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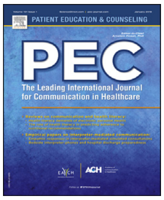

Exploring the applicability of the pregnancy and childbirth outcome set: A mixed methods study

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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.

1. 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

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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.

2. Methods

2.1. 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

Note: 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.

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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.

2.2. Survey

2.2.1. 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 e-mail.

2.2.2. 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).

2.2.3. Analyses

Quantitative data were analyzed using descriptive statistics, with SPSS version 24.0 (IBM Corp., Armonk, N.Y., USA). Free text answers were themed.

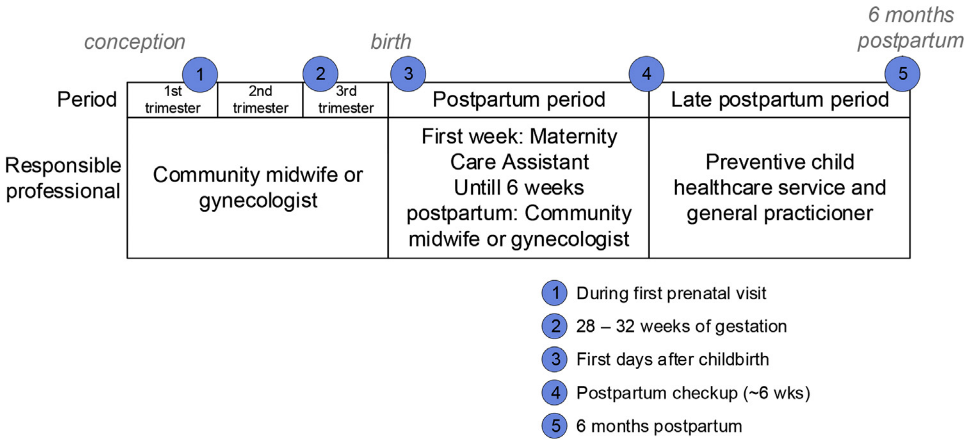

Fig. 1. Data collection time points and perinatal professionals in the Netherlands.
The blue dots indicate the data collection time points during pregnancy and postpartum. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

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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.

2.3. Focus groups

2.3.1. 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.

2.3.2. 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.

2.3.3. 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 B.1) 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.

2.3.4. 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).

Reporting followed the Consolidated criteria for reporting qualitative research (COREQ) [23].

2.4. 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.

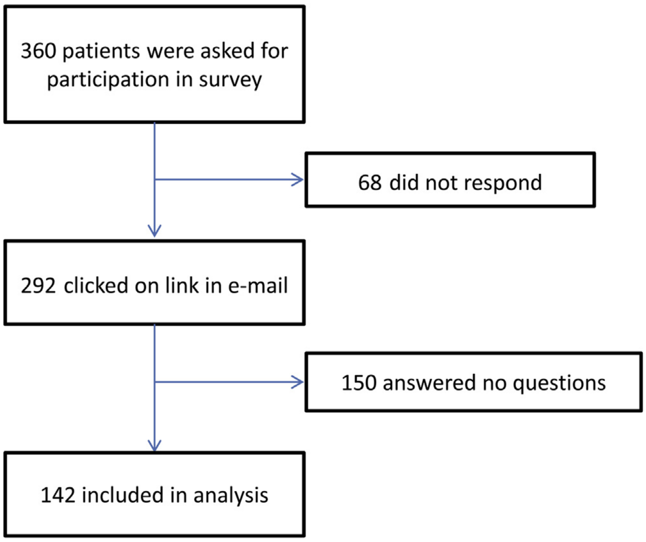

Fig. 2. Survey flowchart participating patients.

3. Results

3.1. Survey

3.1.1. 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.

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 [a]	
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 [b]	
Pregnancy	33 (24)
Childbirth	26 (34)
Puerperium	7 (15)

[a] 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.
[b] Complications could occur during pregnancy, childbirth and/or puerperium, multiple answers were possible.

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

	Professionals (n = 134) N (%)	Administrators (n = 35) N (%)
Profession		
Gynecologist [a]	17 (13)	–
Neonatologist [a]	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)	–

Note: OCN: obstetric collaborative network.
[a] Specialists and residents in training.

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)

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).

3.1.2. 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).

3.1.3. 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 administrators 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.

3.1.4. 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.

3.2. Focus groups

3.2.1. Study population

Characteristics of participants of the three focus groups are displayed in Supplementary table C.1, C.2 and C.3.

3.2.2. 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

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)

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

	Patients	Professionals	Administrators
	Total		
	N (%)	N (%)	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)
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)

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.

3.2.3. 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. 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 .

3.2.4. 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 .

3.2.5. Implementation of the PCB outcome set

A 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

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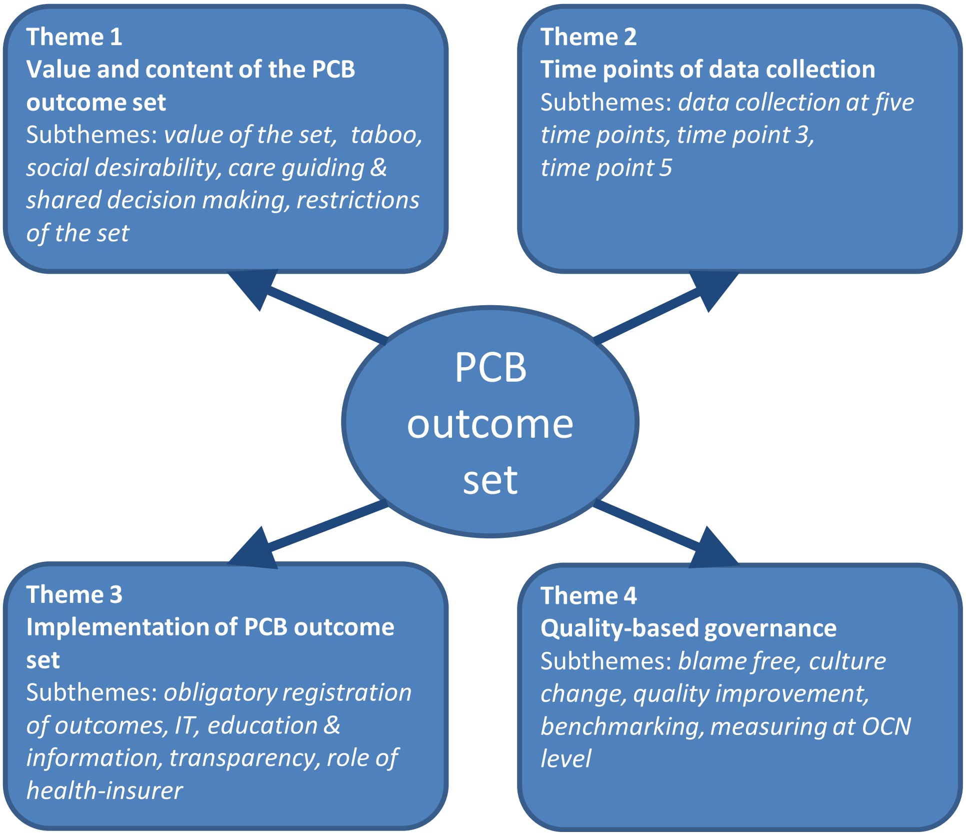

Fig. 3. Main themes and their subthemes on the applicability of the PCB outcome set derived from the focus groups.

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)*

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)*

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

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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)*

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)*

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 .

3.2.6. Quality-based governance

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 is more within reach with the PCB outcome set. However, they emphasized that comparing outcomes within 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 .

4. Discussion and conclusion

4.1. 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

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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.

4.2. 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.

4.3. 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 end-users 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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Declaration of Competing Interest

AF was part of the ICHOM PCB outcome set Working Group. The other authors have no conflicts of interest to report.

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I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi: https://doi.org/10.1016/j.pec.2019.09.022.

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