

RESEARCH ARTICLE

A feasibility study of implementing a patient-centered outcome set for pregnancy and childbirth

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Abstract

Background and Aims: Patient-reported outcome and experience measures (PROM and PREM) can facilitate shared decision making and hold potential to improve healthcare quality. However, their adoption in perinatal care is still limited. The International Consortium for Health Outcomes Measurement (ICHOM) developed a Pregnancy and Childbirth (PCB) outcome set, including PROM and PREM questionnaires. We studied the feasibility to use these PROMs/PREMs in Dutch perinatal care, addressing both women's and professionals' perspective.

Methods: Patients and professionals in primary and hospital care participated. Women under care at one of five timepoints for PROM/PREM collection of the PCB set (2 during pregnancy, 3 postpartum) were e-mailed a questionnaire and discussed their answers with their obstetric professional the next regular visit. Compliance was recorded. After discussing the PROMs/PREMs, usability and experience were assessed with separate surveys amongst women and professionals.

Results: Of 26 women approached, 21 completed and discussed their PROM/PREM questionnaire. Mean questionnaire completion rate was 97%. Average reported time completing the questionnaires was 10 minutes; most women (90%) stated this was acceptable. Women preferred completing questionnaires digitally and discuss their answers with an obstetric professional rather than other care professionals, also 6 months postpartum. Over half of women agreed PROMs/PREMs supported shared decision making (58%), ability to raise issues (60%), and patient-clinician relationship (52%). Six professionals participated: two obstetricians, two clinical midwives, and two community midwives. Most professionals experienced sufficient time to discuss the responses, except at 6 months postpartum. They knew what items to discuss but did not always feel responsible to act upon them. Professionals agreed PROMs/PREMs supported symptom detection and personalized care.

Conclusions: Patients and obstetric professionals consider the PCB set a feasible instrument for PROM/PREM assessment, with good compliance, acceptability and usability. Important determinants of successful implementation are a well-equipped ICT-tool, agreements regarding professionals' responsibilities and how outcomes are discussed or acted upon.

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KEYWORDS

feasibility, implementation, obstetrics, patient-reported outcome measures, perinatal care, value-based healthcare

1 | INTRODUCTION

Routine collection and use of patient-reported outcome measures (PROM) enable focusing on patients' perspective of wellbeing, in both clinical practice and in healthcare quality improvement.^{1,2} In individual patient care, structural PROM collection and use can improve patient-clinician communication, detection of unrecognized symptoms, and even clinical health outcomes.^{3,4} In the past decade, the use of PROMs has, therefore, rapidly grown in orthopedics, oncology, and chronic care settings, but their adoption is still limited in clinical practice of perinatal care.⁵⁻⁷ Even though in this setting, PROMs could add considerable value to patient care and quality improvement, as its general population consists of relatively healthy women at low risk for mortality or severe morbidity, and multiple professional organizations combine planned and acute care in a short time period.^{8,9}

The International Consortium for Health Outcomes Measurement (ICHOM) published a standard outcome set for Pregnancy and Childbirth (PCB), which has recently been translated to Dutch and validated in the Netherlands.¹⁰⁻¹² This standard set comprises clinical outcomes, patient-reported outcome measures, and patient-reported experience measures (PREM), assessed with a questionnaire regarding health status and experiences with care at five different timepoints in pregnancy and the postpartum period. By collecting and using this information in clinical practice, women gain insight in relevant outcomes for themselves and their child. This way, women can be empowered to effectively communicate their health status and make better informed decisions about their care.^{4,13} At the same time, care professionals value patient-reported measures when they are useful for the clinical process, as they can become more aware of patients' issues and are enabled to more patient-centered discussion and action.^{4,14}

Multiple governments have initiated national programs to stimulate the incorporation of PROMs and PREMs in their healthcare system.¹⁵⁻¹⁷ In the Netherlands, the Ministry of Healthcare mandates the implementation of patient-reported measurements throughout the healthcare system, supported by clinician and patient organizations.¹⁸ The primary step of this implementation is incorporation in clinical practice, whereas secondary use for quality improvement and quality benchmarking are subsequent steps in the transition to value-based healthcare. However, to date, knowledge and experience to collect and use PROMs or PREMs routinely in perinatal care are lacking, and little is known about time investment and response burden of the PCB outcome set for both women and obstetric care professionals.^{7,9} At this moment, unfamiliarity and uncertainty seem to hinder the implementation of its patient-reported measures in perinatal clinical practice.¹¹

Therefore, the aim of this study was to assess the feasibility of implementing the PCB outcome set, by piloting the process of collecting its PROM and PREM questionnaires and discuss the responses as part of usual care (ie, the pilot intervention). Barriers and facilitators

to use the PROMs and PREMs in routine perinatal care were evaluated with surveys. We expected this study to provide insights in acceptability, compliance, usability, and preferences of both women and obstetric care professionals using the questionnaires.

2 | METHODS

Within a 3-month pilot, a cross-sectional feasibility study was performed to collect data regarding compliance, usability, and experiences when using the PROM and PREM questionnaires of the PCB outcome set in clinical practice. For this pilot intervention, women receiving perinatal care were asked to complete one questionnaire and discuss their answers with their obstetric care professional during the next regular visit. After discussing the PROMs and PREMs in clinic, both women and obstetric care professionals were sent an evaluation survey regarding usability and experience.

2.1 | Setting

From March 2019 to June 2019, this study was carried out in the perinatal care network of the Wilhelmina Children's Hospital (WKZ) in the Netherlands. Dutch perinatal care is organized in a two-tiered system, with community midwives providing care to low risk patients, while obstetricians in hospitals provide care to medium and high-risk patients. Community midwives refer patients to hospital care if complications arise and cooperate in an Obstetric Collaborative Network (OCN) with their referring partners. The WKZ is a secondary and tertiary referral center, collaborating in an OCN with six community midwifery practices.

2.2 | Participants

Patients: Women receiving perinatal care were recruited at each of the five proposed timepoints to capture data for the PCB outcome set. ICHOM recommends the following timepoints to assess the PROM/PREM domains using standard questionnaires:

- **T1:** first trimester (gestational age between 8 and 16 weeks)
- **T2:** early third trimester (gestational age between 28 and 32 weeks)
- **T3:** at birth (± 3 days postpartum)
- **T4:** first postnatal checkup (between 5 and 6 weeks postpartum)
- **T5:** 6 months after birth (between 22 and 26 weeks postpartum)

For this pilot study, women were asked for only one of these timepoints, because the complete timeline of measurements is spread over 12 months. To assess the feasibility of each timepoint, a sample of five women per timepoint was aimed, including both nulliparous

and multiparous women at each timepoint. Women had to be able to read Dutch language.

Professionals: A sample of obstetric care professionals was selected from all care settings in the OCN: obstetricians, clinical midwives (hospital employed), and community midwives. Each professional was asked to assess and discuss one PROM/PREM questionnaire of each timepoint (T1 to T5) with different women as part of usual care.

2.3 | Pilot intervention: ICHOM Pregnancy and Childbirth outcome set

ICHOM aims to create standard sets of outcomes that matter to patients for each particular disease or condition, including both clinical metrics and PROMs/PREMs. The development and content of their standard set for PCB are described by Nijagal et al.^{10,12} During recent translation and validation of this PCB outcome set, a few PREMs were added to adjust to the Dutch context.¹¹ The PROMs and PREMs comprise 14 domains, measured at five timepoints described above (Figure 1). Each domain has its own measurement instrument(s)—in this case questionnaire (Appendix A). Questions that aim for screening were embedded in several domains: if a woman is not at risk, certain questions are ruled out. That way, the number of questions per timepoint differs per woman (Figure 1), and the burden of filling out many questions is reduced.

In this pilot, the PROM and PREM questionnaires of the PCB outcome set are used as part of routine clinical practice. This process includes the following steps:

- 1 The obstetric care professional explains the purpose and process of the PROM/PREM questionnaires to his/her patient visiting at one of the five timepoints;
- 2 The patient fills out the PROM/PREM questionnaire suitable for that particular timepoint;
- 3 The obstetric care professional and patient discuss the PROMs/PREMs in the next regular visit.

During the pilot period, the first step of this process was combined with obtaining informed consent for the study. The PROM/PREM questionnaire was sent by e-mail and could be returned to the obstetric care professional digitally or taken to the next visit as a hardcopy. If it was not returned 48 hours prior to the following appointment, an e-mail reminder was sent. As the last timepoint (T5) falls outside routine perinatal care, the obstetric care professional scheduled an additional telephone consultation to discuss the responses to this questionnaire.

2.4 | Data collection and analysis

The PROM/PREM questionnaires were retrieved from women's medical records to assess completion rates, along with several baseline characteristics. To calculate the proportion of missing responses per measurement instrument, the missing responses per instrument were divided by the number of women that were supposed to fill the instrument out. This denominator differs, as some instruments are dependent of a screening question (Appendix A), or specific for certain timepoints (Figure 1).

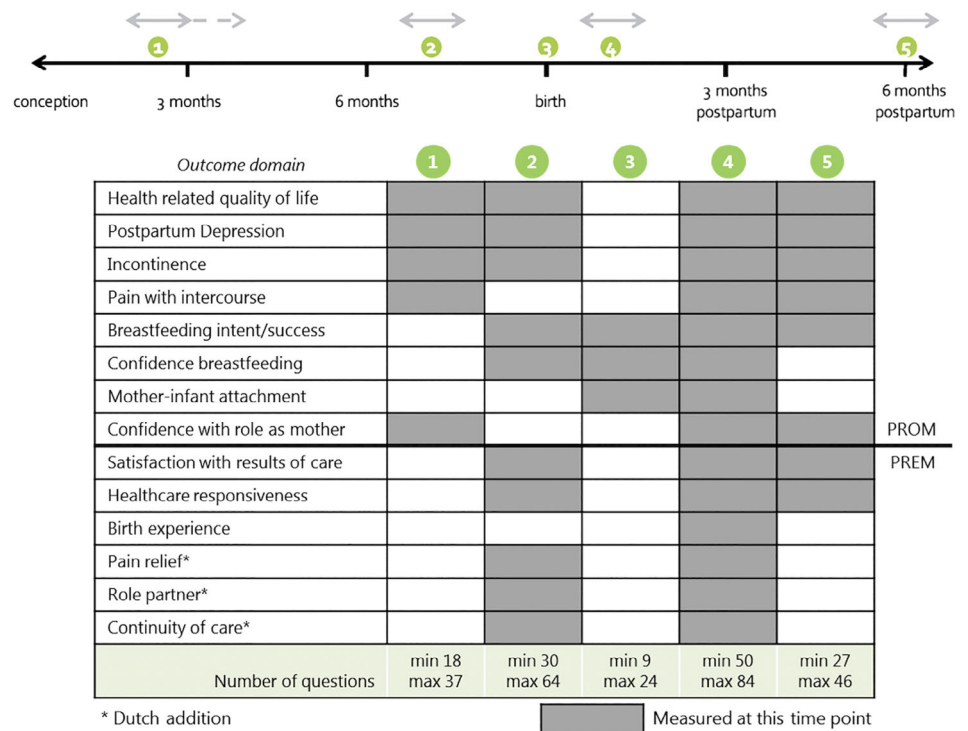


FIGURE 1 Timeline for ICHOM patient questionnaires. Legend: adapted from Nijagal et al¹²

To evaluate usability and experiences, separate evaluation surveys were composed for both patients and obstetric care professionals, regarding barriers and facilitators to using the PROM/PREM questionnaires in daily practice (Appendix B1 and B2). Both surveys were developed through a multidisciplinary focus group discussion with all involved stakeholders. The surveys consisted of multiple-choice questions, with regular opportunities to give free comments. They were collected digitally and anonymously using LimeSurvey, an open source survey tool.¹⁹ Women were invited for their evaluation survey directly after the visit in which they discussed their PROM/PREM questionnaire with their obstetric care professional. The obstetric care professionals received one survey at the end of the pilot period, evaluating all timepoints they had tested (with different women). Quantitative data were gathered and analyzed in Microsoft Excel (version 2010) using basic descriptive statistics. The qualitative data from the open-ended survey questions were subject of a thematic analysis along the survey-themes, to enrich the qualitative survey results.

3 | RESULTS

3.1 | Participants and baseline

Twenty-six women were approached to participate in the study, five of whom did not complete the pilot intervention. Two women that dropped out were excluded from the response analysis, as they did fill out their PROM/PREM questionnaire but could not return it to their care professional due to technical (internet) problems. Three women did not fill out their questionnaire, for different reasons: questions were considered too personal (at T1), fatigue (at T1), and unknown (at T3). Thus, overall response rate was 88% (21 of 24 women). Baseline characteristics of the participating women are presented in Table 1.

Six obstetric care professionals were included: four were employed in the hospital (two obstetricians; two clinical midwives) and two worked in primary care practices (community midwives). The midwives piloted all five timepoints. The obstetricians piloted only T2,

T4, and T5, as they did not have a consultation scheduled with a woman at T1 or T3 during the study period.

3.2 | Response and missing items

The PROM/PREM questionnaires were completed digitally by 14 of 21 women (67%) and on paper by seven cases (33%). As parts of the questionnaires are dependent on screening questions, the number of questions women had to answer differed at each timepoint (Table 2). Overall, a mean number of 34 questions had to be answered and their average completion rate was 97%. Per PROM/PREM instrument, the proportion of missing responses was 23% (3 of 13 women) for sexual function (*PROMIS-SSFAC102*); 14% (1 of 7) for breastfeeding confidence screening (*BFCONFID*); 12% (1 of 8) for fecal incontinence (*Wexner*); and breastfeeding self-efficacy (*BSES-SF*) was left blank in the one case where it should have been filled out (100%). All missing responses were found in questionnaires that had been filled out on paper. In these cases, women replied with a free comment in the margins that the question was not applicable to their situation.

3.3 | Evaluation surveys

All women that filled out and discussed the PROM/PREM questionnaires with their obstetric care professional completed also the evaluation survey afterward. All obstetric care professionals returned their evaluation survey.

3.3.1 | Patients' perspective: completing the questionnaires

Women's self-reported time to complete their PROM/PREM questionnaire was mean 10minutes (range 2-20 minutes), shown per timepoint in Table 2. Most women stated this time-investment was acceptable: 90% rated it "good" or "short." Seven women (33%)—of whom three had tested T4, two T3, one T2, and one T5—would not

TABLE 1 Baseline characteristics patients

		Patients across all timepoints (n = 21) N (%)		Patients per timepoint				
				T1 (n = 4)	T2 (n = 5)	T3 (n = 3)	T4 (n = 5)	T5 (n = 4)
Age (years)		32 IQR	28-34					
Ethnicity	Northern European	18	(85)					
	Mediterranean	3	(15)					
Parity	Primiparous	14	(67)	2	3	1	5	3
	Multiparous	7	(33)	2	2	2	0	1
Care setting	Primary care	9	(43)	3	2	1	2	1
	Hospital care	12	(57)	1	3	2	3	3

Note: T1 = first trimester; T2 = early third trimester; T3 = 3 days after birth; T4 = 5 weeks after birth; T5 = 6 months after birth.

TABLE 2 Patients' experiences and preferences

Completing questionnaires	Overall	T1	T2	T3	T4	T5
Number of questions <i>Mean (min-max)</i>	34 (9-59)	19 (17-21)	43 (31-54)	10 (9-10)	54 (51-59)	34 (27-46)
Completion rate (%) <i>Mean (min-max)</i>	97 (71-100)	100 (100-100)	94 (71-100)	97 (89-100)	98 (93-100)	99 (96-100)
Time to complete (minute) <i>Mean (min-max)</i>	10 (2-20)	9 (5-15)	13 (7-20)	4 (2-5)	14 (10-15)	10 (10-10)
		N (%)				
<i>Acceptability of time spent</i>						
Too long	1 (5)					
Long	1 (5)					
Good	17 (81)					
Short	2 (9)					
Too short	0 (0)					
<i>Willing to fill out all five time points</i>						
Yes	14 (67)					
No	7 (33)					
<i>Preferred device</i>						
Phone/Tablet (application)	8 (38)					
Phone/Tablet (website)	9 (43)					
Computer (website)	8 (38)					
On paper	2 (9)					
Other	0 (0)					
<i>Preferred location</i>						
At home	17 (81)					
Waiting room	3 (14)					
No preference	1 (5)					
<i>Use in clinical care</i>						
<i>Discuss PROM answers</i>						
All answers	7 (33)					
Only deviant answers	9 (43)					
Anonymous use	5 (24)					
Do not fill in at all	0 (0)					
<i>Discuss PREM answers</i>						
Discuss with care professional	17 (81)					
Only anonymous use	3 (14)					
Do not fill in at all	0 (0)					
No response	1 (5)					
<i>Preferred care professional</i>						
Midwife	62 (13)					
Gynecologist	5 (24)					
Other ^a	3 (14)					
<i>Transfer answers to new professional</i>						
Yes	17 (81)					
No	4 (19)					

(Continues)

TABLE 2 (Continued)

Completing questionnaires	Overall	T1	T2	T3	T4	T5
Statements: completing questionnaires		(strongly) agree ^b	neutral		(strongly) disagree	Total N
Goal clear	16 (76)		1 (5)		4 (19)	21
Explanation understood	18 (86)		1 (5)		2 (10)	21
Flyer clear	14 (78)		4 (22)		0 (0)	18
Understood questions well	19 (90)		1 (5)		1 (5)	21
Capable to fill in all questions	14 (67)		3 (14)		4 (19)	21
Pleasant to discuss with partner	9 (45)		9 (45)		2 (10)	21
Statements: use in clinical care		(strongly) agree ^b	neutral		(strongly) disagree	Total N
Pleasant to discuss with professional	14 (70)		5 (25)		1 (5)	21
Supports visit preparation	10 (50)		9 (45)		1 (5)	20
Easier to raise issues	12 (60)		7 (35)		1 (5)	20
Increased shared decision making	11 (58)		8 (42)		0 (0)	19
Better informed	13 (68)		6 (32)		0 (0)	19
Better relationship with professional	11 (52)		8 (38)		2 (10)	21

^aOther = no preference (n = 1); subject dependent (n = 1); nobody (n = 1).

^bStatements were rated on a 5-point Likert scale. For this table, ratings are summarized into three groups. See Appendix D (Figure D.1) for the full ratings.

be willing to complete the questionnaires at all five timepoints. Thematic analysis of open survey questions (Appendix C) indicated that these women mostly debated timepoint T3, just after birth; the other moments were perceived more acceptable. In general, women emphasized the need for a user-friendly system to complete the questionnaires digitally at home. Women repeatedly noted they would prefer to explain their answers in free text areas. Also, it was important that the time frame of questions is clear.

3.3.2 | Patients' perspective: utility in clinical care

The majority of women (76%) wanted to discuss their PROM answers with a care professional, and 81% their PREM answers (Table 2). Others would complete them for quality improvement only. Most women (86%) preferred an obstetric care professional to discuss their answers with—none of them chose their general practitioner, an obstetric nurse, or a preventive child healthcare provider. Few women did not want to discuss all domains with one professional, nor wanted all answers transferred in case of referral to a new care professional. Their main consideration, emerging from thematic analysis (Appendix C), was that specific domains are not relevant for a new situation or professional.

Over half of women recognized that PROMs helped them prepare for the visit (50%), their ability to raise issues (60%), shared decision making (58%), quality of information and patient-clinician relation (52%) (Table 2). Other women (31%-45%) were predominantly neutral about these potential benefits of discussing their answers. According to open-ended survey data (Appendix C), the value of discussing the answers might be lower if no issues emerge from the questionnaires, still women expressed motivation to fill them out for quality improvement purposes. At the same time, it was important to acknowledge

that discussing certain outcomes can be perceived over-alarming, such as the mother-child binding scale addressing emotions in the first week postpartum.

3.3.3 | Professionals' perspective: time investment

Time investment for obstetric care professionals was self-reported at each timepoint (Table 3). On average, discussing patient's answers took them 10 minutes (range 3-20 minutes). At two of five timepoints, the majority of professionals (50% at T1 and 75% at T5) felt they were short in time to discuss all issues raised in patient's questionnaires. Time spent on discussing the answers did not correlate with the amount of questions that patients had answered. Thematic analysis showed (Appendix C) this time was more dependent on the amount of issues raised. Professionals could also gain time because it was clear in advance which subjects were important for their patient to address. To attain this advantage, they debated that insight in the answers before the visit is crucial, emphasizing the need for a well-supporting IT system. Also, to relief their time burden, support of administrative staff was proposed, for example, in explaining the purpose and process of the questionnaires to patients.

3.3.4 | Professionals' perspective: utility in clinical care

According to most care professionals, either a midwife or gynecologist is the preferred professional to discuss the answers at all timepoints. Some professionals would assign T5 to the general practitioner or a nurse, reasoning this is not a regular part of perinatal care and the imbursement structure. However, from thematic analysis also

TABLE 3 Care professionals' experiences and preferences

Time investment	Overall	T1	T2	T3	T4	T5
Explain purpose (minutes) <i>Mean (min-max)</i>	5 (1-10)	-	-	-	-	-
Discuss answers (minutes) <i>Mean (min-max)</i>	10 (3-20)	10 (7-15)	8 (3-15)	6 (3-10)	10 (5-15)	15 (10-20)
Statements: utility per timepoint	T1 (n = 4)	T2 (n = 4)	T3 (n = 2)	T4 (n = 5)	T5 (n = 4)	
Knew what to discuss	N (%)	N (%)	N (%)	N (%)	N (%)	
(strongly) agree ^a	4 (100)	3 (75)	2 (100)	5 (100)	4 (100)	
neutral	0 (0)	1 (25)	0 (0)	0 (0)	0 (0)	
(strongly) disagree	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
Recognized deviant answers						
(strongly) agree	3 (75)	4 (100)	2 (100)	4 (80)	4 (100)	
neutral	1 (25)	0 (0)	0 (0)	1 (20)	0 (0)	
(strongly) disagree	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
Knew what to do if deviant						
(strongly) agree	2 (50)	4 (100)	2 (100)	4 (80)	4 (100)	
neutral	1 (25)	0 (0)	0 (0)	1 (20)	0 (0)	
(strongly) disagree	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	
Felt responsible						
(strongly) agree	1 (25)	2 (50)	0 (0)	3 (60)	1 (25)	
neutral	1 (25)	0 (0)	1 (50)	0 (0)	2 (50)	
(strongly) disagree	2 (50)	2 (50)	1 (50)	2 (40)	1 (25)	
Statements: utility overall (n = 6)		(strongly) agree ^a N (%)	neutral N (%)		(strongly) disagree N (%)	
Goal clear		6 (100)	0 (0)		0 (0)	
Capable of explaining the purpose		5 (83)	1 (17)		0 (0)	
Usable		4 (67)	2 (33)		0 (0)	
Supports signaling symptoms		6 (100)	0 (0)		0 (0)	
Supports identify what matters to my patient		5 (83)	1 (17)		0 (0)	
Supports appropriate care		6 (100)	0 (0)		0 (0)	
Supports relationship with patient		2 (33)	3 (50)		1 (17)	
Supports patient empowerment		1 (17)	4 (67)		1 (17)	
Supports insight in quality of care		1 (17)	5 (83)		0 (0)	
Need real-time insight answers		4 (67)	0 (0)		2 (33)	
Need answers directly in EPD		2 (33)	3 (50)		1 (17)	

^aStatements were rated on a 5-point Likert scale. For this table, ratings are summarized into three groups. See Appendix D (Figure D.2 and D.3) for the full ratings.

emerged (Appendix C) that assigning T5 to an obstetric care professional could be more valuable to both patients and professionals, for evaluation of health status and care given.

Preferences about how to discuss the answers with patients differed little between professionals: if a patient agrees, all of them would discuss deviating answers. In case of deviating answers, most professionals preferred to have standardized information or referral options. At each timepoint, all obstetric care professionals stated they knew what to discuss and what to do in case of deviant answers (Table 3). Yet, it varied widely among professionals whether they felt it as their responsibility to notice and discuss or act upon the

responses. This theme arose in qualitative analysis as well (Appendix C), as professionals emphasized the importance of a clear structure or agreements about their responsibilities. Also, they considered it helpful to share thoughts with colleagues about how to discuss the outcomes with their patients.

Most of the professionals agreed that the PROMs supported the detection of symptoms, contributed to more appropriate care and identifying subjects that matter a patient (Table 3). Professionals rated other possible effects of PROMs rather neutral. How professionals value PROMs also appeared from thematic analysis (Appendix C), indicating better insight in subjects that are important to their

patients and easier detection of psychological issues or pelvic floor problems.

4 | DISCUSSION

In this pilot, we studied the feasibility to use patient-reported outcomes and experiences in perinatal care. Utilizing the PCB sets' PROMs and PREMs as part of routine care, we found good compliance to the questionnaires, acceptability of time burden, and usability in clinic. In patients' and professionals' experience, patient-reported items can be valuable to perinatal care through symptom detection, patients' ability to raise issues and more personalized care.

To the majority of participating women, the time to complete the questionnaires (mean 10 minutes) was acceptable, while patient burden was considered a potential barrier in advance.²⁰ Furthermore, most women were willing to participate at all timepoints in case of future implementation. However, as one-third of the women considered the timepoint just after birth (T3) too burdensome, the added value of timepoint T3 should be evaluated concisely. Still, the response rate was 88% across all timepoints. Non-response correlated with fatigue or, at T1, the questions were considered too personal to share with a care professional, indicating the urge to explain the questionnaires' purpose well. Although with a different purpose, another experience questionnaire in perinatal care reached a 32% response rate.²¹ Compared to this questionnaire, the PCB sets' PROMs and PREMs are used to support individual care instead of care improvement only, which might explain the higher compliance. Also used directly in a clinical setting, the questionnaires of the Osteoarthritis ICHOM set were reported a 71% response rate 3 months post-surgery.⁵ Further possible explanation for our high response rate could be the relatively young and positively engaged population in perinatal care, familiar with digital devices. However, with further implementation, compliance might decrease as this pilot was carried out with dedicated clinical staff in a purposive sample of patients.

Analyzing each domain, the only high missing response rate (23%) was found for "pain with sexual intercourse"—assessed with PROMIS-SSFAC102 at T1, T4, and T5. As most missing responses were found at T4 (6 weeks postpartum), this missing rate could be explained by 20% of women not having reinitiated intercourse 3 months postpartum.²² Although sexual activity is not required to be able to answer the question according to its developers,²³ these results suggest otherwise. However, this domain also addresses a relative taboo and deserves attention in further implementation.

According to participating care professionals, their time in daily clinic to discuss patients' answers was sufficient at most timepoints, except for T5 (6 months postpartum) when current perinatal care and its reimbursement structure has ended. However, women in this pilot clearly preferred to discuss the results obtained at T5 with their obstetric care professional, instead of their general practitioner for example. Moreover, women and professionals did value the evaluation of health status and provided care at this timepoint, both in our pilot and at previous exploration.¹¹ Thus, although potentially

valuable, feasibility of consultation at T5 is questionable, requiring to adapt current care pathways.

Relative advantages of discussing individual outcomes in clinical practice were experienced by both women and professionals, acknowledging it could improve insight in health status and support appropriate, personalized care. These findings correspond with a comprehensive review on how PROMs support patient-clinician communication in oncologic care.⁴ Yet, PROMs' contribution to patient-clinician relationship was rated fairly neutral in our study, possibly caused by the PCB outcome set containing standardized, rather than individualized PROMs (that allow patients to select domains of most relevance to themselves), which have been assumed less supportive for building patient-clinician relationships.⁴ Interestingly, women preferred to discuss both their PROM and PREM responses, whereas sharing individual PREM answers was considered a potential barrier to patients and would yield socially desirable answers.¹¹

Although promising benefits were recognized for use in clinical practice, our findings emphasize the need for a well-supporting IT tool in perinatal care. First, filling out questionnaires was preferably done digitally at home, pertaining to a generation of women reaching their fertility years that are profound users of internet, smartphones, and applications.²⁴ Still, subgroups with lower socio-economic status or migration backgrounds deserve attention and might need in-clinic support. Additionally, real-time data have to be easily accessible for professionals to gain the full potential of PROMs and keep the administrative burden minimal. Furthermore, sharing responses across the care system should be facilitated, as both women and professionals argued this is essential for individual patient value in the complex birth care network. Eventually, merging patient-reported data with clinician-reported outcomes on an aggregate level will be challenging, but essential to future use of the PCB outcome set in shared decision making, quality improvement, benchmarking, and value-based birth care.

To facilitate further implementation in perinatal care, agreements on responsibility and actions upon patients' answers were identified as key factors, ensuring continuity of care and follow-up. For participating professionals, what issues to discuss and how to act upon them was clear, suggesting good acceptability and usability. However, whether professionals felt it their responsibility to notice and discuss or act upon responses differed widely per timepoint. This could be related to the relatively short period of care or the moments of measurement; but might also be caused by some questionnaires concerning general topics that healthcare specialists are not used to incorporate in their tasks. Several solutions were raised by professionals, such as appointing a principal obstetric professional to discuss responses with and creating standard referral options for different outcomes. For the latter, thresholds for each outcome have to be established for this population at all timepoints.

Despite its small sample size, a strength of this feasibility study was to involve both women and care professionals across the perinatal care network this early in the implementation process. Thereby, this article provides an important preliminary view of their experiences and preferences using PROMs and PREMs in routine perinatal

care, which can support further implementation and engage new stakeholders. An important limitation of our study was patients completing only one of the five timepoints, as the pilot was limited to a 3-month period. Assessing all timepoints in each woman may affect perceived questionnaire burden and response rates; as women receive more questions on one hand, but on the other, become more familiar with filling out and discussing the questionnaires as care-usual over the course of pregnancy. Although carried out in the Dutch perinatal care setting, our findings can provide practical information for other regions planning to implement this international standard set.

The main implication for practice emerging from this pilot is the expected benefit of implementing the PCB outcome set in routine care, as women and professionals expressed the value of discussing its PROMs and PREMs individually. The added value for patients and professionals should be evaluated, with attention to specific timepoints, subjects, and professionals' responsibilities. This could not only identify necessary adaptations to the PCB set but also create tension for change in structural aspects needed to reach sustainable implementation, such as IT-systems and care pathways. At the same time, the PCB outcome set has been assessed on an aggregate level in Kenia recently.²⁵ Even though adapted to both Kenyan and Dutch setting, an international standard set creates future opportunities for benchmarking and improvement of the birth care system.

In conclusion, both women and obstetric care professionals consider the PCB set as a feasible instrument for PROM and PREM assessment with good compliance, acceptability, and usability, with the promise to improve perinatal care. Important determinants for successful clinical implementation are a well-equipped supporting IT tool, agreements regarding responsibilities of different professionals, and guidance in how outcomes are discussed or acted upon. Timing of the T5 questionnaire is an important barrier for implementation in current practice. Future research should focus on implementation, identify barriers and facilitators to improve integration in clinical practice, and evaluate the effect on shared decisionmaking, patient empowerment, and clinical outcomes.

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CONFLICTS OF INTEREST

Arie Franx was part of the ICHOM PCB outcome set Working Group. The other authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

Formal analysis and visualization: Alies Depla

Funding Acquisition: Arie Franx, Hiske Ernst, Mireille Bekker

Methodology: Mireille Bekker, Alies Depla, Hiske Ernst, Arie Franx

Resources: Alies Depla (performed the acquisition of participants)

Writing - Original Draft preparation: Alies Depla, Mireille Bekker

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All authors read and approved the final manuscript. The manuscript has not been submitted elsewhere.

TRANSPARENCY STATEMENT

The manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted; and any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DATA AVAILABILITY STATEMENT

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval for this study was granted by the University of Utrecht Ethics Committee (Reference number 19-104/C; approval granted 12/02/2019). Patients signed informed consent before participation to this study.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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