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Authors

Korst, Lisa

Fridman, Moshe

Saeb, Samia

et al.

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RESEARCH ARTICLE

The Development of a Conceptual Framework and Preliminary Item Bank for Childbirth-Specific Patient-Reported Outcome Measures

Lisa M. Korst, Moshe Fridman, Samia Saeb , Naomi Greene, Arlene Fink, and Kimberly D. Gregory

Objective. To develop a conceptual framework and preliminary item bank for childbirth-specific patient-reported outcome (PRO) domains.

Data Sources. Women, who were U.S. residents, ≥ 18 years old, and ≥ 20 weeks pregnant, were surveyed regarding their childbirth values and preferences (V&P) using online panels.

Study Design. Using community-based research techniques and Patient-Reported Outcomes Management Information System (PROMIS[®]) methodology, we conducted a comprehensive literature review to identify self-reported survey items regarding patient-reported V&P and childbirth experiences and outcomes (PROs). The V&P/PRO domains were validated by focus groups. We conducted a cross-sectional observational study and fitted a multivariable logistic regression model to each V&P item to describe “who” wanted each item.

Principal Findings. We identified 5,880 V&P/PRO items that mapped to 19 domains and 58 subdomains. We present results for the 2,250 survey respondents who anticipated a vaginal delivery in a hospital. Wide variation existed regarding each V&P item, and personal characteristics, such as maternal confidence and ability to cope well with pain, were frequent predictors in the models. The resulting preliminary item bank consisted of 60 key personal characteristics and 63 V&P/PROs.

Conclusions. The conceptual framework and preliminary (PROMIS[®]) item bank presented here provide a foundation for the development of childbirth-specific V&P/PROs.

Key Words. Childbirth, patient expectations, satisfaction, patient-reported outcomes, patient-centered outcomes research

With nearly 4 million births annually (Hamilton et al. 2015), childbirth is the number-one reason for hospital admission (McDermott et al. 2017), and women rely on the medical system to provide them with safe and appropriate

care. Childbirth clinical outcomes are a top public health challenge given that rates of severe maternal morbidity (e.g., renal failure, pulmonary embolism, blood transfusion) (Centers for Disease Control and Prevention 2016), and mortality (Centers for Disease Control and Prevention 2017) have been rising and that racial/ethnic disparities have been widening in recent years (Creanga et al. 2014; Fridman et al. 2014). Safety concerns are real: One in five low-risk women experiences maternal or newborn morbidity, and composite hospital morbidity rates exhibit a wide variation (range 3 percent–58 percent), in addition to cesarean morbidity (Gregory et al. 2009; Korst et al. 2014).

There are multiple initiatives to develop national strategies to make childbirth safer (American College of Obstetricians and Gynecologists 2015; California Maternal Quality Care Collaborative 2017; Council on Patient Safety in Women's Health Care 2017; Ohio Perinatal Quality Collaborative 2017). However, these efforts have contributed to a gap between what hospitals believe is needed for safety and what women believe is an optimal childbirth experience (Green, Coupland, and Kitzinger 1990; Goodman, Mackey, and Tavakoli 2004; Rudman, el-Khoury, and Waldenstrom 2007; Bryanton et al. 2008; Childbirth Connection 2013; Mei et al. 2016). Patient-centered outcomes (defined by the Institute of Medicine [now the National Academy of Medicine] as distinct from clinical outcomes and including dimensions such as respect, communication, and physical comfort [Institute of Medicine 2001]) have received less attention than safety issues but are a complementary component of health care quality measurement (Bowling et al. 2012; Lloyd et al. 2014). Details regarding which patient-reported data are most meaningful require development (Deutsch et al. 2012; National Quality Forum 2017a).

The Patient-Reported Outcomes Management Information System (PROMIS[®]) was funded by the National Institutes of Health in 2004 to develop standardized methods for measuring patient-reported outcomes (PROs), and the production of banks of standardized and validated survey items that correspond to various health domains (Cella et al. 2007). To date, PROs have largely been used for clinical research purposes and to guide

Address correspondence to Kimberly D. Gregory, M.D., M.P.H., Department of Obstetrics and Gynecology, Cedars-Sinai Medical Center, Burns Allen Research Institute, Los Angeles, CA; e-mail: Kimberly.Gregory@cshs.org. Lisa M. Korst, M.D., Ph.D., is with Childbirth Research Associates, LLC, Los Angeles, CA. Moshe Fridman, Ph.D., is with AMF Consulting, Los Angeles, CA. Samia Saeb, M.P.H., C.C.R.P., and Naomi Greene, Ph.D., are with the Department of Obstetrics and Gynecology, Cedars-Sinai Medical Center, Burns Allen Research Institute, Los Angeles, CA. Arlene Fink, Ph.D., is with the Division of General Internal Medicine and Department of Health Policy Management, University of California Los Angeles, Los Angeles, CA.

clinical care (Cella et al. 2012). But now, PROs are becoming integrated into “performance measurement” of hospitals and care providers (Centers for Medicare and Medicaid Services 2011, 2017; Miller and Klein 2015).

Our goal was to apply the PROMIS[®] methodology to describe what women most want from childbirth services and, in doing so, provide a foundation for childbirth hospital performance measurement. Our specific objectives were (1) to document the breadth of women’s childbirth health services values and preferences; (2) to conduct a national antepartum survey to test the prevalence, distribution, and statistical significance of PRO items in the framework domains; and (3) to use this information to develop a conceptual framework and preliminary item bank to evaluate women’s childbirth values and preferences.

METHODS

This study complied with all stipulations for human subjects research under Cedars-Sinai Medical Center Institutional Review Board protocol #Pro00037750. The Childbirth PRO Partnership, a group of community partners that included health services providers, health and policy advocates for pregnant women, and currently pregnant or recently pregnant women, participated in all research activities. PROMIS[®] methodology for the development of PRO preliminary item banks was used as the basis for the research approach (De Walt et al. 2007; Patient-Reported Outcomes Measurement System 2013). Briefly, this study followed PROMIS[®] methodology to complete the first stage (Stage 1 of five stages) of the PROMIS[®] Instrument Maturity Model. In this first stage, the item domains are identified and a preliminary item bank is defined and mapped to these domains. Upon completion of Stage 1, items are ready to be further tested for reliability and validity in multiple diverse populations in stages 2–5 (not addressed here).

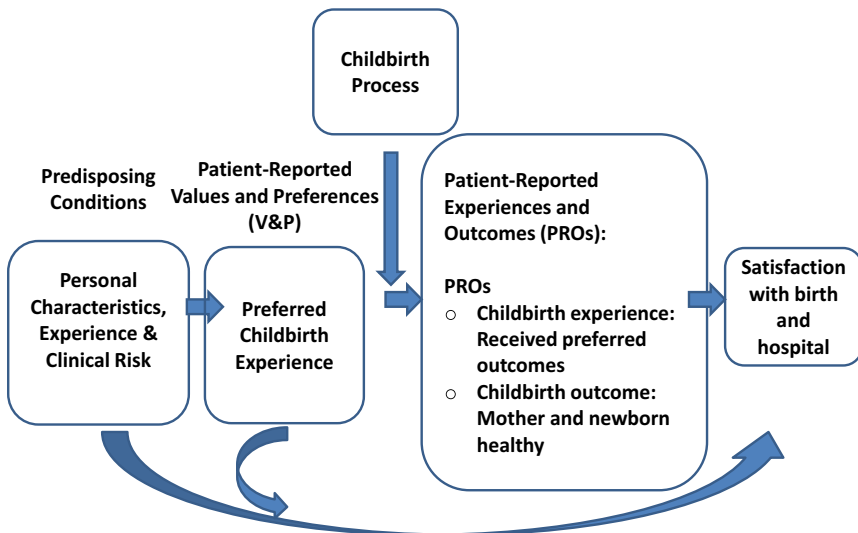
Objective 1: To Document the Breadth of Women’s Childbirth Health Services Values and Preferences

Conceptual Framework for Elaborating PROMIS[®] Domains. As the creation of a childbirth-specific PRO item bank had not been previously approached, we advanced a conceptual framework that could be built on empirically using the PROMIS[®] guidelines (De Walt et al. 2007; Patient-Reported Outcomes

Measurement Information System [PROMIS®] 2013). Based on Andersen's Behavioral Model of Health Services Use (Andersen 2008) and elaborated by multiple theoretical guidelines regarding health expectations and service preferences, health information-seeking, satisfaction, and patient-centered and childbirth outcomes (Sitzia and Wood 1997; Staniszewska 1999; Mead and Bower 2000; Schwarzer and Renner 2000; Goodman, Mackey, and Tavakoli 2004; Janzen et al. 2006; Lyerly et al. 2007), our conceptual framework for this study is presented in Figure 1.

As depicted in Figure 1, we posited that predisposing conditions (e.g., women's prior childbirth experience, personal characteristics, and clinical risk) generate values and preferences (V&P) for the services desired. Upon giving birth, women assess whether these V&P were fulfilled. Finally, women provide summary measures of their satisfaction with their birth and hospital services. These measures are hypothesized to be dependent on (1) predisposing conditions, (2) values and preferences (V&P), and (3) patient-reported experiences and outcomes (PROs) (Cella et al. 2015). V&P capture the concept of "value expectations" (patients' desires, hopes, or wishes concerning clinical events) (Uhlmann, Inui, and Carter 1984; Kravitz 1996). For brevity, we will refer to all "value expectations" as V&P.

Figure 1: Conceptual Framework for Determining Patient-Reported Outcomes (PROs) in Childbirth [Color figure can be viewed at wileyonlinelibrary.com]



This framework implies that, although PROs have been the focus of quality improvement efforts, V&P may be equally or more important in predicting the overall patient experience of childbirth. For example, if a pregnant woman desired a vaginal birth (V&P item), postpartum follow-up would indicate whether she had a vaginal or cesarean birth (PRO item). Satisfaction may depend on either the V&P item or the PRO item or a combination of the two. For the example, satisfaction may depend most strongly on wanting a vaginal birth, actually getting a vaginal birth, wanting and getting a vaginal birth, or wanting and not getting a vaginal birth. All these possibilities must be tested in the analysis plan. We used this framework as a basis for implementing the PROMIS[®] methodology, beginning with the literature review.

Identification of Specific Items That May Be Relevant to Either: (1) V&P, (2) PROs, or (3) Predisposing Conditions That May Affect the PROs. Working with a medical librarian, and relying on Figure 1, we set up a standardized search to perform a comprehensive literature search in PubMed from 1975 to 2014 for English-language patient-reported survey items associated with childbirth and the immediate postpartum period, adapting the approaches used by other PROMIS[®] investigators (De Walt et al. 2007; Klem et al. 2009; Terwee et al. 2009; Patient-Reported Outcomes Measurement Information System [PROMIS[®]] 2013; Khanna et al. 2014). Because our goal was to capture items that reflected the breadth of women's childbirth priorities, we did not assess studies for quality or synthesize study results.

The title and abstract (TIAB) of the first 1,700 articles were read by two investigators who refined the relevance criteria. Criteria that were explicitly required for inclusion of studies were as follows: questionnaires that included patient-reported items; publication in English; focus on women's assessment of the childbirth experience or the consequences of childbirth that occurred during the hospital experience; and relevance to US health care. Criteria for specific exclusion of studies were as follows: editorials, letters, news, or opinion pieces; primary focus not related to patient assessment of her experience (e.g., no trials regarding drugs or specific clinical interventions); discussion of questionnaires in languages other than English or Spanish; case studies of individuals, natural disasters, or epidemics; investigations of factors affecting conception or desire for pregnancy; and lack of results or questionnaire items (e.g., no qualitative studies).

In addition, relying on our conceptual framework, we abstracted items related to "predisposing conditions," such as personal characteristics, pregnancy/delivery history, and prior experiences with childbirth services.

Two investigators reviewed the TIAB from all retrieved studies, and articles meeting relevance criteria by either investigator were retained. The full text of all potentially relevant studies was retrieved and reviewed for relevance; if found to be relevant by at least one reviewer, an article was retained and included in a study database.

Starting with the conceptual framework, and elaborated by the literature search, we created a list of PRO domains or “bins” relevant to childbirth (Cella et al. 2007; De Walt et al. 2007). Then, we abstracted potentially relevant survey items, mapping each item to its appropriate bin. At the framework level, these domains generally housed both V&P and PRO items. For example, if an item asked a pregnant woman her preference for route of delivery, this item was mapped to the “Delivery Route” domain. If an item asked a postpartum woman the route of her delivery, this item was also mapped to the “Delivery Route” domain. Some domains, such as Pain Assessment or Satisfaction, housed only postpartum items because these items could only be asked after the delivery.

We modified bins and added new bins for items that did not easily fit into an existing bin. We also created sub-bins within each domain. This resulted in a series of bins and sub-bins for categorizing the retrieved items and a list of individual items within each bin. These bins became synonymous with “domains” of the conceptual framework.

At the end of this binning process, we had created domains of the conceptual framework. Most domains included both V&P and PRO items. The PRO items included both patient-reported experiences and outcomes.

“Winnowing” is the elimination of items that do not have face validity or which are redundant (De Walt et al. 2007; Patient-Reported Outcomes Measurement Information System [PROMIS[®]] 2009). The goal of winnowing was to identify a limited set of items representative of the domains identified in the literature and ranked as important using a modified Delphi method by the Childbirth PRO Partnership. We divided the bins among four teams, each consisting of at least one investigator and up to three community partners. All the community partners and investigators had an opportunity to weigh in on the domains and items.

The process generated a final set of items. We also identified survey items reflecting predisposing conditions so that the data collected could describe “who wants what,” where “what” represented the V&P/PRO items and “who” represented women’s predisposing conditions (e.g., personal characteristics or beliefs) that might vary in association with these V&P/PROs.

We conducted eight focus group sessions to understand women's experiences in depth and to identify additional important outcome domains. Participating sites included the following: San Judas Clinic (Spanish-speaking women), Pasadena Black Infant Health Program (African American and Hispanic women), New Life Midwifery and BINI Birth (women anticipating delivering at home or at a birth center), Harbor-UCLA Medical Center (women insured by Medicaid), USC Perinatal Group (Asian American women), and Cedars-Sinai Medical Center (mixed group).

Focus group participants were at least 18 years old, pregnant or recently pregnant (less than 1 year postpartum), and living in the United States. Eligible participants recruited by our community partners represented diverse sociodemographic and socioeconomic populations. We deliberately selected participants representative of specific childbirth communities (i.e., Hispanic, Spanish speaking, African American, Asian, low income, or college educated).

We organized and facilitated our focus groups in collaboration with The Childbirth PRO Partnership and conducted sessions in English and Spanish. Our sample size was prospectively determined using qualitative saturation methods (Glaser and Strauss 1967). A community partner (or designee) cofacilitated all focus groups in a community partner facility utilizing a standardized script and guide. The script ensured that all participants received the same disclosure information and rules of conduct. The guide specified the objectives and research questions, provided a general timeline, and outlined probes to maximize group participation.

The focus groups were conducted in-person between June and November 2015 and lasted approximately 60 minutes. Each participant received a \$50 Target gift card for attending the session. With permission of the participants, we recorded the sessions, transcribed, and entered them into *Atlas.Ti*, a computer-assisted qualitative data analysis and research software (Version 7.1.1, USA).

We used a grounded theory approach to our data (Patton 1999, 2001). Several investigators and members of the Childbirth PRO Partnership reviewed the data and collaboratively identified emerging themes. Two independent reviewers mapped participant responses to the domains identified in the literature search (code-by-list) and used the *Atlas.Ti* code manager to identify the most referenced domains. We categorized major and minor themes under the bins described above and created additional bins as needed, as well as modifying the conceptual framework and domain definitions with respect to the themes that surfaced in the qualitative data analysis.

Objective 2: To Conduct a National Antepartum Survey to Test the Prevalence, Distribution, and Statistical Significance of PRO Items in the Framework Domains

Survey Development and Administration. We developed and administered a national survey using a subset of the predisposing conditions and V&P identified in Objective 1. Prior to administration, we piloted the resulting instrument among 30 English-speaking women (Fink 2005), assessing content and construct validity, interpretability, and respondent and administrative burden for use in online administration. We conducted the pilot survey in person using individual laptops and online via videoconferencing. Community partners cofacilitated all sessions. We edited or removed survey items per participant feedback.

We created a Spanish version using a professional translation service and piloted it among women with Spanish as their primary language using similar methods.

Survey completion time was <30 minutes. Responses for items in the predisposing condition domains were formatted individually. Responses for items in the V&P domains were constructed on a 5-point Likert scale, for example, “not at all important” to “extremely important,” or “strongly disagree” to “strongly agree.”

All U.S. pregnant women ≥ 18 years old who had completed at least 20 weeks of gestation were eligible. The Nielsen Company (Nielsen) recruited women through their online panels (Critical Mix, Survey Sampling, Market Cube, Peanut Labs, and Prodege), and data were weighted to more closely represent the demographics of U.S. reproductive age women (Nielsen Company 2017).

Nielsen sent potential participants an e-mail invitation containing a unique URL, and respondents were screened to determine their eligibility. Eligible respondents proceeded with the survey and received weekly reminders if they did not respond. The online survey was administered from secure servers using digital fingerprint technology to prevent duplicate entries. Nielsen designated all eligible participants who completed a subset of mandatory items as having “completed” the survey. Nielsen had specific protocols to assure survey completeness and the distribution of incentive payments (approximately \$15 cash equivalent in Nielsen points). Nielsen monitored survey completeness on a weekly basis and left the survey open until the goal of at least 2,700 completed surveys was reached. Incomplete surveys were not analyzed.

Analytic Methods. We weighted the national survey data to replicate the distribution of demographic variables from the 2011–2013 National Survey of Family Growth (Centers for Disease Control and Prevention 2014) and the 2014 Current Population Survey (United States Census Bureau and United States Bureau of Labor Statistics 2014), and by Nielsen’s proprietary propensity score to mitigate potential selection bias because of online recruitment methods.

Women who planned to have a cesarean delivery or who planned to deliver at home or in a birth center are not described here because of small sample sizes that did not allow for factor analysis or modeling. We used subpopulation analysis methods for weighted data to compute statistics for the women anticipating or considering vaginal delivery in a hospital. This is the most prevalent and relevant delivery expectation for American women. Subpopulation analysis methods are needed as we derived the data weights for the full sample, not for sample subsets. Statistical analysis was performed using SAS, version 9.3 (Cary, NC, USA). All analytical tests were two-sided. Means are reported with standard deviations (SD).

Exploratory Factor Analysis. We performed an exploratory factor analysis to evaluate the domains of predisposing conditions and V&P, and to establish construct validity. We performed factor analysis for the V&P items using both a segmented factor analysis to validate the anticipated domains, and an overall analysis (to allow for potential shifting of closely related questions from one domain to another).

We used standard criteria to determine the number of factors and which items loaded to a factor. We applied distinct oblique rotations and selected the rotation providing better factorization in terms of separation of loadings for continued evaluation. We also tested Cronbach’s alpha correlation as a measure of internal validity for each factor. The final set of factors was selected based on empirical fit and confirmed face validity with the Childbirth PRO Partnership, retaining factor-based scores (total score for items included divided by the number of items in the factor) for subsequent analyses, and items that did not load on any factors.

Descriptive Analysis. We examined the continuous distribution of each V&P item and factor. To simplify analysis and interpretation of the results, the investigators determined whether the ordinal or interval scale responses could be categorized as either two-level or three-level variables. Two-level variables were used when a V&P item exhibited a monotonic preference or trend, and

three-level variables were used for V&P items that had a U-shape or mound-shape distribution preventing binary collapsing. In general, and if possible for the two principal response scales, scores 1–3 were collapsed versus scores 4–5. Bivariate analysis was performed for each V&P by all key predisposing conditions.

Modeling. For each V&P item, we performed multivariable logistic regression modeling (generalized logistic for three-level items) to identify the associated predisposing conditions. Each model contained the following variables: maternal age, race/ethnicity, educational level, US region, parity (nulliparity/multiparity with no prior cesarean/ prior cesarean), any medical/pregnancy-related complications, gestational age at the time of the survey, and multiple gestation. To limit the number of additional predisposing conditions assessed in each model, we entered in an item's model only those conditions associated with the V&P item resulting in a $p < .05$ in bivariate analysis.

Objective 3: Using the Study Data, Finalize the Conceptual Model and Preliminary Item Bank

The selected items were then formatted in a uniform style using published PROMIS[®] standards (De Walt et al. 2007). We then performed cognitive debriefing for content validity of the items (Patient-Reported Outcomes Management System 2013). On the basis of additional discussion with the Childbirth PRO Partnership as well as interviews with pregnant and postpartum women, we crafted a final iteration of the preliminary item bank, specifying the relevant domains in the conceptual framework. The final childbirth-specific preliminary item bank included items specifying V&P, PROs, and predisposing conditions.

RESULTS

Objective 1: To Document the Breadth of Women's Childbirth Health Services Priorities

Building on the initial conceptual framework, the search strategies identified 5,102 unique titles, and from these, we identified 5,902 relevant V&P/PRO items. In collaboration with the Childbirth PRO Partnership participants, we categorized these items into 19 domains and 58 subdomains (Table 1). We conducted a total of eight focus groups with 45 women of varying age, race/ethnicity, socioeconomic backgrounds, and U.S. regions. Each focus group

Table 1: Initial Domains and Subdomains Identified through Literature Review and Focus Groups, and the Number of Items per Domain

<i>Domains, N = 19</i>	<i>Subdomains, N = 58</i>	<i>Total Items (N = 5,902)</i>
Clinical concerns	Provider competence; safety; preterm labor; intrapartum complications; indication for cesarean delivery; maternal and newborn clinical outcomes; additional maternal/neonatal hospitalization	259
Communication	Communication with providers regarding labor and delivery, and regarding newborn	181
Confidence	Confidence/self-efficacy	109
Continuity	Continuity of care/care coordination; provider availability	96
Decision making	Decision making and birth plans; maternal control	395
Empathy	Cultural competence; discrimination; provider empathy; provider support; respect/privacy	219
Feeding newborn	Breastfeeding/bottle feeding	249
Interventions in labor	Labor interventions; food and drink in labor	157
Labor management	Hospital admission; labor management; labor and birth positions	244
Location of delivery	Birth environment; childbirth location; provider type	257
Mental health	Anxiety/fear/worry; depression; maternal psychological issues	970
Newborn	Newborn/ newborn care; neonatal intensive care unit (NICU); nursery environment	355
Summary measures	Cesarean delivery experience; negative experience; overall experience	303
Pain assessment	Labor pain assessment; labor pain expectations	131
Pain management	Cesarean delivery anesthesia; epidural; labor pain management	505
Parenting	Family impact; fetal attachment; parental concerns	192
Postpartum	Postpartum care; postpartum environment; postpartum long term issues; postpartum work intention	353
Route of delivery	Route of delivery; vacuum/forceps; vaginal birth after cesarean (VBAC); cesarean delivery anxiety	497
Support	Labor social support; labor teaching; nursing support; partner support	430

included three to ten women. One focus group ($n = 8$) was facilitated in Spanish. We captured the values and preferences of women who anticipated delivering or who had delivered at a hospital, freestanding birth center, or home.

Focus group data confirmed the importance of these 19 priority domains, with the three most frequent domains discussed being communication, the need for support/empathy, and involvement in decision making. Only one new subdomain that was not part of the literature search emerged

from the focus groups—health insurance concerns. This included the nuances of different types of services, hospitals, and deductibles in different types of networks. While this concern arose in only one focus group, all women within that group thought it was important, each raising her own individual coverage issues. As a result, we added insurance/cost of care as a subdomain under “decision making.” After the winnowing process, 68 V&P items and 64 items describing predisposing conditions remained.

Objective 2: To Conduct a National Antepartum Survey to Test the Prevalence, Distribution, and Statistical Significance of PRO Items in the Framework Domains

The survey was administered in November 2015 over a 2-week period. Of 22,503 logins to the survey, 2,757 respondents met all eligibility criteria and completed it; 29 (1.1 percent) were in Spanish. All responses were collected within a 2-week period. Of these respondents, 2,033 (73.7 percent) anticipated a vaginal birth in a hospital; 217 (7.9 percent) anticipated a hospital birth but were uncertain regarding the planned delivery route; 393 (14.3 percent) anticipated a cesarean delivery; 23 (0.8 percent) anticipated delivery in a freestanding birth center; 47 (1.7 percent) anticipated delivering at home; 17 (0.6 percent) anticipated a vaginal delivery but were unsure of location; and 27 (1.0 percent) gave inconsistent or incomplete responses.

Exploratory factor analysis yielded a two-factor solution within the predisposing conditions: *discrimination* (6 items, $\alpha = 0.89$) and *confidence* (8 items, $\alpha = 0.76$). Both factors used the 5-point response scale (1) strongly disagree to (5) strongly agree. If any one of four items regarding clinical risk were answered affirmatively, then an aggregate variable, “pregnancy complications” was marked “Yes.” These four items included (1) the presence of a pre-existing medical condition; (2) the presence of a pregnancy-related condition such as gestational diabetes or hypertension; (3) being told that the pregnancy was “high-risk”; and (4) being told that the fetus had a problem. We retained all other predisposing conditions as independent items.

Descriptive results of predisposing conditions for those who were anticipating or considering vaginal deliveries in the hospital ($n = 2,250$) are shown in Table 2.

Exploratory factor analysis yielded a four-factor solution within the V&P. Overall and segmented factor analyses were consistent. These factors were as follows: (1) *choice of labor environment* (6 items, $\alpha 0.72$); (2) *communication regarding the newborn* (8 items, $\alpha 0.89$); (3) *option to use labor tub, ball, or stool* (3 items, $\alpha 0.90$); and (4) *desire to avoid interventions* (6 items, α

Table 2: Frequency of Predisposing Conditions in the National Sample [No. (%)]. The Unweighted Number of Participants was 2,250; the Weighted Number of Participants was 2,218. Numbers May Not Add to 100% Due to Rounding

<i>Characteristic (N Total Weighted)</i>	<i>Total (Weighted) (%)</i>
Age (years) (<i>N</i> = 2,218)	
18–24	546 (24.7)
25–29	581 (26.2)
30–34	733 (33.1)
35–39	292 (13.2)
40–54	62 (2.8)
Race/ethnicity (<i>N</i> = 2,218)	
Asian	81 (3.7)
Black	425 (19.2)
Hispanic	383 (17.3)
Other	100 (4.5)
White	1,229 (55.4)
Highest educational level (<i>N</i> = 2,218)	
High school or less	784 (35.4)
Some college	674 (30.4)
College 4 years or more	760 (34.2)
Income* (<i>N</i> = 2,084)	
<\$15,000	556 (26.7)
\$15,000 to <\$35,000	680 (32.6)
\$35,000 to <\$75,000	503 (24.1)
≥\$75,000	346 (16.6)
Delivery category (<i>N</i> = 2,218)	
Multiparous with no prior cesarean delivery	1,149 (51.8)
Multiparous with prior cesarean delivery	395 (17.8)
Nulliparous	674 (30.4)
Gestational age ≥ 34 weeks (<i>N</i> = 2,218)	664 (29.9)
Pregnant with more than one baby (<i>N</i> = 2,218)	178 (8.0)
Use of infertility treatment this pregnancy (<i>N</i> = 2,213)	218 (9.9)
Intentional pregnancy (<i>N</i> = 2,107)	1,438 (68.2)
First prenatal care visit in first trimester (<i>N</i> = 2,199)	1,745 (79.4)
Body mass index (<i>N</i> = 2,198)	
Underweight (< 18.5)	173 (7.9)
Normal (18.5–24.9)	1,073 (48.8)
Overweight (25.0–29.9)	549 (25.0)
Obese (≥30.0)	403 (18.4)
Rating of overall health during pregnancy as poor/fair (<i>N</i> = 2,215)	130 (5.9)
Rating of mental/emotional health during pregnancy as poor/fair (<i>N</i> = 2,215)	296 (13.4)
Pregnancy complications [†] (<i>N</i> = 2,179)	901 (41.4)

continued

Table 2. *Continued*

<i>Characteristic (N Total Weighted)</i>	<i>Total (Weighted) (%)</i>
Currently has a spouse or partner ($N = 2,218$)	2,056 (92.7)
Having immediate help or social support if needed ($N = 2,218$)	1,975 (92.8)
Having negative memories from a previous labor or birth: somewhat to strongly agree ($N = 2,217$)	554 (25.0)
Having anybody repress, degrade, or humiliate them over a long period of time (abuse 1) ($N = 2,215$)	648 (29.3)
Having anybody threatening to hurt them or someone close to them (abuse 2) ($N = 2,211$)	550 (29.4)
Having anybody trying to physically abusing them (abuse 3) ($N = 2,212$)	543 (24.6)
Having anybody trying to force them into sexual actions (abuse 4) ($N = 2,216$)	476 (21.5)
Abuse aggregate (any of abuse 1, 2, 3, or 4) ($N = 2,205$)	887 (40.2)
Having personally experienced discrimination [‡] ($N = 2,189$)	605 (27.7)
High confidence in the birth process [§] ($N = 2,170$)	1,497 (69.0)
Very to extremely confident filling out medical/health paperwork by oneself ($N = 2,217$)	1,721 (77.6)
Feeling pressure to have a cesarean birth from the provider, family, or friends ($N = 2,085$)	346 (16.6)
Public health insurance ($N = 2,098$)	998 (47.6)
Need to travel ≥ 30 minutes from home to deliver ($N = 2,131$)	619 (29.0)
Person who will deliver baby ($N = 2,161$)	
Family practitioner	275 (12.7)
Midwife	251 (11.6)
Obstetrician	1,475 (68.3)
Partner	159 (7.4)
Need for an interpreter ($N = 2,182$)	149 (6.8)
Anticipated coping with labor pain: very well to extremely well ($N = 1,973$)	751 (38.0)
Feeling that giving birth is being in a very helpless condition: somewhat to strongly agree ($N = 2,211$)	732 (33.1)
Feeling that it is better not to know in advance about the processes of giving birth: somewhat to strongly agree ($N = 2,213$)	477 (21.5)
Worried about the birth ($N = 2,217$)	1,353 (61.0)
Will be making a birth plan ($N = 2,215$)	1,203 (54.3)
Planning tubal sterilization ($N = 1,707$)	314 (18.4)
United States (U.S.) generation ($N = 2,183$)	
Neither respondent or parent born in the United States	167 (7.7)
Respondent but not parent born in the United States	191 (8.8)
Both respondent and parent born in the United States	1,824 (83.6)
U.S. region ($N = 2,218$)	
East	397 (17.9)
Midwest	464 (20.9)
South	840 (37.9)
West	518 (23.3)

continued

Table 2. *Continued*

<i>Characteristic (N Total Weighted)</i>	<i>Total (Weighted) (%)</i>
Religion: none or atheist (<i>N</i> = 2,211)	411 (18.6)
Heterosexual (<i>n</i> = 2,212)	2,025 (91.6)
Survey taken in Spanish (<i>N</i> = 2,218)	23 (1.0)

*2014 household income before taxes, in dollars.

[†]An aggregate variable defined as having one or more of the following: a pre-existing or chronic maternal condition, a gestational condition, a high-risk pregnancy, or a problem with the fetus.

[‡]A factor combining six items asking whether the respondent had ever experienced discrimination because of racial, cultural, financial, insurance, gender, or disability (Likert scale (1) = “not at all” to (5) = “very much,” alpha = 0.89). “Yes” was defined as a factor-based score ≥ 2 .

[§]A factor combining the following eight items: (1) I feel confident in protecting my own interests during pregnancy and childbirth; (2) I know where to get information regarding childbirth options; (3) I want to be in charge of planning my care; (4) Giving birth is a powerful experience; (5) My job as a mother is to make sure my baby is born healthy; (6) I believe I will be in control; (7) I expect my childbirth will go smoothly; and (8) Childbirth is a safe experience for the mother. [Likert scale (1) = “strongly disagree” to (5) = “strongly agree,” alpha = 0.76]. “Yes” was defined as a factor-based score ≥ 4 .

0.80). All of the involved items used the “importance” response scale. We retained all other V&P as independent items.

Final V&P items and factor-based scores were collapsed to produce binary V&P with the exception of three V&P items that remained as three-level variables. These variables were as follows: assessment of breastfeeding encouragement (too little, just right, or too much), agreement that respondent would talk to family first before making decisions (yes, maybe, no), and preference to leave all choices to the provider (yes, maybe, no). We calculated factor-based scores and collapsed to produce binary items for all the above factors.

As detailed in the methods, we used logistic regression models to identify the predisposing conditions associated with the V&P items or factors. Thirty-seven models were created using the predisposing conditions as predictors, for the purpose of describing “who” wanted each item. The results of the models are shown in Appendix SA2. For example, for the V&P factor “desire to avoid interventions,” 589 of 2,168 women (27.2 percent) responded “Yes.” Predisposing conditions positively associated with women more likely to want to avoid interventions were as follows: having high confidence, having negative memories of the previous birth, having experienced discrimination, and anticipating that they would cope well with pain. Predisposing conditions negatively associated were as follows: being in the oldest age stratum and being multiparous with no prior cesarean birth.

The desire for specific childbirth services and outcomes varied not only across demographic groups, but also across women with different levels of confidence, different levels of pain coping ability, and different attitudes toward childbirth preparedness. Although 41.4 percent reported having a complicated pregnancy, this perception did not appear to impact women's desired outcomes, as it rarely contributed to the models. Some models performed better than others, with c-statistics ranging from about 0.6 to 0.8.

Of the 37 V&P tested among women anticipating vaginal birth in a hospital, some were desired by nearly all respondents (e.g., having reassurance/comfort from the nurse [96.1 percent]), some by a moderate proportion of the respondents (e.g., wanting to eat/drink during labor [56.0 percent]), and some by relatively few respondents (e.g., wanting acupuncture/acupressure as a pain treatment option [6.5 percent]).

Objective 3: Using the Study Data, Finalize the Conceptual Model and Preliminary Item Bank

The final set of domains and subdomains for V&P/PRO items is in Table 3, and predisposing conditions are presented in Appendix SA3. The resulting preliminary item bank consisted of 60 predisposing conditions and 63 V&P/PROs.

DISCUSSION

This work provides a foundation for assessing what is important to women during their childbirth experience and emphasizes the need for both antepartum and postpartum data collection to assure the reporting of women's predisposing conditions, service values and preferences, childbirth experiences, and clinical outcomes. Our conceptual framework suggests that for childbirth, measurement of both values and preferences (V&P) and PROs (outcomes) will be important. Using PROMIS[®] methodology and a community-based research approach, we developed a conceptual framework, a preliminary item bank of predisposing conditions, and items relevant to V&P and PROs for childbirth in a hospital, completing the first of five stages of the PROMIS[®] Instrument Maturity Model (Patient-Reported Outcomes Measurement Information System 2013).

The final conceptual framework had 19 domains and 58 subdomains, and the preliminary item bank had 63 V&P/PROs and 60 personal characteristics

Table 3: Framework and Preliminary Item Bank for Childbirth Patient-Reported Values and Preferences and Experiences/Outcomes (V&P/PROs). The Sentence Structure of V&P Items Would Be Appropriate for Antepartum Administration, and the Structure of PRO Items Would Be Appropriate for Postpartum Administration

<i>V&P/PROs Domain</i>	<i>Subdomain</i>	<i>V&P/PRO Item</i>
Location	Location	<ul style="list-style-type: none"> • Where do you expect to deliver (hospital, freestanding birth center, home)/where did you deliver
Route of delivery	Route of delivery anticipated	<ul style="list-style-type: none"> • How do you expect to give birth (vaginal vs. cesarean delivery)/how did you give birth
Labor management	Want tub/ball/stool (factor)	<ul style="list-style-type: none"> • Important/got to use labor tub • Important/got to use birth ball • Important/got to use birth stool
	Want to avoid interventions (factor)	<ul style="list-style-type: none"> • Important/got to avoid induction • Important/got to avoid IV • Important/got to avoid Pitocin augmentation • Important/got to avoid cesarean • Important/got to avoid vacuum/forceps delivery • Important/got to avoid episiotomy
	Want to avoid continuous monitoring	<ul style="list-style-type: none"> • Important/got to avoid continuous electronic fetal monitoring
	Other labor concerns	<ul style="list-style-type: none"> • Important/got to eat/drink during labor • Important/got to use shower during labor • Important/got to use massage
	Labor and birth position	<ul style="list-style-type: none"> • Want to deliver/delivered while lying on back • Important/got to choose labor/delivery position
Continuity of care	Hospital admission process	<ul style="list-style-type: none"> • No current items*
	Familiar with providers	<ul style="list-style-type: none"> • Important to know/knew doctor in advance • Important to know/knew midwife in advance • Important to know/knew pediatrician in advance
Communication and decision making	Decision making	<ul style="list-style-type: none"> • Plan to leave/left choices to doctor/midwife • Will talk/talked with family before making decisions

continued

Table 3. Continued

<i>V&P/PROs Domain</i>	<i>Subdomain</i>	<i>V&P/PRO Item</i>	
Empathy/respect	Follow birth plan	<ul style="list-style-type: none"> • Will refuse/refused treatment believed not necessary • Can only be assessed postpartum 	
	Staff communication	<ul style="list-style-type: none"> • Important to have/got debriefing regarding labor events • Important to have/got debriefing regarding feelings 	
	Cultural competence	<ul style="list-style-type: none"> • Important to have/got staff respect for spiritual beliefs/culture 	
	Empathy	<ul style="list-style-type: none"> • Important to have/got reassurance from nurse 	
	Respect	<ul style="list-style-type: none"> • Important to have/got adequate space/food for support person 	
Feeding	Want choices in the environment	<ul style="list-style-type: none"> • Important to have/got female provider • Important/got to walk around during labor • Important/got to have a private room • Important/got to have providers help with positions/methods of delivery • Important/got to have choice of who is in the room during procedures/exams • Important/got to be involved in decisions re pain • Important/got to have reassurance from doctor/midwife 	
		<ul style="list-style-type: none"> • Plan/was able to breast feed, bottle feed breast milk, bottle feed formula 	
	Feeding type	<ul style="list-style-type: none"> • Important to have/got practical support for feeding • Important to have/got information regarding breast feeding within 24 hours • Important to have/got information regarding bottle feeding within 24 hours 	
	Practical support	<ul style="list-style-type: none"> • Important to have/got encouragement for breastfeeding 	
	Encouragement		
	Newborn	Immediate care	<ul style="list-style-type: none"> • Important to have/got to have baby placed skin to skin immediately after birth
		Rooming in	<ul style="list-style-type: none"> • Important to have/got to have baby stay in room with mother
		Nursery or neonatal intensive care unit (NICU) environment	<ul style="list-style-type: none"> • No current items

continued

Table 3. *Continued*

<i>V&P/PROs</i>		
<i>Domain</i>	<i>Subdomain</i>	<i>V&P/PRO Item</i>
	Newborn care	<ul style="list-style-type: none"> • Important to have/got information regarding day-to-day care of newborn • Important to have/got information regarding vaccines • Important to have/got information regarding baby's sleep position • Important to have/got information regarding baby's sleep location
Pain management	Options for labor	<ul style="list-style-type: none"> • Consider use of/got massage • Consider use of/got walking • Consider use of/got to use breathing techniques • Consider use of/got to use shower/tub • Consider use of/got to use mental strategies • Consider use of/got narcotics • Consider use of/got epidural • Consider use of/got nitrous oxide gas • Consider use of/got to use TENS unit • Consider use of/got acupuncture/acupressure
	Options for cesarean birth	<ul style="list-style-type: none"> • No current items
Postpartum care	Postpartum	<ul style="list-style-type: none"> • No current items
	Postpartum environment	<ul style="list-style-type: none"> • No current items
	Postpartum care	<ul style="list-style-type: none"> • Important to have/got tubal sterilization • Important to have/got hospital stay >48 hours
Support	Social support partner	<ul style="list-style-type: none"> • Important to have/got to have spouse/partner in-room
	Social support children	<ul style="list-style-type: none"> • Important to have/got to have other children in-room
	Social support other family	<ul style="list-style-type: none"> • Important to have/to have other family in-room
	Social support friends	<ul style="list-style-type: none"> • Important to have/got to have friends in-room
	Doula	<ul style="list-style-type: none"> • Important to have/got to have doula in-room
Clinical concerns	Maternal/neonatal childbirth complications	<ul style="list-style-type: none"> • Can only be assessed postpartum

continued

Table 3. *Continued*

<i>V&P/PROs Domain</i>	<i>Subdomain</i>	<i>V&P/PRO Item</i>
Summary measures	Maternal/neonatal readmission	• Can only be assessed postpartum
	Provider competence	• No current items
	Safety	• Can only be assessed postpartum
	Satisfaction with birth	• Can only be assessed postpartum
	Satisfaction with hospital	• Can only be assessed postpartum
Pain assessment	Loyalty to hospital	• Can only be assessed postpartum
	Intrapartum	• Can only be assessed postpartum
Parenting	During cesarean birth	• Can only be assessed postpartum
	Postpartum	• Can only be assessed postpartum
	Family impact	• No current items
	Fetal attachment	• No current items
	Parental concerns	• No current items

*Some of the domains or subdomains state “no current items.” This occurred because, although potential items were identified through literature and focus groups, and the domain was felt to be important by the Childbirth Patient-Reported Outcomes Partnership, during the current effort, the Partnership viewed these areas as less important to develop and include in the national survey.

that were important predictors of these V&P/PROs. Several domains in the framework were not represented in the national antepartum questionnaire because they pertained to services or outcomes that could only be assessed postpartum, for example, assessment of pain experienced and satisfaction with the birth. Further development of these domains will require the design and implementation of a postpartum survey to explore relevant items. The domains reported here were limited to women anticipating vaginal hospital births and limited to the immediate hospital experience. Priorities of women planning out of hospital births or cesarean deliveries were not addressed.

The list of key predisposing conditions related to the V&P domains represents an important strength of this framework, displaying variation across a wide range of patient characteristics, such as having a high level of confidence regarding the birth or having previous negative birth experiences. Provider awareness of these important patient characteristics is often limited. It is also noteworthy that perceived pregnancy complications rarely appeared in the models. The perception of having a complicated pregnancy did not appear to impact women’s desired outcomes. Such a finding remains to be studied in the

context of linkage of V&P/PROs to the electronic medical record to compare how providers' and pregnant women's views of their clinical risk may differ. Given providers' uppermost concern for childbirth safety, it is important to understand and bridge any identified discrepancy regarding what is believed to be required to have a safe delivery.

The results of the 37 V&P models confirmed that childbirth is a highly preference-sensitive condition (Wennberg, Fisher, and Skinner 2002) and our work suggests that women's preferences vary with respect to potential childbirth outcomes. Postpartum assessment of whether women got what they wanted is required to test this hypothesis. Ultimately, as described in Figure 1, it is unknown whether predisposing conditions, V&P, PROs (outcomes), or "gaps" between V&P and PROs may be the best predictors of women's satisfaction with their care.

An early attempt to address this void was first published in a national survey, "Listening to Mothers," in 2002. The report described childbirth experiences but did not systematically address V&P or PROs (DeClercq et al. 2002). The International Consortium for Health Outcomes Measurement (ICHOM) has recently developed a much broader and less specific set of standards for measuring Pregnancy and Childbirth outcomes that include several maternity patient self-reports (International Consortium for Healthcare Outcomes Measures 2017). Furthermore, Gartner et al. (2014) developed core domains for women's birth-specific priorities that were largely consistent with our work. Our work narrows this long-standing evidence gap and offers a tool for assessment of women's values and preferences for childbirth.

The strengths of this work include the use of PROMIS[®] methodology to develop and build on the conceptual framework, the community-based participatory research approach, and the recognition that predisposing conditions, V&P, and PROs are all required to understand women's expectations and assessment of their care. The data reported from the national survey were restricted to women's V&P and did not specifically include PROs; however, most PROs were easily derived from the V&P, that is, by rephrasing the V&P item to ask whether the respondent actually got what she wanted. Other limitations include the focus on the immediate childbirth experience in the hospital, the lack of statistical power to model V&P for women anticipating cesarean delivery or out-of-hospital births, and the potential for recruitment bias using national online panels. This study was weighted to approximate its relevance to reproductive age women, which may differ slightly from the distribution of demographic characteristics of women who actually give birth (see Appendix SA4). It is important to emphasize that the preliminary item

bank produced here only completes Step 1 of the 5 steps of the PROMIS Instrument Maturity Model, and Steps 1–4 of 12 steps in the NQF pathway for the development of performance measures (National Quality Forum 2013). Key next steps include the postpartum testing of these V&P/PROs, and the implementation and testing of the items in a multihospital environment.

The NQF (National Quality Forum 2017b), our national clearinghouse for the assessment and endorsement of health care performance measures, has published standards for the design and selection of PROs that relate to the performance of health care organizations. They have emphasized that the incorporation of the patient perspective into health care services quality monitoring must assure that the infrastructure is in place to document and respond to that perspective, and that valid and comprehensive measures of that perspective are in place. The work described here lays a foundation for further development of childbirth V&P and PROs as hospital performance measures of the childbirth experience.

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SUPPORTING INFORMATION

Additional supplemental material may be found online in the Supporting Information section at the end of the article.

Appendix SA1: Author Matrix.

Appendix SA2: Results of Multiple Logistic Regression Models for Women Considering Having a Vaginal Delivery (Total N , weighted = 2,218).

Appendix SA3: Framework and Preliminary Item Bank for Predisposing Conditions. The Predisposing Conditions Would Be Appropriate for Antepartum Administration.

Appendix SA4: Unweighted and Weighted Demographic Profile of Antepartum Survey Participants ($N = 2,757$).