together and a bond is developed between the healthcare provider and the person receiving the care.

CHALLENGES IN SOCIAL OBSTETRICS

All obstetrics professionals are committed to promoting the health of mother and child. Yet there are factors that can make this difficult. Some of these factors are emotional and cognitive in nature: shame, having difficulty trusting people (such as healthcare professionals), anxiety, low self-esteem, low intelligence level, or poor health literacy skills (see Box 2 for additional information on poor health literacy skills). Other factors are external: living in a deprived neighbourhood, being unemployed, having financial problems, or suffering from social isolation. How living in a deprived neighbourhood affects health outcomes is shown in Figure 1.

Bouchra is ashamed of the abuse she is suffering and of her alcohol addiction. When her midwife asked "You don't drink alcohol, do you?", she didn't dare to admit that she actually does drink. In addition, she is afraid of the consequences of staying with her partner as well as of those of leaving him: she could get into financial difficulties or possibly never have children. Moreover, she is socially isolated. Her alcohol addiction meant that she was regularly late for work and was therefore fired, and she avoided contact with friends and family for fear of them finding out about her addiction. In addition, Bouchra is used to solving her problems herself and it is therefore not in her nature to ask for or accept help.
Patrick grew up surrounded by a lot of violence. He is determined not to get angry right away when he feels powerless, but he has no idea how to react when things don't go his way. He is terrified that Bouchra may leave him and of going to jail. He feels it would be better if no one knows how things are in their home.

Lisanne does not trust healthcare providers. She values the opinions of people around her (such as when she stopped taking the birth control pill). She is aware that she is struggling with many problems, but she is overwhelmed by them and does not know where to start

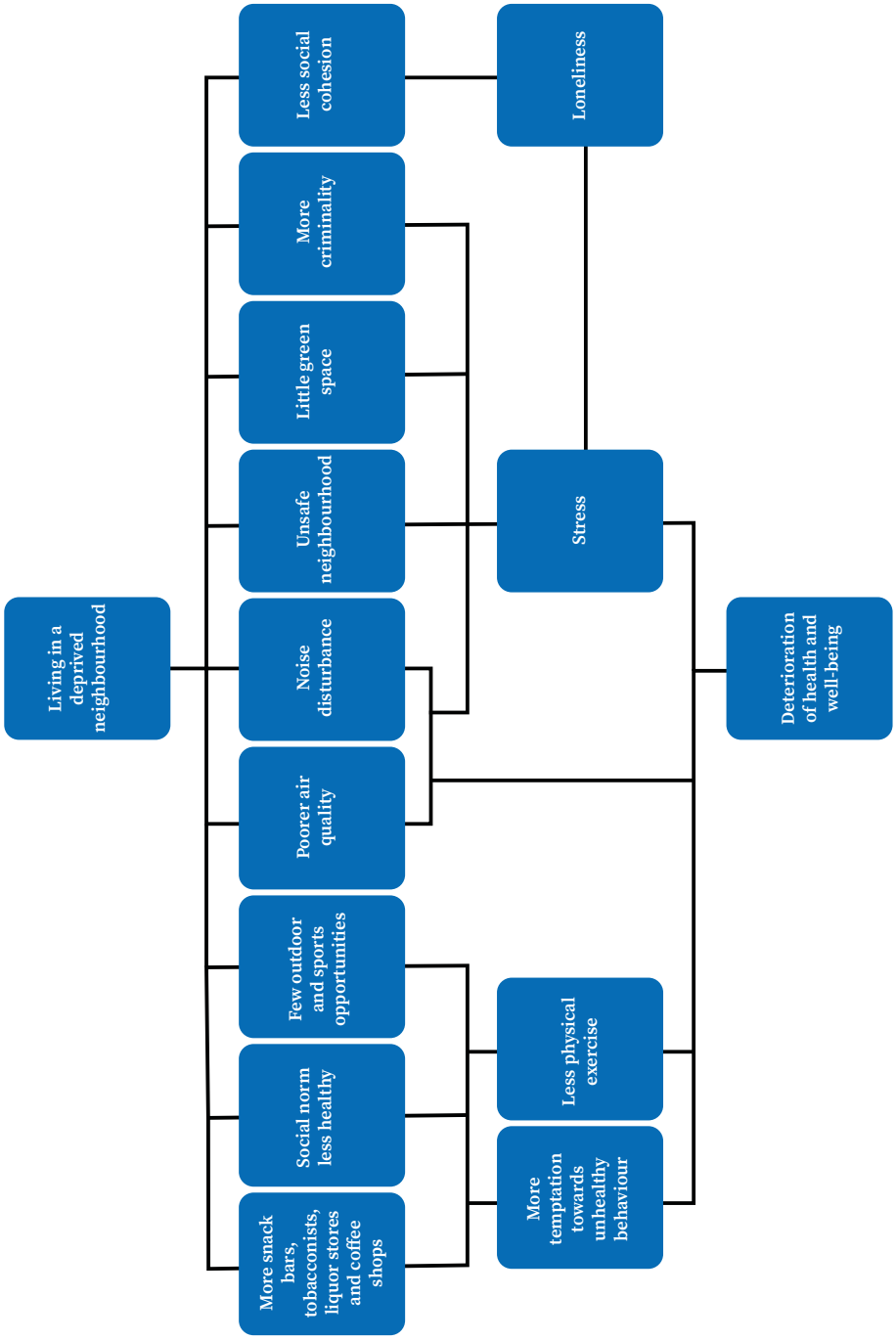

Figure 1. Example of how the social environment can have a negative impact on the health of mother and child.

addressing them. Without a diary she regularly forgets appointments with her midwife and without money for public transport she cannot always get there. The midwife gave her a brochure about debt assistance featuring a happy white couple in front of their big house on the front page. Lisanne could not identify with this situation and got the feeling that the leaflet was not meant for her. While reading it there were large parts that she did not understand, so the leaflet ended up in the wastepaper basket. The midwife discussed the need to find her own home, but Lisanne is extremely uncomfortable with the thought of living alone, far away from her mother and friends. When she mentioned this to the midwife, the midwife ignored her concerns and started talking about how important it is for her to quit smoking. Lisanne feels that the midwife thinks she is stupid and is afraid that the midwife will have her child put into care. As a result, she left the consulting room feeling sad and powerless.

These examples illustrate the challenges faced by pregnant women and their partners. But healthcare professionals and our healthcare system also face challenges. The effect of living in a deprived neighbourhood is difficult to imagine if you have never lived there yourself. Not all issues are immediately apparent, assumptions are easily made, you may feel reluctant to ask about sensitive information such as income, and it is sometimes difficult to see beyond your first impression. The feeling that a woman or her partner does not trust you can lead to misunderstanding and frustration. A busy consultation schedule leaves little room for you to take the time.
Listed below are several strategies that can contribute to establishing a good relationship with – and thus good care for – pregnant women. However, there is not a single correct approach, and improving care for vulnerable pregnant women is not an easy fix. Each healthcare provider has their own style, and every pregnant woman has different needs. Safe and respectful care that fits these needs is important for *all* pregnant women, not just those who are most vulnerable.

BUILDING THE RELATIONSHIP

The pregnant woman

Mutual trust is essential for a good relationship between healthcare provider and care recipient, and one of the keys to building trust is respect. Healthcare providers must respect pregnant women's boundaries and encourage them to set limits. Have understanding for their situations and social context, avoid judgement and accept that not everything can be solved at once. A home visit can help you to understand the social context. Groups of teens loitering outside the flat and an

empty fridge can immediately explain why someone is experiencing a lot of stress. It also makes it clear why tackling a pregnant woman's housing problem can actually be more important than smoking cessation. By taking the effort to visit the pregnant woman in her familiar surroundings, you can strengthen your relationship with her. Home visits enable you to renew the contact with someone who repeatedly fails to attend appointments. You can show her that you consider her to be important, and you can explore what is preventing her from coming to appointments and, if possible, take action to help her. Sometimes these barriers can be easily resolved, which can have a major effect on your mutual relationship and on the care you provide. Consider, for example, the time of an appointment: a woman with a 9-to-5 job might prefer to have an appointment early in the morning, while someone with an off-peak public transport discount card might rather come later in the day.

For a relationship based on mutual trust, it is important to get to know each other. This takes time; don not feel pressured to learn everything about someone in a single consultation. Bring up things you previously discussed during follow-up consultations. For example, if the woman is looking for a job, you can actively ask about her job search in a subsequent consultation. This will make her feel she is being treated as a person and not just as someone who is pregnant. It may also help some women to talk about things you may have in common during the physical examination. You can decrease the distance to others by sharing how you yourself, as a parent, also encounter parenting problems and are uncertain about things. As a healthcare professional, it is up to you to decide how much you want to share about yourself. It is easier to build a relationship of trust if the pregnant woman has a fixed point of contact in the team of care providers, such as a case manager or primary care worker. Make it immediately clear that this person is her point of contact for any questions or problems and provide her with an easy way to contact this person. People are put off if they have to struggle through various choices in an automated menu. You can make it easy for clients to get in touch with their contact person by allowing them to send text messages or a WhatsApp message, for instance. Do not forget the legal aspects: make a note of any contact with the client/patient in the records and respond to messages actively by calling back as soon as possible.

If you are serious about building a relationship of trust, you may feel reluctant to sound out the client about problems. However, identifying problems, offering a listening ear, and looking for support together may actually improve the relationship with the pregnant woman. Standardised screening tools and questionnaires, such as R4U and Mind2Care, may help. These kinds of tools include questions about psychosocial factors such as income and can help healthcare providers ask the right questions. Most pregnant women do not mind answering these types of questions as long as they understand why they are being asked. Most women will

give honest answers.
Risk factors should be discussed with all women. After all, we do not know beforehand who is vulnerable or who lacks protective factors. Take Bouchra and Lisanne, for instance. Avoid making assumptions, either before or after asking questions. A low income (risk factor for vulnerability) does not always mean that someone has financial problems, as being able to deal with scant funds well is in fact a protective factor. Conversely, a high income does not guarantee that someone has no debts. Try to ask questions in a neutral way and ask the woman to summarise what has been discussed in her own words. This helps to bring uncertainties to the surface. Finally, vulnerability is a dynamic process. Vulnerability can change during pregnancy and in the postpartum period, for instance due to a death within the woman's social network or by finding a job (in Figure 2 we give an example of work as a protective factor). Therefore, keep asking specifically if anything has changed since the last visit.

Increasing a woman's self-esteem and avoiding focus solely on problems, creates a positive atmosphere. For example, specify things that are going well, compliment the client on even the smallest of steps forward (e.g. compliment Lisanne that she has stopped smoking marihuana since she knows she is pregnant, rather than focusing on the fact that she still smokes cigarettes), and respect and encourage

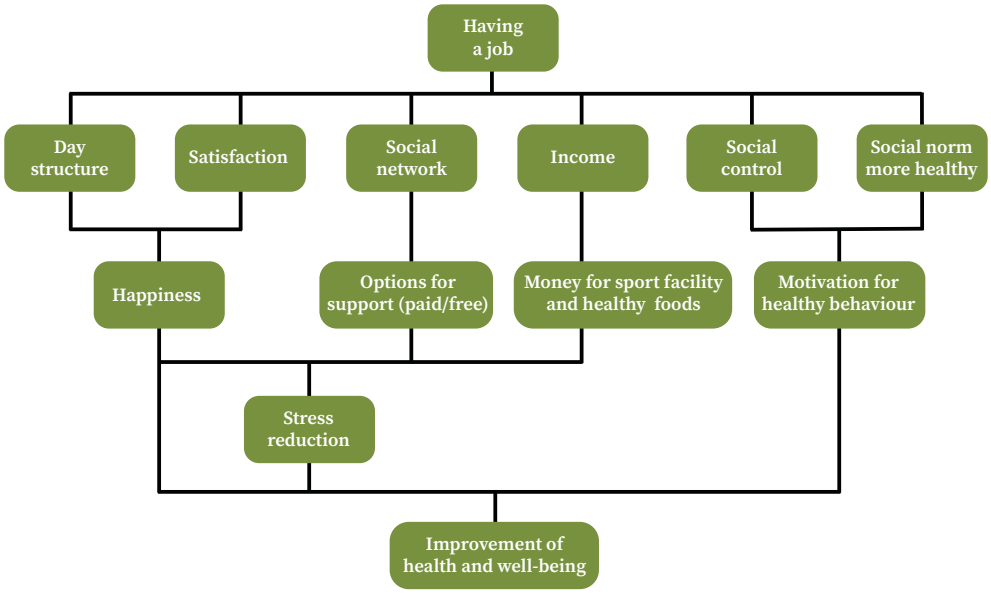

Figure 2. Example of the mechanisms underlying the positive impact of having a job on the health of mother and child.

the client's own input. Telling women it is their fault that the baby is not growing properly will only increase their guilt and is often counterproductive. Avoid overloading women with information (which can come across as pedantic) and repeatedly bringing up everything that is not going well, as this can be highly demotivating. Ultimately, you want to be a companion for the vulnerable woman; someone she feels willing and able to open up to. This creates a safe atmosphere in which you, as a healthcare provider, can also discuss risk factors that need addressing, such as smoking.

Women often see a number of professionals, which means that efficient cooperation and communication is necessary to ensure that they receive tailored care. Communicate well with other healthcare providers about relevant issues and about the plan of action. Ensure that everyone is on the same page and prevent that one healthcare provider convinces the pregnant woman that finding a home is now more important than stopping smoking, while another healthcare provider insists that the main priority is quitting smoking. Appointing a case manager or primary care worker can help. Make sure that healthcare providers further down the chain (e.g. maternity practitioners, paediatric physicians or paediatric nurses) are aware of the situation by actively sharing not only medical data, but also social information, with the woman's permission of course. At times it may be helpful to ensure a "warm transfer" between professionals by allowing the pregnant woman to get acquainted with the new healthcare provider in the presence of the current healthcare provider. This may boost the confidence of some women in the new healthcare provider. This is not always necessary; for many medical issues, a written transfer is sufficient.

The partner

The partner is an important person in the woman's life, but may not always accompany her to consultations. As a result, it is often difficult to engage in conversation with them. Discuss the importance of the partner's presence with the pregnant woman and ask them to come together next time. The partner influences many aspects of a woman's life, for example if they happen to be the breadwinner, making it all the more important to include them in further plans. In an unplanned pregnancy, the decision not to terminate the pregnancy may have been a joint decision, but perhaps one of the two would have preferred otherwise. This can put a strain on the relationship. It is therefore important to provide space to discuss concerns and emotions. The partner's perception of the situation is often different from that of the pregnant woman, because they experience the pregnancy differently and perhaps less consciously. Many partners are less knowledgeable about becoming pregnant, about the pregnancy itself and about giving birth, so try to actively involve them and determine whether there are any uncertainties.

The social network

The immediate surroundings and informal network are the first and foremost source of knowledge and support for parents and parents-to-be. Their environment plays a role in the choices they make and can help when it comes to understanding information, seeking help, and caring for the child. In Lisanne's case, for example, she stopped taking the pill on the advice of a friend, but her mother could potentially help raise the baby. These examples show that it is a good to involve the social network as a protective factor. Allow them to come along to appointments if the pregnant woman so wishes, encourage the pregnant woman to bring a trusted support person (especially if she does not have a partner), and provide information to share with the social network. Small things like these can sometimes make a big difference. For example, when making an appointment, put the date and time on an appointment card so that the pregnant woman can easily share it with the person who is taking her to the appointment.

SUPPORT BEYOND THE CONSULTING ROOM

When problems arise, healthcare providers are quick to take action. However, this can lead to reluctance and a lack of understanding, as in Lisanne's case. The wishes and needs of the pregnant woman must be the deciding factor in the care that is offered. The healthcare providers acts as a partner who moves with the client's needs and offers support. The women should be able to make carefully considered decisions, thus it is important to discuss the consequences of certain choices, such as continuing to smoke. Many people find it difficult to ask for help, especially if they have first discussed problems with one healthcare provider, such as their midwife, and then have to raise the alarm themselves with another healthcare provider. This is why it is best to contact other healthcare providers yourself on behalf of the pregnant woman or couple, provide a "warm transfer" if necessary, and follow up to ensure that the organisation contacts the woman. Simply providing the woman with a leaflet about an organisation that she herself can contact often ends up with the leaflet being discarded without being read.

Set priorities together

If a pregnant woman feels overwhelmed by her problems, it may help to sit with her and list the issues she is facing, providing a clear picture of the situation. You can then decide together which problems are to be tackled first and how. One method that can be used for this is the Joint Assessment of Care Needs ('Gezamenlijk Inschatten Zorgbehoeften' (GIZ) in Dutch), which addresses both preventive and additional care. Protective factors and needs are examined in discussions with parents

or parents-to-be and can be followed by a discussion about the kinds of support that can be offered. This support can be informal, such as help from within their social network, or formal, such as assistance from government agencies or counselling services. Try not to look too far ahead and keep the steps manageable. Ask what barriers the woman faces and consider solutions together. In doing so, always take barriers seriously and respect the woman's autonomy.

Informal support from the community

Daily life takes place in various communities, such as churches or mosques, primary schools and sports clubs. These communities play a part in shaping women's standards and values and can provide support where needed. Many municipalities have set up informal networks for parents and parents-to-be, for example cafes for mums. These gatherings take place regularly, are led by professionals, offer women the chance to have fun and meet other mums, and focus on sharing knowledge and experiences in an informal, accessible way. This increases women's knowledge, awareness and social support, and ultimately their self-reliance. Many parents and parents-to-be are also part of digital communities through various online forums and social media. As a professional, you can add your voice by actively participating in such forums and social media.

Individual counselling and support by volunteers can contribute to a larger social network. This could include a support family or buddy. Often, this takes the form of trained volunteers who offer parenting and family support for minor parenting questions, and occasionally more serious and specific problems like debts, as well as things like going along to medical appointments or doing fun activities together. The support provided by volunteers is more informal and therefore creates an atmosphere different from that in the consulting room.

Working in groups

Centering Pregnancy™ and Centering Parenting™ link groups of women to professionals. Pregnant women and young mothers are connected together in groups with women of similar gestational age or mothers with children of the same age. Medical check-ups are carried out during group meetings and the women discuss a variety of topics. They are supervised by a dedicated healthcare professional such as a midwife or a paediatric nurse. The healthcare professional facilitates the discussions, but does not regulate information continuously. Over time, the group grows closer together and learns to trust each other. As a result, the women have open conversations that might otherwise not have been achieved with only a healthcare professional. They give each other support, even with difficult decisions or in enduring difficult changes, such as quitting smoking. This improves pregnant women's levels of knowledge, self-confidence, self-reliance and social network.

Wide range of support from counselling services

Programmes such as Mothers of Rotterdam and 'VoorZorg' (a Dutch word that means both "precaution" and "early care") offer long-term support, and position themselves as partners. They work on building good relationships and mutual trust during home visits. They make use of the existing social network, go along to appointments (such as to the midwife), are approachable, and make care plans in cooperation with the pregnant woman. While they initially take pregnant women by the hand, they are actively involved in increasing self-reliance. The idea behind these types of programmes is that if you help parents and parents-to-be grow in their role, they can set a good example for their children. These children will then become self-reliant as adults in areas such as relationships, financial matters and health. 'Kansrijke Start' (Promising Start), a national action programme, provides an overview of effective interventions aimed at vulnerable parents and parents-to-be (https://menukaart.kansrijkestartnl.nl/). Many of these interventions are aimed at giving parents and parents-to-be a good start through personalised care. The care provided can be short term in the event of temporary problems, but also long term if necessary.

An important part of care during pregnancy, delivery and the postpartum period is discussing how to prevent an unplanned or unwanted pregnancy in the future. Many women are unaware of the various forms of contraception. Furthermore, contraception is not always a priority for women who have just given birth and are busy adjusting to parenthood. An action programme that addresses the issue of contraception is 'Nu niet zwanger' (Not pregnant now), which teaches healthcare providers how to enter into a conversation about conception and contraception with vulnerable women. If women do not have an active desire to have children at that time, they receive help to choose the right kind of contraception for them. This subject can already be discussed during pregnancy or at follow-up checks after giving birth.

CONCLUSION

This chapter has shown that building mutual trust and strong bonds is the first step towards providing high-quality care for all pregnant women. Vulnerable pregnant women more often find it difficult to trust healthcare providers. As a professional, you can make a major difference by entering into a dialogue with pregnant women, opening yourself up, reflecting on yourself, going beyond first impressions and your own assumptions, and by not giving up. In doing so, you will contribute to equal opportunities for all pregnant women.

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Chapter 5

Exploring the applicability of the pregnancy and childbirth outcome set: a mixed methods study

Lyzette T Laureij
Jasper V Been
Marjolein Lugtenberg
Hiske E Ernst-Smelt
Arie Franx
Jan A Hazelzet
on behalf of the PCB outcome set study group
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ABSTRACT

Objective: The International Consortium for Health Outcomes Measurement developed the Pregnancy and Childbirth (PCB) outcome set to improve value-based perinatal care. This set contains clinician-reported outcomes and patient-reported outcomes. We validated the set for use in the Netherlands by exploring its applicability among all end-users prior to implementation.
Methods: A mixed-methods design was applied. A survey was performed to assess patients (n = 142), professionals (n = 134) and administrators (n = 35) views on the PCB set. To further explore applicability, separate focus groups were held with representatives of each of these groups.
Results: The majority of survey participants agreed that the PCB set contains the most important outcomes. Patient-reported experience measures were considered relevant by the majority of participants. Perceived relevance of patient-reported outcome measures varied. Main themes from the focus groups were content of the set, data collection timing, implementation (also IT and transparency), and quality-based governance.
Conclusion: This study supports suitability of the PCB outcome set for implementation, evaluation of quality of care and shared decision making in perinatal care.
Practice Implications: Implementation of the PCB set may change existing care pathways of perinatal care. Focus on transparency of outcomes is required in order to achieve quality-based governance with proper IT solutions.

INTRODUCTION

Traditionally in healthcare, professionals document clinical findings and health outcomes, which may be included in quality registries. These registries commonly contain condition-specific process indicators and outcomes that primarily focus on morbidity and mortality. Analyses of data from these registries may provide insight into for example etiology, treatment effects and temporal trends in healthcare. Supplemented with process indicators, e.g. the time between a patient's first appointment and start of treatment, registries may provide feedback on the performance and quality of the delivered care. However, when focusing on recording of traditional outcomes alone, other outcomes that matter to patients' health-related quality of life are undervalued in the evaluation and improvement of quality of care. From a patient perspective not only the occurrence of a disease is important but also the impact of the disease and its treatment on the patient's ability to participate in normal daily activities. Such outcomes are best reported by patients themselves rather than by health professionals, henceforth referred to as 'professionals'.[1–5]

Patient-reported outcomes (PROs) may be defined as any information stemming directly from patients related to the impact of their condition or its treatment on their health, functioning and symptoms.[3,6] PROs can be used at an individual patient level to provide patient and professionals information about a patient's current health status or treatment response and any relevant temporal changes thereof. When PROs are used complementary to professional-reported data on an aggregate level, they can also provide useful information on performance and quality of care, at the level of the professional, institution or overarching health care system and be used for improvement activities.[4,5]

Healthcare outcomes, including PROs and professional-reported outcomes, need to be balanced against the costs needed to achieve those outcomes in order to create value for patients, a principle known as value-based healthcare (VBHC).[7] The International Consortium for Health Outcome Measurement (ICHOM) develops outcome sets for specific (groups of) medical conditions aimed at standardizing quality assessment according to the VBHC principle.[8] These outcome sets contain both professional-and patient-reported outcomes as well as initial patient conditions which are designed to cover the full cycle of care per condition, i.e. including short-and long-term outcomes, instead of outcomes per specialty or care episode. This allows all professionals to jointly be accountable for the outcomes and the perceived value for the patient.[7–9]

Up until 2019, ICHOM has developed 26 outcome sets which together cover 54% of the global disease burden.[10–13] Countries may differ in culture and health service systems. For this reason, implementation of these outcome sets requires tailoring

to the local situation, involving relevant stakeholders including patients, professionals and administrators. Using such an approach ICHOM outcome sets have been implemented into routine practice in various settings.[14–16]
ICHOM developed the Pregnancy and Childbirth (PCB) outcome set in 2016 (see Table 1). Use of this PCB outcome set may help standardize assessment of important outcomes in perinatal care and accordingly optimize targeting of quality improvements of the care process.[17] The PCB outcome set contains two variants of PROs, namely patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). PREMs can provide insight in patient experience during the care, for example in the field of communication,[17,18] and as such the PCB outcome set can be used to support shared decision making (SDM).
Perinatal care is a particularly challenging field for implementation of outcome sets because a wide variety of professionals is involved, outcomes are relevant for at least two patient-levels (i.e. the mother and her baby/babies) and substantial costs are involved at the population level in the care around mother and her baby. We are unaware of any studies having formally assessed the requirements for implementation and local tailoring of the PCB outcome set. We aimed to explore the applicability of the PCB outcome set in the Netherlands, a midwife-led and multidisciplinary perinatal care system (see Box 1), involving key stakeholders (i.e. patients, professionals, administrators) in order to generate transferrable lessons for implementation both locally and elsewhere.

Box 1. Perinatal care in the Netherlands, a collaborative system.

Policy structure

Perinatal care is organized through local obstetric collaborative networks (OCNs). An OCN consists of several midwifery practices and maternity care organizations at the primary care level and of at least one hospital (general or tertiary). An OCN develops local protocols and working arrangements for optimal perinatal care. Benchmarking on outcomes is possible at OCN level.

Patient-care

The organization and delivery of perinatal care in the Netherlands is based on risk stratification and accordingly, allocation of pregnant women to three strata of care (primary, secondary and tertiary). Primary care is delivered by community midwives. For each pregnant woman, the community midwife determines whether the woman can receive care from the midwife or whether she should be referred to the gynecologist using the nationally implemented 'List of Obstetric Indications'.[19] When medical and obstetric history and pregnancy, childbirth and puerperium are uncomplicated,

the woman may remain under supervision of the community midwife and may deliver and receive maternity care at home or at a primary care birth center.[20] A maternity care assistant usually assists the new family at home for up to eight days, under supervision of the community midwife. Secondary care is provided by general hospitals. If the pregnancy, childbirth or puerperium is considered as medium-risk, the woman is referred to the gynecologist in a general hospital (secondary care). Childbirth then takes place at the hospital, supervised by a clinical midwife or gynecologist. If the postpartum period is uncomplicated, mother and baby may then go on to receive maternity care at home. Tertiary care is delivered by one of ten Dutch tertiary perinatal centers, which handle specific problems during pregnancy or childbirth which may not be handled in a general hospital, e.g. impending preterm delivery prior to 32 weeks gestation.[20] After the first eight days of the postpartum period, care for the newborn is transferred to the preventive child healthcare (PCHC) service. PCHC monitors development of the child on regular basis until the age of 18 years. The woman usually remains under supervision of the midwife or gynecologist until six weeks postpartum.

METHODS

The project

Perinatal care is network care with multiple patients, professionals and administrators involved. As such, we focused on assessing the applicability of the PCB outcome set for these three user groups. Our study was conducted in five obstetric collaborative networks (OCNs) in the Netherlands from February 2017 until May 2018 (see Box 1 for detailed description of Dutch perinatal care system). The study group, consisting of professionals, researchers and policy makers of the five OCNs, led a survey to assess patient, professional, and administrator views on the content of the PCB outcome set. We furthermore explored the applicability of the PCB outcome set during focus groups. Questionnaires were translated and we explored which existing routine professional-reported data may be used as input for the PCB outcome set, to minimize registration burden for professionals.

Table 1. Content of the outcomes in the Pregnancy and Childbirth outcome set[17]

Category	Item	Description
Survival	Maternal mortality	Death of a woman during pregnancy, childbirth or in the first 42 days postpartum
	Stillbirth and neonatal death	Pregnancy loss after 28 weeks of gestation, death of a live born neonate up to 28 days after childbirth
Morbidity	Severe maternal morbidity	Combination of ICU admission, length of hospital stay, postpartum hemorrhage, readmission and blood transfusion of a woman
	Neonatal morbidity	Combination of length of hospital stay, oxygen dependence and birth injury of a neonate
	Pre-term birth	Live birth before 37+0 weeks of gestation, distinction between spontaneous and iatrogenic pre-term birth
Patient-reported outcome measures	Health related quality of life	Perceived quality of life, tracked via PROMIS Global
	Postpartum depression	Depression during pregnancy or postpartum, screening via PHQ-2, optional further assessment via EPDS
	Maternal confidence and success with breastfeeding	Breastfeeding, combination of duration of breastfeeding and confidence with breastfeeding tracked with the BSES-SF
	Pelvic pain and dysfunction	Combination of incontinence (both fecal and urine) and pain with intercourse, tracked via ICIQ-SF and/or Wexner and PROMIS SFFAC102
	Mother-infant attachment	Feelings of a woman for her child in the first few weeks, tracked via the MIBS
	Confidence in role as a mother	Confidence of a woman regarding looking after her baby
Patient-reported experience measures	Satisfaction with the results of care	Degree of satisfaction of a woman with results of received care
	Shared decision making and confidence in care providers	Confidence of a woman as an active participant in decisions and perceived confidence in healthcare professionals
	Birth experience	Assessment of a woman's birth experience, tracked via BSS_R

ICU: intensive care unit
PROMIS: Patient Reported Outcomes Measurement System
PHQ-2: Patient Health Questionnaire-2
EPDS: Edinburgh Postnatal Depression Scale
BSES-SF: Breastfeeding Self-Efficacy Scale-Short Form
ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form
PROMIS SFFAC102: Patient Reported Outcomes Measurement Information System Sexual Function and Satisfaction
MIBS: Mother-Infant Bonding Scale
BSS_R: Birth Satisfaction Scale-Revised.

Survey

The questionnaire

Our survey was based on the ICHOM consumer validation survey[17], which was originally conducted with respondents mainly from the US and Australia (93.3%), and 5.7% from Europe (none from the Netherlands). This survey aimed to evaluate the perceived relevance of the professional-reported outcomes and PROs (on a nine point scale), and the perceived comprehensiveness of the PCB outcome set (dichotomous question). Respondents who did not agree on the comprehensiveness were asked to suggest outcomes which they felt were missing. We translated the survey into Dutch and answer options were reduced to a three-point scale (important, neutral and not important).

The PCB outcome set suggests collecting data at five time points during pregnancy and the subsequent months (see Fig. 1). Our survey assessed the acceptability of the data collection timing via an extra question.

Because the item 'birth experience' was added to the original PCB outcome set after their validation survey, we did not assess this item in our survey.

The survey was made available online via LimeSurvey, an open source survey tool.[21] Web links to the survey were sent by email.

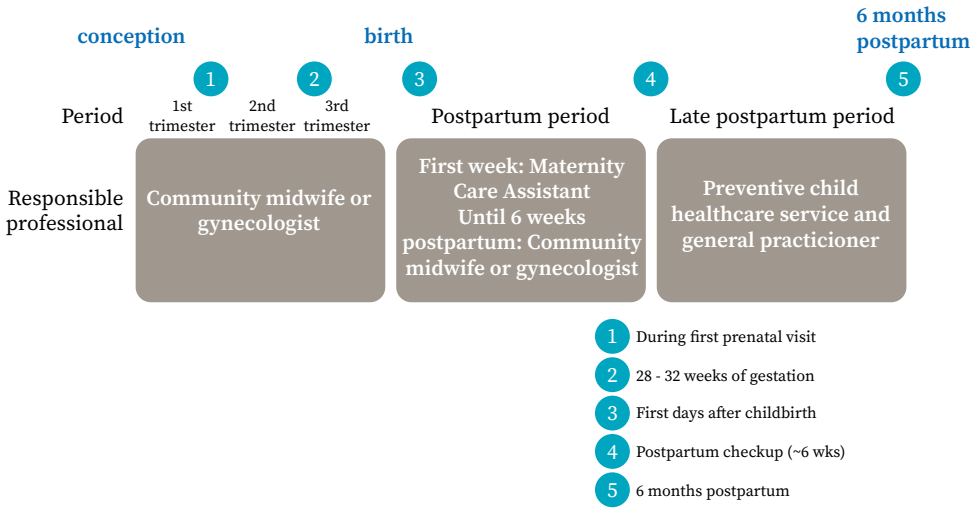

Figure 1. Data collection time points and perinatal professionals in the Netherlands
The blue dots indicate the data collection time points during pregnancy and postpartum.

Participants

The survey was conducted among patients, and among health care administrators and professionals with slight modifications.
Participants were recruited during October 2017 until January 2018 in the five OCNs. Details of how the survey was conducted are supplied in the supplement (Supplementary file A).

Analyses

Quantitative data were analyzed using descriptive statistics, with SPSS version 24.0 (IBM Corp., Armonk, N.Y., USA). Free text answers were themed.
According to ICHOM's approach in their initial survey, professional-reported outcomes and PROs were considered relevant if at least 70% of the participants scored them as 'important'. We additionally assessed respondents' opinions on comprehensiveness of the PCB outcome set and timing of data collection, which we considered appropriate if 75% of participants agreed. If these thresholds were not achieved, the concerning items were used as input for the focus groups and discussed in the project team to determine whether adjustments to the PCB outcome set should be made.

Focus groups

Aim, design and setting

To further explore the applicability of the PCB outcome set including the findings derived from the survey, separate focus groups were held with each user group: i.e. patients, professionals and administrators.

Selection of participants

For the patient focus groups, a client panel and national patient representation platform for obstetric patients were invited. Criteria for selecting participants were: (a) currently pregnant or mother of a child, (b) age ≥ eighteen years, and (c) sufficient command of the Dutch language. Patients were offered a twenty euro gift voucher for participation.
Administrators and professionals working in perinatal care were invited by project team members via e-mail or in person.
One week prior to the focus groups an information file including information on the PCB outcome set and the main results of the survey was sent to all participants.

Data collection

The focus groups, led by an experienced facilitator (JH or LL), were held between January and May 2018. Prior to the start of each focus group, participants completed a questionnaire on demographic characteristics and the facilitator explained the

purpose and structure of the meeting. Confidentiality was reassured and participants were encouraged to speak freely. Predefined topic lists based on results of the survey and discussions between project team members (see Supplementary table B1) were used to structure the discussion. Results of the focus groups with administrators and professionals that also applied to patients were used as additional input for the patient focus group. All focus groups were audio-taped.

Data analysis

The focus groups were transcribed verbatim. The verbatim was sent back to participants who had indicated to be willing to perform a member check.
Thematic inductive content analysis was applied[22] using the qualitative software program NVivo 11 (QSR International Pty Ltd., 2015). Two researchers (LL and HE) independently coded the three transcripts and compared the coding to reach consensus, resulting in a coding scheme for each focus group. Codes were compared and the relationship between codes was explored to detect emerging themes for each group. Finally, the results of the three focus groups were integrated in an overview of themes and subthemes for all users, yet still demonstrating the differences between user groups. This process was executed by two authors (LL and HE) and supervised by a third author (ML).

Ethical approval

The Medical Ethics Committee Erasmus MC (MEC-2017-477) declared that the rules laid down in the Medical Research Involving Human Subjects Act (also known by its Dutch abbreviation WMO) do not apply to either the survey or the focus groups. As such, the study was exempt from formal medical ethical assessment. All patients in the survey and all participants in the focus groups signed written or digital informed consent.

RESULTS

Survey

Study population

142 patients (39% of those approached) completed the survey (Fig. 2).
Mean age of patient participants was 33 years and the majority were of Western origin (Table 2). Fifty-two patients had a low socio-economic status beneath the 20th percentile. The majority of participants were multiparous and had their pregnancy or childbirth supervised by a clinical midwife or gynecologist, with

some variation between time points. A minority of participants had experienced a complication during pregnancy, childbirth or puerperium.
134 professionals and 35 administrators completed the survey. All relevant groups of professionals and administrators were represented (Table 3).

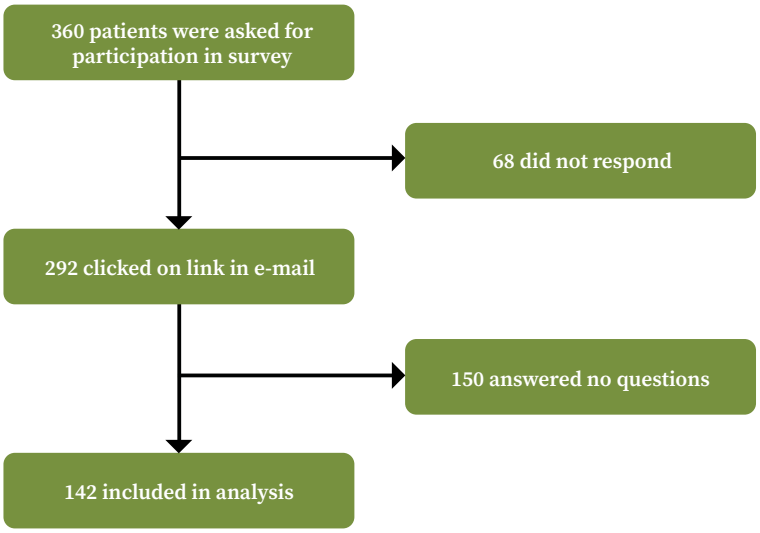

Figure 2. Survey flowchart participating patients

Participants' opinions on Timing of the five time points

The vast majority of patients and professionals, and two-thirds of the administrators felt that timing of the data collection was appropriate (Table 4).

Perceived relevance of the professional-reported outcomes and PROs

Overall, the professional-reported outcomes in the PCB outcome set were considered relevant by the participants (Table 5). With regard to the PROs (Table 6), the two PREMs (satisfaction with care, and health care responsiveness) were judged as relevant by the vast majority of all participants. Regarding the PROMs about breastfeeding (confidence and success), three-quarters of the professionals and administrators perceived these outcomes as relevant. Just over half of the patients considered these items relevant, although of the majority of patients at time point four (i.e. the postpartum period) felt these outcomes were important (data not shown). Pain with sex was considered important by the majority of the adminis-

trators and professionals, while this outcome was considered important by less than half of the patients. The vast majority of the administrators and professionals indicated incontinence (both urinary and fecal) as an important outcome, whereas only two-thirds of the patients did.

Perceived comprehensiveness of the PCB outcome set

The majority of the patients, administrators, and professionals agreed that the PCB outcome set contains the most important outcomes (Table 4).
When asked for items that were considered missing from the PCB outcome set, the following topics were suggested: related to the role of the partner, physical recovery after childbirth, preferences regarding childbirth and continuity of care across time and strata of care.

Table 2. Survey baseline characteristics of participants: patients

	Patients across all time points (n=142) N (%)
Age (years)	33 IQR 30-36
Western origin	113 (83)
Socio-economic status *	
Low (<20th percentile)	52 (37)
Middle (20-80th percentile)	69 (49)
High (>80th percentile)	21 (15)
Parity	
Primiparous	61 (45)
Mulitparous	75 (55)
Pregnancy and/or childbirth supervised by	
Community midwife (primary care)	58 (43)
Clinical midwife or gynecologist (general or tertiary hospital)	78 (57)
Complications in index pregnancy during†	
Pregnancy	33 (24)
Childbirth	26 (34)
Puerperium	7 (15)

* Socio-economic status is based on a zip code proxy by the Netherlands Institute for Social Research (SCP, www.scp.nl) over the year 2016.
†complications could occur during pregnancy, childbirth and/or puerperium, multiple answers were possible.

Table 3. Survey baseline characteristics of participants: professionals and administrators

		Professionals (n = 134) N (%)	Administrators (n = 35) N (%)
Profession			
	Gynecologist*	17 (13)	-
	Neonatologist*	17 (13)	-
	Physician assistant	4 (3)	-
	Clinical midwife	11 (8)	-
	Community midwife	27 (20)	-
	Nurse practitioner	15 (11)	-
	Nurse	16 (12)	-
	Maternity care assistant	27 (20)	-
	Hospital board member	-	8 (24)
	CEO of a department	-	10 (29)
	Head of department in hospital	-	9 (27)
	Chairman of OCN	-	4 (12)
	Chairman of first tier cooperation	-	3 (9)
	missing		1
Work experience			
	0-5 year	17 (13)	15 (43)
	5-10 years	29 (22)	13 (37)
	> 10 years	88 (66)	7 (20)
Organization			
	Hospital (general and tertiary)	86 (64)	14 (40)
	Primary care birth center	13 (10)	-
	OCN	-	1 (3)
	Primary care cooperation	-	5 (14)
	Maternity care organization	19 (14)	15 (43)
	Midwifery practice	16 (12)	-

* specialists and residents in training

Focus groups

Study population

Characteristics of participants of the three focus groups are displayed in Supplementary table C1, C2 and C3.

Table 4. Survey descriptive statistics of questions on capturing most important outcomes with this PCB outcome set and on the timing of the five time points

		Patients N (%)	Professionals N (%)	Administrators N (%)
Are the five time points adequate?		142	126	31
	yes	133 (94)	102 (78)	20 (64)
	no	9 (6)	29 (22)	11 (36)
Are the most important outcomes captured?		126	122	27
	yes	113 (90)	96 (79)	18 (67)
	no	13 (10)	26 (21)	9 (33)

Perceived applicability of the PCB outcome set

Four main themes emerged from the focus groups with regard to the applicability of the PCB outcome set: value and content of the PCB outcome set, time points of data collection, implementation of PCB outcome set and quality based governance. These themes and subthemes (Fig. 3) are described in detail below, with illustrative quotes in Box 2 –5.

Value and content of the PCB outcome set

The majority of participants in all groups felt that the PCB outcome set is of great value and contains a complete representation of important outcomes within perinatal care, and that it would be a useful addition to perinatal care. All groups considered the outcomes, be it professional-reported or patient-reported, to be complementary and interrelated. Nonetheless, some professionals felt that the outcomes could also be independent of each other and can be interpreted independently.

With regard to PROMs, both patients and administrators reported a taboo on some of these outcomes, e.g. pelvic dysfunction, and a lack of knowledge regarding the prevalence and treatment possibilities. Patients mentioned that this taboo may be reduced by filling in questionnaires regarding the PROMs in the PCB outcome set multiple times (i.e. during the five time points) and discussing the results with a professional. Patients emphasized that it is the task of their professional to discuss PROMs, especially the 'taboo PROMs' and that discussing these outcomes should be integrated into regular care.

All groups viewed PREMs as important outcomes. However, patients reported to feel dependent on their professional and mentioned a high risk of providing social desirable answers if responses are linked to the individual patient.

Table 5. Survey participant's ratings per outcome: professional-reported outcomes

		Patients Total N (%)	Professionals N (%)	Administrators N (%)
Maternal mortality		132	126	29
	important	101 (77)	116 (92)	27 (93)
	neutral	26 (20)	8 (6)	2 (7)
	not important	5 (4)	2 (2)	0 (0)
Stillbirth		132	126	29
	important	113 (86)	122 (97)	28 (97)
	neutral	16 (12)	3 (2)	1 (3)
	not important	3 (2)	1 (1)	0 (0)
Neonatal death		132	126	29
	important	113 (86)	121 (96)	28 (97)
	neutral	15 (11)	4 (3)	1 (3)
	not important	4 (3)	1 (1)	0 (0)
Maternal morbidity		132	126	29
	important	110 (83)	123 (98)	29 (100)
	neutral	18 (14)	2 (2)	0 (0)
	not important	4 (3)	1 (1)	0 (0)
Neonatal morbidity		132	126	29
	important	110 (83)	121 (96)	28 (97)
	neutral	18 (14)	4 (3)	1 (3)
	not important	4 (3)	1 (1)	0 (0)
Preterm birth		131	126	29
	important	115 (88)	118 (94)	28 (97)
	neutral	13 (10)	7 (6)	1 (3)
	not important	3 (2)	1 (1)	0 (0)
Birth injury		131	126	29
	important	114 (87)	123 (98)	29 (100)
	neutral	14 (11)	2 (2)	0 (0)
	not important	3 (2)	1 (1)	0 (0)

Table 6. Survey participant's ratings per outcome: patient-reported outcomes

	Patients Total N (%)	Professionals N (%)	Administrators N (%)
Health-related quality of life	127	124	28
important	91 (72)	87 (70)	21 (75)
neutral	32 (25)	35 (28)	7 (25)
not important	4 (3)	2 (2)	0 (0)
Confidence with breastfeeding	127	124	28
important	75 (59)	91 (73)	21 (75)
neutral	44 (35)	31 (25)	5 (18)
not important	8 (6)	2 (2)	2 (7)
Success with breastfeeding	127	124	28
important	70 (55)	92 (74)	21 (75)
neutral	48 (38)	27 (22)	7 (25)
not important	9 (7)	5 (4)	0 (0)
Incontinence	127	124	28
important	81 (64)	89 (72)	26 (93)
neutral	39 (31)	29 (23)	2 (7)
not important	7 (6)	6 (5)	0 (0)
Pain with sex	127	124	27
important	57 (45)	70 (57)	22 (82)
neutral	48 (38)	46 (37)	3 (11)
not important	22 (17)	8 (7)	2 (7)
Postpartum depression	127	124	27
important	101 (80)	117 (94)	26 (96)
neutral	25 (20)	6 (5)	1 (4)
not important	1 (1)	1 (1)	0 (0)
Confidence in role	127	124	27
important	78 (61)	92 (74)	22 (82)
neutral	45 (35)	30 (24)	5 (19)
not important	4 (3)	2 (2)	0 (0)
Mother-infant attachment	127	124	27
important	94 (74)	109 (88)	26 (96)
neutral	29 (23)	12 (11)	1 (4)
not important	4 (3)	2 (2)	0 (0)

Table 6 - Continued. Survey participant's ratings per outcome: patient-reported outcomes

		Patients Total N (%)	Professionals N (%)	Administrators N (%)
Satisfaction with care		127	124	27
	important	104 (82)	115 (93)	27 (100)
	neutral	23 (18)	9 (7)	0 (0)
	not important	0 (0)	0 (0)	0 (0)
Health care responsiveness		127	124	27
	important	98 (77)	112 (90)	27 (100)
	neutral	29 (23)	12 (10)	0 (0)
	not important	0 (0)	0 (0)	0 (0)

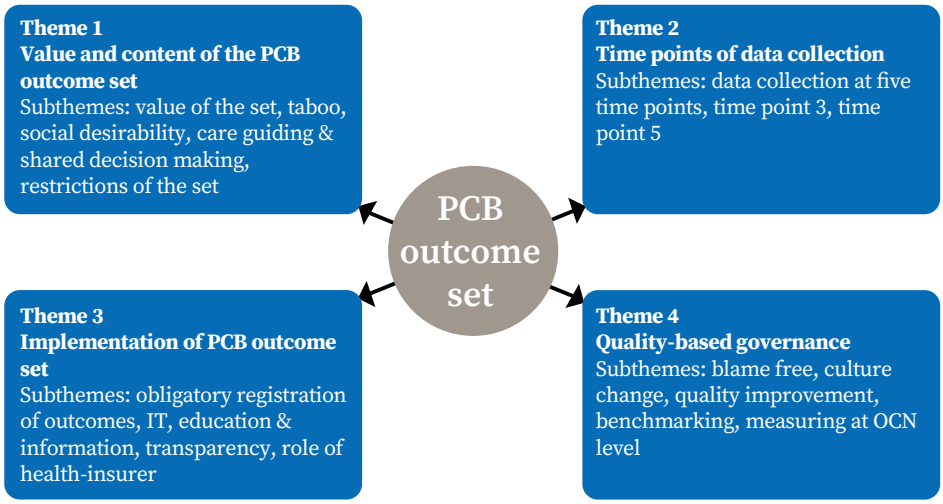

Figure 3. Main themes and their subthemes on the applicability of the PCB outcome set derived from the focus groups

Patients suggested completing PREMs anonymously, yet professionals noted that anonymous PREMs are difficult to interpret.
Professional and patients both felt that the complete set of outcomes can facilitate professionals to better guide care for their patients. Professionals also considered discussing the outcomes with their patients as an extra form of care. According to professionals, it allows patients to be better prepared because completing the questionnaires forces them to overthink the visit and address certain problems

during the visit. Patients mentioned the same benefits of discussing the outcomes with healthcare professionals. Patients and professionals endorsed that by collecting and discussing important outcomes SDM is supported. Patients stated that confidence in professionals is very important when discussing outcomes during all time points, but especially during time point three and five. With respect to restrictions of the current set, both patients and professionals underlined the importance of involving the partner in perinatal care, an item which is currently not covered by the PCB outcome set. Also professionals and patients underlined the lack of (dis)continuity of care outcomes in the PCB outcome set.

Box 2: Illustrative quotes on value and content of the PCB outcome set

Sub theme value of the PCB outcome set:
"... but I think that this is all very important and very good... So for the results herein [the PCB Set], I think it is extremely good that the experiences of the women themselves are captured [in the Set] ."
(Focus group patients, currently pregnant woman)

Sub theme taboo:
"And I also think that the more people question and discuss this [outcome in the Set], the less-" *(pregnant woman)*
"-high the threshold is." *(other pregnant woman)*
(Focus group patients)

Sub theme restrictions of the PCB outcome set:
"Especially the father, I believe. He experiences a lot of things differently compared to the mother; he is standing next to it and not in the middle of it."
(*Focus group professionals, maternity care assistant)*

Sub theme discussing outcomes with professionals:
"But I think it does make a difference whether you feel at ease with someone whether you want to talk about it. And then it may not even matter to you if someone else reads it, however, to talk about it, I believe that you would prefer to do this with someone you know."
(Focus group patients, currently pregnant woman)

Time points of data collection
Whereas professionals and administrators stated that data collection at five time points might be too taxing for patients, patients generally indicated that they would

not mind to fill in questionnaires multiple times. Patients reported that their compliance is likely to be maximized if safety, i.e. both regarding privacy and IT, is ensured. To increase their compliance, they also stated that questionnaires should contain relevant questions, outcomes should be discussed with their professional and an explanation on the PROs should be provided.
With respect to time point three both professionals and patients indicated that this is an important moment for interventions if problems occur. However, they mentioned that the interpretation of these PROs relies heavily on the timing and the designated professional discussing these outcomes.
All groups considered time point five as a valuable moment to revisit the perinatal care professional. Such a visit is currently lacking in perinatal care in the Netherlands. The groups agreed on the added value of discussing the outcomes and evaluating care at this time point, but differed in their views on which type of professional should discuss the outcomes. Whereas patients generally preferred the community midwife and felt that preventive child healthcare (PCHC) professionals were less suitable to discuss outcomes at this time point, professionals and administrators considered this to be an important task for PCHC professionals. They indicated that this could strengthen the connection between perinatal care and PCHC.

Box 3: Illustrative quotes on the time points of data collection:

Sub theme data collection at five time points:

"Personally, I really would not mind [to fill in 5 questionnaires]." *(pregnant woman)*
"Me neither, I would be willing to fill them in." *(several participants)*
(Focus group patients)

Sub theme time point 5:

"We always offer the postpartum check-up six weeks after delivery, but you notice that it is really too early to talk about it [childbirth] for some women. It would then be very nice to measure this because it is very easy to select these women. [...] And one would think that you can filter that during time point five."
(Focus group administrators, board member of an OCN)

Implementation of the PCB outcome setA recurrent theme in all focus groups was the implementation of the PCB outcome set. Both patients and administrators suggested that registration of the outcomes in the PCB outcome set should be obligatory, in order to make implementation successful. According to professionals

and administrators, direct access to outcomes derived from PROs in an adequate IT system was considered essential for delivering good care. Proper IT-arrangements were also considered essential to prevent excessive and duplicate registration, which would also benefit implementation.
Adequate education and information was formulated as a precondition for successful implementation by administrators and patients. Both for professionals, in order to effectively discuss outcomes with their patients, and for patients and professionals to underline the importance of measuring outcomes and the importance of these outcomes. Both patients and professionals indicated that information and education would be helpful to reduce the risk of social desirability and taboo on certain outcomes. All groups felt that exposure of the outcomes to patients, professionals and administrators, is necessary for implementation. They indicated that SDM and improving outcomes require transparency. However, administrators worried about the consequences of transparency of the outcomes; wrongful interpretation of outcomes by patients and health-insurers, e.g. when published on a website without additional information, was seen as a risk. Also, several professionals and administrators mentioned the role of the health-insurer as a possible barrier to implementation. They were hesitant about quality-based payment and interpretation of outcomes by health-insurers. Both professionals and administrators stressed that the PCB outcome set must be implemented step by step.

Box 4: Illustrative quotes on implementation of the PCB outcome set

Sub theme education:

"Yes, I also think about why do we need to fill in the questionnaire when providing information, what is done with the results eventually, then maybe you understand the need... what is in it for me."
(Focus group patients, mother)

Sub theme role of health-insurer:

"I would be hesitant if the health insurer gets it [the outcomes], because I am not convinced that they will interpret it correctly..."
(Focus group professionals, community midwife)

Quality-basedgovernance

All groups expressed that the PCB outcome set offers possibilities to focus on improvement of quality of care. Both administrators and professionals indicated that quality-based governance in more within reach with the PCB outcome set. However, they emphasized that comparing outcomes with an OCN must be

conducted blame-free and within a safe environment. In addition, administrators suggested that a culture change is needed in order to create an environment in which it is normal to address each other on outcomes.
All groups stated that in order to use outcomes for quality improvement, it should be part of the OCN's policy plan. Patients additionally mentioned that the outcomes should also be used to improve individual patient care.
Administrators and professionals reported mixed views on the use of benchmarking on outcomes. Professionals suggested that benchmarking should be implemented in small steps, first at the level of the OCN and without (financial) consequences. Professionals indicated that a next step would be clear agreements with the health insurers on the consequences of benchmarking on a national level. Both administrators and professionals emphasized that it is yet unclear whether the casemix in the PCB outcome set makes a sufficient distinction between different patient groups.
In order to increase quality of care, measuring outcomes and discussing them at an OCN level was considered to have the potential to stimulate learning from each other by administrators and professionals. Joint responsibility by all health care professionals involved in perinatal care, for both positive and negative outcomes, was set as a precondition by these groups.

Box 5: Illustrative quotes on quality based governance

Sub theme blame-free:
"It is very useful that you are allowed to, or may, show vulnerability, you are not to blame, you know. I think that is véry important."
(Focus group administrators, board member of an OCN)

Sub theme measuring at OCN level:
"Yes of course it depends on whether you see it both as a common goal, so to say. So if you only look at your own outcomes within your own practice, or at your own outcomes within the hospital, there is still no common outcome. So then you really need to tackle it together as an OCN."
(*Focus group professionals, clinical midwife)*

DISCUSSION

In this mixed methods study the applicability of the PCB outcome set was explored among patients, professionals, and administrators in five OCNs in the Netherlands. All user groups recognized the potential value in perinatal care of the PCB outcome set in which they believed the most important outcomes were represented. Also, the timing of data collection of the PCB outcome set was evaluated as appropriate. Essential preconditions for successful implementation mentioned by all user groups were: an adequate IT system, and education and information for both patients and professionals. To use the outcomes of the PCB outcome set for quality improvement, a culture change among professionals and transparency of outcomes were considered necessary.

A strength of this study is that we used both quantitative and qualitative data methods, thereby ensuring triangulation.[22] The results of the survey were used as input for the focus groups and the outcomes of both the survey and focus groups were discussed in the interdisciplinary working group. The focus group analysis generally supported the survey findings and provided an explanation and in-depth understanding of the arising issues. Furthermore, by involving all stakeholders, including professionals and administrators, we were able to gain a complete overview of users' perceived applicability, contributing to the robustness and generalizability of the results.

A limitation of our study is its sample size; the intended inclusion of 250 patients in the survey was not achieved. Selection bias is another potential limitation. We only included Dutch-speaking participants for both the survey and focus groups. Their perspectives, especially from patients, may differ from those with an immigrant background. On the other hand, both primary, secondary and tertiary care patients were represented and 17% of the included patients in the survey was of non-Western origin. Therefore, we expect that the potential influence of selection bias on the results was limited.

The comprehensiveness of the PCB outcome set was supported by all user groups. Consistent with the findings of the previous consumer validation survey of the PCB outcome set by Nijagal et al.[17], a vast majority of patients agreed that the PCB outcome set covered the most important outcomes. Some PROMs were perceived as less relevant as compared to others, similar to the consumer validation survey.[17] Possible explanations for this include the perceived taboo on certain outcomes (e.g. pelvic dysfunction) and lack of knowledge about the importance and incidence of these taboo-related outcomes[24-28], which was also reported by the participants.

PREMs were indicated as important, although patients in our focus group noted that these may yield socially desirable answers due to patients' dependence on their professional. This may restrict reliability of PREMS, and anonymously

collected PREMS may be a useful solution.[29]
Patients generally felt that timing of data collection in the PCB set was appropriate. Data collection at five time points was not considered as a burden by patients. It is interesting to note that time point five (i.e. six months postpartum) was considered a valuable data collection point by all user groups, particularly as perinatal care in the Netherlands currently only extends up to six weeks postpartum. Patients and professionals both regarded discussing the long-term outcomes of pregnancy and childbirth with the expert professional of importance. Whether working with the PCB outcome set actually benefits patient care requires further study through an implementation project.
Providing patients with adequate information on the importance of outcomes and of measuring them was mentioned as a key factor. The fact that outcomes were going to be discussed with professionals was considered to contribute to the motivation to complete questionnaires. Signaling a decline in scores of certain PROs over time or an unfavorable PRO at one of the time points, and discussing them with the patient, will allow institution of appropriate interventions in order to improve outcomes. In this way, implementation of the PCB outcome set may enhance individualized care via SDM. Follow-up research during implementation of the set is required to assess whether this actually leads to improved maternal and perinatal outcomes. Completing PROMs can also lead to a better patient understanding of their condition and empowers patients to discuss certain topics with their professional.[30] This mechanism was also acknowledged by patients in our focus groups.
Another key factor was the importance of educating professionals on applying VBHC. This precondition has previously been acknowledged by post-implementation studies of other ICHOM outcome sets.[15,16] Similar to our work, these studies also identified adequate IT as an important key factor for successful implementation. The need for adequate IT was recognized, particularly to minimize registration burden among professionals.
According to professionals and administrators the PCB outcome set also provides opportunities for comparing outcomes to improve quality of care (i.e. benchmarking). Professionals emphasized that a culture change is necessary in order to safely address each other on outcomes. Consistent with our results, both Arora et al. and Porter and Teisberg stated that professionals need to lead these culture changes and the process of comparing outcomes.[9,16]
Also, the role of the health-insurer in terms of financial consequences was highlighted. Administrators and professionals in our focus groups feared the financial consequences of measuring outcomes and making them transparent towards insurers. Clear agreements with insurers on the consequences of transparent outcomes and introducing benchmarking on outcomes step by step on a small scale seem proper solutions which were suggested by participants in the focus

groups. Implementing an outcome set on a small scale first was also advised by Arora et al.[16] Further research is required into the effects of benchmarking on quality of perinatal care.
Two outcomes were currently missed by the user groups, namely continuity of care and the role of the partner. Dutch patients, professionals and administrators suggested to add these subjects to the PCB outcome set. This shows that for assessing and improving quality of care for different settings, some context-specific outcomes can be added to the PCB outcome set.

CONCLUSION

Our study shows that the PCB outcome set is accepted as an appropriate instrument for evaluation of quality of perinatal care and SDM by all patients, professionals and administrators in the Dutch perinatal care system. The PCB outcome set was found to contain the most important outcomes as judged by end-users. Minor context-specific additions were suggested by the user groups. The suggested timing of the data collection was also judged as adequate and data collection was perceived to add value to perinatal care. It is essential that adequate IT support is warranted and that education on the PCB outcome set is provided to professionals and patients. Finally, our methodology may serve as an example for other perinatal healthcare systems across the globe, and other disease or patient groups for whom ICHOM develops outcome standards.

Practice implications

- The implementation of the ICHOM PCB outcome set with additional outcomes regarding the role of the partner and continuity of care must be closely monitored in an implementation pilot. Further research should focus on the value of the PCB outcome set to patients, professionals and administrators in perinatal care.
- The additional evaluation of patient-reported outcomes at six months postpartum according to the PCB outcome set would require a change of daily practice. This time point is seen by endusers as a valuable addition to perinatal care. In order to fully utilize the added value of discussing the outcomes, special attention must be paid to make patients feel familiar with professionals especially at this time point.
- The focus of working with the PCB outcome set for both professionals and administrators must be on transparency of the outcomes, to be able to make progress towards quality improvement. Outcomes must be made transparent to all stakeholders involved in perinatal care.

- During implementation of the PCB outcome set, attention must be paid to the feasibility of working with the PCB outcome set for professionals. Development of IT solutions for transferring data and merging professional-reported data with patient-reported data is essential in order to reduce registration burden, and to support benchmarking. Additionally, adequate data could provide insight in perinatal outcomes. The effect of working with the PCB outcome set on these outcomes can be assessed during implementation.

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SUPPLEMENTARY FILES

Supplementary file A

Patients

Each OCN led the survey of participants whose pregnancy/postpartum period was at a specific time point, see supplemental table 1. We had a target number of inclusions of 50 per time point, thus 250 in total. Eligibility criteria were: (a) age eighteen years or older, (b) sufficient understanding of Dutch language and (c) specific time point criteria (see table A1). One week after sending the original invite, a reminder was sent to potential participants by e-mail.

Professionals

The survey was distributed by e-mail according to the snowball-method: each project team member spread the survey among colleagues in their OCN, and asked the receivers to spread the survey. We aimed to reach both clinical and community midwives, gynecologists (second and third tier), physician assistants, (specialized) nurses, pediatricians and neonatologists, and maternity care assistants. LL and HE regularly asked members of the working group to remind their colleagues to complete the survey.

Administrators

Every project team member was asked to suggest administrators in his or her OCN to participate in the survey. In each OCN we aimed to reach board members of: hospitals, OCNs, maternity care organizations, midwife practices, and primary care birth centers. Also heads of departments (gynecology or neonatology) were approached.

A reminder was sent several weeks after sending the first invitation.

Table A1. patient recruitment for survey

Time point	OCN (city)	Hospital in OCN	How participants were reached	Specific criteria at inclusion	Recruitment procedure
1 (until 16 weeks of gestation)	Leiden	tertiary	midwives and gynecologists	gestational age between 12 and 16 weeks	during regular controls, e-mail with link to survey sent by researcher
2 (28-32 weeks of gestation)	Zwolle	tertiary	midwives and gynecologists	gestational age between 28 and 32 weeks	during regular controls, e-mail with link to survey sent by researcher
3 (first week after birth)	Haarlem	general	maternity care organization	max. 1 week postpartum	e-mail sent by maternity care organization
4 (4 – 6 weeks postpartum)	Rotterdam	tertiary	primary care birth center	between 2 and 8 weeks postpartum	during post-partum stay, e-mail with link 4 weeks after delivery
5 (6 months postpartum)	Utrecht	tertiary	maternity care organization	between 22 and 26 weeks postpartum	e-mail sent by maternity care organization

Regarding time point 4: patients admitted to a primary care birth center were asked to participate after explanation of the survey by maternity care assistants. Because of a low number of inclusions, participants were recruited according to the same method as described for time point 3 and 5.

Supplementary file B

Table B1. Topics discussed during the focus groups

Administrators	Professionals	Patients
Importance of PROMs	Comprehensiveness of PCB outcome set	Burden and compliance
Shared responsibility PCB outcome set	Burden for patients	Social desirability
Shift measuring outcomes to improving outcomes	Importance of PROMs	Comprehensiveness of PCB outcome set
Responsibility	Shared responsibility PCB outcome set	Discussing outcomes
Time point 5 (designated professional, responsibility)	Time point 5 (designated professional, responsibility)	Shared decision making
Culture change	Discussing outcomes with patients	Quality of health care
Benchmarking	Aggregated outcomes	Transparency of outcomes
	Benchmarking	Time point 3 and 5
		Data collection and storage

Supplementary file C (table C1, C2 and C3)

Table C1. Baseline characteristics of focus group: administrators

Gender	Profession	Organization	Work experience (years)
F	board member	OCN	3
F	board member	OCN	4
F	board member	OCN	6
F	board member	OCN	3
F	deputy head of department	tertiary hospital	2
F	board member	primary care birth center	10
F	CEO	maternity care organization	10

Table C2. Baseline characteristics of focus group: professionals

Gender	Profession	Organization	Work experience (years)
F	community midwife	midwifery practice	24
F	community midwife	midwifery practice	26
F	community midwife	midwifery practice	18
F	maternity care assistant	maternity care organization	18
F	maternity care assistant	maternity care organization	26
F	community midwife	midwifery practice	7
F	clinical midwife	general hospital	11
M	resident in gynecology	general hospital	2
F	clinical midwife	tertiary hospital	27
F	gynecologist	general hospital	5
F	resident in gynecology	tertiary hospital	6
F	gynecologist	tertiary hospital	3

Table C3. Baseline characteristics of focus group: patients

Age	Partner	Education level	Ethnicity	Duration of pregnancy	Parity	Age of youngest child	(desired) Place of (last) delivery	Complicated pregnancy/ childbirth
30	yes	high	Dutch	24 weeks	0	-	home	no
35	yes	high	Dutch	-	2	12 months	general hospital	no
30	yes	high	Dutch	-	1	9 months	home	no
27	yes	high	Dutch	32 weeks	1	24 months	general hospital	no
33	yes	middle	Dutch	30 weeks	2	6 years	general hospital	no
36	yes	middle	Dutch	-	2	18 months	primary care birth center	no

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Chapter 6

Patient-reported outcome and experience measures in perinatal care to guide clinical practice: prospective observational study

Anne L Depla
Marije Lamain-de Ruiter
Lyzette T Laureij
Hiske E Ernst-Smelt
Jan A Hazelzet
Arie Franx
Mireille N Bekker
On behalf of the BUZZ project team
Journal of Medical Internet Research 2022;5;24(7):e37725

ABSTRACT

Background: The International Consortium for Health Outcomes Measurement has published a set of patient-centered outcome measures for pregnancy and childbirth (PCB set), including patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). To establish value-based pregnancy and childbirth care, the PCB set was implemented in the Netherlands, using the outcomes on the patient level for shared decision-making and on an aggregated level for quality improvement.
Objective: This study aims to report first outcomes, experiences, and practice insights of implementing the PCB set in clinical practice.
Methods: In total, 7 obstetric care networks across the Netherlands, each consisting of 1 or 2 hospitals and multiple community midwifery practices (ranging in number from 2 to 18), implemented the PROM and PREM domains of the PCB set as part of clinical routine. This observational study included all women participating in the clinical project. PROMs and PREMs were assessed with questionnaires at 5 time points: 2 during pregnancy and 3 post partum. Clinical threshold values (alerts) supported care professionals interpreting the answers, indicating possibly alarming outcomes per domain. Data collection took place from February 2020 to September 2021. Data analysis included missing (pattern) analysis, sum scores, alert rates, and sensitivity analysis.
Results: In total, 1923 questionnaires were collected across the 5 time points: 816 (42.43%) at T1 (first trimester), 793 (41.23%) at T2 (early third trimester), 125 (6.5%) at T3 (maternity week), 170 (8.84%) at T4 (6 weeks post partum), and 19 (1%) at T5 (6 months post partum). Of these, 84% (1615/1923) were filled out completely. Missing items per domain ranged from 0% to 13%, with the highest missing rates for depression, pain with intercourse, and experience with pain relief at birth. No notable missing patterns were found. For the PROM domains, relatively high alert rates were found both in pregnancy and post partum for incontinence (469/1798, 26.08%), pain with intercourse (229/1005, 22.79%), breastfeeding self-efficacy (175/765, 22.88%), and mother-child bonding (122/288, 42.36%). Regarding the PREM domains, the highest alert rates were found for birth experience (37/170, 21.76%), shared decision-making (101/982, 10.29%), and discussing pain relief ante partum (310/793, 39.09%). Some domains showed very little clinical variation; for example, role of the mother and satisfaction with care.
Conclusions: The PCB set is a useful tool to assess patient-reported outcomes and experiences that need to be addressed over the whole course of pregnancy and childbirth. Our results provide opportunities to improve and personalize perinatal care. Furthermore, we could propose several recommendations regarding methods and timeline of measurements based on our findings. This

study supports the implementation of the PCB set in clinical practice, thereby advancing the transformation toward patient-centered, value-based health care for pregnancy and childbirth.

INTRODUCTION

Background

Currently, health care systems are moving toward high-value care, adapted to each individual patient.[1,2] These health care systems prioritize patients' health goals in care decisions and quality improvement, above processes and clinical parameters. The transformation into a patient-centered, value-driven system is dependent on access to data that capture what matters most to patients.[3-5] Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) provide standardized assessment of patients' health status or experience with health care directly from the patient.[6] Integrated into routine care, these measures can facilitate patient-provider communication, improve patients' experiences, and enhance detection and management of their health status.[7-9] When aggregated, PROMs and PREMs foster inclusion of patients' perspective in continuous quality improvement, along with clinical measures that have already been captured for quality performance.[10]

Just as in other disciplines, perinatal care may benefit from systematic PROM and PREM assessment to enhance quality of care. Moreover, patient-reported outcomes of perinatal care, such as depression or incontinence, may have serious long-term consequences for the health of the mother and child and might currently be undervalued. The interest in, and use of, PROMs and PREMs has grown in perinatal care, but most PROMs and PREMs in this field are assessed anonymously for quality improvement or research purposes only, whereas PROMs and PREMs, if integrated in clinical care on an individual level, could provide perinatal caregivers an opportunity to detect symptoms and adapt care appropriately, as well as encourage patients to think, and speak, about their current well-being and experiences.[12] Nevertheless, clinical integration of PROMs and PREMs has many challenges such as selecting relevant topics, valid assessment instruments, measurement moments, and threshold values that require action.[3,13,14]

The International Consortium for Health Outcomes Measurement (ICHOM) has published a core set of patient-centered outcome measures for pregnancy and childbirth (PCB set), proposing standardized measures of clinical outcomes as well as patient outcomes and experiences over the full cycle of care.[15] For its pa-

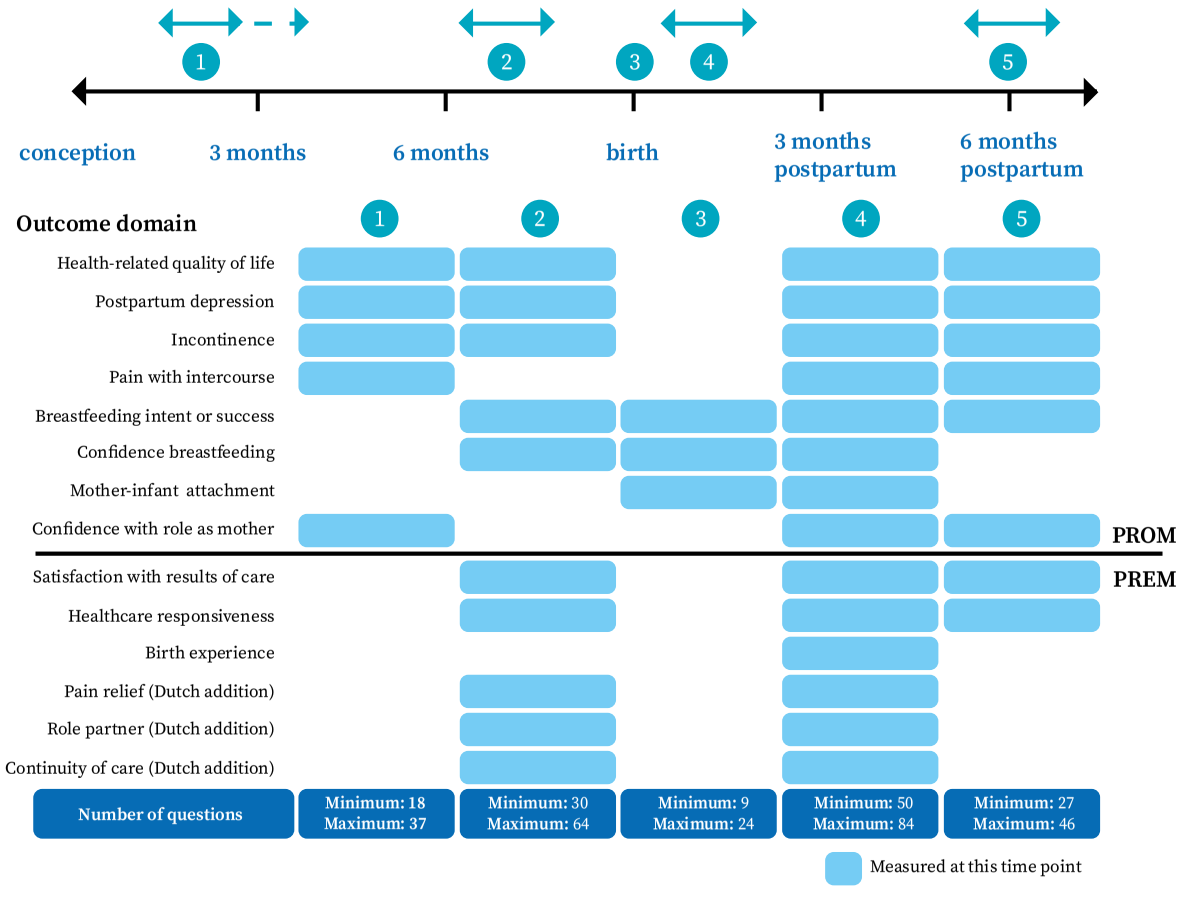

Figure 1. Pregnancy and childbirth outcome set: patient-reported domains and moments to measure (adapted from Nijagal et al[16]). PREM: patient-reported experience measure; PROM: patient-reported outcome measure.

tient-reported domains, the PCB set includes measurement instruments (ie, questionnaires) and a timeline for assessment: at 5 time points throughout pregnancy and post partum until 6 months after birth (Figure 1).[16] Recently, the feasibility and acceptability of the PCB set were studied in clinic and its patient-reported domains collected for research purposes.[17-19] In addition, some of its measurement instruments were evaluated for validity and reliability in a maternity population.[20-22] However, little is known regarding compliance with the PROM and PREM questionnaires of the PCB set and the clinical performance of threshold values that require action throughout pregnancy and the postpartum period.

Study Rationale

In an implementation project across the Netherlands, 7 regions incorporated the PCB set in clinic over the full cycle of perinatal care with all care professionals involved. In the journey toward value-based perinatal care, the primary goal was to discuss individual PROMs and PREMs as part of regular care and use them for shared decision-making to personalize care accordingly (level 1 of value-based health care). Furthermore, aggregated PROM and PREM results could be used for patient-centered quality improvement (level 2 of value-based health care). During the project, we closely monitored first experiences and practice insights of the regions' incorporation of patient-reported measures into routine perinatal care at an individual level. This study aimed to report compliance with the PROM and PREM questionnaires, the outcomes per domain throughout pregnancy and post partum, and the clinical use of threshold values. Our findings can support clinical implementation of value-based health care with the PCB set, accelerate the transformation toward personalized care, and contribute to governance of the PCB set to retain its international comparability.

METHODS

Study design

An observational study was conducted to report and gain insight into PROMs and PREMs as part of clinical routine for personalized perinatal care. This paper is written following the Strengthening the Reporting of Observational Studies in Epidemiology checklist.[23]

Setting

This study was carried out as part of a project involving the implementation of the PCB set in Dutch perinatal care called the Dutch abbreviation of Discuss Outcomes

of Pregnancy with the Pregnant Woman (BUZZ) project. In total, 7 regions across the Netherlands joined forces to implement the PROM and PREM domains of the PCB set in routine clinical practice. The implementation was supported by Zorginstituut Nederland and coincided with a nationwide ministry program to enhance value-based health care and shared decision-making.[24] Each participating region consisted of 1 or 2 hospitals and 2 to 18 community midwifery practices (Table 1) collaborating in local obstetric care networks (OCNs; refer to Textbox 1 for an explanation of Dutch perinatal care organization). Data were collected from February 2020 to September 2021.

Textbox 1. Organization of Dutch perinatal care

Organization of Dutch perinatal care

- Dutch perinatal care is organized in a 2-tier system.
- Community midwives provide primary care for low-risk pregnancies and act as gatekeepers to specialist care. These midwives have their own professional autonomy, responsibilities, and financial arrangements.
- For medium-to high-risk pregnancies, hospital-employed obstetric care professionals provide secondary or tertiary specialist care.
- Of all women receiving perinatal care, up to 70% visit both health care tiers.[25]
- Over the last decade, a more integrated obstetric care system has been advised by the ministry of health, which is partly being realized by collaboration of both tiers in obstetric care networks

Participants

Women receiving perinatal care at a participating organization were invited to complete PROM and PREM questionnaires as part of usual care. Women who additionally gave informed consent to use their answers for research were included in this study. Informed consent was obtained in the PROM and PREM questionnaire itself. As this study aimed to report outcomes of the PCB set as is, we report the results of all PROM and PREM questionnaires collected within the project period; no target size was predetermined.

Implementation in Clinical Practice

The primary purpose of the BUZZ project was to use PROM and PREM questionnaires to guide individual perinatal care. Pregnant and postpartum women were invited to fill out questionnaires as part of routine care and their obstetric care professional discussed the answers in their next regular visit. The BUZZ project

Table 1. Implementation strategy per obstetric care network

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7
Timepoint 1 First trimester			✓	✓	✓	✓	
Timepoint 2 Third trimester	✓	✓	✓	✓	✓	✓	
Timepoint 3 Maternity week			✓	✓	✓	✓	✓
Timepoint 4 Postpartum 5-6 weeks		✓	✓	✓	✓	✓	✓
Timepoint 5 Postpartum 6 months			> [a]		✓		✓
Collection	Stand-alone data capture tool	EHR [b]	EHR [b]	Stand-alone data capture tool	Stand-alone data capture tool	Stand-alone data capture tool	Paper
Hospitals	1	1	1	1	1	1	2
Community midwifery practices	3	2	13	2	2	9	18
Patient group	All	All	All	Women in vulnerable situations	Diabetes + history of CS [c]	GBS+ [d]	Induction with AROM [e] by CM [f]

[a] Planned to implement, at the end of project period; [b] HER: electronic health record; [c] CS: caesarean section; [d] GBS+: urine sample positive for Group B streptococcus in pregnancy; [e] AROM: artificial rupture of membranes; [f] CM: community midwife

was explicitly organized within OCNs to ensure continuity of care over the full cycle of care for pregnancy and childbirth. The project team of each OCN made local decisions to enhance implementation in their practice on several key points (Table 1):

- Mode of administering questionnaires: some sites could capture questionnaires through their electronic health record (EHR), others used a stand-alone data capture tool, and 1 site used paper questionnaires (whatever at that moment was considered the most optimal to use the responses in their clinical setting).
- Population and time points: most sites chose to start small by either selecting a few time points for PROM and PREM assessment or a specific patient group.

- Site-specific adaptations: some sites made minor adaptations to the questionnaire content. For example, 1 site dismissed the screening questions for depression and used the full questionnaire in all women.

Outcome Measures

The PCB set's PROM and PREM domains were captured as proposed by ICHOM with questionnaires at 5 time points during pregnancy and post partum (Figure 1).[16] Each domain is assessed with its own measurement instrument, consisting of one or more questions (Multimedia Appendix 1). At every time point only relevant domains are assessed. In some domains, one or more screening questions can either rule in or rule out further questions for that domain. To fit Dutch perinatal care, a few domains have been added to the original PCB set (Figure 1).[17] Before implementation, the translated Dutch questionnaires were tested among 4 women with low health literacy by the Dutch center of expertise on health disparities (Pharos). Minor adaptations were carried out where possible; questionnaires already validated in Dutch were not adapted. For each measurement instrument a clinical threshold value (alert) was defined according to existing literature or, if not available, determined by the multidisciplinary national BUZZ project team, informed by expert opinion (Multimedia Appendix 1). The alerts supported care professionals interpreting the answers, indicating worrisome outcomes through a color-coded dashboard (or calculated by hand in case of paper questionnaires). As clinical data could not yet be merged (digitally), a few casemix variables were collected through the questionnaires: age, gravidity, parity, postal code, and ethnicity.

Data Analysis

Only the data of women who gave informed consent were uploaded by project leaders to a central and highly secure digital research environment. Data merging and analysis was performed on this secured server using R software (version 4.0.2; The R Foundation for Statistical Computing).[26] Duplicate and blank questionnaires resulting from technical problems were removed. In addition, questionnaires with only the first item filled out, requesting informed consent or social support, were excluded because we could not determine whether this resulted from a technical problem. A new option to answer a question was added by 1 site (ie, not applicable): these answers have been considered missing in analysis because they were not included in the national (validated) scoring systems. Secondary analysis of these data was considered, but the numbers were too small. Questions that were answered unintentionally, for example, a full depression questionnaire filled out despite having scored a negative screening, were removed. The casemix variables gravidity and parity are reported as state in current pregnancy: if parity and gravidity were equal, parity was corrected to gravidity–1. Comple-

tion rates were calculated per question and per measurement instrument. If applicable, sum scores were calculated according to a predefined scoring system. Missing items were excluded from this calculation; therefore, sum scores with one or more missing items are lower by definition. Alerts were calculated according to the thresholds provided in Multimedia Appendix 1. In an additional sensitivity analysis of domains with multiple questions, results with >25% missing items were removed, and their mean sum scores and alert rates were compared with the complete analysis.

Ethics Approval

The Medical Ethics Review Committee of the Erasmus Medical Center (MEC-2020-0129) declared that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study. Therefore, it was exempt from formal medical ethics assessment. For each site, local approval was obtained from the regional ethics board.

RESULTS

Overall

In total, 1923 unique questionnaires were collected, most of them during pregnancy (Table 2). The median moments of completion corresponded well with the proposed time points (Figure 1). Some T2 and T4 questionnaires were completed earlier than the proposed window, whereas a few T1 questionnaires were filled out too late. The questionnaires were filled out by 1318 individual women, of whom 838 (63.58%) completed 1 questionnaire, and the remaining 480 (36.41%) completed up to 4 questionnaires. Their baseline characteristics are presented in Table 3. Sum scores and alerts per domain and time point are presented in Tables 4 and 5. Multimedia Appendix 2 contains figures that show each domain's scores and alerts.

PROM per Domain

Social Support

Of the 1092 women who were asked the social support question, administered at the first time point in pregnancy that each site had implemented, 44 (4.03%) scored an alert, meaning that they had 1 or no person near them to count on in time of difficulty. A comparison of T1 and T2 showed a slightly higher alert rate at T2 (17/25, 6.8%) than at T1 (26/815, 3.19%).

Quality of Life

The quality-of-health domain, assessed with the Patient-Reported Outcomes Measurement Information System–Global Health Short Form, had few alerts at all time points. The alerts were based on the sum score; no alerts came from a high pain score. In additional analysis, calculation of subscores for mental and physical health showed no variation across time points.

Table 2. Moment of completing questionnaire completion (N=1923)

Time point	Value, n (%)	Moment of questionnaire completion Median (range)
First trimester (T1)	816	15 (9-27)[a]
Early third trimester (T2)	793	28 (23-37)[a]
Maternity week[b] (T3)	125	5 (4-5)[c]
Postpartum, 6 weeks[b] (T4)	170	3 (0-12)[d]
Postpartum, 6 months (T5)	19	27 (22-30)[d]

[a] Moment occurred in weeks of pregnancy.
[b] The exact moment of completion was missing for maternity week and 6 weeks post partum for 123 and 127 questionnaires, respectively. Because of the information technology system setup, we do know that maternity week questionnaires were completed mostly between 1 and 3 weeks post partum and 6 weeks post partum questionnaires between 3 and 5 weeks post partum.
[c] Moment occurred in days post partum.
[d] Moment occurred in weeks post partum.

Table 3. Participant characteristics (N=1318)

Characteristics	Values
Age (years), median (range); missing: n=77	32 (17-46)
Parity, n (%); missing: n=330	
Nulliparous	360 (36.43)
Multiparous	628 (63.56)
Ethnicity, n (%); missing: n=143	
Western	1057 (89.96)
Other	118 (10.04)

Table 4. Outcomes per patient-reported outcome measure domain.

Domain and subdomain	Time point	Value, n (%)	Score, median (range)	Alerts, n (%)	Missing[a], n (%)
Social support	All	1092 (56.79)	3 (0-3)	44 (4.06)	7 (0.64)
Quality of life					
	All	1798 (93.5)	37 (7-50)	21 (1.17)	1 (0.06)
	T1[b]	816 (45.38)	38 (7-50)	6 (0.74)	0 (0)
	T2[c]	793 (44.1)	37 (7-50)	12 (1.52)	1 (0.13)
	T4[d]	170 (9.45)	38 (14-49)	2 (1.18)	0 (0)
	T5[e]	19 (1.06)	37 (19-46)	1 (5.26)	0 (0)
Mental health					
Screen depression					
	All	1756 (91.32)	0 (0-6)	61 (3.52)	25 (1.42)
	T1	798 (45.44)	0 (0-6)	33 (4.19)	10 (1.25)
	T2	776 (44.19)	0 (0-5)	22 (2.85)	5 (0.64)
	T4	163 (9.28)	0 (0-5)	5 (3.27)	10 (6.13)
	T5	19 (1.08)	0 (0-4)	1 (5.26)	0 (0)
Full depression[f]					
	All	103 (5.36)	10 (0-25)	47 (52.22)	13 (12.62)
	T1	51 (49.51)	11 (0-23)	27 (52.94)	0 (0)
	T2	39 (37.86)	7 (0-25)	13 (44.83)	10 (25.64)
	T4	12 (11.65)	12 (3-25)	6 (66.67)	3 (25)
	T5	1 (0.97)	N/A[g]	1 (100)	0 (0)
Incontinence and dyspareunia					
Screen, urine					
	All	1798 (93.5)	—[h]	469 (26.91)	55 (3.06)
	T1	816 (45.38)	—	150 (20.15)	22 (2.7)
	T2	793 (44.1)	—	266 (34.64)	25 (3.15)
	T4	170 (9.45)	—	45 (27.78)	8 (4.7)
	T5	19 (1.06)	—	8 (42.1)	0 (0)
Screen, stool					
	All	1798 (93.5)	—	15 (0.86)	57 (3.17)
	T1	816 (45.38)	—	3 (0.38)	23 (2.82)
	T2	793 (44.1)	—	6 (0.78)	26 (3.28)
	T4	170 (9.45)	—	6 (3.70)	8 (4.71)
	T5	19 (1.06)	—	0 (0)	0 (0)

Table 4 - Continued. Outcomes per patient-reported outcome measure domain.

Domain and subdomain	Time point	Value, n (%)	Score, median (range)	Alerts, n (%)	Missing[a], n (%)
Screen, flatus					
	All	1798 (93.5)	—	388 (22.26)	55 (3.06)
	T1	816 (45.38)	—	149 (18.77)	22 (2.7)
	T2	793 (44.1)	—	190 (24.74)	25 (3.15)
	T4	170 (9.45)	—	44 (27.16)	8 (4.71)
	T5	19 (1.06)	—	5 (26.32)	0 (0)
Full urine[f]					
	All	469 (24.39)	6 (0-18)	185 (39.45)	0 (0)
	T1	150 (31.98)	6 (0-15)	62 (41.33)	0 (0)
	T2	266 (56.72)	5 (1-18)	100 (37.59)	0 (0)
	T4	45 (9.59)	6 (1-15)	19 (42.22)	0 (0)
	T5	8 (1.71)	7 (3-12)	4 (50)	0 (0)
Full stool and flatus[f]					
	All	394 (20.49)	3 (0-17)	385 (97.96)	1 (0.25)
	T1	151 (38.32)	3 (0-10)	147 (98)	1 (0.66)
	T2	193 (48.98)	3 (0-14)	190 (98.45)	0 (0)
	T4	45 (11.42)	3 (0-17)	43 (95.56)	0 (0)
	T5	5 (1.27)	2 (2-3)	5 (100)	0 (0)
Pain with intercourse					
	All	1005 (52.26)	0 (0-5)	229 (24.65)	76 (7.56)
	T1	816 (81.19)	0 (0-5)	161 (20.72)	39 (4.78)
	T4	170 (16.91)	1 (0-5)	59 (44.36)	37 (21.76)
	T5	19 (1.89)	0 (0-5)	9 (47.37)	0 (0)
Breastfeeding					
Breastfeeding intention	All (T2)	793 (41.24)	—	172 (22.4)[i]	25 (3.15)
Breastfeeding success					
	All	314 (39.6)	—	116 (39.46)[j]	20 (6.37)
	T3[k]	125 (39.81)	—	45 (36)[j]	0 (0)
	T4	170 (54.14)	—	61 (40.67)[j]	20 (11.76)
	T5	19 (6.05)	—	10 (52.63)[j]	0 (0)
Screen, breastfeeding confidence[f]					
	All	765 (39.78)	4 (1-5)	175 (23)	4 (0.52)
	T2	596 (77.91)	4 (1-5)	150 (25.25)	2 (0.34)
	T3	80 (10.46)	4 (2-5)	13 (16.46)	1 (1.25)
	T4	89 (11.63)	4 (1-5)	12 (13.64)	1 (1.12)

Table 4 - Continued. Outcomes per patient-reported outcome measure domain.

Domain and subdomain	Time point	Value, n (%)	Score, median (range)	Alerts, n (%)	Missing[a], n (%)
Full breastfeeding self-efficacy[f]					
	All	175 (9.1)	40 (4-64)	124 (72.94)	5 (2.86)
	T2	150 (85.71)	41 (14-64)	104 (71.23)	4 (2.67)
	T3	13 (7.43)	36 (12-54)	11 (84.62)	0 (0)
	T4	12 (6.86)	27 (4-52)	9 (81.82)	1 (8.33)
Role transition					
Mother-child bonding					
	All	288 (14.98)	2 (0-11)	122 (44.85)	16 (5.56)
	T3	125 (43.4)	2 (0-8)	56 (45.9)	3 (2.4)
	T4	163 (56.6)	2 (0-11)	66 (44)	13 (7.98)
Role as mother					
	All	1005 (52.26)	4 (1-5)	3 (0.31)	40 (3.98)
	T1	816 (81.19)	4 (2-5)	1 (0.13)	26 (3.19)
	T4	170 (16.91)	5 (2-5)	1 (0.64)	14 (8.24)
	T5	19 (1.89)	5 (1-5)	1 (5.26)	0 (0)

[a] Completely missing.
[b] T1: first trimester.
[c] T2: early third trimester.
[d] T4: 6 weeks postpartum.
[e] T5: 6 months postpartum.
[f] Optional subdomain, dependent on screening question or questions.
[g] N/A: not applicable.
[h] Answer options were yes or no; therefore, there are no median and range values.
[i] Alert means no intention to breastfeed.
[j] Alert means feeding baby only formula.
[k] T3: maternity week.

Mental Health

In 3.52% (61/1731) of the women completing the 2-item depression screening (Patient Health Questionnaire-2 [PHQ-2]) an alert was scored, without variations over time. Women with an alert on the PHQ-2 filled out the full depression questionnaire (ie, Edinburgh Postnatal Depression Scale-10 [EPDS-10]). As 1 region dismissed the PHQ-2 screening questions, 29 women filled out the EPDS-10 directly. The EPDS-10 exceeded the clinical threshold in 52% (47/90) of the women, meaning that 2.67% (47/1760) of the women in the whole population screened positive for depression. The numbers with regard to the EPDS-10 results were too small to allow for interpreting variations over time.

Table 5. Outcomes per patient-reported experience measure domain.

Domains and subdomains	Time point	Value, n (%)		Score, median (range)	Alerts, n (%)	Missing[a], n (%)
Satisfaction with care						
	All	982 (51.07)		3 (1-4)	4 (0.43)	58 (5.91)
	T2[b]	793 (80.75)		3 (1-4)	4 (0.53)	45 (5.67)
	T4[c]	170 (17.31)		4 (2-4)	0 (0)	13 (7.64)
	T5[d]	19 (1.93)		3 (2-4)	0 (0)	0 (0)
Health care responsiveness and shared decision-making						
	All	982 (51.07)		16 (2-16)	101 (10.67)	35 (3.56)
	T2	793 (80.75)		16 (2-16)	82 (10.72)	28 (3.53)
	T4	170 (17.31)		16 (2-16)	17 (10.43)	7 (4.12)
	T5	19 (1.93)		14 (4-16)	2 (10.53)	0 (0)
Birth experience	All (T4)	170 (8.84)		30 (8-40)	37 (23.27)	11 (6.47)
Pain relief						
Information ante partum	All (T2)		793 (41.24)	1 (0-2)	310 (41.33)	43 (5.42)
Experience at birth	All (T4)		170 (8.84)	3 (1-4)	4 (2.65)	19 (11.18)
Partner role						
During pregnancy	All (T2)		793 (41.24)	3 (0-5)	56 (7.35)	31 (3.91)
At birth	All (T4)		170 (8.84)	4 (0-5)	1 (0.66)	18 (10.59)
Continuity of care						
	All	963 (50.08)		11 (4-12)	55 (6.08)	58 (6.02)
	T2	793 (82.35)		11 (4-12)	49 (6.54)	44 (5.55)
	T4	170 (17.65)		11 (4-12)	6 (3.85)	14 (8.24)

[a] Completely missing.
[b] T2: early third trimester.
[c] T4: 6 weeks postpartum.
[d] T5: 6 months postpartum

Incontinence and Dyspareunia

The screening question for urine and flatus incontinence was positive in 1 of 4 women. This proportion was lower at T1 than at the other time points. Screening for stool incontinence was positive in 0.86% (15/1741) of the cases, mostly at T4 (6/162, 3.7%). The full questionnaires in case of a positive incontinence screening resulted in alert rates of 39.4% (185/469) on urine incontinence (International Consultation on Incontinence Questionnaire, Short Form) and 97.96% (385/393) on

flatus or stool incontinence or both (Wexner scale). Women who screened positive for flatus incontinence but not to stool incontinence scored lower on the Wexner scale (median 3; range 0-11) than women who screened positive for stool incontinence with or without flatus incontinence (median 6; range 1-17). In 24.7% (229/929) of the women, an alert was scored on dyspareunia, with a lower alert rate at T1 than at the other time points.

Breastfeeding

During pregnancy, 77.6% (596/768) of the women intended to breastfeed their baby. After giving birth, 64% (80/125) of the women indicated that they would breastfeed their baby (fully or combined with formula) in the first week post partum, which decreased over time: 59% (89/150) at 6 weeks and 47% (9/19) at 6 months post partum. Of the 761 women who were breastfeeding (T3 or T4) or intended to (T2), 175 (23%) scored an alert on the screening question for confidence in breastfeeding. This alert rate was higher during pregnancy than during the postpartum period. After a positive screening question, the full breastfeeding self-efficacy questionnaire (ie, Breastfeeding Self-Efficacy Scale-10) gave an alert in 72.9% (124/170) of the cases.

Role Transition

The mother-child bonding questionnaire (Mother-to-Infant Bonding Scale) had a median score of 2 (range 0-11) and 44.9% (122/272) alert values. No difference was seen over time. The single question about confidence in the role as mother scored almost no alerts, and the median score was equal to the maximum score.

PREM per Domain

Individual Insight Into PREMs

Before answering PREM questionnaires at T2 (early third trimester), the women could choose whether to give their care professional direct insight into their answers because the answers could affect the dependent relationship with their care professional. The answer to this question was not reported by all participating sites. We received data of 175 women, of whom 26 (14.9%) did not agree to share the answers of their PREM questionnaire directly with their caregiver.

Satisfaction With Care

This single-question domain, filled out by 924 women, scored almost no alerts, and the median score was 3 out of 4 (range 1-4).

Health Care Responsiveness and Shared Decision-making

Total scores were high, with a median of 16 (range 2-16) without variation over

time. Still, the alert rate for this domain was 10.7% (101/947), based on a negative answer to one or more questions. Of the 101 women scoring an alert, 59 (58.4%) answered in the negative to just 1 of 8 questions. The alerts per question provided insight into direction for improvement, such as information provision about care decisions.

Birth Experience

Assessed with the 10-item Birth Satisfaction Scale, Revised, at T4, this domain gave an alert in 23.3% (37/159) of the women and had a median total score of 30 (range 8-40). The Birth Satisfaction Scale, Revised, subscales scored a median of 11 (range 2-16) for stress, 14 (range 4-16) for quality of care, and 5 (range 0-8) for women's attributes. Comparing women with and without an alert on the sum score, the subscales stress and women's attributes decreased by 50%, whereas the subscale quality of care decreased by 21%.

Pain Relief

During pregnancy, at T2, 41.3% (310/750) of the women indicated that the options for pain relief had not been discussed with their care professional yet. Post partum, most women were satisfied with the options for pain relief that were offered during childbirth.

Partner Role

Women were asked whether care professionals had engaged their partner enough in their care. This was insufficient for 7.4% (56/762) of the women during pregnancy and for 0.7% (1/152) during labor.

Continuity of Care

In total, 6.1% (55/905) of the women answered in the negative to one or more questions about continuity of care, with a median score of 11 (range 4-12). This domain had a slightly higher alert rate in pregnancy than during the postpartum period. In 96% (53/55) of the alerts, the women scored only 1 of the 3 questions negatively. Most alerts resulted from a negative answer to the question about knowing who their principal care provider was. In 23.5% (213/905) of the cases, the women had received perinatal care from just 1 care professional. Excluding these, the overall alert rate was 7.9% (55/692) and the median score 10 (range 4-12).

Adherence to the Questionnaires

Overall, 84% (1615/1923) of the questionnaires were filled out completely. Per domain, the percentage of completely missing answers ranged between 0% and 13%, as presented in Tables 4 and 5. Certain domains were skipped more often, such as the EPDS-10 (depression) and the Patient-Reported Outcomes Measure-

ment Information System–Sexual Function and Satisfaction (PROMIS-SFFAC102; pain with intercourse).

Missing rates per question are listed in Multimedia Appendix 3 and ranged from 0% to 16%. Evaluated per question, no remarkable missing patterns were found that could not be explained by site-specific adaptations to the questions. In Multimedia Appendix 4, missing patterns per domain are visualized. In additional sensitivity analysis of domains with multiple questions, sum scores and alert rates did not significantly change after ruling out the questionnaires with >25% missing items. Here, we chose to report the complete case analysis, best reflecting clinical use, because these results were not ruled out from individual reports to care professionals.

DISCUSSION

Findings and Recommendations

This study reports the results of an innovation in perinatal care in the Netherlands: implementation of ICHOM's PROM and PREM domains for pregnancy and childbirth to guide individual patient care in 7 OCNs. The large cohort resulting from this project showed good adherence to the questionnaires. In several domains, such as incontinence and breastfeeding, the high alert rates revealed opportunities to improve and personalize perinatal care for individual women on outcomes that matter to them. In addition, our results indicate that some measurement instruments and their timing as proposed by ICHOM are less suitable for clinical use. On the basis of these findings, we present several recommendations regarding the methods and timelines of PROM and PREM assessment in clinical practice.

Overall, adherence to the questionnaires was good, similar to PROM adherence when used for routine oncologic care.[7]

High missing rates per instrument could be explained by technical issues, site-specific adaptation to the questionnaires, or questions addressing a relatively taboo subject, such as those included in the EPDS-10 and PROMIS-SFFAC102 (depression and pain with intercourse, respectively). In preimplementation tests, the PROMIS-SFFAC102 question also seemed difficult to understand despite language adjustments. Adapting the answer options might help, or an alternative instrument should be selected. Although they may be imperfect, the questions on these taboo subjects were answered by most women. Especially, these taboo subjects create more awareness at both patient and care professional levels, thereby increasing the likelihood of problems being recognized and addressed in clinic.

Median moments of completion corresponded well with the timeline of data collec-

tion as proposed by ICHOM. In contrast to the provider expectations described by Chen et al[27], the questionnaire administered shortly after childbirth (T3) resulted in a large group of respondents in this study who completed them mostly within 2 weeks post partum. At this point, there is an excellent opportunity to improve breastfeeding outcomes and mother-child bonding. As final maternal checkup with an obstetric care professional is at 6 weeks post partum in the Netherlands, the questionnaire at 6 months post partum (T5) is practically difficult to arrange for care providers. As a result, most OCNs chose to skip T5 to enhance feasibility; thus, few questionnaires were collected. Although practically challenging, patient views on this timing should be considered because this moment previously has been shown to be valuable to reflect on long-term recovery after pregnancy and childbirth.[17,28]

Our findings in the mental health domain indicate that the first instrument of the 2-step screening (PHQ-2) is missing an unacceptable proportion of women at risk for depression, in line with the findings of Slavin et al.[21] The prevalence of perinatal depression has been reported at a rate of 7% to 20% during pregnancy and up to 22% in the first year post partum.[29] In our cohort, the prevalence of depressive symptoms was only 2.7% over the whole period of pregnancy and childbirth up until 6 months post partum. As the main purpose in clinical care is to identify women at high risk for depression, we strongly recommend removing the PHQ-2 and screening all women for depressive complaints with the EPDS-10, despite an increased response burden. The EPDS-10 has been thoroughly validated and has been shown to be acceptable to women in pregnancy and post partum.[30,31] Furthermore, 2 PREM domains showed striking results. Women answered almost always in the positive to the PREM satisfaction with results of care, despite multiple PROM alerts suggesting that their results were not as positive. This might be explained by women expecting incontinence to be a normal result of pregnancy and childbirth. Either way, this single question did not differentiate between women who were satisfied and those who were unsatisfied with their care and does not add value to shared decision-making or quality improvement. The PREM on information provision about pain relief options gave unexpected high alerts: 41.3% (310/750) of the care professionals had not discussed this yet with their patient. This might indicate that the timing of the assessment does not fit clinical practice because the T2 questionnaire was completed at 28 weeks of pregnancy on average and regular pathways plan to discuss pain relief later. Overall, each domain in need of adjustment based on our results is listed in Textbox 2, along with proposed adaptations to enhance their use in clinical practice.

In several domains, high alert rates revealed opportunities to adapt care accordingly and improve individual outcomes. For example, a high prevalence of incontinence and pain with intercourse was found over the course of pregnancy, as expected from previous research on these topics.[32] Breastfeeding success rates

were low, which corresponds to provider-reported breastfeeding numbers in the Netherlands from 2018.[33] Strikingly, many alerts were scored on breastfeeding confidence and self-efficacy during pregnancy. This provides important opportunities for all perinatal care professionals involved to improve breastfeeding outcomes. At the same time, threshold values for alerts on several instruments must be evaluated for clinical use to determine whether women scoring an alert want help and whether clinicians have the instruments to provide this help. For example, the threshold for the Mother-to-Infant Bonding Scale was set quite low based on the literature[34,35,] resulting in many alerts on mother-child bonding. At this moment, it is unknown whether women want their care professional to address these alerts, and clinical guidelines on when and how to act are lacking.[36] However, in perinatal care too, structural PROM monitoring did create openings for dialogue between patients and care professionals to personalize and improve care on these themes.[2] Regarding experience domains, 85.1% (149/175) of the women in this study agreed to making their individual answers to PREMs visible to their care professionals, but the remaining 14.9% (26/175) disagreed. These numbers both affirm the acceptability of individual PREM use and underline the importance of providing women an opportunity to choose, considering their dependent relationship with care professionals. In general, evaluating results of all women, the sum scores of the PREM instruments often did not differentiate very much, but separate answers gave valuable information about directions for improvement. For example, most alerts in the domains continuity and health care responsiveness resulted from negative answers to specific items: about knowing their principal care professional and information provision, respectively. In birth experience, the PREM with the highest alert rate, the subscales most affected in women with an alert on the sum score were stress and women's attributes. Until now, the literature on individual PREM use to guide clinical practice has been scarce because anonymous use is mostly advocated, for quality improvement only.[17,37]

Strengths and Limitations

To our knowledge, this project was one of the first experiences with incorporating the complete PCB set into clinical practice to guide individual perinatal care. Although it was challenging, each participating site collaborated with a multidisciplinary transmural team of care professionals (part of an OCN) for implementation to ensure continuity of care over the whole cycle of care in a patient-centered approach. For this study, we have performed thorough additional analyses such as sensitivity analysis and appraisal of the use of screening questions, leading to practice implications for several domains. The sample size was large, and our results reflect the true clinical use of all patient-reported domains in the PCB set in various settings across the Netherlands. Nevertheless, because of this practical and local approach, nonresponders were not registered; therefore, we cannot

Textbox 2. Proposed adaptations to pregnancy and childbirth set content.

Mental health

Remove Patient Health Questionnaire-2 and use only the Edinburgh Postnatal Depression Scale-10 to screen depressive symptoms because current 2-step screening rules out too many women at risk for perinatal depression.

Incontinence

Use the first question of the International Consultation on Incontinence Questionnaire, Short Form, and first 3 questions of the Wexner scale as screening questions because they ask the same questions as the current screening questions. The current screening questions create an unnecessary response burden and have led to inconsequential answers.

Pain with intercourse

Adjust the answer options or replace the instrument considering its relatively high missing rate and signs that the question is hard to understand.

Role as mother

Replace with another instrument because this single question does not differentiate between women who were confident and those who were insecure in their role as mother. As patients proposed this subject originally, it should be maintained in the pregnancy and childbirth set.[22]

Satisfaction with care

Remove or replace with another instrument because this question does not differentiate between women who were satisfied and those who were unsatisfied with their care or provide insight into the direction for improvements.

Pain relief

Measurement at T2 (early third trimester) is often too early because most perinatal care professionals discuss pain relief options later in the care path. We recommend involving patients to determine the optimal timing in pregnancy to discuss options for pain relief during childbirth.

Social support

Ask it at each time point because women's social networks can change throughout pregnancy and post partum. This domain was originally designed as a casemix factor but is used in clinical practice also as an outcome to act upon.

Before asking questions about patient experiences
Ask the woman whether her answers to the patient-reported experience measure questions may be made visible to her care professional individually because women are in a dependent relationship with their care professionals.

report any response rates. In addition, variation over time in our results should be interpreted with caution because of different numbers of results per time point-especially, the numbers at 6 months post partum were too small to enable drawing any conclusions. Another limitation was the absence of questionnaire translations, restricting the participants to Dutch-speaking women only. Moreover, because no resources were available to support completion of the questionnaires, women with low (digital) health literacy are likely to be underrepresented, although women with language barriers or low health literacy probably have higher prevalence of pregnancy-related issues and thus greater opportunities to improve their outcomes.[38] This reveals an important concern regarding the transformation to value-based care: it could worsen existing health inequities even further. Therefore, efforts should be made to standardize the questionnaires to facilitate translation into multiple languages. Furthermore, when implementing PROMs and PREMs as part of value-based care, all stakeholders involved should be well informed about their purpose and supported with multiple solutions to embed the PCB set structurally in clinic; for example, through group consultations.[39]

Implications for Practice

On the basis of the first efforts to incorporate the PCB set into clinical practice, we have proposed several adaptations to its content and structure to better fit routine perinatal care (Textbox 2). At the same time, international governance of the PCB set is essential to maintain comparability for care improvement purposes. In addition, although we tested their clinical usefulness, further validation is needed of all the measurement instruments and their clinical thresholds during pregnancy and post partum, which has been started successfully in another cohort.[20-22] Although the numbers per region could not be compared because of differences in pilot setup (eg, patient group selection), data capture was more feasible when PROMs could be embedded in their own EHR. When used in performance management, PROM and PREM results would preferably be merged with clinical outcomes, ideally through the EHR. Although beyond our main scope, merging patient-reported data with clinical outcomes from EHRs was explored in this project. In concordance with previous findings40, this seemed very challenging, depending on the software systems available. This study focused on the content of

the PCB set; future work should investigate other factors influencing implementation in the patient, care professional, and organization contexts.[41]

CONCLUSIONS

This study shows that the PCB set is a useful tool to capture and discuss patient-reported outcomes and experiences that need attention during pregnancy, childbirth, and post partum. These are promising findings in the journey toward patient-centered, personalized, and value-based perinatal care. In the future, merging patient-reported data with clinical outcomes and casemix factors would be even more valuable to improve quality of health care both at an individual level and an aggregated level.

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Chapter 7

Women's experiences with using patient-reported outcome and experience measures in routine perinatal care in the Netherlands: a mixed-methods study

Lyzette T Laureij
Anne L Depla
Shariva S Kariman
Marije Lamain-de Ruiter
Hiske E Ernst-Smelt
Jan A Hazelzet
Arie Franx
Mireille N Bekker
On behalf of the BUZZ project team
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ABSTRACT

Objectives: To gain insight into the experiences of women with completing and discussing patient-reported outcome measures (PROM) and patient-reported experience measures (PREM), and tailoring their care based on their outcomes.
Design: A mixed-methods prospective cohort study.
Setting: Seven obstetric care networks in the Netherlands that implemented a set of patient-centred outcome measures for pregnancy and childbirth (PCB set), published by the International Consortium for Health Outcomes Measurement.
Participants: All women, receiving the PROM and PREM questionnaires as part of their routine perinatal care, received an invitation for a survey (n = 460) and an interview (n = 16). The results of the survey were analysed using descriptive statistics; thematic inductive content analysis was applied on the data from open text answers and the interviews.
Results: More than half of the survey participants (n = 255) felt the need to discuss the outcomes of PROM and PREM with their care professionals. The time spent on completing questionnaires and the comprehensiveness of the questions was scored 'good' by most of the survey participants. From the interviews, four main themes were identified: content of the PROM and PREM questionnaires, application of these outcomes in perinatal care, discussing PREM and data capture tool. Important facilitators included awareness of health status, receiving personalised care based on their outcomes and the relevance of discussing PREM 6 months post partum. Barriers were found in insufficient information about the goal of PROM and PREM for individual care, technical problems in data capture tools and discrepancy between the questionnaire topics and the care pathway.
Conclusions: This study showed that women found the PCB set an acceptable and useful instrument for symptom detection and personalised care up until 6 months post partum. This patient evaluation of the PCB set has several implications for practice regarding the questionnaire content, role of care professionals and congruity with care pathways.

Strengths and limitations of this study

- This study had a prospective design and was incorporated in an implementation project as part of routine perinatal care.
- As a result of the embedding in an implementation project, we were able to combine the results of a large sample size of survey participants with semi-structured interviews to explore survey answers in-depth, which increased the generalizability of our results.
- These are the first experiences from patient perspective regarding completing and discussing patient-reported outcome measures (PROMs) and patient-re-

ported experience measures (PREMs) during routine perinatal care.
- A limitation of this study was the unequal representation of time points for PROM and PREM collection in our interview sample, due to the nature of the implementation project.
- The evaluation survey had a response rate of 35%, which creates a risk for non-response bias that should be considered when interpreting our results.

INTRODUCTION

Healthcare systems are increasingly focusing on creating value for patients.[1] Therefore, patient-reported outcome measures and experience measures (PROM and PREM) are progressively used to guide individual patient care, in quality improvement, and for research purposes. PROM and PREM are defined as information that is provided by patients concerning the impact of their condition, disease or treatment on their health and functioning.[2,3] In routine care, patients complete PROM and PREM via standardised questionnaires – both generic and disease specific – between visits to care professionals. Care professionals receive notifications about alarm symptoms, such as pain or functional complaints and can review longitudinal PROM and PREM reports over time. This way, symptoms and impairments are more likely to be detected, creating an opportunity to personalise care based on individual needs.[4] In chronic care settings, this approach has been shown to improve shared decision making, patient–clinician relationship and health outcomes.[5,6]

In perinatal care, important outcomes expressing quality of life and social participation can be detained from PROM and PREM, such as maternal depression, incontinence and birth experience. PROM and PREM may differ greatly and may be independent of provider-reported outcomes, describing far-reaching effects on women's lives.[7,8] Additionally, PROM and PREM may highlight important outcomes from the patient perspective that remained hidden when collecting provider-reported outcomes only. Therefore, implementation of standardised PROM and PREM, including the adaptation of individual care pathways based on individual outcomes, is essential to further personalise and improve quality of perinatal care from the patient perspective. The International Consortium for Health Outcomes Measurement (ICHOM) provided a set of patient-centred outcome measures for pregnancy and childbirth (PCB set) for perinatal care containing both provider-reported and patient-reported outcomes.[9] Prior research in the Netherlands found this set to be acceptable and feasible for implementation by all important stakeholders including women.[10,11] However, little is known regarding women's experiences with completing the PROM and PREM and receiving care based on their

individual outcomes as part of routine perinatal care.
In the Netherlands, a nationwide implementation project was initiated to facilitate shared decision making by implementing the PROM and PREM of the PCB Set in regular perinatal care. To achieve successful implementation, identifying unanticipated influences, facilitators and barriers among the users during the early implementation process of PROM and PREM is crucial.[12] Our preimplementation research identified women as important users next to perinatal care professionals.[10,11] Insights into first women's experiences with receiving personalised care based on their individual PROM and PREM during pregnancy, childbirth and the postpartum period will enhance and improve further implementation of PROM and PREM as part of routine perinatal care. Therefore, alongside the nationwide implementation project, we conducted a mixed-methods study to gain insight into the experiences of women with completing and discussing PROM and PREM, and tailoring their care based on their outcomes in a routine perinatal care setting.

METHODS

Design

Mixed-method prospective cohort study to gain insight into women's experiences with using the PROM and PREM of the ICHOM PCB set for perinatal care in clinical practice among women receiving perinatal care.

Setting

This study was conducted in seven obstetric care networks (OCNs) participating in a nationwide implementation project of the ICHOM PCB set in the Netherlands. Alongside the implementation project in clinic, this study was performed to evaluate women's experiences with this innovation in routine care. The implementation project aimed integration of the PCB Set into routine perinatal care, that is, that women were invited to complete PROMs and PREMs and discuss them with their care professional as part of routine perinatal care at five time points during their pregnancy or postpartum period. At these time points, different care professionals may have been responsible for the participants' health (see Figure 1). Women received an information leaflet regarding the purpose of the PROM and PREM before filling out their first PROM and PREM questionnaire and could complete the questionnaires digitally at home. Care professionals were informed about the content of the PCB Set (Figure 2) and how to interpret the results. Training on how to discuss the outcomes was available if needed. Care professionals discussed the results of the PROM and PREM during the next regular visit directly after each

time point, also at 6 months post partum. Implementation plans differed among the OCNs to enhance local implementation; OCNs collected PROM and PREM during at least one time point, this was not necessarily time point 1 (see Table 1).

Patient and public involvement statement

Simultaneously with the implementation of the PCB set, this study was conducted to gain insight into women's experiences with completing and discussing PROM and PREM. Both the clinical implementation project and this study were a continuation of previous projects that actively involved women as important stakeholders, resulting in changes into the Dutch PCB set, as well as providing insight into facilitators and barriers to be addressed during the implementation of the PCB set in routine care. In this study, we sent out a survey and conducted interviews with women. The study was designed in close collaboration with care professionals, while taking into account previous findings from surveys, interviews and focus group interviews with women.[10,11,13] Also, the PROM and PREM questionnaires used in clinic were tested for comprehensiveness among four women with low health literacy skills supported by Pharos, a national centre of expertise in decreasing health inequities.[14] Small language adaptations were made based on this test.

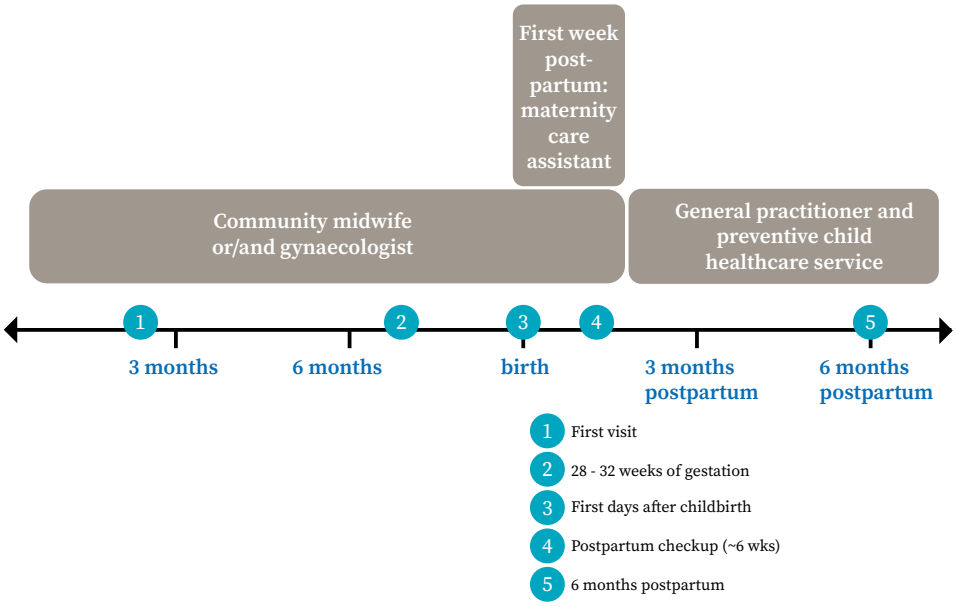


Figure 1. Time points for data collection (PROM and PREM) and involvement of different care professionals, according to current practice in the Netherlands.
The blue dots indicate the five time points for data collection during pregnancy and postpartum. Above the timeline, the involved care professionals are shown. In this project, the outcomes of the PROMs and PREMs were discussed with an obstetric care professional during all time points[9].
PREM, patient-reported experience measure; PROM, patient-reported outcome measure.

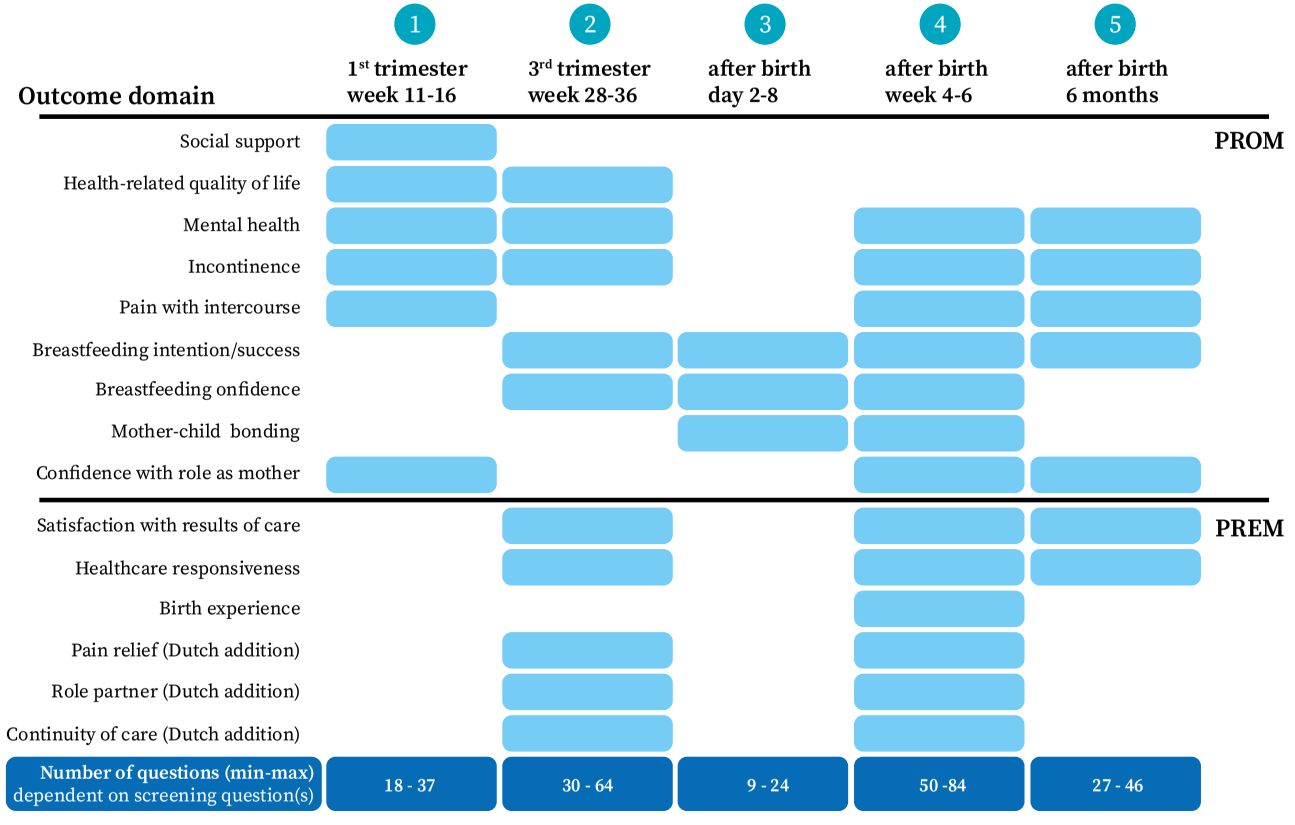


Figure 2. Pregnancy and childbirth set as applied in the Netherlands: domains and moments to measure (adapted from Depla et al[22]).
The blue dots indicate the five time points for data collection during pregnancy and post partum (see also figure 1). The outcome domains are divided into patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). Below, the number of questions of the total questionnaire (PROM and PREM) per time point is shown.

Table 1. Implementation of time points per obstetric care network

	OCN 1	OCN 2	OCN 3	OCN 4	OCN 5	OCN 6	OCN 7
Time point 1: first visit			✓	✓	✓	✓	
Time point 2: 28-32 weeks of gestation	✓	✓	✓	✓	✓	✓	
Time point 3: first days after childbirth			✓	✓	✓	✓	✓
Time point 4: post-partum check-up		✓	✓	✓	✓	✓	✓
Time point 5: 6 months postpartum					✓		✓

Participants

As our study was conducted within a large implementation project of the PCB set, all women who received PROM and PREM questionnaires as part of their routine perinatal care in one of the participating OCNs were eligible for this study. Women were invited to participate in this study via a digital link immediately after filling out a PROM/PREM questionnaire at home. They were asked to complete a short evaluation survey and optionally participate in a telephone interview regarding their experiences with completing and discussing the PROM and PREM.
Inclusion criteria for this study were as follows:

- Women completed at least one questionnaire of the PCB set.
- Women were 16 years or older during the first data collection time point.
- Women gave their informed consent to use their answers for research.

Data collection

Data collection was performed from March 2020 to September 2021. The researchers composed of a short evaluation survey (online supplemental Table 1). This anonymous survey was offered to participants via a digital link directly after completing their PROM and PREM. One OCN collected this evaluation survey on paper. No case mix questions were asked to minimise response burden for women who had already completed the PROM and PREM questionnaire. Answers to this survey were not visible to care professionals. At the end of this evaluation survey, participants were asked to provide their telephone number for an in-depth evaluation interview by phone. First, all participants who provided their telephone number were approached for a semistructured interview by one of the researchers (see for topic list Table 2). Further on, purposive sampling was performed, for example, selecting women that had filled out PROM and PREM at time points 3–5, or women who gave specific answers in the evaluation survey. Additionally, care profession-

als were asked to actively recruit women with decreased health literacy skills for an interview by the researchers. Data collection was ended as soon as thematic saturation was accomplished (see the Data analysis section). All interviews were audiorecorded and transcribed verbatim.

Data analysis

The quantitative data from the evaluation survey were analysed using descriptive statistics with SPSS V.25 (IBM). Free-text answers were analysed with thematic analysis supported by Microsoft Excel (V.16). The transcriptions from the interviews were checked for accuracy with the original audiotapes by LTL. The software program Atlas.ti V.9 was used to support thematic inductive content analysis.[15]

Table 2. Topic list used for the interviews

Topics	Sub topics
Course pregnancy/ childbirth	General Health / Experiences pregnancy
Time spent on completing PROM and PREM - experiences	Experiences completing PROM and PREM Experience on time spend Motivation for completion of PROM and PREM Reasons for (not) completing PROM and PREM in the future Time point 1 and 2: thoughts regarding completing PROM and PREM multiple times during pregnancy and after childbirth Time point 3-5: experiences with completing PROM and PREM after childbirth up until 6 months post partum
Comprehensiveness PROM and PREM	Understanding PROM and PREM: language used, reason why PROM and PREM were asked, information provision Social desirability PREM regarding experiences with care providers: completing and discussing
Discussing PROM and PREM with care professionals	Experiences regarding discussing PROM and PREM Adverse outcomes of PROM and PREM Taboo topics Bond with care professional Unexpected outcomes Resistance regarding discussing PROM and PREM Advantages and gains of discussing PROM and PREM
Improvements and suggestions	Results of evaluation survey Previously completed PROM and PREM Important topics
Preferred care provider	Time point Outcomes that are discussed
Shared decision making	Care pathway – participant's influence Discussing wishes and fears regarding pregnancy and childbirth Patient – care professional relationship

PROM: patient reported outcome measures. PREM: patient reported experience measures.

LTL and SSK independently coded the transcripts to create a set of preliminary codes and compared the codes to reach consensus. To detect emerging themes, we merged matching codes and explored links between codes. An overview was constructed of themes and subthemes for women's experiences with completing and discussing PROM and PREM. This overview was compared with the free-text answer analysis of the open-ended questions from the survey and combined into an integrated overview. The integrated overview was discussed with ALD, ML-dR and MNB and subthemes were identified as facilitators and barriers. Reporting followed the Standards for Reporting Qualitative Research.[16]

RESULTS

Survey

A total of 460 participants (35%) filled out the patient evaluation survey from a total of 1318 women who completed at least one PROM and PREM questionnaire. Descriptive statistics of the survey are shown in online supplemental table 2 and online supplemental figure 1a–d. Regarding the time spent on completing the questionnaires, 87% of participants indicated this as 'good'.

The comprehensiveness of the questions was indicated as 'good' by most participants (78%). The need to discuss the outcomes of the questionnaires with the care professional differed: of the participants 39% answered 'not really', and 35% 'a little', and 20% 'yes'. Of the participants that wanted to discuss the outcomes, the majority preferred their obstetric care professional for this. The answers from the open-ended questions are to be discussed below.

Interviews

Twenty-six participants provided their telephone number for the interview, none of these participants had completed PROM and PREM during time point 3 (maternity week). Sixteen interviews were conducted. We interviewed two participants that completed PROM and PREM during time points 1 and 4, nine during time point 2, and three during time point 5. The average age of participants was 34 years (29–39 years) and the majority were higher educated (14 of 16), that is, completed an education at a university or university of applied sciences. Four participants received perinatal care for the first time; they were pregnant for the first time or had given birth to their first child. Six participants had received perinatal care by a community midwife, five by a gynaecologist in the hospital, and five by both community midwives and gynaecologists.

Themes

The facilitators and barriers identified from the open-ended questions and interviews were allocated to four overarching themes (see table 3): (1) Content of the PROM and PREM, (2) Application of the outcomes of PROM and PREM in perinatal care, (3) Discussing PREM and (4) Data capture tool. These themes including facilitators and barriers are described below in detail, with illustrative quotes.

Content of PROM and PREM questionnaires

Most participants found the language of the PROM and PREM clear and understood the questions. Participants felt that the PROM and PREM covered most important topics and were of a good length. Most participants emphasised the importance of PROM and PREM addressing taboo topics, such as incontinence, depression and pain with intercourse. In the interviews, participants shared that completing PROM and PREM on these topics created awareness about their current health status and potential problems during pregnancy, childbirth and first months post partum (see quote 1).

> Quote 1 Awareness of taboo topics: [Complete PROM/PREM to prepare for their next visit]
> *"I assume [advantages] for both parties: for yourself because you think about everything, also things you wouldn't consider at first. And I expect it [capturing PROM and PREM] would be helpful for a care professional as well, because he can ask further than just the topics a patient brings up at that moment." (T4)*

However, the language of some questions was too difficult, especially for lower educated women, and several PROMs were not specific in timing or location of physical complaints. This led to different interpretations of the questions. Regarding the content of the PREM, participants experienced discrepancy between the timing of the questions and the care received. For example, at time point 2, options for pain management during childbirth had often not been discussed yet, thus participants answered negative to the PREM addressing this. Another issue mentioned by the interview participants in relation to PREM, was that they often received care from multiple care professionals. They stated that they had to average their experiences when completing the PREM. Several participants reported that they missed the answer option 'I don't know (yet)' or 'not applicable' in some questions, and the possibility to explain their answers. Also, participants missed the possibility in the questionnaires to point out important outcomes. This topic was expanded during the interviews; participants wanted to be able to indicate outcomes important to discuss during the following visit (see quote 2).

Quote 2 No opportunity to explain answers or pointing out important topics [Opportunity for explanation during completion of PROM and PREM]
"You should have a choice: whether you want to discuss it [your answers] or not, whether you want to be referred or not. […] You could put it [an open text field] at the end of the questionnaire: 'If you want consultation on this, if you have a top 3 or top 5 or something of the things that were just asked, what are the topics you would like to discuss with your midwife?'" (T2)

Although most important topics were covered in the PROM and PREM, some participants stated that there was too little attention for prevalent physical problems. They missed questions concerning pelvic pain and haemorrhoids, especially at time point 2. Lastly, the timing of one specific topic was debated by several participants: the PROM breastfeeding. At time point 2, this topic was experienced as too early since most women did not know whether they intended to breastfeed and could not properly answer the full questionnaire about self-efficacy. At time point 4, participants indicated it felt too late to discuss problems with breastfeeding.

Application of the outcomes of PROM and PREM in perinatal care

Most participants indicated that filling out PROM and PREM helped them in preparing their next visit to their obstetric care professional. They stated that thinking about the topics addressed by the questionnaires made them know better what to expect from and to discuss in the following visit. Interview participants also pointed out that the use of PROM and PREM led to discussion of topics that previously were no part of the conversation with their care professional. Some participants indicated that they were unaware of some topics being pregnancy related, such as psychological problems. Furthermore, some participants from the interviews said that they felt their care was personalised based on their individual outcomes, for example, extra attention, information, or a referral for specialised care (see quote 3 and quote 4).

Quote 3 Care is personalised based on individual outcomes
"Then she [the care professional that discussed her outcomes with her] said she could refer me to a clinic for pelvic problems if I wanted to. […] I thought that was very good. They directly did a follow-up and offered me sort of an option like 'you could this'." (T5)
Quote 4 Care is personalised based on individual outcomes [her PROM answers indicated depressive symptoms]
"Well… personally I think I, and they too [care professionals], gave some extra attention to my mental health." (T2)

At time point 5, one participant from the interviews felt relieved that her care profes-

sional paid attention to her incontinence and psychological problems. She felt that otherwise she would not have had any care professional to discuss these issues with. Despite the availability of an information leaflet and their care professionals' explanation, many participants had misunderstood the aim of the project. They thought it was a research project and that their answers would be used for research purposes only. This indicates that the information about the purpose of PROM and PREM for individual care was insufficient, which posed a major barrier to complete questionnaires multiple times (see quote 5).

Quote 5 Insufficient information on the aim personalised care based on PROM and *PREM*

"It was not clear to me why it [PROM and PREM] was asked. And I also can't remember that it [PROM and PREM questionnaires] included an introduction text or something like that… maybe that was included you know… but for me it was not clear what they wanted to do with that information [her answers]" (T2)

Furthermore, some participants stated it was uncertain when the outcomes of their questionnaire would be discussed with them; not all participants had their outcomes discussed during the first visit after completing the PROM and PREM. One participant said that her outcomes had never been discussed with her. Several participants mentioned that completing PROM and PREM gave them the feeling of 'impersonalised care', as if care professionals tried to avoid the conversation about these topics. Other interview participants felt unsure about how the outcomes of the PROM and PREM would impact the quality of care of their individual care pathway. For example, when filling out negative experiences regarding one specific care professional, they preferred to receive care from another care professional because of their negative experience. Some participants, from both the survey and the interviews, felt that discontinuity in care professionals posed a barrier to discuss the outcomes. They did not feel at ease discussing outcomes with a care professional they had never met before (see quote 6). Interview participants also did not always know which care professional was responsible for their outcomes.

Quote 6 Discontinuity of care professional

"Nothing really popped up [from her answers to the questionnaires], but if that would have been the case than I think it is harder to discuss some topics with a person [care professional] that I have never met. Especially because some of these topics are sensitive and vulnerable." (T1)

Discussing PREM

Participants stated that the PREM was an important facilitator for them to complete the PROM and PREM. They stressed that they found it very important

that care professionals in general have insight into patients' experiences with their provided care. Additionally, participants from the interviews thought that the insight into individual PREM may lead to improved quality of individual care. Especially participants that had completed PREM at time point 5 stated that the PREM was important to complete and to discuss, because it helped them to process the pregnancy and postpartum period (see quote 7).

> Quote 7 Discussing PREM at time point 5 important for reflection on pregnancy and childbirth [After completing the T5 questionnaire]
> *"The fact that she [care professional] called back, that she called back actually concerned, and just … just was talking with me and explained things. That has really, also in my head, enormously helped to sort things out. […] Yes, I really look back on that [childbirth and postpartum period] better now." (T5)*

Additionally, analysis of aggregate PREM results may indicate improvement topics, according to the interview participants. At the same time, a barrier was identified in overlap; some participants received PREM and other evaluation questionnaires from their community midwives post partum, and it was unclear for them whether these outcomes were also sent to their midwives. Ambiguous opinions were found regarding discussing PREM individually. Some participants, who were satisfied with the care they received, indicated they would have preferred addressing negative experiences directly with their care professional, instead of via PREM (see quote 8). In contrast to participants who had negative experiences: they explained it felt easier to indicate this via PREM instead of discussing it face to face with their care professional.

> Quote 8 Negative PREM preferably face to face [addressing care experiences with care professional]
> *"I believe it is fairer when they [care professionals] hear it from me personally, but I can imagine that some people don't feel comfortable with that and prefer to leave their feedback anonymously and that eventually it will reach the care professional anyway." (T2)*

Additionally, some participants stated to feel dependent of their care professional during their care pathway, which posed a barrier to report negative experiences in the PREM.

Data capture tool

Participants indicated that they preferred to complete PROM and PREM digitally. Completing the PROM and PREM on mobile phones or tablets was preferred by most women. However, participants pointed out technical issues as a major

barrier; PROM and PREM questions and answers that were not entirely visible on a mobile phone led to incomplete or incorrect outcomes according to some women (see quote 9).

> Quote 9 Technical problems and bugs [Completing PROM and PREM]
> *"On my smartphone I can't see all the questions. On the iPad, some answer options disappear, so I must check three times whether my answers are completed correctly. For example, satisfaction is measured on a scale from 1 to 4. But when I go to the next page and back, it appears to be a scale from 1 to 10." (T2)*

Table 3. Overarching themes and identified facilitators and barriers

Themes	Facilitators	Barriers
1. Content of PROM and PREM questionnaires	Clear language PROM and PREM covering all important topics Good length of questionnaires Awareness of taboo topics	Language of some questions too difficult Some PROM questions not specific in time or location Discrepancy questions with care path and situation Absence of answer option "I don't know (yet)" or "not applicable" No opportunity to explain answers or pointing out important outcomes Too little attention to physical problems (time point 2) (Timing of) PROM breastfeeding
2. Application of the outcomes in individual care	Better preparation for next visit/ appointment Discussing topics that were not discussed before Care is personalised based on individual outcomes Discussing outcomes at Time point 5	Insufficient information on the aim personalised care based on PROM and PREM Uncertainty when outcomes are discussed Feeling of impersonalised care Unsure of impact on individual quality of care Discontinuity of care professional
3. Discussing PREMs	PREM being included in the questionnaires Insight in individual PREM improves individual quality of care Discussing PREM at Time point 5 important for reflection on pregnancy and childbirth Analysis of aggregate PREM for care improvement Completing PREM safer option in case of dissatisfaction	Receiving multiple questionnaires regarding experiences Negative PREM preferably face to face Dependency of care professional
4. Data capture tool	Completing questionnaires digitally Availability on mobile phones or tablets	Technical problems and bugs Privacy issues

PROM: patient-reported outcome measures, PREM: patient-reported experience measures

Also, some participants received PROM and PREM belonging to a different time point or received the same PROM and PREM multiple times. Furthermore, several interviewed participants stated that it was unclear which organisation sent the invitation to complete the questionnaires and which care professionals had access to their answers. This made them have doubts regarding privacy (see quote 10).

> Quote 10 Privacy issues [Completing questions regarding incontinence, mental health, physical complaints]:
> *"And yes, those are questions of a kind that you would only complete honestly if you are completely sure that you can trust that they will end up at the right person." (T2)*

DISCUSSION

This mixed-methods study provides insight into the first experiences of women with completing and discussing PROM and PREM at different time points during and after pregnancy as part of routine perinatal care. The evaluation survey results showed that the time spent on completing the PROM and PREM was acceptable, and their content was comprehensive. Most survey participants felt the need to discuss the outcomes. In the interviews, participants were mainly positive about discussing their individual PROM and PREM outcomes with their perinatal care professionals. Women's barriers and facilitators to complete and discuss PROM and PREM individually were identified in four overarching themes.

Strengths and limitations

A strength of this study was the prospective design, incorporated in an implementation project as part of regular care. Its results supported further implementation of the outcome set, as they were directly translated into adaptations in the clinical project, such as IT improvements and an option to further explain an answer. Accordingly, by providing PROMs and PREMs throughout pregnancy and the postpartum period, women can become aware of what high-quality care encompasses, and of complications or symptoms that can occur. This awareness can empower women and support them to adjust their care pathway to their individual preferences and values. Another strength was the large sample size of survey participants combined with semistructured interviews to explore survey answers in-depth, which increased the generalisability of our results. Also, the participation threshold was lowered by conducting the survey anonymously and the interviews by telephone, limiting the risk of selection bias. However, the survey response rate of 35% does create a risk for non-response bias. Despite our efforts to minimise the risk of selection bias with purposive sampling, mostly higher

educated women were included, and only Dutch speaking women could participate to the surveys. This was inevitable to some extent, as the sample was taken from an already selected population: women completing the PROM and PREM were Dutch speaking only and had a relatively good health literacy, as no support was provided with completing them. This limitation should be taken into account when interpreting our findings and stresses the importance of future efforts to engage all women when implementing PROM and PREM to prevent further health inequities. Nevertheless, this exploration of patient experiences with individual PROM and PREM was the first among women receiving perinatal care. A second limitation, resulting from the outline of the implementation project, was the unequal representation of time points for PROM and PREM collection in our interviews. Despite our strategy to ask care professionals to recruit participants for the interviews directly, that is, without filling out the survey, we could not interview women who had completed PROM and PREM at time point 3 (maternity week).

Compared with literature

In line with findings in other disciplines, discussing PROM and PREM with care professionals as part of routine perinatal care was found to improve patient satisfaction and willingness to complete the questionnaires.[6,17-19] Participants felt better prepared for their next visit and discussed topics that were not discussed before, which reconfirms results from large studies in chronic care settings.[19-21] At the same time, a significant part of our survey respondents did not feel the need to discuss their outcomes. Moreover, for some women completing the questionnaires even felt as impersonalised care. As the survey was offered directly after completing the PROM and PREM, survey participants had not yet discussed their outcomes with their care professional. These findings indicate that discussing outcomes are an essential part of using PROM and PREM in clinical practice.[6] Another explanation could be inadequate information provision, as several women stated that the purpose of the PROM and PREM was unclear to them. As women's perception of this purpose largely depends on their care professional, care professionals may improve this by actively using PROM and PREM as a part of routine care. For example, by encouraging women to consider which outcomes they want to discuss in the next visit.

Using individual outcomes to tailor care was an important facilitator to complete PROM and PREM over the course of pregnancy and postpartum. Nevertheless, two important barriers to use PROM and PREM individually were raised by our participants as well. First, discrepancy between the timelines of provided care and the PROM and PREM was pointed out. For example, a PREM questioning information provision on pain relief was sent to women, before care professionals addressed this topic according to standard care. Synchronising the time points of the PCB set with routine perinatal care pathways may solve this barrier. Based on

compliance to the PROM and PREM and results of the PROM and PREM, concrete recommendations to adapt the PCB set's content and timeline have been suggested in a recent publication, and are in accordance with women's experiences found in this study.[22] Second, discontinuity in care professional was posed as a barrier, as discussing PROM and PREM with different care professionals lead to discomfort among participants. Discussing outcomes in the multidisciplinary setting of perinatal care may be easier if a principal care professional is allocated to every pregnant woman. A relationship of trust between care professional and patients may be a crucial facilitator for completing and discussing PROM and PREM, especially when discussing taboo topics such as incontinence.[23] This may provide opportunity to improve perinatal care outcomes, as several taboo topics have been shown highly prevalent and only 15% of the affected women bring them up during a postpartum check-up.[22,24] Additionally, although hard to accomplish by perinatal care professionals, our participants stated that evaluating their outcomes at 6 months post partum with a perinatal care professional was of added value to the regular postpartum check-up. This reconfirms previously reported patient views regarding time point 5 of the PCB set.[10,11] Compared with the check-up at 6 weeks post partum, at 6 months post partum, most women have further recovered in multiple domains and resumed their work and social life. Hence, at this moment, the sustainability and severity of physical or mental problems can be determined and referred for, improving long-term outcomes of perinatal care.

Confirming preimplementation studies, our participants emphasised that PREM were an important facilitator to complete the questionnaires.[10,11] However, evidence on individual PREM use as part of clinical practice is scarce. This study revealed different opinions among women: some preferred to address negative experiences face to face, some felt PREM made it easier to raise and others felt too dependent on their care professional to discuss a negative experience at all. Future research should evaluate the possible effects of offering each woman a choice whether her individual answers are visible to care professionals and discussed as part of her care.

As shown before from a professional perspective, a good functioning data capture tool for assessment and real-life visualisation of patient-reported measures is essential for successful implementation.[6,25,26] In our patient evaluation, technological issues of the data capture tools were also a major barrier for completing the questionnaires. Although challenging in terms of interorganisational collaboration and IT infrastructure, this project was one of the first to attempt system-wide implementation of ROM and PREM as a standard part of individual perinatal care to guide individual care and personalised care pathways. In the transformation towards healthcare systems that provide patient-centred care over the full cycle of care, it is essential to use data capture tools that facilitate information exchange between all healthcare tiers involved with a disease or condition.

Future research and implications

To achieve personalised care based on PROM and PREM, patient engagement is essential but requires efforts at several points. For successful implementation, women will benefit from a system-wide data capture tool, a principal care professional to discuss their outcomes with and a timeline of PROM and PREM collection that fits clinical care: matching their appointments and content of care pathways. Also, an open-text field to explain answers and point out outcomes they want to discuss could empower women to take an active role in their care. Lastly, when completing PROM and PREM, women should be clearly informed about (1) the purpose of using their answers for personalised care and (2) the topics addressed by the questionnaires at each time point and their relation to PCB. Since care professionals are crucial in providing this information and in discussing the outcomes, future research may focus on the experiences of care professionals with PROM and PREM use in perinatal care. To engage care professionals, it would be useful to evaluate training strategies, but also their perceived benefits when working with PROM and PREM. These could include direct improvement of individual care for their patients, as well as insight into the results of their efforts in terms of patient outcomes.[13] These practice implications resulting from women's reflections on individual level PROM and PREM use can advance structural integration of women's perspective in clinical care. Although clinical integration can enable group level use, further research is still needed to explore how PROM and PREM can contribute to embed patients' perspective in research and management decisions as well.

CONCLUSIONS

This study reported the first patient experiences with completing and discussing PROM and PREM as part of perinatal care. The ICHOM PCB set was found to be an acceptable and useful instrument for symptom detection and personalised perinatal care up until 6 months postpartum. Women's reflections on these PROMs and PREMs allow several practice implications to improve the questionnaire content, the role of care professionals and congruity with routine care pathways.

ACKNOWLEDGEMENTS

We acknowledge the women participating in this study. We thank the participating care professionals for approaching women and for discussing the PROMs and PREMs.

SUPPLEMENTARY FILES

Supplementary Table 1. Evaluation Survey

1) I found the time needed to complete the PROM and PREM ...

☐ Too much

☐ A lot

☐ Good

☐ Short

2) Were you able to properly complete all PROM and PREM?

☐ Yes

☐ No, I did not understand all questions

☐ No, the questions were too personal

☐ Other: .....

3) During the next visit, you will discuss the outcomes of the PROM and PREM with your care provider. Do you feel the need to discuss the outcomes?

☐ Yes —▸ Go to question 3b

☐ A little —▸ Go to question 3b

☐ Not really —▸ Go to question 3c

☐ Not at all —▸ Go to question 3c

3b) Who do you prefer to discuss your outcomes with?

☐ Community midwife

☐ Clinical midwife

☐ Gynaecologist

☐ Maternity care assistant or nurse

☐ Preventive Child Healthcare services

☐ General practitioner

☐ No preference

3c) Can you please explain why you do not prefer to discuss your outcomes?

.....
.....
.....

4) Do you have any remarks regarding the PROM and PREM or suggestions for improvement?

.....
.....
.....

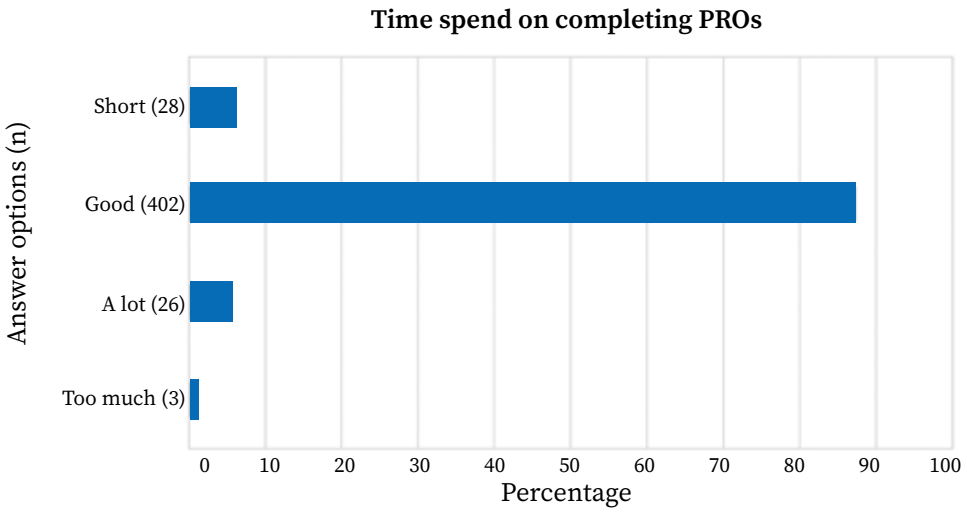
5) Do you give permission for an evaluation by telephone in the future?

☐ Yes, my telefpone numeber is: .....

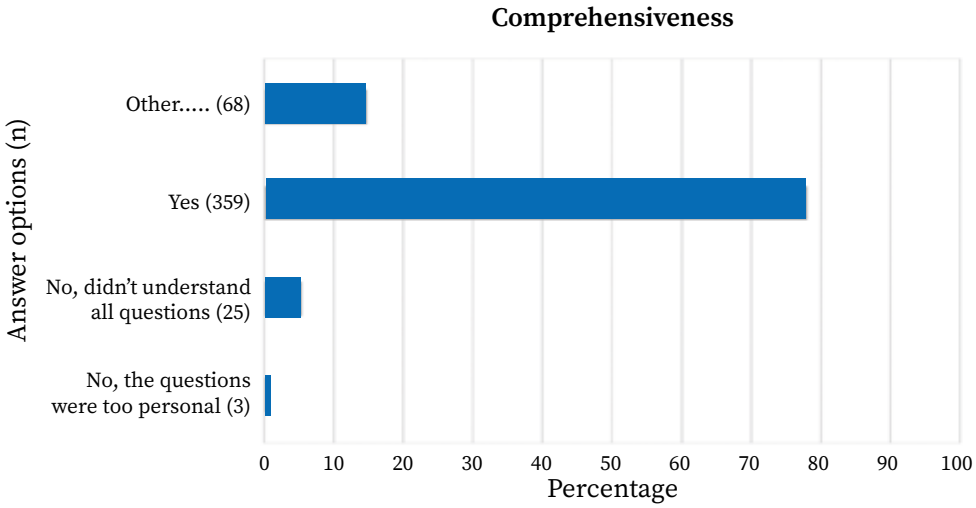
☐ No

Supplementary Table 2. Survey participants per time point

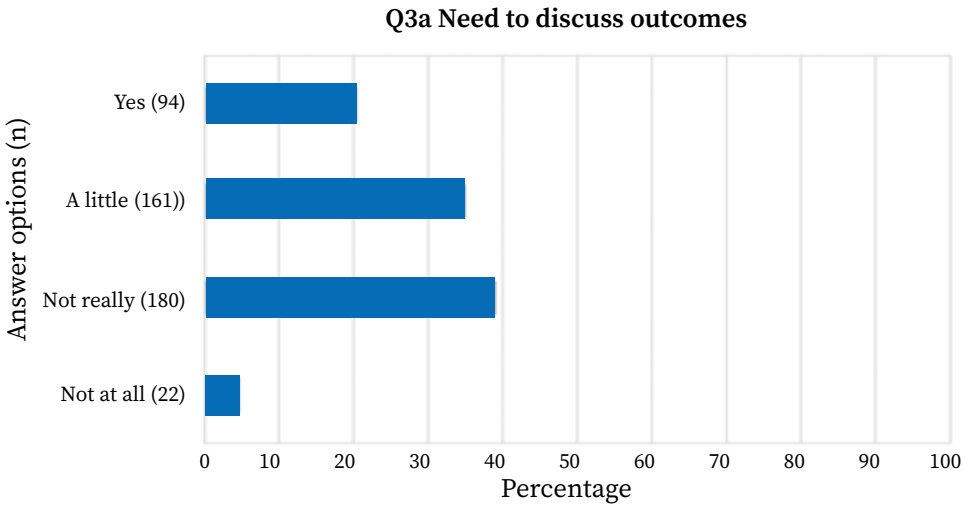
Time point	n
T1	93
T2	337
T3	10
T4	9
T5	11
Total	460



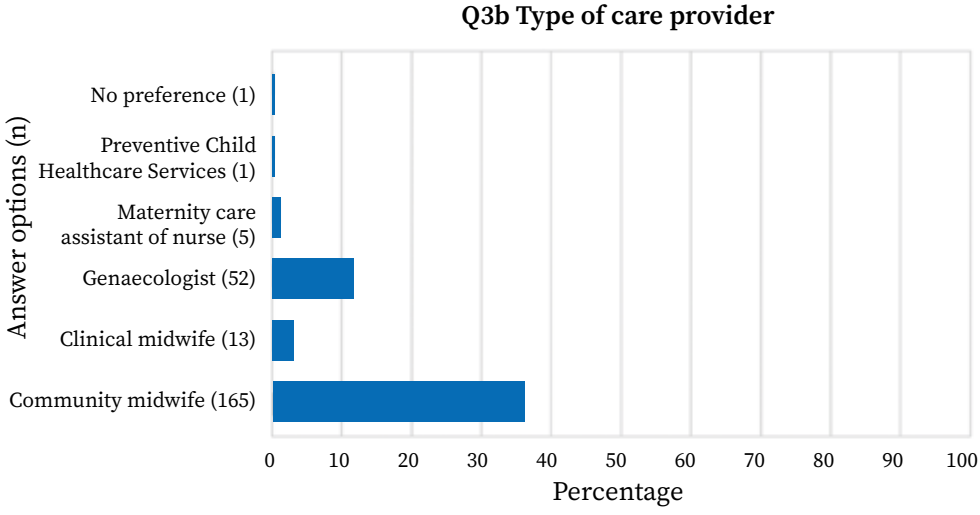
Supplementary Figure 1a. Q1 I found the time needed to complete the PROM and PREM…



Supplementary Figure 1b. Q2 Were you able to properly complete all PROM and PREM?



Supplementary Figure 1c. Q3 During the next visit, you will discuss the outcomes of the PROM and PREM with you care provider. Do you feel the need to discuss the outcomes?



Supplementary Figure 1d. Q3b Who do you prefer to discuss your outcomes with?

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Chapter 8

Statistical process control methods to support change initiatives in perinatal care using patient-reported outcomes and experience measures: a proof of concept for continuous improvement

Lyzette T Laureij
Anke G Posthumus
Anouk Klootwijk
Jan A Hazelzet
Arie Franx
Bas B van Rijn

ABSTRACT

Healthcare is shifting more and more towards patient-centered care, supported by actively incorporating patients' self-reported health and quality-of-life measures, as well as experiences with receiving healthcare captured in structured outcome data. These outcomes are better known as patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). In addition to the more traditional use of clinician-reported outcomes measures (CROMs), it is expected that measuring PREMs and PROMs may help to monitor the quality of delivered healthcare over time and thereby aide quality improvement (QI) efforts. In industry, and to a limited extent in healthcare, statistical process control (SPC) charts have proven valuable tools to follow data over time for monitoring QI projects. SPC charts allow for on-going and evidence-based monitoring of real-time data and recognition of deviant patterns suggestive of deviations and other trends in quality metrics in need of improvement. Yet, the application of SPC charts to value-based healthcare initiatives, and in particular the suitability for QI projects involving PREMs and PROMs have not been evaluated. To explore the applicability of this method, we previously conducted a retrospective cohort study within an obstetric care setting, using a dataset of PROMs, PREMs and CROMs collected for a cohort of individuals several months after childbirth. Utilizing this data, we generated and evaluated the use of four types of SPC charts, including the application of pre-specified statistical rules for interpreting data-over-time as stable or unstable processes and the ability to detect special cause variation within the data. Our findings suggest that SPC charts based on PROMs/PREMs are indeed suitable for integration into QI projects and propose that their utilization can facilitate monitoring of healthcare quality metrics, as well as timely recognition of unforeseen events and health outcomes suitable for health care improvement.

What is already known on this topic

In the literature, much is known about the generation and interpretation of statistical robust SPC charts in QI projects in healthcare. Likewise, more and more QI projects build on SPC charts to support the process of continuous improvement of outcomes in healthcare. However, there is limited experience with PROMs and PREMs applied in SPC charts as part of QI plans based on outcomes over time.

What this study adds

This study provides a proof of concept of the application of PROMs, PREMs and CROMs data in the application of SPC charts. PROMs and PREMs proved to be suitable for the application in SPC charts.

How this study might affect research, practice or policy

PROMs and PREMs highlight important outcomes of care for patients and are thus new targets for QI. As we showed, it is now feasible to build SPC charts based on PROMs and PREMs, and these can therefore be tracked over time in the context of QI projects.

SPC charts for quality improvement (QI) in healthcare including the patient perspective

Patient-reported Outcome Measures (PROMs) and Patient-reported Experience Measures (PREMs) have revolutionized healthcare by capturing valuable insights directly from patients about their health status, treatment outcomes, and overall experiences within the healthcare system. As healthcare continues to evolve towards patient-centered care, the integration of PROM/PREMs has become instrumental in assessing the effectiveness of interventions, enhancing clinical decision-making, and improving healthcare delivery. At the micro-level, the application of PROMs/PREMs involves their integration into routine clinical care. Conversely, at the meso-level, healthcare organizations utilize PROM/PREMs to evaluate overall patient reported outcomes of a certain care pathway and experience within their facilities. Administrators can then assess various aspects of care delivery, including accessibility, communication, and satisfaction with services. By collecting and analyzing these data, hospitals and healthcare systems can identify areas for improvement, implement targeted interventions, and shape policies aimed at optimizing patient satisfaction and engagement. Traditionally, hospitals use clinician-reported outcomes measures (CROMs) for quality improvement (QI) projects, e.g. morbidity and mortality, or door-to-needle-time. A common analytical approach in these QI projects is the use of statistical process control (or Shewhart) (SPC) charts.[1,2] These were originally developed in engineering and have been broadly applied in healthcare since several decades. SPC charts are grounded in solid statistical theory and enable rigorous time-series analyses that are easy to interpret, and provide valuable insights into variation of outcomes over time.[3] Importantly, the application of SPC charts allows for distinction between random variation (i.e. variation that is the result of a stable process) and special cause variation (i.e. variation that is the result of a low probability event, usually caused by an external factor or intervention).[2,4-8] Implementation of such techniques are particularly useful in clinical medicine, as there is a known tendency amongst clinicians, as in other fields, to over-respond to random variation in the occurrence of (rare) clinical events.[9]

Many have elucidated the technique and applicability of SPC charts in health-

care.[10-12] By also integrating PROMs/PREMs in SPC charts, a more comprehensive, patient-centered understanding of healthcare performance is obtained. However, to our knowledge there have been no published QI projects that systematically monitor PROMs/PREMs based on SPC charts. We hypothesize that PROMs/PREMs are highly suitable for enhancing QI initiatives when integrated with SPC charts, considering the advantages of these charts. This study builds upon our previously gathered obstetrics data.[13] The outcomes of this study prompted further investigation of specific PROMs and PREMs for potential application in improvement processes.

The aim of this paper is to demonstrate how PROMs/PREMS can be used in combination with conventional CROMs, for ongoing QI monitoring based on SPC charts. By doing so, we aim to advance knowledge on how healthcare organizations can leverage PROM/PREMs to drive more efficient and patient-centered QI initiatives.

Short overview of our project

The dataset used for this case study represents a retrospective cohort of women who received obstetric care at the Erasmus University Medical Center, Rotterdam, the Netherlands.[13] PROMs/PREMs were collected via an online survey. We derived routinely collected patient characteristics and CROMs from the electronic medical record (EMR). These CROMs contain information on every pregnancy and childbirth from 16 weeks of gestation onwards, e.g. gestational age, mode of delivery, maternal and neonatal morbidities and birth weight.[14] The collected PROMs/PREMs were based on the Dutch version of the International Consortium for Health Outcomes Measurement (ICHOM) Pregnancy and Childbirth standard outcome set.[15-17]

Selection of outcomes for SPC charts and quality improvement

The PROMs/PREMs outcomes from the abovementioned study formed the starting point for this study. We selected PROMs or PREMs to test their applicability for different SPC charts and QI goals as a proof of concept. The different outcomes selected are shown in Table 1, and the rationale behind their selection is described below:

1. *Pain relief in both spontaneous and iatrogenic preterm deliveries.* The PREM "pain relief" aims to evaluate how well pain was managed and relieved during labor and childbirth. Our previous study showed that women with a preterm delivery were more likely to score below a clinical threshold for suboptimal scores than women who delivered at term.[13] This outcome was selected because it offers a straight forward starting point for QI.
2. *Birth experience.* We chose a validated PREM from the ICHOM set, of which we have previously demonstrated that it is negatively influenced by casemix factors such as social deprivation.[13] Therefore, the PREM "birth experience"

(BSSR[18]) offers opportunities to personalize care for a disadvantaged subgroup, with the aim of improving the overall quality of care and reducing potential inequalities.

3. *Mental quality of life sub score.* The PROMIS-10 consists of three parts: physical quality of life, mental quality of life, and the Visual Analogue Score (VAS). We selected the mental quality of life sub score for QI, since mental health is a vital but often overlooked outcome parameter for pregnant women and may be an important focus for QI.
4. *Understandable information provision.* The PREM "Shared decision-making and confidence in healthcare providers" is designed to assess the extent to which pregnant women feel engaged in shared decision-making processes with their healthcare providers and their level of confidence in the care provided. We chose a single item on understandable information provision within this PREM, because it offers a concrete point of action for improvement.

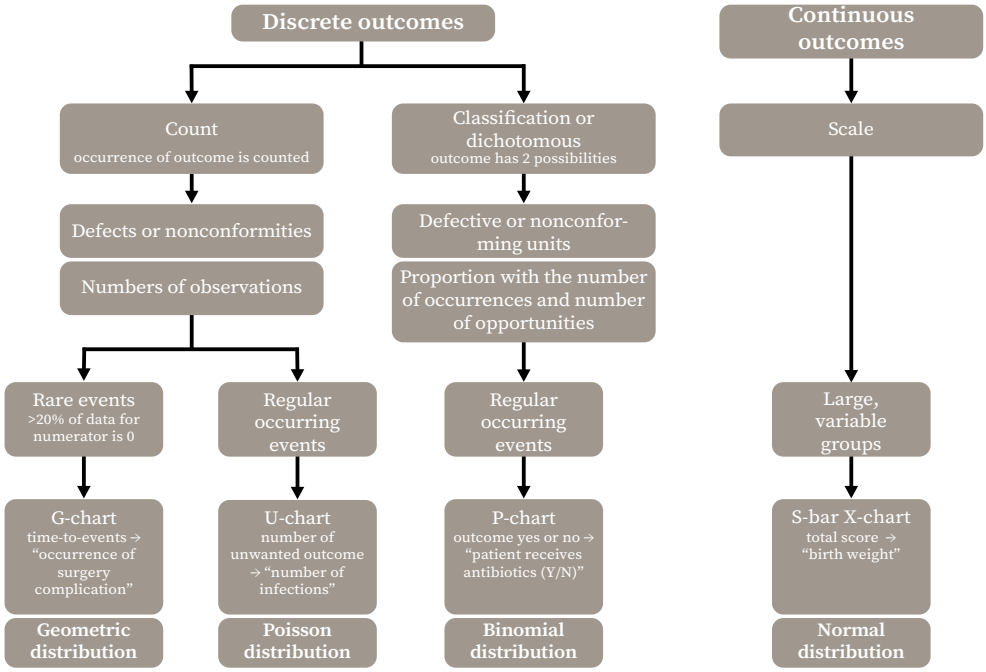

Figure 1. flowchart of used charts based on the data.

Table 1. Overview of the selected outcomes

Outcome	Definition	Source	Score for chart	Interpretation of score	Type of chart
Pain relief in premature deliveries	Alerts scored on the PROM pain relief during delivery among all women that delivered their baby before gestational age of 37 weeks	EMR: delivery < 37 weeks of gestation Survey: PROM Pain relief (two questions on pain relief during delivery)	Number of days between the occurrence of an alert on pain relief	↑ more days between events CL: 50th percentile of the distribution, UCL indicates the amount of expected variation in the process. LCL is set at 0.	G-chart
Birth experience	Total score of BSSR1 (mean), with a range from 0-40 points	Survey: the BSSR is a 10 item scale with a 5-points Likert-scale per question (range from strongly agree [4 points] – strongly disagree [0 points]) on items 1, 3, 5, 6, 9, and 10 and reversed scored on items 2, 4, 7, and 8	Total mean scores of BSSR over time [0-40 points]	↑ better birth experience	X-bar and S-chart
Perceived quality of life: mental health	Mental health sub score of the PROMIS-10 questionnaire	Survey: question 2, 4, 5, and 8. Answer options questions 2, 4, and 5 have a 5-point Likert scale: Excellent [5 points] – Poor [1 point]. Question 8 has a 5-point Likert scale: Never [5 points] – Always [1 point]	Total mean scores of PROMIS-10 mental health over time [4-20 points]	↑ better mental health in quality of life	X-bar and S-chart
Shared decision making: understandable information provision	Extent to which the explanation of the healthcare providers was understandable as experienced by women	Survey: Single item derived from the outcome Shared Decision making, question 5: "Was the given information by the healthcare providers understandable?" Answer options range from No [0 points], Some extent [1 point], to Yes [2 points]	Proportion of all women that experienced the given information as not understandable or to some extent understandable versus all scores on this question. Group 1: alert, group 2: no alert	↑ more alerts	P-chart

[1] BSSR: Birth Satisfaction Scale Revised[18], a validated scale for measuring birth satisfaction, EMR: electronic medical record, CL: central line, LCL: lower control limit, UCL: upper control limit

SPC chart selection and methodology

Different types of SPC charts are required for the four outcomes we employ in this proof of concept. Figure 1 illustrates the different types of charts. It is necessary to differentiate between discrete and continuous outcomes. In continuous data, it is essential to verify a normal distribution, e.g. birth weight. The S-bar X-chart is then used. For discrete outcomes, distinction is based on whether an outcome consists of 'count data' or dichotomous data. In the case of count data, in healthcare, 'defects' or 'nonconformities' refer to deviations, errors, or failures in processes, procedures, or patient care that do not meet established standards, guidelines, or expectations (e.g. surgical complications). If some of these 'defects' or 'nonconformities' are rare; the G-chart, displaying the time between occurrence of events, is used. For more regularly occurring events U-chart are used. For dichotomous data, the concept of 'defective or nonconforming units' translates to 'patients or cases with defects or nonconformities.' A 'defective' or 'nonconforming unit' in healthcare represents a patient or case where care or treatment has not met the expected standards, resulting in adverse outcomes, suboptimal care experiences, or complications. Our data was derived from two years of monthly birth counts of women that completed at least one questionnaire of the PROMs/PREMs and were linked to medical records (total n= 708). Group sizes according to PROM/PREM outcome varied (Table 1). We checked each outcome for normality of distribution by visual inspections using histograms (see Table 1). Additional details on the PROM/PREMs used, including questionnaires, scoring, and traditional statistical analyses, are available in our previous publication.[13]

Interpretation of the SPC charts

Every chart has a central line (CL), based on the mean or median score for every unit of time, i.e. the month of birth. Lower control limit (LCL) and upper control limit (UCL) lines are plotted at three standard deviations (SD) below or above the mean score for every subgroup.[5] The outcome of every SPC chart is plotted chronologically per birth month and displayed as a single dot. We used SPSS version 25.0 and in Minitab version 19.

In line with the literature, we selected four rules to identify an unstable process that warrants further investigation:[5,19]

1. If a data point falls outside the control limits (< 3SD or > 3SD from the mean), it suggests that the process is out of control (potential special cause variation).
2. If 6 consecutive data points fall on the same side of the mean or CL, it indicates a significant shift in the process (unstable process).
3. Two out of three consecutive points appearing beyond 2SD on the same side of the CL (i.e., two-thirds of the way towards control limits) may indicate an unstable process (process is becoming less predictable).
4. If six consecutive data points exhibit a consistent increasing or decreasing pattern, it suggests a systematic shift in the process (special cause variation).

If none of these rules are exceeded, we label the shown variation over time as normal, i.e. expected variation and a stable process. If one of the abovementioned rules is exceeded, we consider the variation as of a special cause. Then, there may be an underlying process that causes the unstable process.[20] This requires further investigation before an intervention is implemented and effects on the outcome are measured. For QI projects, a stable process is important as a basis for measuring effects of an intervention. Changes in the SPC chart are then more likely due to the implemented intervention instead of a variation of normal.[2]

The SPC chart as a first step for QI based on PROMs and PREMs

In the following paragraph, we present the SPC charts that we used for our data as a starting point for QI.

1. Pain relief in preterm deliveries

To explore trends in the number of alerts scored using the PREMs survey for pain experience (adequate to insufficient pain relief during labor) for women in preterm labor, we constructed a G-chart for rare events, as displayed in Figure 2. In our study 48 women (7%) had a preterm delivery.[13] This G-chart shows the number of

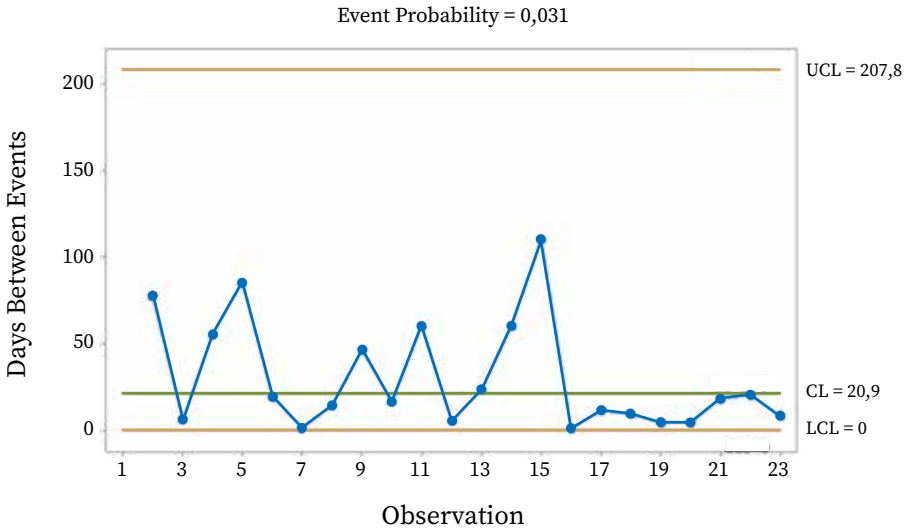

Figure 2. G-Chart for Pain relief in premature deliveries
This G-chart shows the days between the occurrence of an alert on the PREM Pain relief among women who had a preterm delivery. On the x-axis, all unique observations were plotted from 1 January 2018 until 31 December 2019. On the y-axis, the days between the occurance of the events, ie an alert, was plotted.
The count data of the alerts per month is shown in table x in the supplemental files.
UCL: upper control limit. This limit is calculated for this specific outcome.
CL: center line. This line is the 50th percentile of the distribution.
LCL: lower control limit. This limit is set at 0 for G charts.

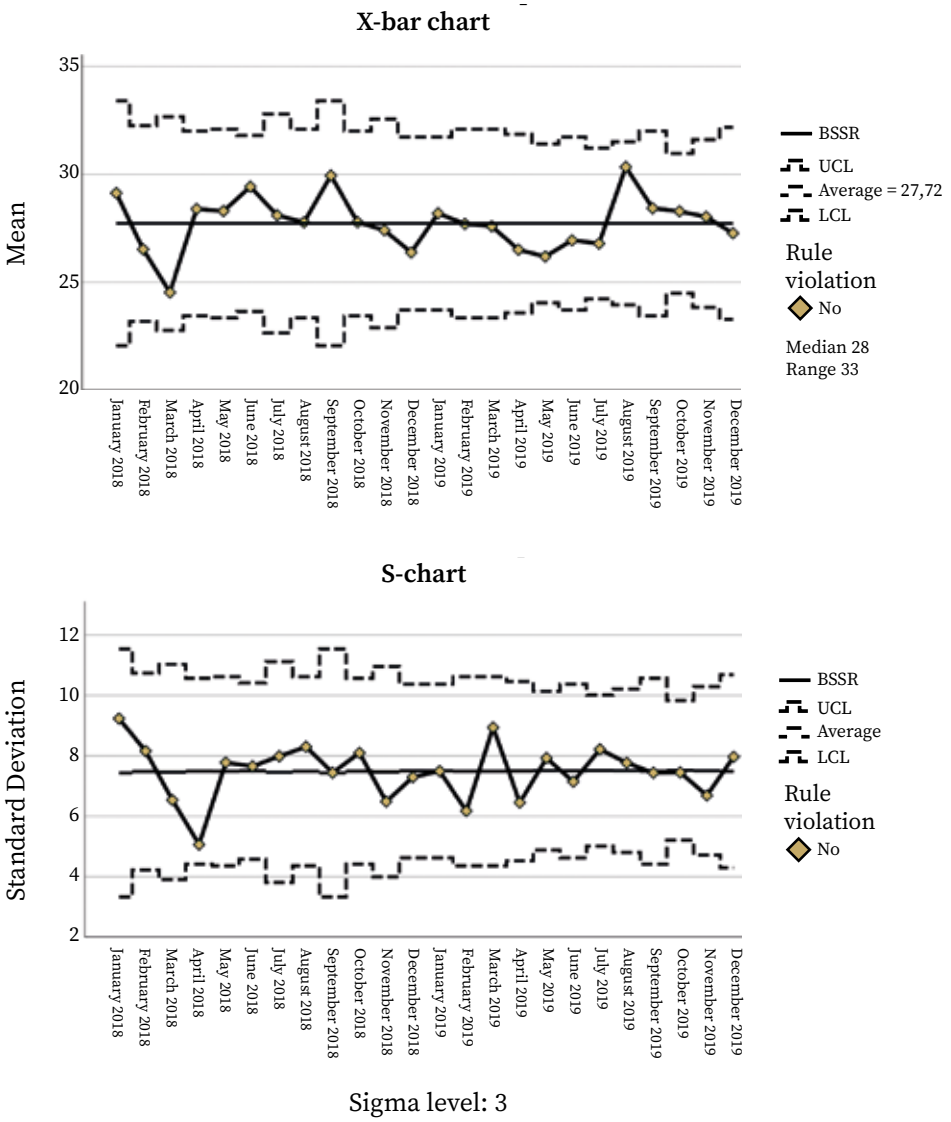

Figure 3. X-bar S-chart for birth experience
This X-bar S-chart shows the X-bar chart and S-chart for birth experience. Both charts are necessary for the evaluation of special cause variation.The X-bar control limits are derived from the S-chart, since the UCL and LCL are plotted at +/- 3 SD per mean score per month. When the values in the S-chart are out of control, the X-bar chart control limits are not accurate. So first, the S-chart is evaluated and when it is in control, then the X-bar is evaluated for special cause variation. The S-chart shows the control chart for the Standard Deviation (SD) over time for the PREM Birth Experience. On the x-axis the months are plotted. On the y-axis, the standard deviation is plotted. For the X-bar chart, on the x-axis the months are plotted, and on the y-axis the mean scores for the PREM Birth Experience. The UCL and LCL differ per month, since the SD differs.
UCL: upper control limit, set at +3SD per month.
LCL: lower control limit, set at -3SD per month.

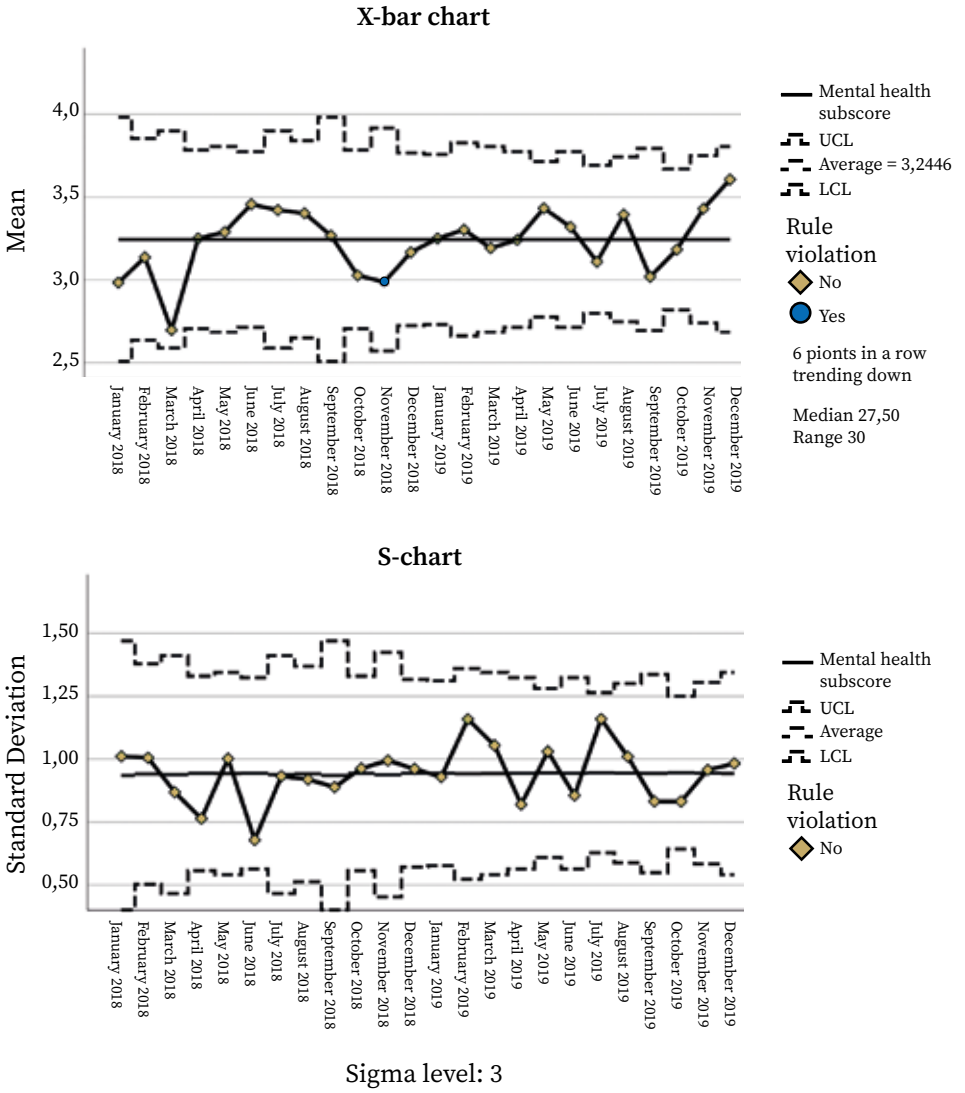

Figure 4. X-bar S-chart for perceived quality of life: mental health
This X-bar S-chart shows the X-bar chart and S-chart for perceived quality of life: mental health.. Both charts are necessary for the evaluation of special cause variation.The X-bar control limits are derived from the S-chart, since the UCL and LCL are plotted at +/- 3 SD per mean score per month. When the values in the S-chart are out of control, the X-bar chart control limits are not accurate. So first, the S-chart is evaluated and when it is in control, then the X-bar is evaluated for special cause variation. The S-chart shows the control chart for the Standard Deviation (SD) over time for the PROM subscore mental health. On the x-axis the months are plotted. On the y-axis, the standard deviation is plotted. For the X-bar chart, on the x-axis the months are plotted, and on the y-axis the mean scores for the PROM subscore mental health. The UCL and LCL differ per month, since the SD differs. UCL: upper control limit, set at +3SD per month.
LCL: lower control limit, set at -3SD per month.

days between the occurrence of an alert on the PREM "pain relief" among these women. On the x-axis, all unique observations were plotted from 1 January 2018 until 31 December 2019. On the y-axis, the days between the occurrence of the events, i.e. an alert, was plotted. The mean time (CL) number of days between the occurrence of subsequent events was nearest to 21 days. The probability of an alert on pain relief in this subgroup was 0.03, meaning that the chance of an alert occurring on any given day is estimated at 3%. Using the key rules to detect special cause variation, no statistical deviations from random variation were detected, i.e. there is normal variation.

2. Birth experience

To explore the PREM for birth experience, we constructed an X-bar S-chart (Figure 3). This PREM was completed by 694 women. Both the X-bar and S-chart are necessary for the evaluation of stability of the process. The X-bar control limits are derived from the S-chart. When the values in the S-chart are out of control, the X-bar chart control limits are inaccurate. So first, the S-chart is evaluated: it shows the SD over time, with months on the x-axis and the SD on the y-axis. For the X-bar chart, months are on the x-axis, and mean scores on the y-axis, with varying UCL and LCL due to differing SDs. The S-chart was 'in control' with no rules exceeded. Similarly, the X-bar chart showed no rules were violated, indicating no special

3. Mental quality of life sub-score

Similar to the PREM "birth experience", we applied the X-bar and S chart methodology to explore perceived quality of life for mental health based on the PROMIS-10 questionnaire (Figure 4). Six hundred-fifty-two women completed the PROMIS-10 questionnaire, including the questions regarding mental health. The S-chart was in control. In the X-bar chart, with on the x-axis the months and on the y-axis the mean scores for this outcome, there was an exceeding of a rule. Six points in a row were trending down from June 2018 up until November 2018. This chart indicates special cause variation that occurs within the boundaries of the upper and lower control limits (i.e. an unstable process). This should prompt further exploration of potential causes.

4. Understandable information provision

To evaluate information provision to patients, we focused on the PREM "shared decision making", which was filled out by 708 participants. For this analysis, we focused on the dichotomous question: "Was the given information by the care providers understandable?"[13] Because of the dichotomous outcome(yes/no, see Table 1), a P-chart was used (Figure 5) to represent the proportion of individuals that scored an alert over time. Seventy-five women (11%) scored an alert, implying the provided information by healthcare providers was insufficiently understand-

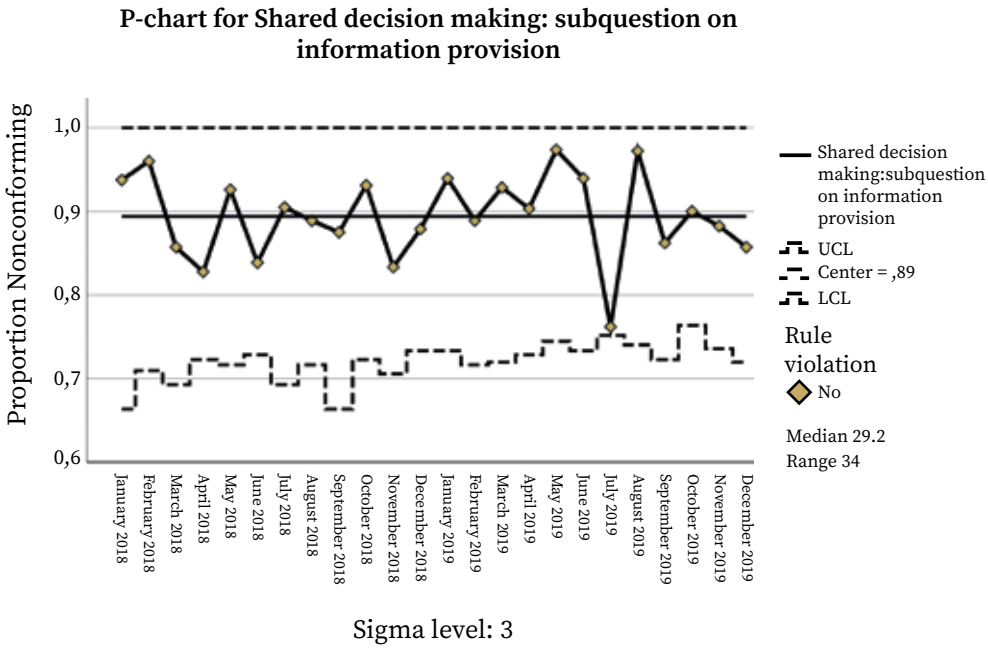

Figure 5. P-chart for Shared decision making: understandable information provision
This P-chart shows the proportion of alerts on the PREM Shared decision making subquestion on information provision. On the x-axis, the individual months are plotted. On the y-axis, the alerts are plotted as "proportion noncorfming": every alert is a nonconforming event or unwanted event. They are calculated as proportions: number of alerts per completed questionnaires per month.
UCL: upper control limit. This limit is set at 1.0, the maximum score, ie all participants scored an alert that month.
LCL: lower control limit: This limit is set at -3SD from the centre line per month.

able for them. In Figure 5, on the x-axis, the individual months are plotted. On the y-axis, the alerts are plotted as "proportion nonconforming": every alert is a nonconforming event. They are calculated as proportions (number of alerts per completed number of questionnaires per month). On more than one occasion relatively large differences in the proportions of alerts between months were detected. However, again, there were no rules violated and therefore the variation in the outcome was considered as common cause variation.

DISCUSSION AND RECOMMENDATIONS

This proof of concept regarding the utilization of SPC charts based on PROMs/PREMs in combination with CROMs helps to advance knowledge on how healthcare can enrich their QI with patient-reported data. PROMs/PREMs SPC charts proved to be suitable for implementation in QI projects.
The first step consists of gaining insights into relevant PROM/PREM outcomes over time, based on recent historical data plotted in SPC charts. Subsequently, a QI intervention is selected and implemented. The SPC charts play a pivotal role in determining whether this intervention then leads to desired special cause variation or whether the process continues to demonstrate random variation over time.

Considerations

Applying SPC charts in QI plans

In the light of our outcomes, several charts showed common cause variation or a stable process. However, the presence of this stability does not mean that the variation is acceptable or that these outcomes should be disregarded in QI. For instance, for Birth Experience (Figure 3) it could be argued that the variation in the mean across months demonstrates a wider dispersion than desirable. Consequently, a plausible approach could involve adjusting the UCL and LCL by modifying the SD, for example by setting the UCL and LCL at a range of 2SD form the mean instead of the conventional 3SD. This adjustment results in narrower limits, hence reducing the acceptance of variation to define a stable process.
In cases involving special cause variation, it is imperative to identify external factors influencing the process. Failure to do so may obscure whether changes are due to the QI intervention or pre-existing external factors.[20,21] When implementing an intervention in the care process, process instability is desired due to the improvement. Eventually this is followed by new stability over time, and new control limits are set on all the data.[20,21] At times, multiple QI cycles are required for a successful implementation, leading to an iterative improvement process.[6,22,23]
Additionally, SPC charts can guard against unnecessary interventions in care. For instance, our outcome in the G-chart (Figure 2) for rare events demonstrated a 3% change in alerts (i.e. unwanted events) on any given day. This observation can prevent an 'overresponse' to rare events, potentially avoiding the burden of additional protocols and staff workload. Furthermore, this chart shows that the time between events appeared to be more stable in more recent months. This may indicate that stabilization of the process already took place, without an intervention. Prospective data can assist healthcare providers and managers in determining whether the occurrence of these 'unwanted events' is sufficiently rare or if an

intervention is necessary. This highlights the clinical applicability of these charts.

Statistical robustness of SPC charts

In our proof of concept we implemented a maximum of four rules to detect special cause variation. Increasing the number of rules increases the occurrence of a Type I error, i.e. the found special cause variation is "false positive".[2] Conversely, a lower number of rules may result in missing or overlooking special cause variation.[5,6,19] The determination of the number of rules applied in SPC charts to identify special cause variation remains contingent upon the objectives of the QI project.[24,25] The decision-making process regarding the amount of rules involves different factors, such as balancing precision, resource allocation, risk tolerance, and process stability.[5] Varying project goals may necessitate different levels of sensitivity and precision in detecting deviations from the norm.[24] Moreover, the inherent stability and complexity of the process being monitored influence the choice of rules; more stable processes may warrant fewer rules, while complex or less stable ones might require more stringent criteria.

Quality management literature stresses the crucial need for a robust volume of data points to fortify SPC charts. The reliability of these charts significantly depends on both the quantity and quality of collected data. A larger dataset enables a more comprehensive understanding of process behavior, aiding in accurate detection of special cause variation and informed decision-making.[5,24] Retrospective data collection serves as an advantageous starting point. It provides insights into historical trends, and pinpointing areas for further investigation or intervention in QI projects.[26] However, supplementing retrospective data with ongoing and prospective data collection is crucial for continuous comprehension of process dynamics.[5,26]

What is next

This integration of SPC charts based on PROMs/PREMs into QI projects has the potential to narrow the gap towards patient-centered and data-driven care. Presently, clinicians rely on research methods like randomized controlled trials (RCTs) or cohort studies persists in healthcare. These methods are essential for establishing causality and treatment efficacy within controlled experimental settings. As a next step, SPC charts continuously monitor underlying process variability and performance, providing immediate feedback on process stability, trends, and deviations in standard care processes.[26] By incorporating PROMs and PREMs into standard care, data is not limited by inclusion and exclusion criteria as it is in RCTs. These criteria may potentially result in non-representative samples that deviate from the broader patient population. SPC charts offer a real-time and more comprehensive depiction of outcomes than traditional research strategies. This makes them more user-friendly and applicable in QI.

Robust IT support is essential for QI projects using PROMs/PREMs with SPC charts. EMRs are not designed for data extraction, necessitating assistance from data scientists.[27] Once assembled, new patient data can be added with a standardized script. User-friendly systems like Minitab and R generate SPC charts with a single click, making them practical at the departmental level.[28,29] These charts are easy to interpret, visualizing outcomes in real-time and requiring less statistical expertise. Incorporating SPC charts into real-time dashboards further engages healthcare providers, promoting the improvement of outcomes including PROMs and PREMs.

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Chapter 9

Intervention through eHealth and personalized postpartum care to enhance the self-efficacy of postpartum women in vulnerable circumstances: findings from a process evaluation

Lyzette T Laureij
Jacqueline Lagendijk
Jasper V Been
Hiske E Ernst-Smelt
Arie Franx

INTRODUCTION

In perinatal care, significant disparities in pregnancy outcomes occur. Women experiencing a combination of risk factors often face an increased risk of adverse pregnancy outcomes.[1,2] This group is commonly referred to as vulnerable and is characterized by a combination of risks spanning both medical and non-medical domains. These women frequently have pre-existing health issues, often accompanied by lower health literacy skills. Lower health literacy, in turn, can impede the comprehension of reliable information.[3-5] Additionally, this group is characterized on average by lower self-efficacy compared to non-vulnerable pregnant women. Reduced self-efficacy can be both a consequence of the accumulation of various risks and act as a mediator for increased risks of adverse pregnancy outcomes. The combination of reduced self-efficacy with a higher likelihood of health problems underscores the importance of timely identification of pregnant women with (potential) risks. Postpartum care plays a pivotal role in this context. Postpartum care focuses on the prevention of health problems for both mother and child, facilitated via the presence of a maternity care assistant (MCA) at the family's home during the postpartum period. MCAs have a multifaceted role; next to prevention and early recognition of health issues they assist new families in developing health literacy skills. Given the preventive nature of postpartum care combined with care provided at home, this type of care is well suited to help identify health problems.[6] The randomized controlled trial (RCT) *"De Beste Start"* focused on early identification of possible medical and non-medical risks in pregnant women by maternity care organizations and on the provision of personalized care during the postpartum period. The research project combined risk-based postpartum care with tailored information provision via eHealth. From the moment of registration with the maternity care organization until the sixth week after childbirth, women in vulnerable circumstances had access to a supportive eHealth application on their mobile phones. Via this approach of early risk identification, combined with enhancing health literacy through tailored information delivery, we aimed to enhance the self-efficacy of women in vulnerable circumstances.

The study involved seven maternity care organizations, an educational institution, and a developer of eHealth tools in its design and execution. Together with the eHealth developer, the eHealth application was developed and tested. Prior to and during the study, employees of participating maternity care organizations were trained in research procedures, communication techniques, and the use of the eHealth application. During the inclusion period, planned from November 2019 to March 2020, an insufficient number of women were included to conduct a robust statistical analysis on the collected data. Furthermore, technical issues with the eHealth application arose, and the restrictive measures related to emergence of

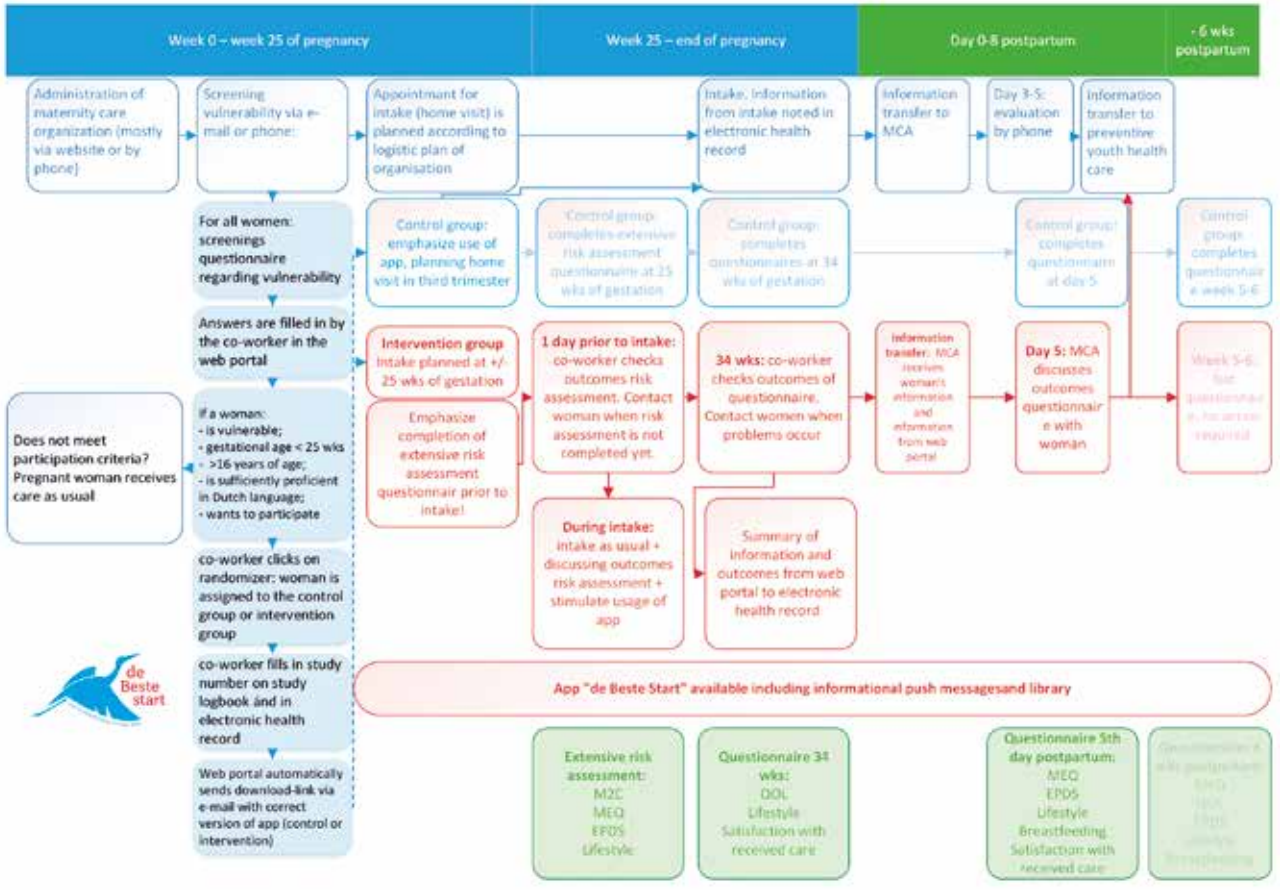


Figure 1. Study design including protocol to be implemented in maternity care organizations
MCA: maternity care assistant, M2C: mind 2 care questionnaire, MEQ: maternal empowerment questionnaire, EPDS: Edinburgh Postnatal Depression scale, QOL: quality of life

the COVID-19 pandemic had an impact on the feasibility of the study. Consequently, after consultation with the funding body ZonMw (Netherlands Organisation for Health Research and Development), the study was terminated on April 28, 2020. Because previous research indicates that certain aspects of the intervention can lead to improved outcomes for postpartum women in vulnerable circumstances,[6-9] it is important to gain insight into the extent of the intervention's actual implementation, how the feasibility of the research project was experienced in everyday practice, and how both the intervention and research were perceived by the implementers and participants.[10,11] By conducting an evaluation study, we aim to provide these insights via understanding the facilitating and inhibiting factors related to the study's execution and the intervention itself in order to provide recommendations for improvement.

METHODS

In this chapter, we describe the research design of the RCT and subsequently outline the setup of the process evaluation.

The research project *"de Beste Start"*

The *Beste Start* project was an open-label, randomized controlled trial conducted in the South-West region of the Netherlands to assess the effectiveness of a complex intervention aimed at increasing maternal self-efficacy during the postpartum period. The intended start date of the study was September 2019, but actual inclusion commenced in November 2019. The inclusion period was originally planned to extend until March 2020, with the follow-up period concluding in December 2020.

Study Design

The RCT was initially designed to be conducted across seven maternity care organizations in the Netherlands, each with at least one branch in the South-West region of the Netherlands (see Figure 1 for an extensive overview of the study design).

Registration and Randomization

All women who enrolled at one of the participating maternity care organizations were screened for vulnerability by answering a set of questions. If a woman was indicated as vulnerable and met the inclusion criteria (see Figure 1), she was randomized into either the intervention or control group. Women who did not qualify for participation in the study received standard care from the maternity care organization. Following inclusion and randomization, participants in the interven-

tion group received an email invitation to download the app 'de Beste Start' on their smartphone. Figure 2 provides an overview of the application 'de Beste Start'. Also, an appointment was scheduled for an early home visit by a maternity care organization representative around the 25th week of pregnancy. Participants in the control group also received an email invitation, but were granted access only to the basic app 'de Beste Start'. Participants in the control group received standard care from the maternity care organizations, i.e. an intake around 32-36 weeks of pregnancy by phone or at home to determine the amount of hours of postpartum care.

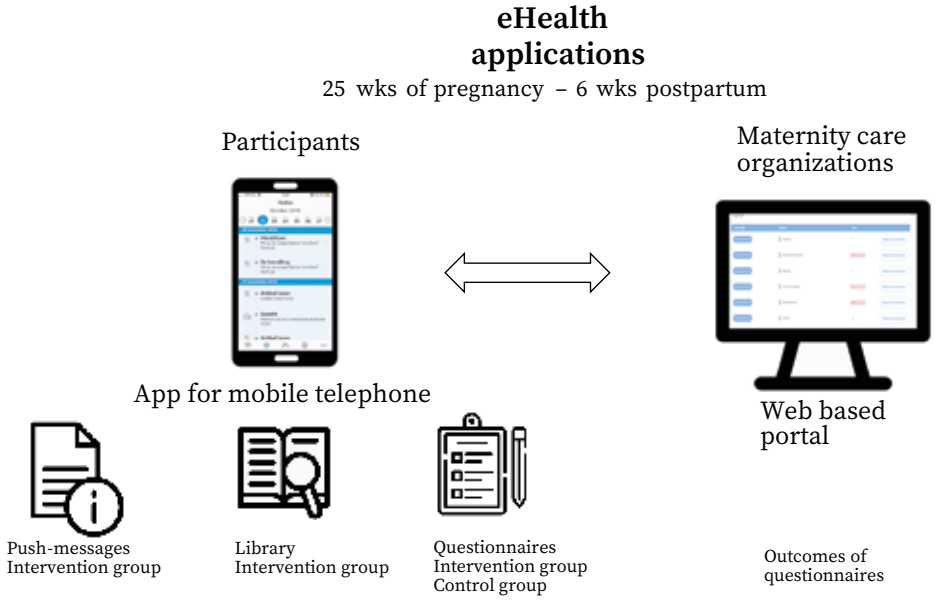


Figure 2. the eHealth applications 'de Beste Start'

Determination of vulnerability

In order to determine a woman's vulnerability, several screening questions were formulated.

Two questions could be extracted from the woman's electronic health record:

1. Is the woman's 4-digit postal code corresponds to a registered disadvantaged neighborhood: if yes → 1 point
2. Is the participant's age <20 years? If yes → 1 point

Other questions were asked during the welcome call (see full questionnaire in appendix 1):

1. Not having a partner/being a single mother OR living without partner → 1 point
2. No fixed abode or residence → 1 point
3. Net monthly income of household < 1749 euros per month → 1 point
4. No completed education after high school → 1 point
5. Smoking and/or drinking alcohol during pregnancy → both 1 point
6. Currently receiving treatment or received treatment for mental health issues in the past → 1 point
7. Usage of medication such as antidepressants, anxiolytics or sleep medication → 1 point
8. The co-workers suspicion that the client is vulnerable in other domains → 1 point (this question was introduced from December 2019 onwards)

If the total score exceeded 3 points, the woman was classified as vulnerable and found eligible for participation. From December 2019 onwards, this threshold was lowered to 2 points.

Early Home Visit

Participants in the intervention group received an extensive risk assessment questionnaire via the app 'de Beste Start' at 24 weeks of pregnancy, covering both medical and non-medical risk factors. The results were visible to employees of the maternity care organization through the web portal. During the early home visit at 25 weeks of pregnancy, the maternity care organization representative discussed identified risks with the participant, and together, they determined the necessary care. Furthermore, during this home visit the regular intake process took place, which normally is scheduled in the third trimester. This includes the determination of the number of hours of postpartum care according to the National Indication Protocol.[12]

Evaluation at 34 Weeks of Pregnancy

Around the 34th week of pregnancy, women in the intervention group received evaluation questions regarding the care provided during the home visit via app 'de Beste Start'. The employee of the maternity care organization had access to the outcomes of the evaluation questions via the web portal and could take action accordingly. For example, if a participant was not satisfied with the care received, an employee could then contact her to discuss her perceived dissatisfaction and may adapt care accordingly.

Tailored Postpartum Care during the Postpartum Period

MCAs who were assigned to provide postpartum care to women in the intervention group were informed about the results of the risk assessment and of any actions taken. Care was adjusted accordingly, for example by informing the midwife or guidance to other healthcare providers for help. On the 5th day after childbirth,

women received a comprehensive questionnaire, including an assessment of self-efficacy. The MCA had access to the questionnaire outcomes via the web portal and discussed them with the woman.

Control Group

After randomization, women in the control group received standard care, which included an intake during the third trimester of pregnancy, usually around 32 weeks of gestation, to determine the number of hours of care during the postpartum week, following the usual practices of the maternity care organization.

eHealth Application and Web Portal

The eHealth application consisted of a smartphone app and a web portal (Figure 2). The app had three functions: 1) sending push messages with informative content on self-efficacy, pregnancy, and childbirth; 2) a library containing over 140 articles with information on self-efficacy, pregnancy, and childbirth; and 3) sending out questionnaires. The app was made available to the women. Employees of the maternity care organization had the ability to access the questionnaire outcomes for women in the intervention group via the web portal. The questionnaire results of women in the control group were shielded from the maternity care organization employees.

Preparation and Training

Starting from October 2018, exploratory discussions were held with the seven maternity care organizations to align the research protocol with the local organizational structure as much as possible. In June 2019, October 2019, and January/March 2020, three training sessions were organized for employees (administrative staff and intakers who perform the home visit) of the maternity care organizations. Each training session included information on dealing with vulnerable pregnant women (including communication techniques) and was conducted by an experienced trainer from the Kersten van de Pol education center. Instructions were also provided about the eHealth application and the web portal. Accreditation was granted from the Knowledge Center for Maternity Care (KCKZ in Dutch) for the training sessions. MCAs were separately informed by members of the research team.

Sample Size and Study Duration

Based on the sample size calculation, 494 women were needed to evaluate the effect of the intervention. For this calculation, we assumed an individual improvement in self-efficacy score of 50%, represented by a shift from a score in the 10th percentile to the 20th percentile on the maternal empowerment questionnaire.[6,13] Based on the yearly number of women that the maternity care organizations cared for, and an estimated proportion of vulnerable women of 25%, we estimated the

Table 1. Research questions regarding the Hasson Framework

Concept	Sub part	Research question	Execution and data collection
Adherence	Coverage	Which proportion of the target population participated in the intervention?	Logbook
	Content	To what extent were the various steps of the study, including the intervention, executed correctly according to the plan?	Survey among employees of maternity care organization, interviews with managers and intakers, logbook
	Frequency	Were the various steps of the research protocol and the intervention carried out for each woman?	Survey among employees of maternity care organization, interviews with managers and intakers, logbook
	Duration	Were the intervention steps implemented for as long as planned?	Survey among employees of maternity care organization, interviews with managers and intakers, logbook
Potential moderators	Intervention complexity	How complex is the research protocol?	Survey among employees of maternity care organization, interviews with managers and intakers, logbook
	Facilitation Strategy	What measures were taken to support the implementation of the intervention?	Survey among employees of maternity care organization, interviews with managers and intakers, interview met trainer of education center and app developer, logbook
	Quality of Delivery	To what extent were the components of the research protocol executed correctly?	Survey among employees of maternity care organization, interviews with managers and intakers, logbook
	Participant responsiveness	What were the barriers and facilitators of the intervention for the participating women?	Survey among employees of maternity care organization
		How do the participating women perceive the relevance of the intervention and its outcomes?	Interviews with managers and intakers, interviews with participating women in the intervention group
	Recruitment Strategies	What steps did the participating maternity care organizations take to engage their clients in participation?	Survey among employees of maternity care organization

Table 1 - Continued. Research questions regarding the Hasson Framework

Concept	Sub part	Research question	Execution and data collection
		What steps did the participating organizations take to motivate women to continue participating?	Interviews with managers and intakers
		Are there target-specific barriers to participation in the intervention?	Interviews with participants women in the intervention group
	Context	Are there target-specific barriers to participation in the intervention?	Survey among employees of maternity care organization, interviews with managers and intakers, logbook
Component analysis		Which parts of the research were essential or effective?	Survey among employees of maternity care organization, interviews with managers and intakers, interviews with participating women in the intervention group

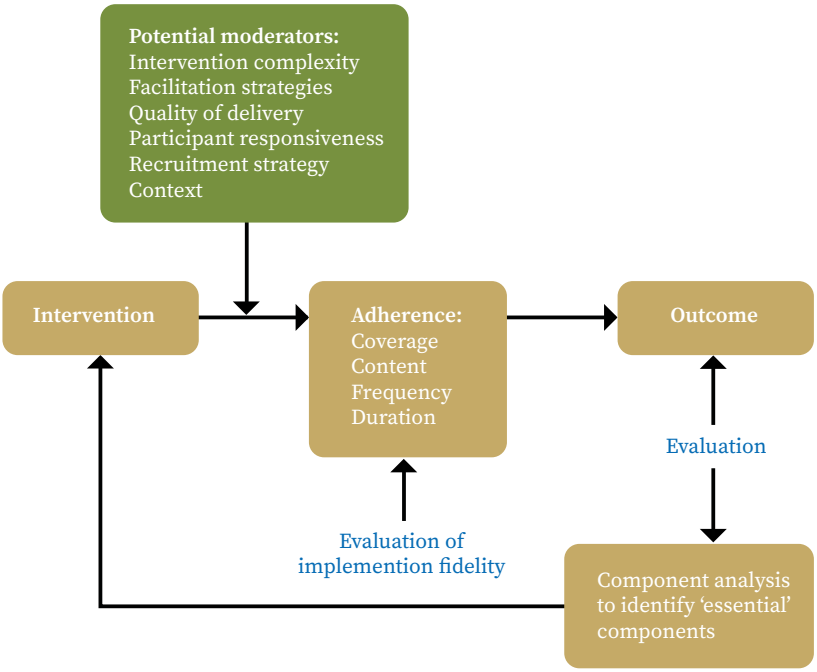


Figure 3. The Hasson Framework (2010)

inclusion duration to be five months. The intended start date was October 1, 2019, but it was postponed to early November 2019 due to delay in delivery of the eHealth application (app and web-based platform). The intended end date of the inclusion period was March 31, 2020.

Evaluation Research: Process Evaluation and Outcome Measures

Due to substantial delay in the RCT's schedule, the study was terminated on April 28, 2020. Through this evaluation study, we aim to gain insights into the facilitators and barriers related to the RCT's implementation. We also wanted to assess which parts of the study were executed according to plan and which were not. This led to the following research question: to what extent was the study conducted as described in the protocol?

The Hasson framework was used to conduct the process evaluation; it was employed to examine the integrity of the research's implementation and the intervention itself (Figure 3).[14,15] This framework focuses on the systematic evaluation of implementation integrity ('fidelity') and the potential factors that influenced this integrity. The primary outcome measure of the process evaluation was considered the integrity of the implementation of the research project and the intervention.

For this evaluation, we focused on the three concepts of the framework, applied to research participants and employees of the various maternity care organizations (Table 1). To answer the research question, data were collected from a survey, interviews, focus groups, and the study logbook.

Participants

Maternity Care Organizations:
For the process evaluation, five from the seven organizations that had the intention to start the RCT were approached. Two organizations were not able to participate in the RCT due to financial and/or logistical problems. The process evaluation differentiated between management, intakers, administrative staff, and MCAs.

Participants of RCT 'de Beste Start':
The process evaluation also focused on the feasibility of the intervention. Since pregnant and postpartum women played a significant role in the intervention, participants of the RCT were approached for the process evaluation.

Third Parties:
Given that training sessions, eHealth, and collaboration with chain partners were crucial components of the RCT 'de Beste Start', the trainer of the education center, eHealth developer, and community midwives were also approached for participation in the evaluation.

Data Collection

Study Logbook:
During the research project, researchers maintained a study logbook in collaboration with the participating maternity care organizations. This logbook documented the logistic process of the research for each organization, including the intervention and any changes. It also recorded the number of clients approached and included in the study. Any changes to the study protocol were noted.

Survey:
All involved employees of the five maternity care organizations were asked to complete a questionnaire in June 2020. The questionnaire was sent via email, with a single reminder. The survey consisted of 15 statements about various aspects of the RCT 'de Beste Start': general aspects, registration, home visit, 34-week pregnancy questionnaire, postpartum week, eHealth, and the research study itself (see Appendix 1). Response options were provided on a five-point Likert scale ("Strongly Disagree" to "Strongly Agree"). There were also a few open-ended questions which allowed them to provide explanations. The survey results were also used to shape the interviews.

Table 2. Data from the logbook regarding inclusions and registered women (clients) from the participating maternity care organizations

	Organization 1	Organization 2	Organization 3[2]	Organization 4[3]	Total[4]
Registered women	1284	229	145	132	1790
Inclusions	51 (4%)	17 (7%)	8 (6%)	4 (3%)	80 (5%)
Vulnerable and registered before 25 weeks of pregnancy	200 (16%)	26 (11%)	15 (10%)	6 (5%)	247 (14%)
Inclusion-rate[1]	26%	65%	53%	67%	32%
Vulnerable and registered after 25 weeks of pregnancy	37 (3%)	2 (1%)	0 (0%)	0 (0%)	39 (2%)
No risk identification questions asked during registration	407 (32%)	112 (49%)	1 (1%)	0 (0%)	520 (29%)

[1] percentage included from the group of women (clients) who were registered before 25 weeks of pregnancy and were perceived as vulnerable (≥2 points)
[2] 854 women were registered during the inclusion period from December 2019-April 2020. Of these, 145 completed the screening questions. Only the gestational age and scores of vulnerability of these 145 women are known. These 145 clients are therefore used for the calculations.
[3] For this organization, this concerns the period December 2019-January 8, 2020.
[4] Organisation 5 has not initiated the research and is therefore not included in this table.

Table 3. Participants of the process evaluation

	Maternity care organization					Participants (pregnant and postpartum women in intervention group)	Education center	eHealth developer	Midwives
	1	2	3	4	5				
Survey	13	17	12	1	5	N/A	N/A	N/A	N/A
Interview manager	1	1	1	0	1	N/A	N/A	N/A	N/A
Group interview intakers	2	1	1	0	0	N/A	N/A	N/A	N/A
Interview stakeholders	N/A	N/A	N/A	N/A	N/A	N/A	1	1	2
Interview pregnant and postpartum women in the intervention group	N/A	N/A	N/A	N/A	N/A	3	N/A	N/A	N/A

(Group) Interviews:
A recording was made of each interview.

Managers:
Interviews were scheduled with the managers of the five participating maternity care organizations in August 2020. These semi-structured interviews were conducted using a topic list (see Appendix 2).

Intakers:
A group interview was organized with intakers in September 2020. Two intakers from each of the five participating organizations were invited to participate. The semi-structured group interview was conducted digitally through Microsoft Teams using a topic list with statements (see Appendix 3).

Participants of the RCT:
Participants were interviewed through individual semi-structured interviews using a topic list (see Appendix 4). The interviews took place in August, September, and October 2020. Participants received a €15 gift card for their participation.

Midwives:
During the interviews with employees of the maternity care organizations, the theme of 'collaboration with the chain of obstetric healthcare providers' emerged strongly. To gain a more comprehensive view of this process, additional interviews were organized with two community midwives (see Appendix 5).

Other Stakeholders:
In October 2020, the trainer of the education center and eHealth developer were interviewed using a topic list.

Data Analysis

Quantitative data from the study logbook and survey were analyzed using descriptive statistics. The data from the survey's open-ended questions and the data from the interviews were analyzed by applying thematic content analysis.

Medical Ethical Approval

Ethical approval for the conduct of this process evaluation was granted by the Medical Ethics Review Committee of Erasmus MC (MEC-2020-0488). All participants provided informed consent for participation in this study and for the use of their data.

RESULTS

1. Results of the RCT 'de Beste Start'

Study Logbook

Participation of Maternity Care Organizations in the Research

Of the seven maternity care organizations involved in the preparation of the RCT, five organizations intended to start the research in November 2019. Two organizations actually conducted the intervention study according to the developed study protocol, which included performing early home visits for the intervention group (see Figure 4).

Adjustments to the Study Protocol

The RCT started in November 2019. By December 9, 2019, the largest maternity care organization had 10 inclusions, while 40 were needed according to the calculations. To reach the required number of inclusions on time, the criteria for client inclusion were adjusted on December 17, 2019; instead of requiring three or more points (see Determination of vulnerability in the Method section), vulnerability was adjusted to include clients with ≥2 points. Additionally, a subjective measure of vulnerability was added: a suspicion of vulnerability by an employee of the

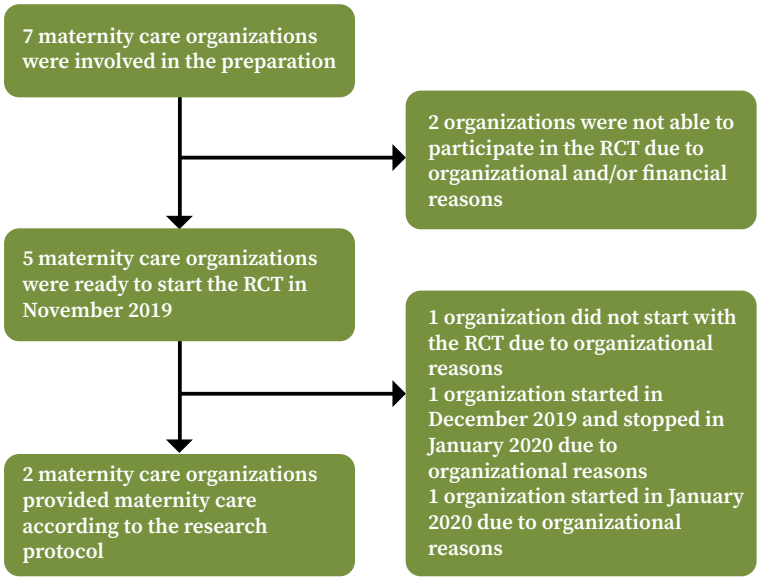


Figure 4. Flowchart of participating maternity care organizations

maternity care organization, even if not explicitly indicated in the questionnaire, was counted as a point for vulnerability.

Descriptions of the participants of the RCT

The data from the study logbook were used to gain insight into the inclusions (see Table 2). A total of 80 participants were included, which accounted for 5% of the total number of women registered with one of the participating maternity care organizations during that period. In total, 247 women met the inclusion criteria. Also, 39 women were vulnerable according to the screening questions, but registered themselves after 25 weeks of gestation, i.e. too late for participation. Screening questions were not asked during registration for 520 women (29%). There was a large variation in these and other factors among the various organizations (see Table 2).

2. Results of the Process Evaluation

Participation in the Process Evaluation

For the survey, 65 employees from the five maternity care organizations were approached, and 48 (74%) of them participated (Table 3). These participants included employees involved in the RCT 'de Beste Start', such as MCAs, intakers, administrative staff, and managers. Organization 4 indicated that due to organizational reasons, they could not participate in the interviews. The intakers from organization 5 who were involved in the research were no longer employed, and no one from this organization participated in the group interview.

Seven pregnant and postpartum women were willing to participate in an interview. Interviews were conducted with three of them.

Data from the study logbook, survey, and (group) interviews were analyzed using Hasson's model (Figure 3). Facilitators and barriers were defined for each phase of the intervention and are elaborated below.

Preparation phase of the RCT 'de Beste Start'

Facilitators and barriers

From the management teams of the maternity care organizations, there was great willingness to participate in this research project. During preparatory discussions with the organizations, they enthusiastically contributed to optimizing the research plan and adapting it to the local organization of care. However, the research protocol proved to be complex, with the protocol and specifically the intervention affecting multiple organizational processes. The introduction and implementation of a complex eHealth application further complicated matters. The organizational structure of maternity care organizations proved to be complex and

involved various (types of) employees, and integration of the research protocol into existing processes of the organizations was therefore challenging. For example, a new client meets - via telephone or in person - the administration department during registration, the intaker during the home visit, the planner directly after childbirth, and then one or two MCAs during the postpartum week. All these individuals had essential roles in identifying pregnant women in vulnerable circumstances, assessing risk factors, and responding to identified risks, among other tasks. Therefore, many employees were involved in each organization, and it was important for the researcher to identify key persons within each organization to manage the involved employees. Moreover, more employees needed training than initially anticipated. The training also focused on the application of conversation techniques, including the assessment and discussion of risk factors with vulnerable clients. Interviewees indicated that the organization's employees felt that their conversation techniques had actually improved. However, scheduling the training sessions was challenging. Managers mentioned that accommodating a large portion of the staff's schedules was costly, so, at times, they opted to send some employees to the training, and having them inform others. Additionally, it was found that additional training and intensive support were necessary for the execution of the research protocol, as well as the use of eHealth. Two maternity care organizations withdrew from the research project during the preparation phase due to business-related reasons. In other organizations, staffing shortages led to delayed or no initiation of the project. This occurred particularly when key employees were absent for an extended period, or when work procedures had to be significantly modified to accommodate the research. The latter issue was also financially driven; there was limited financial capacity to perform additional actions or employ extra staff to execute the research.

Execution Phase – Maternity Care Organizations

Facilitators and barriers

One significant advantage of following the research protocol, according to the maternity care organizations, was the ability to perform a fast and easy risk identification at the beginning of the care process, during registration by the maternity care organization. This allowed the organizations to adjust care from the start of their care process, such as allocating more time for the home visit. This was then also applied to pregnant women in vulnerable circumstances who were not included in our research. During the conversations while registering the women where the risk identification took place (known as welcome calls), employees mentioned that the project created an opportunity to discuss other issues with the client. As a positive consequence, an improved bond with the client was established right from the registration stage, especially when risk

identification was conducted by intakers. However, the execution of this risk identification was perceived as a significant logistical burden. Welcome calls took longer, and additional actions were required in administration. Asking the questions for risk identification was a significant barrier for employees, and they only dared to ask these questions by mentioning they were obliged to because of the research project. Risk identification sometimes led to client's misunderstanding because it was not clear for them why maternity care organizations needed this information. Furthermore, a short questionnaire was designed with a select number of risk factors, but it turned out that some clients in vulnerable circumstances had other issues that were not captured by the questionnaire. Organizations also spent a considerable amount of time verifying whether the installation of the eHealth app (following an email referral) was successful and assisting with its installation. Organizations noted that explaining a randomized controlled trial with a complex intervention to (potential) participants, i.e. pregnant women in vulnerable circumstances, was challenging, and scheduling an early home visit was also difficult. Women were often still working or hard to reach by phone around 25 weeks of pregnancy. Due to the shorter time between registration and home visits, it was challenging to schedule the home visit on time. In some Obstetric Collaborative Networks (VSVs in Dutch), scheduling the intake around 25 weeks of pregnancy was already standard policy for pregnant women in vulnerable circumstances and aligned well with the agreements made. Interviews with managers and intakers indicated that the extensive risk assessment questionnaire during the woman's home visit and the important role of MCAs during the postpartum week were valuable for identifying risk factors. This was especially due to their presence inside the woman's home and their extended stay during the postpartum week. However, a second contact around the 34th week of pregnancy was often needed to check whether the woman had acquired the necessary items (such as a crib, a baby bath, hot water bottles) for the first week postpartum. It also became apparent that during the home visit, the extensive risk assessment questionnaire via the app was often not completed and this still needed to be done; this prolonged the visit. Furthermore, it was found that the web portal did not function well on tablets, making it difficult to use in postpartum care. Some women in vulnerable circumstances either registered after 25 weeks of pregnancy or their vulnerability became apparent later in pregnancy, rendering them ineligible for inclusion. Despite the fact that the part of the intervention related to the postpartum week was not implemented due to termination of the study, managers and intakers believed that MCAs were the ideal individuals to discuss outcomes of the questionnaires with women during the postpartum week; especially because they established a strong bond with the women through their extended contact. Employees of maternity care organizations mentioned that late identification of vulnerability, sometimes even in the postpartum week, was common. This resulted in

complex situations where employees of maternity care organizations felt responsible for coordinating extra care. These hours were not reimbursed, but organizations still took the lead in organizing care for these issues beyond the indicated hours. In such situations, it was often unclear what the role of the MCA was, such as being asked to observe for the Child Care and Protection Board. Additionally, employees of maternity care organizations mentioned that not all MCAs possessed the necessary competencies to provide care to vulnerable clients, and not all were willing to provide this more complex care. Some MCAs, however, were highly motivated to support women in vulnerable circumstances. Managers believed that additional training and motivation were needed for MCAs to care for women in vulnerable circumstances.

Execution Phase – Clients

Facilitators and barriers

Interviews showed that women in vulnerable circumstances found it logical for risk identification questions to be asked to better assess their needs during registration. These participants also stated that they responded honestly and did not feel resistance to discussing their issues with the maternity care organization. However, the logbook and interviews with organization staff revealed that many clients did not understand why the maternity care organization asked risk identification questions, especially the question about income, which often met with resistance. Many eligible women were not interested in participating in the research because they were already involved in other studies or after they had been allocated to the control group. Interviews with participants and the logbook also revealed that women in vulnerable circumstances experienced a lot of stress at the beginning of pregnancy and had many things to organize. Consequently, they sometimes did not want to participate, or they could not remember the details of the research. Many women in vulnerable circumstances were not proficient in the Dutch language, hindering participation in the research. One participant in the interviews also mentioned that she found the app too difficult, and speaking Dutch was easier for her than reading. Additionally, installation of the app was problematic for all participants of the interviews, possibly due to outdated devices or a lack of understanding of the app's operation. As a result, they did not use the app. The early home visit was appreciated because it allowed participants to familiarize themselves with postpartum care early on and receive information about the items they needed to purchase. There was still sufficient time to make these purchases. As a disadvantage of the intensive introduction during registration and the early home visit, participants mentioned that the postpartum week still felt far away, and the gap between the home visit and the actual postpartum week was quite long. They had a lot of trust in MCAs and were willing to discuss ques-

tionnaire outcomes with them. Participants primarily sought information about baby care and other non-medical information from their MCA – rather than from family or friends. However, they mentioned that it was beneficial to have access to various information sources before and after the postpartum week, preferably through a digital app.

Midwives from Participating Regions

Facilitators and barriers

The two interviewed midwives questioned the added value of a home visit by intakers if a woman is highly vulnerable and already receiving assistance (such as family guidance from preventive child healthcare services or social work). They felt that in such cases, an intake could be just as effective via telephone, potentially resulting in cost savings. However, midwives emphasized the importance of maternity care organizations when it came to identifying pregnant women in vulnerable circumstances during a home visit. They also considered the early home visit as important if vulnerable circumstances were suspected because it provided a longer timeframe to organize care. During this early home visit, according to them, maternity care organizations could encourage clients to purchase the necessary items, the availability of which could potentially be checked by phone around 34 weeks of pregnancy. They also found it very helpful to receive information about the woman in vulnerable circumstances from maternity care organizations (both intakers and MCAs) but noted that they themselves did not sufficiently inform maternity care organizations when they observed risks. They acknowledged that this could make it difficult for maternity care organizations to provide appropriate early care for these women in vulnerable circumstances. Moreover, midwives often provided minimal guidance and information about postpartum care to women in vulnerable circumstances and believed they could improve this aspect for these women. Regarding better information transfer and exchange, midwives mentioned that a shared electronic health record would be highly desirable, a point that was also raised in discussions with maternity care organizations. During the postpartum week, midwives considered MCAs to have a crucial role because they spent an extended period in the woman's home and had both a preventive and a signaling role. Finally, midwives pointed out that they noticed staffing problems and occasional financial difficulties in maternity care organizations, which sometimes resulted in suboptimal care for postpartum women in vulnerable circumstances.

Education center

Facilitators and barriers

The employees of the maternity care organizations' need for training in conversation techniques and the importance of focusing on pregnant women in vulnerable circumstances for maternity care organizations were facilitators for participation in the research according to the trainer from the education center. At the same time, the complexity of care for pregnant and postpartum women in vulnerable circumstances posed challenges to providing care and participating in research. During participation in various training sessions, the trainer observed significant differences in the learning abilities of maternity care organization employees and varying attitudes toward acquiring new insights. A general barrier was that some training sessions were postponed due to organizational circumstances, and, due to these circumstances, some organizations placed less emphasis on the quality of care. Finally, it appeared that little attention was given to training for non-registered employees of maternity care organizations (administrative personnel and intakers).

eHealth Developer

Facilitators and barriers

The provided training for employees of the maternity care organizations focused on conversation techniques and the use of eHealth. This combination was unique for the eHealth developer and had not been applied before but was effective for this group of practically educated healthcare professionals. The 'Beste Start' application was developed with a relatively limited budget and a lot of effort from both the eHealth developer and the researchers. However, during the rollout of the application, the eHealth developer encountered various inhibiting factors at maternity care organizations and in the technology itself. Using the application and web portal required digital skills, which were insufficient in some pregnant women in vulnerable circumstances and among maternity care organization employees. Some training sessions and the implementation of research activities were spaced too far apart, contributing to these issues. Furthermore, it became evident that devices such as desktops, laptops, tablets, and phones needed to be up-to-date due to security requirements and for proper application use. The developed eHealth application aimed to provide information as well as collect responses through questionnaires, which proved to be complex both in terms of technology and usability.

RECOMMENDATIONS

The execution of the planned research and the intervention was not successful. The aim of the process evaluation was to gain insight into adherence to the research protocol and the facilitators and barriers. While some maternity care organizations implemented the research up to the early intake, the evaluation also considered the components that were not executed. Consequently, the facilitators and barriers were transformed into concrete recommendations focused on three pillars: education and development, the care process, and research. In this way, specific recommendations are provided that can be used for the improvement of postpartum care for women in vulnerable circumstances. A summary of these recommendations and facilitators and barriers is included in an attached factsheet (Appendix 7).

Education and Development

- Regularly train all employees of maternity care organizations (including intakers and office personnel) in communication techniques and care for women in vulnerable circumstances because postpartum care for this population can be complex.
- This training should focus on knowledge about the needs of this population, as well as on communication techniques to identify risk factors. Currently, MCAs are the primary focus of training, as they need to earn sufficient points for re-registration. However, our evaluation revealed that while employees found it useful to learn communication techniques during training, there were still barriers to asking risk identification questions. Women also did not always respond well to these questions. Therefore, additional and regular training for all employees with client contact is recommended.
- Provide women in vulnerable circumstances with digital, accessible, and understandable information during pregnancy and the postpartum period. Women have this need, and maternity care organizations can contribute to ensuring that the information they provide is accessible to them. The need for information is particularly pronounced during and after the postpartum week, but maternity care organizations can also offer information during pregnancy about the intake process, necessary items to purchase, and the role of the MCA.
- Develop this information collaboratively with the target group, i.e. women in vulnerable circumstances, to ensure that it aligns with their needs and abilities. Since these women may have limited digital literacy, it is crucial that digital information is user-friendly. Attention to attractive visual design, easy

navigation, and the use of visual aids is recommended.
- Evaluate with the women in vulnerable circumstances whether they understand and use this information and provide support if necessary. Women in vulnerable circumstances may require more assistance in navigating eHealth applications, making eHealth a valuable addition to the care for vulnerable women as well.

Care Process

- Ensure as an obstetric care provider that the referral to maternity care organizations occurs at 12 weeks of pregnancy. In this manner, there is ample time to facilitate the exchange of data and potentially accommodate the consideration of a woman's vulnerable circumstances within the care pathway. The obstetric care provider also benefits from personalized postpartum care in the postpartum period and is jointly responsible for the referral.
- Clarify the roles and responsibilities of maternity care organizations for women in vulnerable circumstances, both as a partner in the obstetric care network and in information provision towards pregnant women. Maternity care organizations play a critical role due to their behind-the-door function, but there is ambiguity regarding the scope of work and the role of their healthcare providers in the (obstetric) care network. It is also essential for women to understand the tasks and role of maternity care organizations before enrolling. Risk identification questions may then be viewed as logical rather than burdensome.
- Actively participate as a maternity care organization in the development and implementation of the care pathway for women in vulnerable circumstances. Currently, information transfer mainly occurs unidirectional from maternity care organizations to midwifery care providers after the home visit. However, for scheduling care, it is desirable for maternity care organizations to be informed in advance about non-medical risk factors and treatment plans for women in vulnerable circumstances via their obstetric care provider.
- Collaborate in the care for pregnant women in vulnerable circumstances, such as via creating a joint plan for data exchange between obstetric care providers and maternity care organizations. This ensures that data exchange also occurs from obstetric care providers to maternity care organizations. This way, maternity care organizations are informed promptly about the existence of non-medical risk factors, and risk identification questions can be adapted accordingly.
- Conduct an early home visit at 25 weeks of pregnancy when vulnerability is suspected. This provides more insight into the woman's situation, allowing for the earlier provision of appropriate care and assistance. It is also important for obstetric care providers to emphasize the key role of postpartum care and

ensure timely enrollment. While the timeframe for addressing issues after the early home visit is longer, the window for scheduling the home visit for this sometimes challenging-to-reach group is shorter.
- Schedule a second contact point in the care pathway for pregnant women in vulnerable circumstances by maternity care organizations. During this second contact, it can be verified whether the necessary items are bought, and changes in non-medical risk factors can be assessed.

Research

- Continue investing in quality improvement and research participation as a maternity care organization. This is crucial for defining the role of maternity care organizations in the obstetric care networks. Despite the unsuccessful RCT, maternity care organizations are enthusiastic partners in research and play a significant role in the obstetric care chain. However, continuous research and potential improvement of care processes are necessary for quality enhancement.
- Involve maternity care organizations and the target population in the design and execution of (follow-up) research on pregnant women in vulnerable circumstances from the beginning. This way, organizations can early on indicate what is feasible for them.
- Provide practical support within maternity care organizations by having a research team member assist in research execution. This research team member can handle administrative tasks and provide support to key personnel in managing staff. This approach also facilitates the early identification of potential issues in research or intervention execution.

This evaluation endeavor of a failed RCT has both strengths and weaknesses. A major strength is the use of a mixed methods approach, incorporating logbooks, surveys, and interviews. Additionally, diverse perspectives were included, involving third parties (midwives, eHealth developers, and an education center trainer) to obtain a comprehensive view. The insights of women in vulnerable circumstances were gathered through both logbooks and participant interviews. Furthermore, we also engaged with organizations that did not commence the research. Unfortunately, one organization could not participate in the process evaluation, potentially leading to an incomplete picture. Moreover, since the intervention was not fully implemented, some of the facilitators and barriers are based on assumptions. Nevertheless, the study provided a comprehensive understanding of the current situation. There is also a potential selection bias in the participant interviews, as they mostly involved enthusiastic employees and key personnel. Recruiting participants from the intervention group proved challenging; out of 80 participants, only seven were willing to be interviewed, with ap-

pointments successfully scheduled for three of them. As with previous research on this target population and the perspectives shared by maternity care organizations, this study confirms that pregnant women in vulnerable circumstances are a difficult-to-reach group for research.

CONCLUSION

The RCT 'de Beste Start' was partially executed according to the research protocol. The process evaluation yielded specific recommendations that can be applied within postpartum care and the chain of obstetric care organizations with which maternity care organizations collaborate. Embedding a complex intervention within a complex organizational structure proved challenging. Pregnant women in vulnerable circumstances remain a hard-to-reach client group for research inclusion. Staffing and financial challenges make it difficult for maternity care organizations to conduct research. Nevertheless, maternity care organizations are enthusiastic research partners, and it is essential that they continue to actively participate in research to optimize care for women in vulnerable circumstances in the future.

APPENDIX:

Bijlage 1 Inclusiecriteria

Een cliënt moest aan de volgende inclusiecriteria voldoen om deel te mogen nemen aan de Beste Start:

- De cliënt is de Nederlandse taal voldoende machtig om informatie te lezen en vragenlijsten in te vullen.
- De cliënt is bij aanmelding voor kraamzorg maximaal 25 weken zwanger, omdat dan nog een vervroegd intake huisbezoek kan plaatsvinden.
- De cliënt is 16 jaar of ouder.
- De cliënt scoort ≥3* punten op de onderstaande vragenlijst.

* vanaf december 2019 is dit verlaagd naar 2 punten.

Bijlage 2 Survey

Vragenlijst Medewerkers Kraamzorgorganisaties

Casemix

Wat is je functie?

☐ kraamverzorgende
☐ Consulent/intaker
☐ zowel kraamverzorgende als consulent/intaker
☐ administratief medewerker
☐ managementfunctie
☐ directiefunctie
☐ overig, namelijk:

Hoelang ben je werkzaam in je huidige functie?

☐ <5 jaar
☐ 5-10 jaar
☐ >10 jaar
☐ ik ben in opleiding

Wat is je geboortejaar? _____

Bij welke organisatie ben je werkzaam?

☐ Kraamzorg Rotterdam
☐ Kraamzorg de Bakermand
☐ Kraamcentrum DAT (vervolg vraag: Ik ben werkzaam bij vestiging Zuid-Holland, Roosendaal, Zeeland)
☐ Allerzorg kraamzorg
☐ Kraamzorg XL

Heb je één of meerdere scholingen gevolgd van de Beste Start? (de aftrap in juni 2019, scholing 1 in september 2019, scholing 2 in januari of maart 2020)

☐ ja alle drie
☐ ja, één of twee
☐ nee, geen (vervolg vraag: open vraag: hoe ben je ingelicht over de studie de Beste Start?)

1. De interventie (logistiek)

Algemene vragen over de interventie

Het onderzoek de Beste Start richtte zich op kwetsbare zwangeren. Binnen het onderzoek werden zwangere vrouwen ingedeeld in de interventiegroep of de controlegroep. De interventiegroep kreeg toegang tot de volledige app met informatieve berichten en vragenlijsten. Zij kregen ook een huisbezoek bij 25 weken, waarbij de risicoscreening werd besproken. Zo nodig werd de zorg afgestemd op deze risico's.

De controlegroep kreeg ook toegang tot de app, maar dan zonder de informatieve berichten.

De volgende vragen gaan over de interventie. Je wordt gevraagd om je mening te geven over de volgende stellingen.
Het doel van de interventie was voor mij duidelijk.
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens
De interventie paste goed in mijn dagelijkse werk.
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens
Kan je je antwoord toelichten? Waarom vond je de interventie goed of juist niet goed in je dagelijkse werk passen?
Veranderingen door de interventie per onderdeel van de kraamzorg

Aanmelding
De aanmelding van nieuwe cliënten liep tijdens het onderzoek anders dan voorheen. Tijdens het onderzoek werd iedereen gescreend op kwetsbaarheid bij de aanmelding. Dit werd gedaan door middel van een aantal korte vragen over het hebben van een partner, inkomen, huisvesting, et cetera. Bij sommige organisaties ging dit telefonisch, bij andere organisaties via een formulier.
De volgende vragen gaan over de aanmelding en screening op kwetsbaarheid.
Was je betrokken bij de aanmelding van nieuwe cliënten?
☐ ja
☐ nee
☐ weet ik niet
De screening op kwetsbaarheid bij de aanmelding vind ik een goed moment.
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens
Kan je je antwoord toelichten? Waarom vond je de screening bij de aanmelding een goed moment, of juist niet?

Ik vond het nuttig om bij aanmelding te weten welke cliënten kwetsbaar zijn.
☐ helemaal mee oneens
☐ mee oneens

☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

De screening op kwetsbaarheid bij de aanmelding geeft een goed beeld van wie er kwetsbaar is.
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Miste je kenmerken van kwetsbaarheid die niet in de screeningsvragen voorkwamen?
☐ Nee, ik vond de vragenlijst bij aanmelding volledig
☐ Ja, namelijk:

Huisbezoek

Het huisbezoek voor cliënten in de interventiegroep verliep anders dan voor de andere cliënten. De uitslagen van de vragenlijsten werden besproken met de cliënt.

De volgende vragen gaan over het huisbezoek.

Was je betrokken bij het huisbezoek?
☐ ja
☐ nee
☐ weet ik niet

Ik vond het prettig om voorafgaand aan het huisbezoek te weten dat iemand kwetsbaar was.
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Ik vond het lastig om de gesignaleerde risico's te bespreken met de cliënt.
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Als ik wist dat een cliënt kwetsbaar was (ook de cliënten in de controlegroep of die niet mee wilden doen) gebruikte ik die kennis bij de intake.
☐ helemaal mee oneens
☐ mee oneens

☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens
Kan je dit toelichten?

Vragenlijst bij 34 weken zwangerschap

Als de cliënt 34 weken zwanger was, kreeg zij een vragenlijst. Deze vragenlijst was gericht op de ervaring met de geleverde zorg tijdens de intake en enkele andere uitkomsten.
De volgende vragen gaan over de 34 weken vragenlijst.
Ik vond het nuttig om rondom de 34e zwangerschapsweek te weten hoe het met de cliënt ging.
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens
Ik vond het nuttig om te weten wat de cliënt van de intake vond (ervaring met de geleverde zorg).
☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Kraamweek

De kraamzorg in de eerste week na de bevalling verliep voor cliënten in de interventiegroep anders dan voorheen. De kraamverzorgende werd geïnformeerd over de gesignaleerde risico's bij de cliënt. Cliënten vulden een vragenlijst in tijdens de kraamweek. De uitslagen hiervan werden besproken. Cliënten in de controlegroep kregen de standaardzorg en vulden ook een vragenlijst in. De uitslagen van deze groep waren niet zichtbaar.
De volgende vragen gaan over de kraamweek.
Deelde jij informatie over de cliënt met de kraamverzorgende of was je werkzaam als kraamverzorgende?
☐ ja, ik deelde informatie met de kraamverzorgende of ik ben kraamverzorgende
☐ nee, ik deelde geen informatie met de kraamverzorgende of ik ben geen kraamverzorgende
☐ weet ik niet
Als kraamverzorgende: Ik vond het goed dat ik van te voren wist dat ik zorg ging

leveren bij een vrouw in een kwetsbare situatie.
Als andere medewerker kraamzorgorganisatie: ik vond het goed dat de kraamverzorgende van te voren wist dat zij zorg ging leveren bij een vrouw in een kwetsbare situatie.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Ik vond het bespreken van de uitslagen van de vragenlijsten met de kraamvrouw bij mijn werk passen als kraamverzorgende.
Ik vond dat het bespreken van de uitslagen in de kraamweek bij het werk van de kraamverzorgende paste.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Kan je je antwoord toelichten?
Heb je opmerkingen over de uitvoering van het onderzoek?

De volgende vragen/stellingen gaan over het onderzoek in het algemeen.
Door dit onderzoek was je misschien meer tijd kwijt aan de aanmelding, het huisbezoek en in de kraamperiode. Ik vond de extra tijd die ik kwijt was aan de kwetsbare zwangeren het waard.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Kan je een voorbeeld geven waaruit blijkt dat je de tijdsinvestering het wel of niet waard vond?
De interventie had als doel om kwetsbare kraamvrouwen zelfredzamer te maken. Ik vond dat de interventie zorgde voor een betere zelfredzaamheid van de kwetsbare kraamvrouw. (midi)

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

2. eHealth

De interventie bestond voor een groot deel uit eHealth, namelijk de app voor de cliënten en het platform voor de zorgmedewerker.

Ik kan goed met digitale toepassingen (zoals apps en platformen) omgaan.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Ik vind dat de informatievoorziening in de app bijdraagt aan zelfredzaamheid voor de kwetsbare zwangere.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Vanaf 25 weken zwangerschap ontvingen de cliënten in de interventiegroep informatieve berichten. Ik vond deze timing goed.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Kan je je antwoord toelichten? Als je de timing van de start van de berichten via de app niet goed vindt, kan je aangeven waarom niet? En welk moment in de zwangerschap of erna vind je dan beter passen?

Ik denk dat de cliënten goed met de app om kunnen gaan.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Ik vond de app makkelijk in gebruik.

☐ helemaal mee oneens
☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Ik vond het platform makkelijk in gebruik.

☐ helemaal mee oneens

☐ mee oneens
☐ noch mee oneens, noch mee eens
☐ mee eens
☐ helemaal mee eens

Heb je opmerkingen over de app of over het platform?
Heb je nog suggesties of opmerkingen over het onderzoek?

Bijlage 3 Topic list managers

1. Wat vond je van de interventie? (grand tour question) Ingaan op nut van interventie – alternatieve zorg voor kwetsbare zwangeren. Kort aanstippen rol van de kraamzorg hierin.
2. Trouwheid aan het protocol (Adherence):
   - Content: welke onderdelen van het onderzoek (inclusief interventie) zijn uitgevoerd volgens vooraf opgestelde plan? Wat waren redenen om af te wijken van het plan?
   - Frequency: werden de verschillende stappen van het onderzoek en de interventie bij elke cliënt en vervolgens bij elke deelnemer uitgevoerd? Wat waren redenen om af te wijken van het plan?
   - Duration: waren de stappen van de interventie geïmplementeerd als gepland?
   Tot waar in het protocol was er geïmplementeerd?
   Als bepaalde stappen niet zijn uitgevoerd maar wel waren afgesproken: wat waren redenen om dit niet uit te voeren?
   Voorzag je nog problemen binnen je organisatie met delen van de interventie die nu niet uitgevoerd zijn?
   - Compleetheid: wat vond je van de informatie die beschikbaar was om de interventie uit te voeren? Denk aan scholing, map (reader), contact onderzoeker.
3. Factoren die individueel van invloed zijn op uitvoerbaarheid en haalbaarheid van het onderzoek/interventie (Potential Moderators).
   - Intervention complexity: Kan je vertellen of je het onderzoek complex vond? En toelichten?
   Wat vond je van de veranderingen in zorgproces? (uitvoerbaarheid)
   Wat vond je van de eHealth applicaties (app en platform)? (zie ook punt 8, kort houden)
   Doelgroep kwetsbare zwangeren: complexiteit doelgroep, uitleg interventie aan hen etc. Ervaar jij deze groep als complex, waarom wel/niet? Indien aangegeven wordt dat kwetsbare zwangeren later in beeld komen, cijfers laten zien dat dit meevalt (KZR bijvoorbeeld), Oplossingen voor dit punt? Toeleiding naar kraamzorg?
   - Facilitation Strategy & Context: wat is er ondernomen om de implementatie van de interventie te ondersteunen?

Ik wil graag ingaan op een aantal onderdelen van jullie organisatie met betrekking tot het onderzoek (Welke factoren op politieke, economische, organisatorische vlakken hebben interventie beïnvloedt?) In gaan op de punten van MIDI:
A. Formele bekrachtiging management: stond je als manager achter de interventie? Wisten je medewerkers dat? Hoe heb je dat laten blijken? Wat is het effect hiervan geweest denk je?
B. Vervanging bij personeelsverloop: als er mensen weggingen/uitvielen die essentiële rol hadden in de interventie, hoe werden dezen vervangen? Had dat effect op de uitvoer van het onderzoek?
C. Capaciteit/bezettingsgraad: was er voldoende personeel om de interventie uit te voeren? Op welke vlakken wel/niet? Waren de problemen in de uitvoer van de interventie opgelost met meer personeel?/Was de uitvoer van het onderzoek makkelijker met meer personeel?
D. Financiële middelen: de innovatie kostte extra tijd en dus indirect geld.
Was er ruimte om extra dingen zoals onderzoek op te pakken? Zijn daar afspraken over gemaakt met directie bijvoorbeeld? Waren er veranderingen in de financiële mogelijkheden tijdens looptijd onderzoek (toelichten)?
In hoeverre had dit invloed op de uitvoer van het onderzoek?
E. Tijd: aanvullend op D, was er voldoende tijd voor de medewerkers om de interventie uit te voeren? Welke punten van het onderzoek kosten veel tijd? Welke punten vielen mee qua tijdsbesteding? Denk je dat meer tijd en/of financiële middelen de haalbaarheid van het onderzoek hadden vergroot? Toelichting antwoord.
F. Coördinator: was er 1 of meerdere personen beschikbaar als coördinator van de interventie? Heeft dat geholpen in de uitvoer? Zou dat helpen?
G. Turbulentie in organisatie: waren er andere veranderingen waar de organisatie mee te maken had? Denk aan COVID, fusies/overnames, indeling in VSV/KSV, (rol)verschuivingen van belangrijke personen binnen de organisatie?
Had dit invloed op de uitvoer van het onderzoek?
H. Beschikbaarheid informatie over gebruik informatie
I. Feedback aan gebruiker: Was er terugkoppeling aan alle betrokken medewerkers over de stand van zaken van het onderzoek? Hoe ging dat?

- Quality of delivery:
  als we kijken naar het vooraf opgestelde plan voor jullie organisatie, is het onderzoek dan uitgevoerd volgens plan?
  Welke punten wel, niet, reden voor afwijken plan?
  Wat vind je van de uitvoer van de intakes volgens het studieprotocol? Wat vind je van de taak van de kraamverzorgende tijdens de kraamweek ttv het onderzoek? (doorvragen op competenties, wie is geschikt voor deze taken, ligt dit bij de kraamzorg etc.)
- Participant responsiveness:
  Wat heb je terug gehoord van de cliënten over de interventie? (bijv. over vra-

genstellen bij de aanmelding)
Wat waren de barrières en bevorderende factoren van de interventie voor de deelnemers?
Heb je van deelnemers terug gekregen hoe zij de interventie hebben ervaren? Wat vonden zij van de relevantie en de uitkomsten?
- Recruitment strategies:
Hadden jullie een plan gemaakt om de cliënt te overtuigen mee te doen/te motiveren door te gaan met het onderzoek?
Kan je doelgroep-specifieke barrières benoemen die cliënten hadden om deel te nemen? Onderscheidt de kwetsbare zwangeren in jullie organisatie zich nog ten opzichte van andere regio's? Wat vind je van de stelling 'er is geen veralgemeniseerde strategie mogelijk gericht op kwetsbare zwangeren van toepassing op alle kraamzorgorganisaties'.

4. Doelgroep kwetsbaren: alternatieve strategieën voorleggen gebaseerd op mogelijke barrières in de uitvoer van het onderzoek en de interventie (voorbeelden: screening kwetsbaarheid via verloskundig zorgverlener versus AVG-beperkingen, latere aanmelding versus weinig tijd voor uitvoering plan gericht op individuele risico's van cliënt, aangevuld met punten uit de survey) hier ook ingaan op organisatie specifieke plan
5. Bereiken kwetsbare zwangere:
We hoorden terug dat cliënten verbaasd waren over de extra vragen bij inschrijving. Vind jij het de taak van de kraamzorg om te inventariseren of iemand kwetsbaar is? Welke zorgverlener is de aangewezene? Merkten jullie barrières bij cliënten m.b.t. stellen van de screeningsvragen? Wat vond je van de screeningsvragen?
6. Voordelen en nadelen van elementen uit de interventie in dagelijkse praktijk.
Wat vind je van de vroege identificatie van kwetsbare zwangeren? Voordelen qua zorg/beleid/planning? Is de zorg aangepast op kwetsbare zwangeren, ook als zij niet meededen aan het onderzoek? Kan je voorbeelden geven? Wat vind je van het huisbezoek bij 25 weken? Kan je voor- en nadelen noemen? Wat vind je van de aangepaste zorg in de kraamweek? (inlichten kraamverzorgende, extra aandacht voor de gevonden risico's)
Zijn er onderdelen van de interventie die jullie behouden hebben in jullie dagelijkse logistieke proces? (of die je eventueel zou willen invoeren)
Aanvulling resultaten survey
7. Digitaal/eHealth: Wat vond je van de app Beste Start? Voordelen voor cliënt?
Wat vond je van het platform? Wat vond je van het beoordelen van uitslagen van vragenlijsten? In hoeverre zijn de medewerkers digitaal-vaardig genoeg? In hoeverre zijn de cliënten digitaal-vaardig genoeg? (denk aan SES, gezondheidsvaardigheden, taalbarrière). Als je kijkt naar de zorg die jullie leveren, is er dan behoefte aan eHealth? Of aan zo'n bibliotheek van informatie?

8. Indien organisatie is gestopt tijdens inclusie, of niet gestart is: motivatie stoppen/niet starten (indien dit niet is gebleken uit MIDI organisatie)
9. Component analysis: haalbaarheid van verschillende onderdelen van de interventie. (volgt uit bovenstaande, eventueel ingaan op onduidelijke punten)
10. Stel dat jouw organisatie opnieuw mee zou doen aan een onderzoek gericht op kwetsbaren, wat zou je dan anders doen? Zijn er nog dingen die niet aan bod zijn gekomen, maar die je belangrijk vindt om te vertellen?

Bijlage 4 Topic list intakers

1. Wat vond je van de interventie? (grand tour question) Ingaan op **nut van interventie** – alternatieve zorg voor kwetsbare zwangeren.
   Kort aanstippen rol van de kraamzorg hierin.
2. - **Compleetheid**: wat vond je van de informatie die beschikbaar was om de interventie uit te voeren? Denk aan scholing, map (reader), contact onderzoeker.
3. Factoren die individueel van invloed zijn op uitvoerbaarheid en haalbaarheid van het onderzoek/interventie (**Potential Moderators**).
   - **Intervention complexity**: Kan je vertellen of je het onderzoek complex vond? En toelichten?
   Wat vond je van de veranderingen in zorgproces? (uitvoerbaarheid)
   - **Facilitation Strategy & Context**:
   C. Capaciteit/bezettingsgraad: was er voldoende personeel om de interventie uit te voeren? Op welke vlakken wel/niet?
   Waren de problemen in de uitvoer van de interventie opgelost met meer personeel?/Was de uitvoer van het onderzoek makkelijker met meer personeel?
   E. Tijd: had je voldoende tijd voor de extra taken? Als je screeningsvragen stelde, leverde dit je dan wat op later?
   Intake: intake moest je voorbereiden, was dat haalbaar? Hoeveel tijd kostte het per participant? maar leverde dat je ook tijdswinst op bij intake? Of andere voordelen?
   Welke onderdelen kostten het meeste tijd? Wat viel er mee qua tijd, of qua uitvoer?
4. Deden je collega's allemaal mee aan de uitvoer van het onderzoek? Waarom wel/niet?
5. Wat vond je van de screeningsvragen? Velen vonden het spannend om ze te stellen. Compleetheid van de risico's? Mantelzorg?
   Barrière bij cliënten? Hoe kan dat? Hoe los je dat op?
   Leverde het Voordelen of nadelen op bij de intake dat je de vragen al gesteld had?
   Denk je dat de risicoscreening bij aanmelding een haalbare strategie kan zijn om in te voeren, zodat kwetsbaren eerder in beeld komen? (tijdsinvestering, klantcontact aan de telefoon etc)

6. Wat vond je van de intake bij 25 wkn?
   Wat vond je van het bespreken van risico's? Hoe pakte je dit aan? Hoe reageerden cliënten? Wat vond je spannend of deed je niet?
   Denk je dat de intake gerichter is als problematiek van te voren bekend is of dat de band intensiveert door stellen screening?
   Wat is jouw mening over het vervroegde huisbezoek? (timing, tijd tussen intake-partus, aanpak problematiek?)
   In hoeverre sluit dit aan bij verwachting van de doelgroep. Hoe benut je het intake gesprek beter bij deze doelgroep?
   Vind je dat binnen het LIP je voldoende de zorg kan afstemmen op kwetsbare zwangeren?
7. Doelgroep kwetsbare zwangeren: complexiteit doelgroep, uitleg interventie aan hen etc. Ervaar jij deze groep als complex, waarom wel/niet? Indien aangegeven wordt dat kwetsbare zwangeren later in beeld komen, cijfers laten zien dat dit meevalt (KZR bijvoorbeeld). Mogelijk wel onderrapportage: als iemand zich laat aanmeldt, heb je misschien niet de screeningsvragen gesteld. Denk je dat het haalbaar is om intake vroeg te doen? Wat zijn de voor- en nadelen?
8. F: Taken: wat vind je van de taak die bij de kraamverzorgende lag? Dus geïnformeerd zijn over de risico'svan de cliënt, daar de zorg op aanpassen. En eventueel het bespreken van een vragenlijst tijdens de kraamperiode?
9. - **Participant responsiveness:**
   Wat heb je terug gehoord van de cliënten over de interventie? (bijv. over vragenstellen bij de aanmelding)? Voelden cliënten zich in een hokje geplaatst? Waren ze daarover verbaasd of vonden ze het vervelend?
   Wat waren de barrières en bevorderende factoren van de interventie voor de deelnemers?
   Heb je van deelnemers terug gekregen hoe zij de interventie hebben ervaren? Wat vonden zij van de relevantie en de uitkomsten?
   - **Recruitment strategies:**
   Hoe was het om het onderzoek uit te leggen aan mogelijke participanten?
   Hadden jullie een plan gemaakt om de cliënt te overtuigen mee te doen/te motiveren door te gaan met het onderzoek?
   Kan je doelgroep-specifieke barrières benoemen die cliënten hadden om deel te nemen? Onderscheidt de kwetsbare zwangeren in jullie organisatie zich nog ten opzichte van andere regio's? Wat vind je van de stelling 'er is geen veralgemeniseerde strategie mogelijk gericht op kwetsbare zwangeren van toepassing op alle kraamzorgorganisaties'.
10. **Doelgroep kwetsbaren:**
    Wat dacht je van te voren hoeveel kwetsbaren er zouden zijn? Viel het mee/tegen?

Wat doe je al anders in de zorg voor kwetsbare zwangeren?
Wat is je mening over screening op kwetsbaarheid via verloskundige en overdracht van die intake aan kraamzorg? Voor-/nadelen en AVG?
We hoorden terug dat cliënten verbaasd waren over de extra vragen bij inschrijving.
Vind jij het de taak van de kraamzorg om te inventariseren of iemand kwetsbaar is?
Welke zorgverlener is de aangewezene?
Merkten jullie barrières bij cliënten m.b.t. stellen van de screeningsvragen?
Behoefte aan een interventie als deze? Ligt hier de winst? (of bijv bij gezamenlijke intake met de verloskundige/inzage in het dossier van de verloskundige etc).

11. Is de zorg aangepast op kwetsbare zwangeren, ook als zij niet meededen aan het onderzoek? Kan je voorbeelden geven?
Zijn er onderdelen van de interventie die jullie behouden hebben in jullie dagelijkse logistieke proces? (of die je eventueel zou willen invoeren)
wat is jullie rol als kraamzorg voor kwetsbare zwangere tov verloskundige/ maar versus huisbezoek/kijkje achter de voordeur. Is er voldoende samenwerking tussen obstetrisch zorgverlener en kraamzorg?
12. **Digitaal/eHealth**: Wat vond je van de app Beste Start? Voordelen voor cliënt?
Wat vond je van het platform? Wat vond je van het beoordelen van uitslagen van vragenlijsten?
In hoeverre vind je jezelf en je collega's digitaal-vaardig genoeg?
In hoeverre zijn de cliënten digitaal-vaardig genoeg? (denk aan SES, gezondheidsvaardigheden, taalbarrière).
Als je kijkt naar de zorg die jullie leveren, is er dan behoefte aan eHealth? Of aan zo'n bibliotheek van informatie?
13. Hoe zie jij de ideale zorg voor je voor kwetsbare zwangeren?
Stel dat je opnieuw mee zou doen aan een onderzoek gericht op kwetsbaren, wat zou je dan anders doen? Wat zou je meten om effect te meten?
14. We gaan ook cliënten interviewen. Wat zou je van hen willen weten?
Zijn er nog dingen die niet aan bod zijn gekomen, maar die je belangrijk vindt om te vertellen?

Bijlage 5 Topic list participanten

1. Grand tour

1. Je deed mee aan het onderzoek de Beste Start.
Waarom denk je dat je uitgenodigd werd om deel te nemen aan dat onderzoek?
Zoals je weet, is dit onderzoek eerder gestopt dan we gepland hadden. We willen graag meer weten over hoe deelnemen aan zo'n onderzoek is voor de deelnemers. Je zat in de interventie groep, dat betekende dat je toegang kreeg

tot de app de Beste Start en het huisbezoek of de intake wat eerder plaats vond, namelijk toen je 25 wkn zwanger was.
Hoe vond je dat, dat je in de interventie groep zat? Hoe had je de controle groep gevonden?
Het kan zijn dat je niet alles hebt meegemaakt omdat het onderzoek eerder is gestopt.
Weet je nog hoever je zwanger was toen het onderzoek stopte?

2. Wat verwachtte je van het onderzoek?

Kan je vertellen wat je van het onderzoek vond? Wat heb je er van gemerkt?
Doorvragen op vragen bij aanmelding
uitleg procedure
toeleiding app
App zelf

2. Algemeen&aanmelding

3. Wat vind je van kraamzorg? Bij de aanmelding werden vragen gesteld over je situatie (eventueel herinneren). Wat vond je hier van? Gaf je eerlijk antwoord? Weet je waarom die vragen gesteld werden?
4. Vertrouwde je de kraamzorg? Durfde je eerlijk te zijn? Waarom wel of niet?
5. Vond je het logisch dat de kraamzorg deze vragen stelde? Waarom wel of niet?
6. Wilde je meteen mee doen toen ze het vroegen? Of moesten ze je overhalen? Wat gaf voor jou de doorslag? Heb je wel eens vaker mee gedaan aan een onderzoek?
7. Was alles duidelijk over het onderzoek bij aanmelding?

3. eHealth

8. Je moest een app installeren. Kan je vertellen hoe dat ging? (email, app downloaden, inloggen)
9. Werkte de app? (kreeg je push messages?)
10. Heb je de berichtjes gelezen? Zo ja, wat vond je ervan? Lang/kort?
11. Heb je gebruik gemaakt van de bibliotheek? Waarom wel/niet? Wat vond je van de informatie in de bibliotheek?
12. Heb je de app gebruikt?
13. Wat vind je van een app met informatie tijdens je zwangerschap en kraamperiode? Waar zoek je normaal informatie? Voordelen/nadelen?
14. In de kraamperiode gaf de app ook informatie. Van welke vitamines je baby moet hebben, tot informatie over depressie en shaken baby. Wat vind je van die informatie? Nuttig of juist niet? Miste je nog informatie?
15. Had je het idee dat de veiligheid van je gegevens goed geregeld was? Speelde dit nog mee?
16. Heb je tips hoe de app ontwikkelaar de app kan verbeteren?

4. **Intake**

17. Voorafgaand aan de intake was het de bedoeling dat je een uitgebreide vragenlijst invulde. De intaker/consulent van de kraamzorgorganisatie ziet de antwoorden op de vragenlijst. Tijdens de intake wordt dit besproken met je. Hoe ging dat? Wat vond je van de vragenlijst?
Indien niet ingevuld: vragenlijst uitleggen (screening op problemen).
Wat vind je ervan dat de kraamzorg daar naar vraagt/kijkt? Toegevoegde waarde?
18. Bespreek je eerlijk alle problemen met de intaker? Waarom wel/waarom niet? Met wie eventueel wel? Verloskundige?
19. Wat vond je van het moment van de intake bij 25 wkn?
20. Wat vond je van de intake? Wat waren je verwachtingen (informatie, uitleg over inhoud kraamzorg etc)?
21. Had je na de intake een goed beeld van kraamzorg?
22. Had je nog contact na de intake en voor je bevallen was? Is dat wenselijk?

5. **Vragenlijst 34 wkn**

23. Rondom 34 wkn zwangerschap werd er weer een vragenlijst gestuurd. Over wat je vond van de intake en hoe het met je ging. Wat vind je van deze vragenlijst? Ook als je hem niet ingevuld hebt? Zeg je eerlijk wat je van de intake vond?

6. **Kraamzorg**

24. Tijdens de kraamweek komt de kraamverzorgende bij je thuis. Zij helpt je met het zorgen voor je baby en let ook op jouw gezondheid. Tijdens het onderzoek was er ook in de kraamweek een vragenlijst die je in moest vullen over hoe het met je gaat en hoe zelfverzekerd je je voelt in het zorgen voor je baby. De kraamverzorgende zou dan de antwoorden met je bespreken. Wat vind je hiervan? Hoort dit bij de kraamzorg? Wat vind je van die zelfverzekerdheid en dat daar aandacht voor is?

7. **Algemeen**

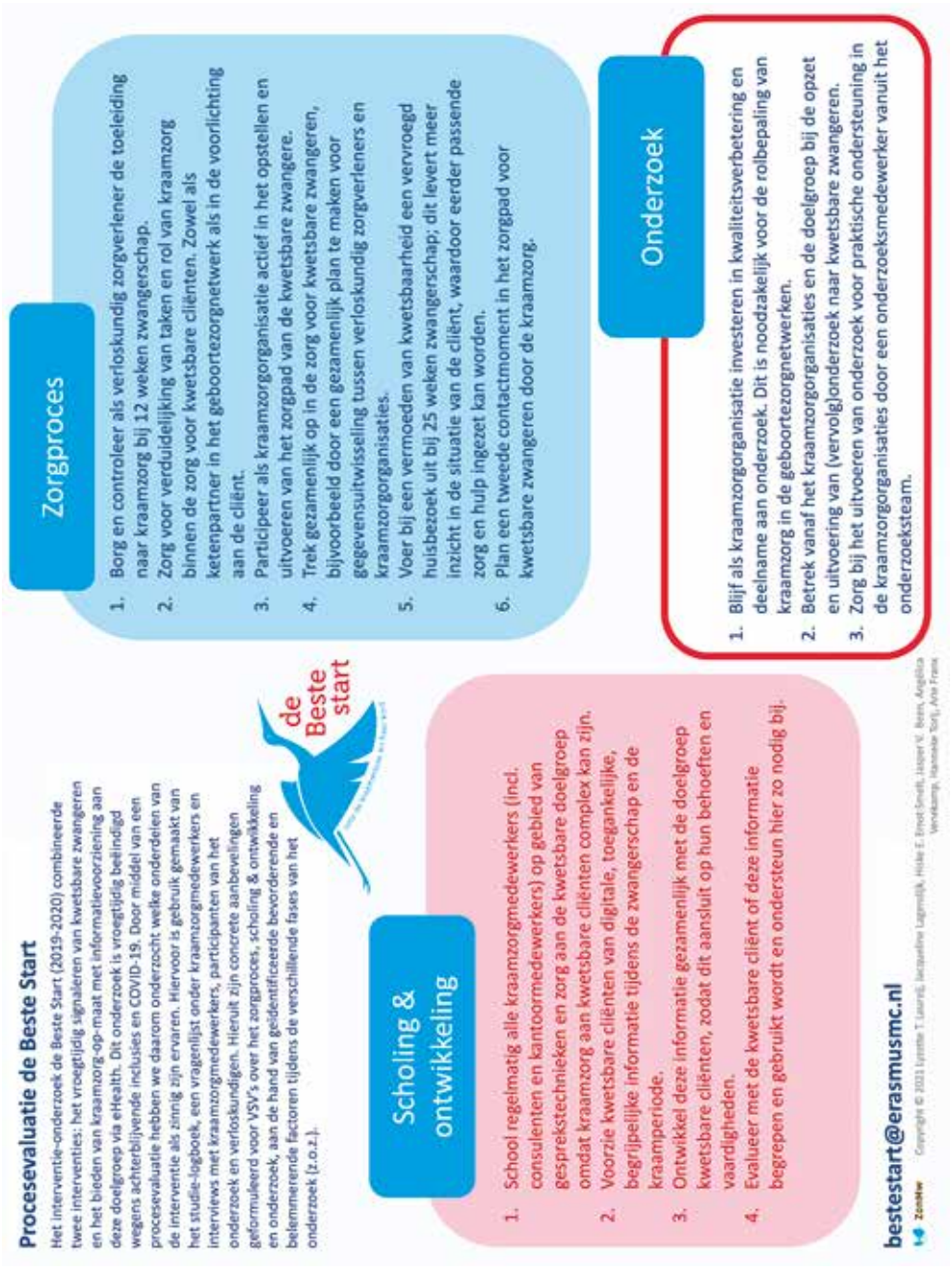
25. Vind je het de rol van de kraamzorg om samen met jou te kijken of er problemen zijn en hoe je die aan kan pakken? (evt doorvragen: we hoorden van andere deelnemers dat ze het gek vonden dat de kraamzorg vragen stelde bij aanmelding of bij de intake, wat vind je daarvan? Hoort dit bijvoorbeeld bij de verloskundige of de gynaecoloog? Of helemaal bij niemand?)
26. Dit onderzoek had als doel om je zelfredzamer te maken. Dat betekent dat je toegang hebt tot goede informatie, zelfverzekerder bent in de zorg voor je kind en controle hebt over je situatie. Wat vind je van dat doel? Heeft dat zin voor jou?
27. Heb je het idee dat een app met goede informatie daaraan bijdraagt? Waarom wel/niet?
28. Heb je het idee dat kraamzorg-op-maat, dus vroege intake en kraamzorg specifiek gericht op mogelijke problemen, daaraan bijdraagt? Waarom wel/niet?

29. Wat denk jij dat jou zou helpen om je zelfredzamer te maken voor tijdens/na je kraamperiode? Hoe zou de kraamzorg daar bij kunnen helpen?

Bijlage 6 Topic list verloskundigen

1. Hoe is de zorg voor kwetsbare zwangeren geregeld in jouw praktijk? (samenwerking keten uitvragen)
2. Een van de onderdelen die naar voren komt, is de risicoscreening op kwetsbaarheid in de zwangerschap. In ons onderzoek hebben we de kraamzorgorganisaties bij aanmelding enkele vragen laten stellen om kort te kunnen screenen op kwetsbaarheid. In de evaluatie gaf men aan, dat zij vinden dat dit beter door de verloskundige kan worden gedaan. Screenen jullie op kwetsbaarheid? Wat is je mening over screening door kraamzorg? Wat zijn de stappen die je neemt bij een kwetsbare zwangere?
3. De kraamzorgorganisaties zouden in de ideale wereld meer samenwerking zien hierin, dus dat zij gevonden risico's overgedragen krijgen van de verloskundig zorgverlener. Wat vind je daarvan? Gebeurt dat nu al? Welk moment? Een oplossing zou bijvoorbeeld zijn gezamenlijk dossier, of inzage in het dossier van de zwangere, wat vind je daarvan?
4. Hoe is in jouw praktijk de toeleiding naar kraamzorg geregeld? Wat voor informatie geef je? Pas je die aan als het een kwetsbare zwangere is, hoe dan? Wat kan daar beter in denk je? (doorvragen op sturing van keuze voor organisatie etc).
5. Het huisbezoek werd in onze interventie eerder gedaan, rondom de 25 wkn. Wat vind je daarvan?
   Huisbezoek is een ideaal moment om een uitgebreide risicoinventarisatie te doen, met in acht neming van de thuissituatie van de cliënt. Organisaties geven aan dat een gecombineerd huisbezoek samen met de verloskundige prettig zou zijn. Wat vind je daarvan? Zou het uitvoerbaar zijn?
6. Tijdens het onderzoek bleek dat cliënten verbaasd waren dat kraamzorg bij aanmelding (of überhaupt) inhoudelijke vragen stelt. Het kan zijn dat cliënten dus niet op de hoogte zijn van het medische aspect van kraamzorg, zoals het uitvoeren van medische controles en een meldplicht etc. Herken je dat beeld? Wat zou je hier als verloskundige aan kunnen doen?
7. Hoe zie je de samenwerking met de kraamzorg tijdens de kraamweek, in het licht van kwetsbare kraamvrouwen?
   We horen terug van de organisaties dat veel problematiek toch pas in de kraamweek aan het licht komt. De Kraamzorgorganisaties voelen zich dan verantwoordelijk voor het op tuigen van extra zorg enzovoorts, wat in indirecte uren moet. Herken je dit beeld? Kan je er meer over vertellen? Is dat voor jou ook vaak het moment dat de situatie pas echt duidelijk wordt? Hoe kunnen we dat voorkomen in de toekomst?

Bijlage 7 Factsheet



Bevorderende en belemmerende factoren interventie-onderzoek de Beste Start

In de voorbereidingsfase

Bevorderende factoren:
+ kraamzorgorganisaties (KZO's) toonden grote bereidheid tot deelname aan onderzoek
+ KZO's toonden grote bereidheid tot verbeteren onderzoeksplan
+ sleutelpersonen binnen KZO's geïdentificeerd voor aansturing collega's door onderzoeksteam
+ administratief personeel & intakers werden ook geschoold
+ gesprekstechnieken zijn verbeterd voor het bespreken van risicofactoren met cliënten

Belemmerende factoren:
- complexiteit onderzoek
- identificatie sleutelpersonen KZO's ~~onderzoek~~ langdurig proces
- enkele KZO's trokken zich terug voor start onderzoek door bedrijfsmatige omstandigheden
- personeelstekort leidde tot niet óf later starten met onderzoek bij sommige KZO's
- onvoldoende financiële ruimte bij KZO's voor uitvoer extra handelingen t.b.v. onderzoek
- aanvullende capaciteiten kraamverzorgenden nodig bij complexe casuïstiek
- veel verschillende medewerkers betrokken bij uitvoer onderzoek
- moeizame planning & beschikbaarheid kraamzorgmedewerkers voor de scholing
- moeizame implementatie nieuwe werkwijze en toepassing nieuwe inzichten bij KZO's
- extra scholingen en begeleiding/ondersteuning eHealth noodzakelijk voor KZO's

In de uitvoering - kraamzorgorganisaties

Bevorderende factoren kraamzorgorganisaties:
+ snelle risico-identificatie aan begin van zorgproces
+ meer tijd voor aanpak problematiek door zorg vroeg af te stemmen op kwetsbare zwangere
+ snellere opbouw van relatie cliënt – KZO; door risico-identificatie bij aanmelding aanleiding om overige problematiek te bespreken
+ vroeg huisbezoek is reeds afspraak in sommige VSV's
+ achter-de-voordeur functie van kraamzorg draagt bij aan identificatie kwetsbare zwangere en zorg voor kwetsbare kraamvrouw
+ kraamverzorgenden bespreken risicofactoren met cliënt in kraamweek
+ kraamverzorgenden zijn gemotiveerd om kwetsbare cliënten te helpen
+ hands on mentaliteit kraamverzorgende en organisatie bij identificatie problematiek in kraamweek

Belemmerende factoren kraamzorgorganisaties:
- grote logistieke belasting KZO's
- barrière bij medewerkers om vragen ter risico-identificatie te stellen
- KZO's ervaren onbegrip bij cliënten m.b.t. risico-identificatie
- identificatie alle kwetsbare zwangeren moeizaam te vatten in gestandaardiseerde risico-identificatie
- uitleg onderzoek complex
- toeleiding van cliënten naar eHealth moeizaam
- plannen vroege intake moeizaam door korte tijd tussen aanmelden en intake
- 2e contact nodig rondom 34 weken zwangerschap na vroege intake voor o.a. aanschaf kraamuitzet
- cliënten gebruikten eHealth applicatie niet
- webportal nog niet geschikt voor screenende functie in eerstelijnszorg
- moeizame inclusie participanten onderzoek: potentiële kandidaten konden niet geïncludeerd worden door late signalering en aanmelding van risico zwangeren
- zorg voor kwetsbare kraamvrouwen vraagt extra scholing en motivatie kraamverzorgende
- zorg aan kwetsbare cliënten neemt extra tijd in beslag
- onduidelijkheid verantwoordelijkheden kraamverzorgende voor ketenpartners

In de uitvoering - cliënten

Bevorderende factoren cliënten:
+ logisch dat vragen over risico's werden gesteld door KZO's
+ vertrouwen in KZO's
+ vroegtijdig ontvangen van informatie over aanschaf kraamuitzet
+ vroege kennismaking met kraamzorg
+ informatievoorziening m.n. via kraamverzorgende
+ behoefte aanvullende informatie na kraamweek via eHealth

Belemmerende factoren cliënten:
- onduidelijkheid rol van kraamzorg in het stellen van risico-identificatie vragen
- geen zin in meedoen onderzoek of in controlegroep
- veel stress vroeg in de zwangerschap
- installatie en gebruik eHealth app
- taalbarrière
- gebrekkige digitale gezondheidsvaardigheden
- grote tijdsperiode tussen vroege intake en kraamweek

Verloskundigen uit deelnemende regio's

Bevorderende factoren verloskundigen:
+ identificatie kwetsbare zwangere bij huisbezoek
+ vroeg huisbezoek met aansturing op kopen van juiste spullen
+ achter-de-voordeur functie kraamzorg onbetwist

Belemmerende factoren verloskundigen:
- verificatie kwetsbaarheid bij reeds bekende kwetsbare zwangere niet altijd nodig door KZO's
- informatie uitwisseling van verloskundige naar kraamzorg kan beter
- toeleiding naar kraamzorg vanuit verloskundige kan beter
- toegevoegde waarde kraamzorg komt weinig aan bod tijdens verloskundige zorg
- geen inzicht in elkaars dossiers (kraamzorg – verloskundig zorgverlener)

de Beste start

ZonMw

Vraag 1	Heeft u op dit moment een partner?	☐ Ja → ga door naar vraag 2 ☐ Nee → ga door naar vraag 3 (1 punt)
Vraag 2 (alleen invullen als "Ja" is aangevinkt bij vraag 1)	Woont u samen met uw partner?	☐ Ja ☐ Nee (1 punt)
Vraag 3	Woont u in uw eigen huis? Bijvoorbeeld een huurhuis of koophuis van uzelf of uw partner	☐ Ja ☐ Nee, bijvoorbeeld als u bij familie of vrienden woont (1 punt)
Vraag 4	Wat is het netto inkomen van uw gezin per maand? Dit is het bedrag dat wat u op uw rekening gestort krijgt	☐ Minder dan 1000 euro per maand (1 punt) ☐ 1000 tot 1749 euro per maand (1 punt) ☐ 1750 tot 2499 euro per maand ☐ 2499 tot 3249 euro per maand ☐ meer dan 3250 euro per maand
Vraag 5	Heeft u een opleiding afgemaakt na de middelbare school? Als u de middelbare school niet heeft afgemaakt, vink dan "Nee" aan. Is de cliënt nog met een vervolgopleiding bezig, vink dan ook "Nee" aan.	☐ Ja ☐ Nee (1 punt)
Vraag 6	Heeft u nog gerookt nadat u wist dat u zwanger was?	☐ Ja (1 punt) ☐ Nee
Vraag 7	Heeft u nog alcohol gedronken nadat u wist dat u zwanger was?	☐ Ja (1 punt) ☐ Nee
Vraag 8	Heeft u nu of het afgelopen half jaar begeleiding* gehad voor psychische problemen? * van een psycholoog, psychiater, maatschappelijk werk of praktijkondersteuner van de huisarts Het gaat echt om psychische problemen of angstklachten	☐ Ja (1 punt) ☐ Nee
Vraag 9	Gebruikt u medicijnen tegen depressie, angsten, slaapmedicatie of om rustig te worden? Medicijnen voor schildklier, hoge bloeddruk, suikerziekte enzovoorts tellen niet mee	☐ Ja (1 punt) ☐ Nee
Vanaf december 2019: Vraag 10	Indien je zelf vindt dat de cliënt een extra punt toegekend moet krijgen omdat ze een risicofactor heeft die niet in de bovenstaande vragen staat beschreven. Denk hierbij aan problemen in de vorige zwangerschap, verwijzing naar je organisatie door de verloskundige of maatschappelijk werk omdat ze kwetsbaar is, etc.	☐ Ja (1 punt) ☐ Nee

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Chapter 10

General discussion

GENERAL DISCUSSION

The Dutch healthcare landscape will increasingly face challenges in terms of availability of healthcare personnel and the financial sustainability of the healthcare system in the coming years.[1] The Dutch Healthcare Institute ('Zorginstituut Nederland' in Dutch) proposed a structured set of principles in which healthcare needs to be adapted to remain future-proof, as described in their report 'framework appropriate care' ('kader passende zorg' in Dutch): (1) appropriate care should be value-driven, (2) appropriate care should be developed in collaboration with and around the patient, (3) appropriate care is care in the right place, where care should be close to home, and may be replaced by new forms of care such as eHealth, and (4) appropriate care focuses on health rather than disease.[2] This framework supports the implementation of personalized care also in obstetric care within the context of the value-based healthcare principle. This is also supported by the 'Integral Care Agreement' ('Integraal Zorgakkoord' in Dutch, ICA), which embraces the principle of the framework appropriate care.[3] The ICA is an agreement between the Ministry of Health, Welfare and Sport and numerous professional organizations, including the Federation of Medical Specialists, that represents obstetric care providers. And above all, this ICA legitimizes that the patient group 'women in vulnerable circumstances' is a particular target group in future obstetric care; the socio-economic status of this group of women may contribute to their ability to lead less healthy lives, thereby increasing their risk of experiencing physical or psychological complaints. This group does not always have adequate access to healthcare due to a combination of complex issues or a lack of familiarity with the healthcare system.[3] Therefore, care needs to be tailored to the personal situation, needs, and preferences of these women. This can only be achieved if this care is aligned with their needs and preferences. As such it is important that insight into the needs and preferences of these women is obtained, especially of women in vulnerable circumstances. This facilitates personalized, appropriate care, which can be realized at different levels: the micro-, meso-, and macro-level. From an economic point of view, value-based healthcare can make a difference at the meso and macro levels, but there are opportunities to benefit at the individual patient level (i.e. micro-level) as well.[4] In this thesis, I therefore focused on the development and testing of new strategies to personalize obstetric care based on insights into the needs and preferences of women. I did this with a special focus on women in vulnerable circumstances, so that they may have a greater chance of benefiting from these healthcare innovations. In the following paragraphs, I reflect on the results, discuss the implications for practice and policy, and address future research needs.

Reflection on results

Insights in needs and preferences of women (in vulnerable circumstances)

The Dutch government has designated value-based healthcare based on the standardized outcome sets as the direction towards which healthcare in the Netherlands should evolve. The International Consortium for Health Outcomes Measurements' (ICHOM) Pregnancy and Childbirth Set (PCB) is one of these standard outcome sets, and is intended to assist in empowering women, thereby contributing to enabling them to exert greater control over their healthcare.[5,6] These standard sets offer a comprehensive collection of outcome measures intended to evaluate the quality of care, aligning with the previously mentioned frameworks for sustainable healthcare.[1,2] This is done via standardized collection of clinical outcomes, patient-reported outcome measures (PROMs), and patient-reported experience measures (PREMs). In other healthcare areas, there has already been extensive experience with the implementation of such standardized outcome sets.[7-9] **Chapters 5-7** highlight again that perinatal care is distinctive: it involves an integrated care system where both intra- and extra-mural healthcare providers are engaged and were both mothers and babies are involved. Previous implemented standard sets focused primarily on hospital settings. For proper assessment of value-based healthcare around pregnancy, the outcome information must be relevant for all women and healthcare providers, and must be in line with current care pathways or can inspire to create new care pathways. Therefore, a pre-implementation study was necessary before introducing the ICHOM PCB set to assess its acceptability in the Dutch setting (**chapter 5**). Overall, the concept of completing questionnaires regarding their health and their experiences of care was found very relevant by women, especially when outcomes were to be discussed with their healthcare providers. This underlines the benefits of implementation of value-based healthcare also at the micro-level, thus creating an opportunity to deliver personalized care based on individual outcomes: the needs of women.[10] The results concerning the comprehensiveness of this set aligned with the validation study conducted by its developers,[5] indicating that PROMs such as incontinence and depression were perceived by both women and healthcare providers as less relevant compared to the other outcomes in the set for personalized perinatal care. The lack of information on the prevalence and available treatment options of these outcomes may potentially contribute to keeping these issues in a taboo-like context, not only for women but also for healthcare providers.[11-16] Furthermore, the PREM assessing continuity of care was incorporated into the Dutch version of the PCB set as an add-on, in response to women's expressed desire to capture the commonly perceived lack of continuity of care. This can represent a significant outcome, given the existing encouraging evidence indicating that continuity of care has positive effects on various perinatal outcomes, particularly for women in

vulnerable circumstances.[17,18]

In **chapter 2**, we delved into the factors influencing the utilization of postpartum care among women in vulnerable circumstances. The distribution of postpartum care utilization is markedly unequal, with women who face social risk factors typically utilizing fewer hours of postpartum care. This disparity may carry significant financial implications for the health care system, as lower use of postpartum care is associated with higher cost reimbursement for healthcare use by both mother and child within the first year following childbirth.[19] In 2023, postpartum care involved an out-of-pocket contribution of €4.80 per hour. This contribution was perceived as a potential barrier to the utilization of postpartum care among women in vulnerable circumstances according to healthcare administrators.[20] Remarkably, a primary finding of our study was that women in vulnerable circumstances perceived lack of information provided during pregnancy regarding the content and benefits of postpartum care. This particular group already exhibits lower health literacy skills, and now also appears not adequately and properly informed about this essential care by, for instance, obstetric healthcare providers or other relevant parties (**chapter 2**). In reflection on their postpartum care experiences, women frequently expressed having been unaware of the required financial contribution (out-of-pocket payment). Accordingly, it did not dissuade them from utilization of postpartum care. They also emphasized the essential role of postpartum care in enhancing their self-efficacy, irrespective of the associated costs. However, the out-of-pocket payments for what may be considered an integral component of standard perinatal care seems a confusing policy, potentially challenging equitable accessibility of this service. In contrast to previous research, women in our study reported establishing a strong bond with their maternity care assistants (MCAs).[21-23] As a result, they benefitted from personalized care tailored to their unique needs, and recognized how this personalized approach contributes to the enhancement of their self-efficacy. Given the comprehensive nature of postpartum care, the establishment of mutual trust, active listening to women's needs, and the avoidance of making unwarranted assumptions or prematurely giving up may contribute to the development of this robust and supportive bond as underlined in **chapter 4** as well. The lower utilization of postpartum care hours among women in vulnerable circumstances appears to be linked to the concept of 'unfamiliarity breeds disinterest'. Inadequate information regarding content and benefits of postpartum care contributes to this phenomenon, and after experiencing this care in practice many women are in fact enthusiastic. Since our study was only focused on women in vulnerable circumstances who received at least the minimum amount of postpartum care (i.e. 24 hours), needs and preferences of women in vulnerable circumstances who did not receive any postpartum care may differ.

Dissemination of information pertaining to pregnancy, childbirth, and the postpartum period can, to a certain extent, be facilitated through eHealth solutions. For example, this could be achieved via a digital platform for which effectiveness has been demonstrated and that is stimulated by the Dutch government.[6,24,25] In **chapter 3**, insights from new parents and perinatal care providers underscored the current absence of digital information resources tailored to the postpartum period. Also, there was a perceived lack of guidance tools for healthcare providers to eHealth applications. There is a need for digital information to specifically aim at reaching the vulnerable population, since information regarding the content of postpartum care does not adequately reached them. 'Klantroute Kraamzorg' (costumer journey postpartum care) is such an initiative. This website provides digital information for healthcare providers on how to inform women in vulnerable circumstances about postpartum care.[26] It also provides links to short movies for pregnant women about postpartum care in understandable language and in multiple languages. The integration of eHealth tools may prove valuable in augmenting the provision of information, particularly in the later postpartum phase after the MCA ended postpartum care. Examples are information on (excessive) crying or infant colics (**chapter 3**). Guiding parents towards a reliable eHealth platform by healthcare providers may offer support during this phase. Further research could focus on establishing a collaboration between postpartum care and preventive child health services and implementing a national eHealth platform to benefit all young parents.

Implementation of new strategies to personalize perinatal care

The implementation of PROMs and PREMs to guide and personalize perinatal care, according to the ICHOM PCB set, was part of a pilot program which we conducted in several obstetric care networks (OCNs) in the Netherlands (**chapter 6, 7**). In line with ICHOM's recommendations, this implementation was well prepared, including via assessments of its local applicability (**chapter 5**), and feasibility.[27] Furthermore, the implementation plan was devised in collaboration with relevant stakeholders, focusing on selective subgroups of patients or data collection time points.[28]

At the micro-level, the process of collecting and discussing PROMs and PREMs during care proved beneficial in enabling patients to promptly identify emerging health-related issues or changes in their overall well-being (**chapter 6, 7**). In line with this, women described that health care providers acted upon these outcomes when necessary, for example by providing additional information regarding breastfeeding when this occurred as a problem (**chapter 7**). It was observed that women tended to omit responses to questionnaires pertaining to depression and dyspareunia as part of PROMs and PREMs collection (**chapter 6**). This is in line with our earlier findings as detailed in **chapter 5** as well as with the findings of

the developers of the PCB set itself.[5] Insufficient respondent awareness about the commonality of conditions like dyspareunia and depression, as well as the effectiveness of available treatments, may explain the low response rates to specific questionnaires. This lack of awareness could contribute to societal reluctance in openly addressing these issues, perpetuating a cycle of low response rates and potentially leaving treatable adverse outcomes in women unnoticed by healthcare providers.[29,30] It is plausible that barriers exist for both healthcare providers and patients in raising and discussing these issues (**chapter 6, 7**), but this requires further qualitative research into the considerations of healthcare professionals.

While a substantial 84% of the collected questionnaires regarding the PROMs and PREMs were completed completely during the perinatal care pathway (**chapter 6**), it became evident that not all women realized that completing PROMS and PREMs was an integral aspect of their care. Some were unaware that the outcomes of these questionnaires were intended for discussion with their healthcare provider during their subsequent visits, as opposed to being solely part of a research initiative (**chapter 7**). These misconceptions constituted a noteworthy hindrance to questionnaire completion. They may be founded in insufficiency in information provision regarding the benefits for women in receiving personalized care. Possibly, the digital information regarding the applications of PROMs and PREMs that was provided prior to administering the questionnaires was inadequate, and healthcare providers may need to take a more active role in this regard. On the other hand, improvement may naturally occur as PROMs and PREMs become an integral part of standard perinatal care and other healthcare areas, making the concept less novel for both patients and healthcare providers. This is supported by the findings from **chapter 7**, where we learned that completing questionnaires helped women in preparing for their next healthcare visit. Detecting outcomes that reveal impartial recovery from pregnancy and childbirth, such as dyspareunia and incontinence, or outcomes regarding unprocessed experiences was found important by women (**chapter 7**). Especially during the data collection time point at six months postpartum, addressing these outcomes and referring women to proper care has a large potential value for women (**chapter 7**). Experiencing personalized perinatal care based on PROMs and PREMs could help them to better understand how the use of PROMs and PREMs may benefit them in their care pathway.

First experiences with collecting and discussing PREMs were also made (**chapter 5-7**). PREMs are frequently applied to support quality improvement at meso- and macro-levels, and are typically collected anonymously.[31,32] Women pointed out the potential for quality improvement based on aggregated PREMs, but also noted that there may be a risk of social response bias due to women's reliance on healthcare providers during PREM collection (**chapter 5**). Women

were given the option to discuss their PREMs with their healthcare provider, or to solely allow anonymous collection for quality improvement. For the last option, individual PREM responses were then shielded from healthcare providers (**chapter 6, 7**). A notable 85% of all women opted to discuss their PREMs with a healthcare provider, indicating the potential applicability of PREMs at the micro-level as well. PREMs served as a significant motivator to complete both PROMs and PREMs, but subsequent discussion of the PREMs with healthcare providers posed challenges (**chapter 7**). Women found it challenging to discuss adverse PREMs while still being under care due to a perceived level of dependency. On the other hand, the consultation in which PREMs are discussed may involve an unfamiliar healthcare provider, leading to a sense that discussing PREMs may be less meaningful. Therefore, continuity of care and healthcare provider may be crucial to fully leverage the potential for PREMs to benefit care at the micro-level.

At the meso-level, quality improvement (QI) projects in healthcare are still predominantly based on clinician-reported outcomes measurements (CROMs). In **chapter 8**, PROM and PREM, and CROM data from a retrospective cohort study within perinatal care was used to build Statistical process control (SPC) charts.[33] SPC charts provide real time and ongoing data in a straightforward interpretation, making them accessible to healthcare personnel as well next to researchers.[34-37] The findings from **chapter 8** suggest that SPC charts based on PROMs and PREMs are suited for integration into QI projects. The utilization of these charts can enrich the comprehensive assessment of healthcare quality. By bridging the gap between healthcare provider and patient perspectives, SPC charts based on PROMs and PREMs offer a robust framework for advancing QI efforts and fostering a more holistic understanding of healthcare outcomes. In line with this, an important key factor for implementation of value-based healthcare mentioned by all stakeholders in **chapter 5** was the importance of proper IT support, also recognized in other (pre-) implementation studies.[8,9,38] Data capture tools appeared being unable to link with electronic health records (EHRs), resulting in additional work for healthcare professionals to gain access to PROM and PREM data. Data capture tools exhibited errors in automating sending out questionnaires, resulting in instances where the questionnaires were sent out multiple times to individual women. Also some data capture tools were not user-friendly or mobile-friendly, resulting in the invisibility of some answer options to the women (**chapter 7**). This may have negatively affected the correctness of the aggregated results reported in **chapter 6**.

Various important strategies were previously explored in this thesis, such as continuity of care by maternity care organizations, personalized care based on PROMs, PREMs and medical and non-medical risk factors, and eHealth based information

provision. These aspects may have an individual positive effect on maternal self-efficacy among women in vulnerable circumstances. The *'Beste Start'* intervention ('the Best Start' in English), evaluated via an open-label RCT carried out among maternity care organizations, provided a complex intervention combining these strategies (**chapter 9**). The target population consisted of pregnant women in vulnerable circumstances and the aim of the study was to improve their self-efficacy as a primary outcome.[39] Prior to the commencement of the RCT, an extensive preparatory phase was undertaken by the research team, with a primary focus on development of the eHealth application and on training of personnel associated with maternity care organizations, including MCAs. Despite this extensive preparation, several challenges were encountered during execution of the RCT, such as inadequate and insufficient participant enrollments, withdrawal of maternity care organizations from the study due to staffing and financial constraints, and technical issues with the eHealth application. In combination with the concurrent outbreak of COVID-19, these challenges ultimately necessitated premature termination of the RCT. Given that vulnerable populations are frequently underrepresented in research and often are not the target population, this prematurely terminated RCT still carries learning points relevant for conducting research in this vulnerable population.[40,41] To systematically identify these lessons, we conducted an evaluation study of this project. For this RCT, we developed an eHealth application specifically tailored to address the needs of pregnant and postpartum women in vulnerable circumstances. This application offered a range of functionalities, including the collection of PROMs and PREMs, and the provision of information in a clear and comprehensible manner. The necessity for better information for pregnant women in vulnerable circumstances is evident, and eHealth may support better information provision (**chapter 2, 3, 9**). However, research indicates that vulnerable populations encounter significant barriers when accessing eHealth, including digital illiteracy impeding their ability to seek and use information via digital platforms. Additionally, eHealth applications benefit from parallel care provider support to increase the chances of achieving behavioral changes that could potentially lead to better pregnancy outcomes.[42-44] Despite our app *'de Beste Start'* having been developed in alignment with evidence-based guidelines to create an eHealth application suitable for women in vulnerable circumstances[45], directing these women to this app proved to be challenging (**chapter 9**). It appeared that practical assistance from a healthcare provider could have been instrumental to support this group in engaging with eHealth. Furthermore, the inclusion of vulnerable populations in research poses challenges, partly due to the restrictive nature of eligibility criteria.[40] To truly enable individuals in vulnerable circumstances to benefit from a digital intervention, it is imperative to design an eHealth application that takes into consideration the unique characteristics and requirements of this population.[45] We also encountered various technical issues, the most significant one being

the application's lack of compatibility with older smartphones due to privacy and safety regulations. Consequently, participants who were reliant on these devices had either no access or limited access to the eHealth application. We conducted multiple training sessions for personnel associated with maternity care organizations on effective communication techniques, the use of the eHealth application, and performing research. However, conducting the RCT within maternity care organizations, which historically hardly participate in research, proved unfeasible without intensive support and involvement from the research team. Moreover, it became evident that women did not fully grasp the rationale behind maternity care organizations' interest in gathering information about their characteristics for eligibility screening (i.e. vulnerability identification). This lack of understanding may stem from women being unfamiliar with the objectives and content of postpartum care overall, leading to issues during enrollment with the organization. For maternity care organizations, there was an additional concern that, following the administration of screening questions regarding vulnerability, women might choose to receive maternity care from a different organization due to a lack of comprehension. This concern may be attributed, in part, to the commercial nature of maternity care organizations. Furthermore, an adaptation in the enrollment process imposed additional time demands on already scarce personnel. The process evaluation of this RCT emphasizes the crucial role of recognizing maternity care organizations as key collaborators in the care of women in vulnerable circumstances. However, it also highlights the organizational and staffing hurdles that these organizations face, hampering their ability to establish themselves effectively in this role. Limited research resources, combined with the challenging target population (i.e. women in vulnerable circumstances), and the complex organizational structure of maternity care organizations including their staffing and financial constraints contributed to the objectives set for this RCT in hindsight being overly ambitious given the research budget.[40]

Limitations and Challenges

In this thesis, several studies were conducted with a special focus on women in vulnerable circumstances as the target population, or used deliberate efforts to include at least some women in vulnerable circumstances in our study samples. Vulnerable populations are generally underrepresented in scientific research and in the implementation of new healthcare practices.[40,41,46] This underrepresentation could potentially contribute to the exacerbation of health disparities, as interventions are often tailored to the group of patients participating in scientific research, which typically does not accurately reflect the broader society. **Chapters 2** and **9** of this thesis exclusively concentrated on pregnant and postpartum women in vulnerable circumstances as participants in our research. However, reaching, including, and retaining this particular group proved to be a challenging

endeavor. When research focuses on characteristics of a specific group of patients, it is customary to elucidate this in the patient information forms and in verbal communication regarding the research. However, there exists a stigma regarding "vulnerability", particularly perceived by healthcare providers. This may have led to a delay in inclusions or even a lack of inclusions, especially in **chapter 9**. Healthcare providers may benefit from further training in inclusive communication approaches. By adopting an open, supportive, and non-judgmental approach, healthcare providers can create a safe environment in which pregnant women feel comfortable expressing their concerns and participating in research.[42,47] Additionally, we likely captured only a fraction of the potentially eligible vulnerable population in our research, that merely represented the tip of the iceberg, due to in- and exclusion criteria of our research. For example, the exclusion of individuals with limited proficiency in the Dutch or English language (as observed in **chapter 2** and **9**), or the necessity to limit inclusion to specific gestational weeks excluded in particular women in vulnerable circumstances (**chapter 5-9**). Consequently, we likely failed to include women in the most severely vulnerable circumstances as they are excluded based on these characteristics. Vulnerability is complex and lacks a singular, unequivocal definition, which poses challenges for traditional research methods like RCTs. Our study with vulnerable populations faced additional hurdles, mainly due to complex eligibility criteria.[40] Defining vulnerability using a manageable set of criteria adds further complexity. Initiatives such as the implementation of new strategies as part of standardized care, as we did in **chapter 6, 7** and **8**, may offer a partial solution to this challenge. It may enable a more comprehensive representation of the population, since women are not excluded from regular care based on their characteristics.

In pilots like **chapter 6** and **7**, inadequate information provision may have compromised the clarity of the goal of the pilot. The average literacy level of individuals in the Netherlands is at the B1 level, which signifies that they can understand straightforward texts on familiar topics. This level is considered suitable for most everyday communication. However, patient information is generally developed by individuals with a higher level of education (typically, academic). One potential solution to this discrepancy is to have patient information reviewed for comprehensibility across all target demographics, a practice that is supported by websites and applications, such as 'Leesniveau'.[48] Nevertheless, despite our close collaboration with Pharos[49], an institute specializing in health promotion for vulnerable populations, we encountered substantial challenges in the execution of our studies. Efforts were made to disseminate information related to the objectives of perinatal care based on PROMs and PREMs, to improve patient education, and to train the healthcare providers in the application of PROMs and PREMs within perinatal care.

Recommendations for healthcare providers and policymakers

Personalized care for women in vulnerable circumstances

Currently, the provision of healthcare is primarily rooted in the principle of equality, where patients are treated uniformly, and resources and interventions are applied universally with a focus on equal access to healthcare. However, this approach often fails to address existing disparities in health status and the distinct support required by vulnerable populations, inadvertently perpetuating inequalities in outcomes of healthcare.[50,51] Moreover, when personalized care is delivered solely based on equality, there exists a risk that women in vulnerable circumstances may not receive the enhanced healthcare they require, despite their greater potential for health improvement compared to non-vulnerable individuals.[50,51] **Chapter 2** and **4** indicate that additional efforts to build a trusting relationship with pregnant women in vulnerable circumstances can result in better perceived healthcare experiences. This requires adaptations tailored to the individual needs of pregnant women, in order to enhance care specifically for them: an equity-based approach of providing healthcare. It aims to level the playing field by allocating resources and interventions based on the individual requirements of each woman, ensuring that those with greater needs receive more support, assistance, and resources to achieve equitable health outcomes for all patients. The rationale behind prioritizing care based on equity, rather than equality, is grounded in a theory known as cumulative advantage: it suggests that initial disparities in resources, influenced by factors like socioeconomic background and education, lead to increasing gaps in health outcomes over the life course due to path dependence and continued exposure to risks.[52-54] Health problems emerging early in life, such as preterm birth, cannot be fully compensated later in life.[55] Countries with policies that have a strong focus on reducing social disparities, such as Sweden, appear to have a smaller socioeconomic gap in health outcomes later in life than countries without these policies, for example the United States. Additionally, overall health status of their inhabitants is better on average.[56] It may be that an investment made in individuals situated at the lower end of the health spectrum automatically benefits those positioned higher up the ladder in terms of care and outcomes. It necessitates that healthcare providers are willing to invest in relations with pregnant women in vulnerable circumstances (**chapter 2, 4, 9**). They can support pregnant women in vulnerable circumstances in their personalized care journey, since this type of care based on PROMs and PREMs assumes a certain level of health literacy. Reading and interpreting questionnaires requires language proficiency, while accessing digital healthcare environments, such as Personal Health Environment ('persoonlijke gezondheidsomgeving' in Dutch), requires specific digital literacy. Many people in vulnerable circumstances lack these skills or part of these skills.[45] Their reduced health literacy also affects their

ability to gather information on pregnancy and childbirth, resulting in unequal opportunities for favorable outcomes. An improvement for pregnant women in vulnerable circumstances may entail having a consistent healthcare provider with whom they can establish a strong relationship from the onset of pregnancy, and can discuss their PROMs and PREMs (**chapter 2, 4, 7**). This approach fits in the previously mentioned framework of the Dutch Healthcare Institute for a future-proof healthcare.[2] However, organizational challenges may arise, especially when women receive care from different tiers of obstetric care. Pregnant women in vulnerable circumstances are at increased risk in this regard.[57] Centering pregnancy (CP), for instance, could offer a solution for the care for these women. CP incorporates several important components of care: health assessment, interactive learning and community building. It is provided in a group context with healthcare professionals (mostly community midwives) as facilitators. This type of care favors empowerment, involvement and participation.[58,59] CP has demonstrated significant effectiveness in enhancing health outcomes for both pregnant women in vulnerable circumstances and their infants, and leads to increased satisfaction with healthcare services.[58,60-65] In terms of financial consequences, providing CP comes at extra costs: €45 per woman across the entire pregnancy compared to individual antenatal care, but this needs to be weighed against the higher costs of perinatal care for women in vulnerable circumstances.[66] That is, the provision of individual perinatal care to vulnerable women costs €156 more compared to non-vulnerable women, taking into account the reduced postpartum care utilization and the associated lower costs.[57] Traditionally, CP is led by community midwives. To adopt a more holistic approach to this care, integrating a postpartum care provider such as an MCA into the delivery of CP could have benefits. MCAs possess the ability to establish trust with women in vulnerable circumstances, enhance continuity of care, and offer tailored information regarding the postpartum period, in collaboration with community midwives (**chapter 2**). It may also contribute to getting familiar with postpartum care during pregnancy. Furthermore, it may guide women in vulnerable circumstances towards Centering Parenting afterwards, that is focused on optimizing health of both the mother and the infant in groupcare.[67] Future research should assess whether these additional costs of CP are compensated by reduced adverse outcomes, such as lack of breastfeeding and tobacco smoking among women receiving CP, and the use of fewer healthcare providers.[1,66] It may also be valuable to investigate the impact of CP on fostering a community surrounding women in vulnerable circumstances, and if this may lead to a reduction in the demand for postpartum care.

Postpartum care as an essential part of perinatal care

Postpartum care is essential in preventing maternal and neonatal morbidity and mortality.[68] In the Netherlands, a model of intensive preventive and practical care

at home empowers women to self-manage their newborns while enhancing their self-efficacy (**chapter 2**). Postpartum care is one of the types of care that fits in the vision regarding care of the future of the Dutch government, where care is provided at home or close by as much as possible.[2] However, research into the effectiveness and gains of the Dutch postpartum care is scarce, and co-workers of maternity care organizations are commonly unfamiliar with conducting research. The combination this unfamiliarity with conducting research and the limited resources available for the conduct of a complex RCT appeared to be challenging (**chapter 9**). The process evaluation of our RCT, in line with other research in postpartum care in the Netherlands, highlights the need for continuous education of co-workers of maternity care organizations, including MCAs.[69] Next to MCAs, co-workers without any medical training have pivotal interactions with pregnant and postpartum women at crucial points in their pregnancy or postpartum period. Regular training of these co-workers in communication techniques, and specialized care for pregnant women in vulnerable circumstances may optimize the healthcare process of these organizations. Regarding conducting research with maternity care organizations, the complex organizational structure of maternity care organizations appeared to inhibit the introduction of a complex intervention. Next to training sessions about conducting research, the availability of supporting research personnel – such as a research nurse – on site may help maternity care organizations in performing research and eventually to evolve into robust research partners.

MCAs provide care in the home situation of new families on a daily basis. As such, they are ideally placed to gain essential information about social risk factors of pregnant women. However, there is ambiguity surrounding their scope of work and regarding the role of MCAs within the obstetric care network (**chapter 2, 9**). It is imperative for women to have a clear understanding of the tasks and responsibilities of maternity care organizations before enrolling in their services (**chapter 2**). The responsibility of maternity care organizations is shared with obstetric care providers, especially with community midwives. These midwives are the responsible healthcare providers during the postpartum period when women and their babies are at home, and share the responsibility of referring their patients to such care. As a result, they may also benefit from personalized postpartum care by MCAs. Thus, collaboration across the entire perinatal care pathway including its healthcare providers is crucial.[70] MCAs may also play an essential role during an important data collection time point of the PCB set, i.e. during the first week postpartum. MCAs are at home with the postpartum woman during completing and discussing data at this time point. This time point entails important outcomes regarding breastfeeding and mother-infant bonding (**chapter 5** and **6**).[5] MCAs are key healthcare providers in improving these outcomes since this is already part of their job description.[71]

Lastly, reevaluating out-of-pocket payments for women in vulnerable circumstances in need of this essential care is warranted. Although **chapter 2** did not indicate a substantial inhibitory effect on the number of hours of postpartum care utilized by women in vulnerable circumstances, there remains uncertainty among them about why additional charges are imposed for this type of care, while this is not the case for obstetric care, for example. The need for out-of-pocket payments for postpartum care is also not in line with the appropriate care approach from the Dutch government.[2] Future studies should investigate the cost-effectiveness of abolishing these out-of-pocket payments, combined with improved information provision, and the potential impact on subsequent healthcare expenses.

Invest in data capture tools and data exchange between perinatal care providers

The facilitation of personalized care based on PROMs and PREMs in clinical practice and at the meso-level necessitates robust IT support. Our research (**chapter 5-9**) revealed that using PROMs and PREMs in clinical practice or QI projects is challenging due to the multitude of EHRs and diverse data capture tools. Data exchange among stakeholders in perinatal care remains unguaranteed due to a large number of different EHRs with absent cross-communication, apart from scarce local initiatives where healthcare providers in OCNs operate within the same EHR.[2,72] Moreover, interoperability between perinatal care and other healthcare providers, such as general practitioners and preventive child healthcare services, remains unassured. This imposes excessive administrative burdens on healthcare providers already under time constraints. Notably, 70% of pregnant women encounter obstetric care providers using different EHRs, while 95% receive postpartum care, where interoperability within EHRs is also absent.[73,74] This leads to repetitive intakes in the perinatal care pathway and risks the loss of information on medical and social risk factors, for example resulting into maternity care organizations remaining unaware of a woman's vulnerable circumstances (**chapter 9**). Additionally, in the context of personalized care based on outcomes, MCAs emerge as crucial links in care continuity and outcomes. However, outcome data and characteristics must be transferred to postpartum care providers, such as MCAs, and a critical prerequisite is the exchange of digital health data.[70] Furthermore, outcomes during the postpartum period may necessitate additional support, such as lactation assistance, with essential information relayed to the care provider seeing the woman at 6 weeks postpartum (i.e., PCB set Time Point 4). Without adequate digital support, this process is unmanageable. Additionally, our research indicated challenges in integrating PROMs and PREMs into EHRs, often requiring standalone tools for access to these outcome measures. Sending questionnaires occurred predominantly through standalone data capture tools, intensifies administrative burdens on healthcare providers and creates barriers in effectively utilizing PROMs and PREMs within the clinical setting.[75] From the provider's per-

spective, the implementation of personalized care requires integrating PROMs and PREMs into EHRs and the promotion of collaborative networks.[76] Initiatives such as 'Babyconnect VIPP' are promising for the exchange of important patient-data such as PROMs and PREMs, and for the promotion of collaborative networks. Babyconnect VIPP is a nationwide program commissioned by the Ministry of Health, Welfare and Sport aimed at secure digital data exchange between obstetric healthcare providers. As a region providing perinatal care, one can apply for a subsidy to implement digital data exchange. An important advantage is the existence of a national overarching program that supports the inclusion of EHRs that have not previously participated in digital patient information exchange. Because digital data exchange is carried out on behalf of a region, it is easier for parties such as maternity care organizations to join.[70,77] Structural funding and financial support for development, maintenance, and governance is imperative to ensure sustainable integration of digital information exchange into daily practice of healthcare. To enable quality improvement based on standardized outcome sets like the ICHOM PCB set, extraction of data from EHRs is essential. This data subsequently requires integration with PROMs and PREMs collected via separate data capture tools. PROMs and PREMs have demonstrated their utility in QI cycles, known for their short turnaround times and applicability in open-source programs such as R and Minitab (**chapter 8**). The Dutch government aims to enhance transparency and accessibility of outcome data for shared decision making in the foreseeable future. Therefore, it is advisable to involve data managers and scientists from the onset of the implementation of sets such as the ICHOM PCB set. This ensures early attention to data extraction and interpretation, aligning with the government's goal in the short term.[78]

Future directions

Further development and validation of PROMs and PREMs for perinatal care

The ICHOM PCB set aligns with the growing consensus that outcome standardization and measurement using core outcome sets contribute to harmonizing research findings and universal adoption of outcomes across various care contexts.[79-81] Several PROMs and PREMs from this outcome set have been specifically developed for pregnancy and childbirth, demonstrating clinical utility and applicability, e.g. the Edinburgh Postnatal Depression Scale (EPDS) for depression.[82,83] While some PROMs and PREMs have been validated in general or other fields of healthcare, there is currently limited use or application of these PROMs and PREMs in obstetric care.[5] Furthermore, certain PROMs and PREMs have been specifically devised for this outcome set, or added post-research (**chapter 5**). Progress in this realm is being propelled, notably by Australian government-funded research, leading to recommendations to modify existing PROMs and PREMs or introduce new ones to dif-

ferentiate outcomes.[79,84,85] Consistent with our findings from **chapter 6**, one of the PROMs employed as a screening tool for perinatal depression, the Patient Health Questionnaire-2, and its clinical threshold revealed an unacceptable number of women at risk for depression being overlooked.[86] Additionally, it remains unclear to what extent specific patient characteristics, such as vulnerable circumstances and low health literacy, influence the scores and thresholds of PROMs and PREMs. An Italian study showed, for example, that urinary incontinence is more frequently reported by individuals with higher education levels.[16] This underscores the possible influence of health literacy on PROMs' clinical thresholds, suggesting that women with higher health literacy might possess heightened awareness of certain physical or mental problems and may be more sensitive in self-reporting symptoms.[16,87] Seeking international collaboration and securing sustained funding are crucial to deepen understanding of PROM and PREM validation for pregnant and postpartum women, clinical thresholds of PROMs and PREMs, and insights into outcomes for diverse patient groups, especially women in vulnerable circumstances. Meanwhile, the utilization of PROMs and PREMs in routine perinatal care can contribute to advancing the clinical applicability of this core outcome set.

Longer-term outcomes of perinatal care

The final data collection time point for PROMs and PREMs at 6 months postpartum, as proposed by the developers of the ICHOM PCB set, was initially designed for the collection only of 'longer-term' outcomes related to perinatal care, considering that this period is not typically part of perinatal care in most countries.[5] However, Dutch women perceived this moment as crucial for reflecting on their pregnancy and childbirth experiences, and for discussing both mental and physical complaints with their trusted obstetric care providers. Particularly, the opportunity for these outcomes to guide referral to specific follow-up care was deemed valuable (**chapter 5, 7**). As perinatal care typically ceases after 6 weeks postpartum, engaging in outcome discussions with women at 6 months postpartum presents challenges for perinatal healthcare providers and policymakers. Research has indicated that some PROMs and PREMs may signal issues at 6 months postpartum, such as pain during intercourse, which might otherwise have gone unnoticed in the current organization of care.[33] Potential solutions for discussing outcomes at this time point and guiding individuals towards appropriate care can be sought beyond perinatal care, such as via involving general practitioners or preventive child healthcare services where women and their children typically receive care. Nevertheless, these PROMs and PREMs pertain to both pregnancy and the postpartum period. Obstetric healthcare providers may thus be the appropriate professionals to address these issues, despite the timing of 6 months postpartum falling outside the current obstetric care pathway. In Finland, there is a focus on incorporating this late postpartum period in perinatal care.[38]

Further research into the feasibility of integrating this 6-months postpartum time point into standard care must support insights in where this care can be optimally implemented. The primary consideration should be that women feel supported, rather than prioritizing what seems most convenient for healthcare organizations and policymakers.

Vulnerability in pregnancy

The Dutch government encourages the pursuit of 'appropriate care', which could at least in part imply a shift towards substituting care with eHealth solutions.[2] However, eHealth may not invariably be an appropriate solution for replacing care for pregnant women in vulnerable circumstances. Nevertheless, eHealth can provide support to healthcare providers in certain aspects of care for women in vulnerable circumstances, such as information provision (**chapter 3, 9**). Developing eHealth applications and facilitating their use among pregnant women in vulnerable circumstances requires additional attention and time from healthcare providers. It necessitates practical assistance from a healthcare provider to support this group in engaging with eHealth. Allowing more time for research development and implementation, offering incentives for participation, and fostering partnerships may enhance the success of research involving vulnerable populations.[40] This underscores the necessity for robust collaboration between obstetric healthcare providers, i.e. gynecologists and community midwives, and co-workers from maternity care organizations to deliver personalized care for women in vulnerable circumstances. Implementing a complex intervention partly based on eHealth, such as described in **chapter 9**, could benefit from better collaboration between healthcare providers, improving the early identification of pregnant women in vulnerable circumstances. The integration of CP in perinatal care for women in vulnerable circumstances may support this group also in engaging with eHealth, including the completion of PROMs and PREMs. In this way, Personal Health Environment is also in reach for this vulnerable population. Future research should assess whether this approach indeed leads to improved personalized care and subsequently enhances self-efficacy, and perhaps health outcomes. This could be conducted as a pilot study, as described in **chapter 6** and **7**.

CONCLUSION

The first steps toward personalizing perinatal care to the needs and preferences of women have been taken. PROMs and PREMs have demonstrated their efficacy in fostering women's engagement in their care and promoting their empowerment. Integrating PROMs and PREMs into standard perinatal care necessitates adapting

the current care pathways and requires dedicated commitment from healthcare providers. Additionally, it underscores opportunities for enhancing care and its outcomes, such as the significance of discussing long-term pregnancy and childbirth outcomes with perinatal care providers. Special consideration is warranted for women in vulnerable circumstances in perinatal care. They require dedicated healthcare providers who collaborate closely to ensure continuity of care from pregnancy through the postpartum period, which has proven to be equally vital, and perhaps even up to 6 months postpartum. Structuring care according to the equity principle, prioritizing equality in healthcare outcomes over equal accessibility, can be beneficial. Digital information exchange among healthcare providers and comprehensive, tailored eHealth information on pregnancy and childbirth can support this endeavor. Maternity care organizations can play a pivotal role because of their expertise to assess vulnerability and adapt care to the needs of women in vulnerable circumstances. Further research can delve into exploring ways to effectively combine personalized perinatal care based on PROMs and PREMs and extensive collaboration among healthcare providers to ensure continuity of care. It is crucial to allocate adequate attention and resources to meet the needs of pregnant women in vulnerable circumstances.

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Chapter 11

Summary
Samenvatting

SUMMARY

Pregnancy, childbirth, and the postpartum period are significant times of change for women and their partners. For many women, it is also their first substantial encounter with the healthcare system. In this context, perinatal care plays a crucial role in safeguarding the immediate and lifelong health and well-being of both mothers and babies. It is essential that perinatal care is tailored to the personal needs of pregnant and postpartum women to achieve the best outcomes for all mothers and babies, regardless of their background.
This thesis focuses on two specific aspects of perinatal care: postpartum care for postpartum women in vulnerable circumstances and personalized care based on patient-reported outcomes. The overarching aim of this thesis is to develop and test new strategies to personalize perinatal care, with a special focus on women in vulnerable circumstances, based on insights into their current needs and preferences.
Chapter 1 provides the general background for this thesis.
To develop new strategies, it is crucial to understand the wishes and needs of women in vulnerable circumstances. In **chapter 2**, semi-structured interviews were conducted with 23 pregnant and postpartum women in vulnerable circumstances to gain insight into their needs regarding postpartum care. Key themes that positively and negatively influenced the utilization of postpartum care were identified: information provision, parental self-efficacy, and social network. Insufficient information about postpartum care was found to be a significant barrier to forming realistic expectations and thus hindered its use. Additionally, the mandatory out-of-pocket contribution (€4.80 per hour in 2023) did not directly have a deterrent effect on the utilization of postpartum care for these women. However, the existence of this contribution caused confusion about the usefulness of postpartum care, as this contribution does not apply to obstetric care, for example. Experiencing low self-efficacy led women to want to utilize or actually utilize more postpartum care. Support from the social network influenced expectations of postpartum care during pregnancy, as women were better able to know what to expect. However, if women had a poor social network, this was a facilitator for the use of postpartum care. According to these women, maternity care assistants were extremely good at adapting information based on their needs. This also resulted in a good bond between maternity care assistants and these women. These findings suggest that postpartum care for women in vulnerable circumstances is essential for improving their self-efficacy regarding their own health and that of their newborn. Additionally, postpartum care can be improved by tailoring care to individual needs and providing comprehensive, understandable information. Involving the social network in postpartum care can add value to

postpartum care for this group.
In **chapter 3**, we investigated whether parents of newborns need digital information focused on the postpartum care period and what this information should include. This information could be provided via an eHealth platform alongside regular perinatal care. We conducted focus group interviews with six new parents, six maternity care assistants, five healthcare providers, and two administrative staff members. All user groups emphasized that the current care system lacks an online platform focused on the postpartum period, especially noted by parents who experience a gap in care after the intensive support during the first week postpartum. However, this platform must be personalized and easily accessible. The content on the platform should include information on breastfeeding, growth, and developmental milestones.
All perinatal care providers encounter pregnant women in vulnerable circumstances and their partners. In **chapter 4**, the complexity of providing care to this group is addressed, and this chapter offers practical guidelines for perinatal care providers in caring for them. It is important that care is provided based on mutual trust, where every pregnant woman and her partner receive care with an open mind and without prejudice. Listening carefully to her needs, avoiding assumptions, and providing support are essential. The practical guidelines in this chapter can help healthcare providers optimally engage with pregnant women in vulnerable circumstances to improve their access to healthcare and equity in health outcomes.
One of the ways to provide personalized care to pregnant and postpartum women is by applying value-based healthcare. This involves measuring care outcomes directly from the patient and personalizing care based on these results. This is done using patient-reported outcome measures (PROMs) and experience measures (PREMs), in addition to the outcome measures typically reported by healthcare providers. To use PROMs and PREMs in the Netherlands, the applicability of an internationally developed patient-centered outcome set for pregnancy and childbirth (PCB set) was explored in **chapter 5**. Women (n = 142), healthcare providers (n = 134), and healthcare organization administrators (n = 35) were surveyed about their opinions on the applicability of this set. The survey findings were further explored during three focus group interviews with these groups. The majority of survey participants agreed that the PCB set contains the most important outcomes. The majority also indicated that measuring PROMs and PREMs was relevant. However, the perceived relevance of patient-reported outcomes varied, with PROMs related to depression and incontinence being considered as less important. From the focus groups interviews, it appeared that this might be due to the taboo surrounding these outcomes. Women, in particular, recognized the importance of measuring PREMs and adjusting care accordingly based on the PREMs. Furthermore, it was highlighted that implementation should be done carefully, with IT,

data transparency, and the timing of PROM and PREM collection being important considerations.
Subsequently, the implementation of the PCB set was monitored through a pilot in seven perinatal care networks. During this pilot, completing PROMs and PREMs and discussing the outcomes were standard components of perinatal care in the respective networks. Each network had the freedom to choose the time points for data collection and the types of patient groups in which they integrated PROMs and PREMs into regular care.
Chapter 6 presents the outcomes of the PROMs and PREMs from the women who participated in this pilot. In total, 1923 PROMs and PREMs questionnaires were filled out across five time points, with 84% fully completed. Clinical thresholds for the PROMs and PREMs were established beforehand: scores indicating potentially alarming values for healthcare providers. One in four women scored above the thresholds on screening questionnaires for incontinence and self-efficacy regarding breastfeeding (both PROMs), and experience with childbirth (PREM). This offers opportunities to further personalize care for pregnant and postpartum women. Specific recommendations for the PCB set were made regarding adjustments to clinical threshold and the integration of time points in regular care pathways.
In **chapter 7**, we gained insight into the experiences of women in this pilot with completing and discussing PROMs and PREMs via a survey and interviews. The survey (460 completed questionnaires) took place immediately after completing the PROMs and PREMs, and the telephone interviews (16 interviews) after discussing the results of the PROMs and PREMs with healthcare providers. While the survey revealed mixed needs regarding the necessity of discussing PROMs and PREMs with healthcare providers, the interviews highlighted their significant value. For example, women were referred to appropriate care for incontinence or depression. Women were particularly enthusiastic about discussing PROMs and PREMs at the time point six months postpartum. They became more aware of the possibilities for personalized care based on their responses. However, there were also significant barriers related to completing and discussing PROMs and PREMs, such as inadequate information provision about PROMs and PREMs and their discussion, IT issues with completing the PROMs and PREMs, and the timing of some PROMs and PREMs not aligning with the current care pathway. Additionally, outcomes were sometimes discussed with a healthcare provider with whom the women had not yet established a relationship.
In addition to using PROMs and PREMs in the consultation room (micro-level), PROMs and PREMs can also be used to provide insights into the quality of care at the group level (meso-level), for example, within a perinatal care network or a hospital. In **chapter 8**, we explored whether PROMs and PREMs can contribute to improving the quality of care. It is common to base quality improvement projects

on outcomes reported by care providers, such as mortality and morbidity. We demonstrated that the application of statistical process control (SPC) charts was also possible with PROMs and PREMs. SPC charts are often used to monitor quality processes because they provide an easy interpretation of data over time (e.g., months). We generated and interpreted four different types of SPC charts based on PROMs and PREMs from the PCB set. These PROMs and PREMs were collected in another retrospective study. We found that SPC charts based on PROMs and PREMs are suitable for integration into quality improvement processes, alongside SPC charts based on data from healthcare providers.

Chapter 9 discusses the design, execution, termination, and evaluation of a randomized controlled trial (RCT) that combined several strategies described in the previous chapters of this thesis. The aim of this complex intervention was to improve the self-efficacy of postpartum women in vulnerable circumstances via personalized postpartum care, combined with information provision via eHealth. Postpartum care was personalized based on an early screening for medical and non-medical risk factors and PROMs and PREMs. However, various factors, such as low inclusion rates and the outbreak of COVID-19, led to the early termination of the RCT. To gain insight into facilitators and barriers regarding the implementation of personalized postpartum care among women in vulnerable circumstances, a process evaluation was conducted. This revealed that all staff members of postpartum care organizations could be better supported through training in conducting scientific research and identifying vulnerability risks during pregnancy. Additionally, for the best care for pregnant and postpartum women in vulnerable circumstances collaboration between healthcare providers within the perinatal care chain is very important, especially the information transfer between healthcare providers. It is important to identify vulnerability during pregnancy as early as possible. This may prevent that risks during pregnancy and the postpartum period evolve to manifest problems later in life. It also became clear that postpartum women in vulnerable circumstances, in addition to having poor health literacy, also have poor digital skills. They should therefore be more involved in the development of eHealth, so that it can better meet their needs.

Chapter 10 discusses the implications and recommendations for future research and healthcare. Striving for equality in care outcomes for all women, rather than equality in care provision, can lead to better results for pregnant and postpartum women in vulnerable circumstances. Continuity of care is important in this light. Maternity care organizations, which are involved from pregnancy onwards, can contribute to this continuity of care. Good information provision about the content of this type of care is essential for improving the utilization of postpartum care. More research is needed to tailor this information for women in vulnerable circumstances. Additionally, the research in this thesis shows that it is important to further train staff of maternity care organizations and to continue involving

these organizations in scientific research, so that their care remains a crucial link in perinatal care.
The research in this thesis also indicates that the PROMs and PREMs in the PCB set are suitable for application in perinatal care in the Netherlands. They are particularly effective in detecting outcomes that would otherwise remain unnoticed, and they help women prepare for their visits to healthcare providers. However, further improvement of IT support for the collection and exchange of data, such as PROMs and PREMs, is necessary. Additionally, more research is needed on the applicability of PROMs and PREMs in larger groups, including the establishment of clinical thresholds. Collecting and discussing PROMs and PREMs in the long term, for example, six months postpartum, requires research into proper integration into perinatal care.

SAMENVATTING

De periode van zwangerschap, bevalling en kraamzorg is voor vrouwen en hun partners een belangrijke tijd waarin grote veranderingen plaatsvinden. Het is vaak de eerste keer dat vrouwen voor een langere periode patiënt of cliënt zijn in de gezondheidszorg. Geboortezorg, wat de gehele keten van zorg omvat voor zowel moeder als kind tijdens zwangerschap, bevalling en kraamperiode, speelt hierbij een cruciale rol in het beschermen van de gezondheid en het welzijn van zowel moeders als baby's. Het is essentieel dat de geboortezorg wordt afgestemd op de persoonlijke behoeften van zwangere en pas bevallen vrouwen, zodat we de beste resultaten kunnen behalen voor alle moeders en baby's, ongeacht hun achtergrond.

Er zijn ongelijkheden in de uitkomsten van geboortezorg. Vrouwen met een lagere socio-economische status (SES), ook wel 'zwangeren en kraamvrouwen in kwetsbare omstandigheden' genoemd, lopen een hoger risico op slechte uitkomsten. Bij vrouwen met een lage SES is er sprake van meerdere met elkaar samenhangende kenmerken, zoals een laag inkomen en een laag opleidingsniveau. Vaak hebben deze vrouwen ook problemen op meerdere vlakken, zoals bijvoorbeeld een slechtere gezondheid, alleenstaand ouderschap en gebrekkige gezondheidsvaardigheden. We noemen dit ook wel medische en niet-medische risicofactoren. Deze dragen bij aan een hoger risico op slechte uitkomsten van geboortezorg, zoals te vroeg of te klein geboren kinderen. Naast klinische uitkomsten, verzameld door zorgverleners, is er steeds meer aandacht voor uitkomsten direct afkomstig van de gebruikers van zorg. Deze uitkomsten, gemeten via patiënt-gerapporteerde uitkomstmaten (PROM) en ervaringsmaten (PREM), kunnen waardevolle informatie geven over de kwaliteit van zorg en de perspectieven en de ervaringen van vrouwen.

Waardegedreven zorg maakt gebruik van PROMs, PREMs en klinische uitkomstmaten om de zorg te personaliseren. Echter, het invoeren van PROMs en PREMs in de geboortezorg kan het risico op slechtere uitkomsten voor zwangeren en kraamvrouwen in kwetsbare omstandigheden vergroten. Om de vragenlijsten van de PROMs en PREMs in te kunnen vullen, zijn begrip van de Nederlandse taal en gezondheidsvaardigheden nodig. Daarbij moet men vertrouwen in zorgverleners hebben dat de juiste zorg ingezet wordt aan de hand van hun antwoorden op de vragenlijsten. En juist deze vereisten ontbreken of zijn minder aanwezig binnen de groep zwangeren en kraamvrouwen in kwetsbare omstandigheden. Daarom is het belangrijk om de behoeftes van deze groep te begrijpen. Het overkoepelende doel van deze thesis is het ontwikkelen en testen van nieuwe strategieën om geboortezorg te personaliseren, met een speciale focus op vrouwen in kwetsbare omstandigheden, gebaseerd op inzichten in hun huidige behoeften en voorkeuren.

In **hoofdstuk 1** wordt de algemene achtergrond voor dit proefschrift gegeven.
In **hoofdstuk 2** hebben we semi-gestructureerde interviews afgenomen bij 23 zwangere en pas bevallen vrouwen in kwetsbare omstandigheden om hun behoeften met betrekking tot kraamzorg te onderzoeken. Uit deze interviews zijn belangrijke thema's naar voren gekomen die zowel positief als negatief van invloed zijn op het gebruik van kraamzorg. Deze thema's waren: informatievoorziening, ouderlijke zelfredzaamheid en het sociale netwerk. Zo bleek een gebrek aan informatie over de inhoud van kraamzorg een belangrijke drempel te zijn voor het vormen van realistische verwachtingen en het gebruik van kraamzorg. De verplichte eigen bijdrage voor kraamzorg (€4,80 per uur in 2023) bleek niet direct een remmend effect op het gebruik van kraamzorg voor deze vrouwen te hebben. Wel zorgde het bestaan van deze bijdrage voor verwarring, omdat deze bijvoorbeeld niet gold voor verloskundige zorg in de zwangerschap. Vrouwen die zich minder zelfredzaam voelden, namen juist meer kraamzorg af. Het sociale netwerk speelde ook een rol: vrouwen met een sterk sociaal netwerk wisten beter wat ze konden verwachten van kraamzorg. Voor vrouwen met een zwakker sociaal netwerk was kraamzorg een waardevolle ondersteuning. Volgens de vrouwen die we hebben geïnterviewd, zijn kraamverzorgenden erg goed in het aanpassen van informatie aan de behoeften van moeders en hun pasgeborenen. Dit zorgt voor een goede band tussen kraamverzorgenden en de vrouwen. Onze bevindingen suggereren dat kraamzorg juist voor kwetsbare vrouwen essentieel is om hun zelfredzaamheid te verbeteren op het gebied van gezondheid, zowel voor henzelf als voor hun pasgeborene. Door kraamzorg af te stemmen op individuele behoeften en duidelijke informatie te verstrekken, kunnen we de kwaliteit van kraamzorg verder verbeteren. Ook het betrekken van het sociale netwerk tijdens de kraamweek kan waardevol zijn voor deze groep vrouwen.
In **hoofdstuk 3** hebben we onderzocht of ouders van pasgeborenen behoefte hebben aan digitale informatie over de kraamzorgperiode en wat die informatie zou moeten bevatten. Deze informatievoorziening kan dan bijvoorbeeld geboden worden in de vorm van een eHealth platform naast de reguliere geboortezorg. Hiervoor hebben we focusgroep-interviews gehouden met zes kersverse ouders, zes kraamverzorgenden, vijf verloskundig zorgverleners en twee administratief medewerkers. Alle gebruikersgroepen benadrukten dat er in de huidige zorg een informatieplatform ontbreekt dat zich richt op de kraamperiode. Dit werd vooral genoemd door ouders die een kloof ervaren na de intensieve zorg na de eerste week na de bevalling. Een dergelijk platform moet gemakkelijk toegankelijk en gepersonaliseerd zijn. De inhoud ervan moet informatie bevatten over borstvoeding, groei en ontwikkelingsmijlpalen.
Alle verloskundige zorgverleners hebben te maken met zwangere vrouwen in kwetsbare omstandigheden en hun partners. Goede zorg voor deze groep kan helpen om gezondheidsverschillen tussen zwangere vrouwen en kinderen te ver-

kleinen, door hun kans op goede uitkomsten van zorg te vergroten.
In **hoofdstuk 4** zijn we dieper in gegaan op de complexiteit van het verlenen van zorg aan deze groep in kwetsbare omstandigheden. We hebben praktische handvatten geboden voor zorgverleners, om optimaal contact te kunnen maken met zwangere vrouwen in kwetsbare omstandigheden en hun partners. Zo is het belangrijk dat zorg wordt geboden op basis van wederzijds vertrouwen, zonder vooroordelen. Daarnaast is goed luisteren naar de behoeften van de zwangere vrouw en het vermijden van aannames hierbij essentieel. Deze praktische tips kunnen zorgverleners helpen om de toegang tot gezondheidszorg en de gezondheidsresultaten van kwetsbare zwangere vrouwen te verbeteren.
In **hoofdstuk 5** hebben we onderzocht in hoeverre een patiëntgerichte uitkomstenset voor zwangerschap en geboorte (Z&G set) toepasbaar was om te kunnen gebruiken in Nederland. Deze Z&G set is internationaal ontwikkeld, en bevat PROMs, PREMs en uitkomstmaten die door zorgverleners worden gerapporteerd. Deze set gaat over zwangerschap, bevalling en de kraamperiode tot 6 maanden na de bevalling.
Zwangere en bevallen vrouwen (n = 142), zorgverleners (n = 134), en beheerders van zorgorganisaties (n = 35) zijn middels een enquête gevraagd naar hun mening over de toepasbaarheid van deze set in Nederland. De bevindingen van de enquête hebben we verder verdiept door het houden van drie focusgroep-interviews onder dezelfde groepen als de enquête. De meerderheid van de deelnemers aan de enquête was het erover eens dat de Z&G set de belangrijkste uitkomsten bevat voor zowel klinische uitkomsten als patiëntgerapporteerde uitkomsten. Ook vonden ze dat het meten van PROMs en PREMs relevant was. Maar sommige PROMs, zoals die over depressie en incontinentie, werden opvallend genoeg als minder belangrijk gezien. Uit de focusgroep-interviews bleek dat dit mogelijk te maken heeft met de taboesfeer die om deze uitkomsten hangt. Een PREM werd juist gemist, namelijk een die de continuïteit van de zorg meet. Met name de vrouwen zagen ook het belang in van het meten van PREMs, zeker als daar de zorg vervolgens op aangepast werd. Verder kwam naar voren dat de implementatie van de Z&G set zorgvuldig moet worden gedaan. ICT (zoals het verzamelen en weergeven van PROMs en PREMs in de elektronische dossiers), transparantie van uitkomsten van de zorg en de timing van de verzameling van de PROMs en PREMs zijn hierbij belangrijke punten van aandacht.
Vervolgens werd de implementatie van de Z&G set middels een pilot in zeven geboortezorgnetwerken gemonitord. Tijdens deze pilot was het invullen van PROMs en PREMs en het bespreken van de uitkomsten een standaard onderdeel van de geboortezorg in de betreffende geboortezorgnetwerken. De Z&G set meet op vijf momenten tijdens de zwangerschap en na de geboorte PROMs, PREMs en klinische uitkomstmaten. Deze meetmomenten zijn: aan het einde van het eerste trimester (rondom 12 weken zwangerschap), aan het begin van het derde trimester

(rondom de 28 weken zwangerschap), in de kraamperiode (in de eerste week na de bevalling), zes weken na de bevalling en zes maanden na de bevalling. Elk geboortezorgnetwerk had de vrijheid om te kiezen welke meetmomenten en onder welke patiëntengroepen zij de PROMs en PREMs integreerden in de reguliere zorg.
Hoofdstuk 6 geeft de uitkomsten van de PROMs en PREMs weer van de vrouwen die deel hebben genomen aan deze pilot. In totaal werden er over de vijf meetmomenten 1923 PROMs en PREMs vragenlijsten ingevuld, waarvan 84% volledig was ingevuld. Vooraf waren voor de PROMs en PREMs klinische drempelwaardes ingesteld: scores die voor zorgverleners aangeven dat een waarde mogelijk alarmerend is. We zagen dat een op de vier vrouwen boven de drempelwaardes scoorde op screeningsvragenlijsten voor incontinentie en zelfredzaamheid ten aanzien van borstvoeding (beide PROMs), en ervaring met de bevalling (een PREM). Deze uitkomsten bieden mogelijkheden om de zorg voor zwangere en bevallen vrouwen verder te personaliseren en optimaliseren. Op basis van de uitkomsten deden we concrete aanbevelingen voor verbetering van de Z&G set, zoals aanpassingen van de klinische drempelwaardes en het inpassen van de meetmomenten in de bestaande zorgpaden.
In **hoofdstuk 7** hebben we de ervaringen van vrouwen in deze pilot met het invullen en bespreken van PROMs en PREMs met hun zorgverlener onderzocht middels een enquête en interviews. De enquête (460 ingevulde enquêtes) vond plaats direct na het invullen van de PROMs en PREMs, de telefonische interviews (16 interviews) na het bespreken van de resultaten met de zorgverleners. Uit de enquête kwam naar voren dat er gemengde behoeftes waren met betrekking tot het bespreken van de PROMs en PREMs met zorgverleners. Uit de interviews bleek echter juist dat dit bespreken zeer waardevol gevonden werd. Vrouwen werden daardoor bijvoorbeeld verwezen naar de juiste zorg met betrekking tot incontinentie of depressie. Of zij kregen meer informatie over het geven van borstvoeding. Opvallend was dat met name op het tijdstip zes maanden na de bevalling vrouwen enthousiast waren over het bespreken van PROMs en PREMs. Vrouwen waren zich meer bewust van de mogelijkheden tot gepersonaliseerde zorg naar aanleiding van hun antwoorden. In de huidige geboortezorg stopt de zorg voor moeder en kind bij de verloskundig zorgverleners zes weken na de bevalling. Het meet- en bespreekmoment zes maanden na de bevalling is dus geen standaard onderdeel van de huidige geboortezorg.
Echter waren er ook belangrijke drempels met betrekking tot het invullen en bespreken van PROMs en PREMs, zoals inadequate informatievoorziening over PROMs en PREMs en het bespreken hiervan, en ICT-problemen bij het invullen van de PROMs en PREMs. Ook sloot de timing van sommige PROMs en PREMs niet aan op het huidige zorgpad. Of werden de uitkomsten met een nieuwe zorgverlener besproken waarbij er nog geen vertrouwensband was gecreëerd.
Naast het gebruik van PROMs en PREMs in de spreekkamer (microniveau), kunnen

PROMs en PREMs ook gebruikt worden om inzicht te geven in de kwaliteit van de zorg op groepsniveau (mesoniveau), bijvoorbeeld binnen een geboortezorgnetwerk of een ziekenhuis.
In **hoofdstuk 8** onderzochten wij of PROMs en PREMs op een dergelijke manier kunnen bijdragen aan verbetering van de kwaliteit van zorg. Het is op dit moment gebruikelijk om deze kwaliteitsverbetering met uitkomsten te doen die gerapporteerd zijn door zorgverleners, zoals mortaliteit en morbiditeit. Wij keken of het gebruik van statistical process control (SPC) charts ook mogelijk was met PROMs en PREMs. SPC charts worden vaak gebruikt voor het monitoren van kwaliteitsprocessen, omdat ze een gemakkelijke interpretatie van data geven over de tijd (bijvoorbeeld maanden). Wij genereerden en interpreteerden vier verschillende type SPC charts gebaseerd op PROMs en PREMs van de Z&G set. Deze PROMs en PREMs waren verzameld voor een ander retrospectief onderzoek. De SPC charts op basis van de PROMs en PREMs gaven een robuuste weergave van deze uitkomsten weer over de tijd, waarbij zichtbaar werd dat niet alle charts een stabiel proces lieten zien. Een dergelijk instabiel proces kan een aanleiding zijn voor een kwaliteitsverbeter-proces gericht op deze PROMs en PREMs, naast verbetering van de uitkomsten die door zorgverleners verzameld worden. Daarmee ondervonden wij dat SPC charts op basis van PROMs en PREMs geschikt zijn voor integratie in kwaliteitsverbeter-processen. Ook adviseerden wij dat SPC charts op basis van deze PROMs en PREMs vaker gebruikt moeten worden in deze processen, zodat ook uitkomsten direct afkomstig van patiënten onderdeel zijn van verbetering van de kwaliteit van zorg.
In de eerdere hoofdstukken van dit proefschrift werden belangrijke strategieën besproken met betrekking tot kraamzorg voor kraamvrouwen in kwetsbare omstandigheden, gepersonaliseerde zorg op basis van PROMs en PREMs en de mogelijkheden van informatievoorziening middels eHealth. In **hoofdstuk 9** wordt de opzet, uitvoer, en de uiteindelijke voortijdige staking en evaluatie van een randomized controlled trial (RCT) besproken, die deze eerdere strategieën combineert. Het doel van de studie was om te onderzoeken of deze complexe interventie de zelfredzaamheid van kraamvrouwen in kwetsbare omstandigheden zou kunnen verbeteren via gepersonaliseerde kraamzorg gecombineerd met informatievoorziening via eHealth. Met de uitkomsten van een vroegtijdige screening op medische en niet-medische risicofactoren en PROMs en PREMs werd de kraamzorg gepersonaliseerd. Echter zorgden verschillende factoren, zoals het achterblijven van de inclusies en de uitbraak van COVID-19 ervoor dat de RCT vroegtijdig gestaakt moest worden.
Om inzicht te krijgen in de bevorderende en belemmerende factoren met betrekking tot de implementatie van gepersonaliseerde kraamzorg onder vrouwen in kwetsbare omstandigheden, werd een procesevaluatie uitgevoerd. Hieruit bleek dat medewerkers van kraamzorgorganisaties beter ondersteund zouden moeten

worden middels scholing, in het doen van medisch-wetenschappelijk onderzoek en in risico-identificatie van kwetsbaarheid in de zwangerschap. In de zorg voor zwangeren en kraamvrouwen in kwetsbare omstandigheden is de samenwerking in de keten zeer belangrijk, waarbij de informatieoverdracht tussen zorgverleners essentieel is. Het is belangrijk dat zwangeren in kwetsbare omstandigheden zo vroeg mogelijk in de zwangerschap geïdentificeerd worden, zodat zorgverleners de juiste ondersteuning en zorg in kunnen zetten. Dit kan voorkomen dat risico's in de zwangerschap en kraamperiode leiden tot manifeste problemen later in het leven. Daarnaast bleek uit de evaluatie dat kraamvrouwen in kwetsbare omstandigheden, naast gebrekkige gezondheidsvaardigheden, ook vaak gebrekkige digitale vaardigheden hebben. Zij moeten dan ook meer betrokken worden bij de ontwikkeling van eHealth, zodat dit beter aan hun behoeftes kan voldoen.
In **hoofdstuk 10** worden belangrijkste bevindingen van dit proefschrift besproken, evenals de implicaties en aanbevelingen voor toekomstig onderzoek en de gezondheidszorg. Het streven naar gelijkheid in zorguitkomsten voor alle vrouwen, in plaats van gelijkheid in zorgaanbod, kan leiden tot betere resultaten voor zwangeren en kraamvrouwen in kwetsbare omstandigheden. Continuïteit in zorgverlening speelt hierbij een belangrijke rol. Kraamzorgorganisaties, die al vanaf de zwangerschap betrokken zijn, kunnen bijvoorbeeld bijdragen aan deze continuïteit. Goede informatievoorziening over de inhoud van deze zorg is daarom essentieel. Er is meer onderzoek nodig naar het aanpassen van die informatie voor vrouwen in kwetsbare omstandigheden. Daarbij laat het onderzoek in dit proefschrift zien dat het belangrijk is om medewerkers van kraamzorgorganisaties verder te scholen en deze organisaties te blijven betrekken bij het doen van wetenschappelijk onderzoek, zodat hun zorg een belangrijke schakel in de geboortezorg blijft.
Eveneens blijkt uit het onderzoek in dit proefschrift dat de PROMs en PREMs in de Z&G set geschikt zijn voor gebruik in de geboortezorg in Nederland. Ze zijn bovenal effectief in het opsporen van uitkomsten die anders onopgemerkte zouden blijven, en ze helpen vrouwen bij het voorbereiden van hun bezoeken aan de zorgverlener. Echter is verdere verbetering van de ICT-ondersteuning voor de verzameling en uitwisseling van gegevens, zoals PROMs en PREMs, noodzakelijk. Daarnaast is meer onderzoek nodig naar de toepasbaarheid van PROMs en PREMs in grotere groepen, inclusief de vaststelling van klinische drempelwaardes. Het verzamelen en bespreken van PROMs en PREMs op de lange termijn, bijvoorbeeld na zes maanden, vereist onderzoek naar een goede integratie in de geboortezorg.

Chapter 12

List of publications
Contributing authors
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LIST OF PUBLICATIONS

In this thesis

Insight into the process of postpartum care utilisation and in-home support among vulnerable women in the Netherlands: an in-depth qualitative exploration
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CONTRIBUTING AUTHORS

J.V. Been
Department of Neonatal and Paediatric Intensive Care, Division of Neonatology, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands
Department of Public Health, Erasmus MC, University Medical Centre Rotterdam, Rotterdam, The Netherlands

M. N. Bekker
Department of Obstetrics and Gynaecology, Wilhemina Children's Hospital, University Medical Centre Utrecht, Utrecht, Netherlands

L.J. Breunis
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands
Department of Paediatrics, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

A.L. Depla
Department of Obstetrics and Gynaecology, Wilhemina Children's Hospital, University Medical Centre Utrecht, Utrecht, Netherlands

H.E. Ernst-Smelt
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

A.F. Franx
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

J.A. Hazelzet
Department of Public Health, Erasmus MC, University Medical Centre Rotterdam, Rotterdam, The Netherlands

M. van der Hulst
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

S.S. Kariman
Department of Obstetrics and Gynaecology, Wilhemina Children's Hospital, University Medical Centre Utrecht, Utrecht, Netherlands

A. Klootwijk
Department of Obstetrics and Gynecology, Division Obstetrics and Fetal Medicine, Erasmus MC, Rotterdam, the Netherlands

J. Lagendijk
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

M. Lamain-de Ruiter
Department of Obstetrics and Gynaecology, Wilhemina Children's Hospital, University Medical Center Utrecht, Utrecht, Netherlands
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

M. Lugtenberg
Department of Public Health, Erasmus MC, University Medical Centre Rotterdam, Rotterdam, The Netherlands
Department of Dermatology, Erasmus MC, University Medical Centre Rotterdam, Rotterdam, The Netherlands
Department Tranzo, Tilburg School of Social and Behavioral Sciences, Tilburg University, Tilburg,
The Netherlands

A.G. Posthumus
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

B.B. van Rijn
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands
Department of Obstetrics and Gynecology, Máxima Medical Centre, Veldhoven, the Netherlands
Department of Biomedical Engineering, Eindhoven University of Technology, Eindhoven, the Netherlands

A.R. Rosman
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands
Department of Health Care Studies, Rotterdam University of Applied Sciences, Rotterdam, The Netherlands

E.A.P. Steegers
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands
R.P.M. Steegers-Theunissen
Department of Paediatrics, Division of Neonatology, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

A.J.M. Waelput
Department of Obstetrics and Gynaecology, Division of Obstetrics and Prenatal Medicine, Erasmus MC Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, The Netherlands

PORTFOLIO

Erasmus MC Department	Obstetrics and Gynecology
Research school	Netherlands Institute of Health Sciences (NIHES)
PhD period	February 2017 – December 2020
Promotor(s)	Prof. dr. A. Franx, Prof. dr. J.A. Hazelzet, and Dr. J.V. Been
Co-promotor	Dr. J. Lagendijk

PhD training	**Year**	**Workload (ECTS)**
Courses		
Center for Patient-Oriented research (CPO) course – Erasmus MC	2017	0.3
Searching in medical databases and Endnote course – Erasmus MC	2017	0.8
Basic course Rules and Organisation for Clinical researchers (BROK) course – NFU BROK academy	2018	1.5
Scientific Integrity – Erasmus MC	2018	0.3
Biomedical English Writing – Erasmus MC	2019	2.00
Classical Methods in Data Analysis – UMC Utrechts	2019-2020	6.00
Limesurvey, Gemstracker, and OpenClinica courses – Erasmus MC	2017	0.80

Qualitative Research Methods – VU MC	2017	2.0
Value Based Healthcare, from theory to implementation – Erasmus MC	2017	0.70
Conferences and symposia		
10th World Congress on Developmental Origins of Health and Disease (attendance)	2017	1.00
4th Symposium Urban Perinatal Health (poster)	2017	0.70
Dag van de Kraamzorg (poster)	2017	0.4
Menzis Value-based Healthcare Conference (oral)	2018	1.4
Kick-off pre-implementation project Pregnancy and Childbirth Standard Set in the Netherlands (oral)	2018	1.4
ICHOM Conference 2019 (oral)	2019	1.4
ZonMw Conference on postpartum care (oral)	2020	1.00
Mini symposium Regional Consortium Pregnancy and Childbirth Southwest Netherlands: vulnerable pregnant women (oral)	2020	1.40
20th International Conference on Integrated Care (oral and poster)	2020	2.00
ICHOM Conference 2020 (webinar)	2020	1.00
Symposium 'the best start for the vulnerable postpartum woman and her child' (oral)	2021	1.40

Local research meetings		
Annual Wladimiroff Award Meeting	2017-2020	0.30
Annual Sophia Research Day	2017-2020	0.90
Monthly ACE meeting Pregnancy and Childbirth	2017-2020	0.6
Weekly Obstetric research meeting	2017-2020	5
Erasmus MC PhD Day	2017, 2019	0.60
Teaching activities		
Lecture on valuebased healthcare in perinatal care for co-workers of maternity care organizations – BO college	2017	1.4
Lecture on valuebased healthcare in perinatal care for perinatal care professionals – Perined	2018	1.4
Training co-workers of maternity care organizations regarding doing research, communication techniques for vulnerable women, and eHealth	2019-2020	5.00
Supervising Master thesis of Suzanne van der Laan	2020	2.00

ABOUT THE AUTHOR

Lyzette Thérèse Laureij was born on March 24, 1988, in Gouda, the Netherlands. She grew up in Nieuwerkerk and Capelle a/d IJssel, with her parents, younger sister and two dachshunds. After completing her secondary education at Erasmiaans Gymnasium Rotterdam in 2006, she started studying medicine at Erasmus University Rotterdam. During her study, she pursued a scientific internship at St. Elisabeth Hospital in Curaçao under the supervision of prof. dr. A. Duits, which provided her initial exposure to scientific research involving vulnerable populations.

After obtaining her degree of Medical Doctor in 2014, Lyzette worked as a resident (ANIOS) at the Department of Gynecology and Obstetrics at Amphia Hospital in Breda and later at Haga Hospital in The Hague. During this period, her interest in healthcare management grew, leading her to pursue a Clinical Business Administration program at Tias Business University.
In February 2017, Lyzette commenced her doctoral research as a PhD candidate at Erasmus MC Sophia, Department of Obstetrics and Gynecology, under the supervision of dr. J.V. Been, dr. J. Lagendijk, prof. dr. J.A. Hazelzet, and prof. dr. A. Franx. Initially focused on improving healthcare access for vulnerable postpartum women, her research quickly expanded to include the implementation of outcome measures to enable value-based care in obstetrics. Findings from her research resulted in this thesis.

In March 2021, Lyzette began her training to become a general practitioner in the Rotterdam region, further advancing her commitment to enhancing healthcare delivery and outcomes. Lyzette currently lives in Rotterdam with her husband Arthur, their children Juliette and Duco and their dachshund Pim.

DANKWOORD

Dit proefschrift draagt mijn naam op de kaft, maar velen hebben direct en indirect bijgedragen aan de totstandkoming hiervan. Altijd een populair hoofdstuk in een proefschrift, heerlijk om dit te kunnen schrijven zonder het terug te krijgen met track changes.

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