Public Query Report

Characteristics of Pregnancy-Related Health Events Across Clinical Research Networks Participating in PCORnet®

Rationale for Network Query of PCORnet Data Resources:

This Network query of PCORnet data resources designed to review characteristics of pregnancy-related health events in any health care setting across PCORnet was requested by the Patient-Centered Outcomes Research Institute® (PCORI®) in collaboration with the PCORnet® Network Partners. Network queries are developed, distributed, and processed through the Coordinating Center for PCORnet®.

In 2019, the U.S. Congress passed legislation that reauthorized funding for PCORI, the founding and primary funder of PCORnet, and identified maternal morbidity and mortality (MMM) as a research priority. The maternal mortality rates in the United States were 32.9 per 100,000 births in 2021 and have risen successively over the past few years. Further, the United States ranks last among comparable developed countries in maternal outcomes.[1]

A national-scale infrastructure provided by PCORnet has the capacity to support national health system research efforts on MMM. PCORnet® Network Partners convened a workgroup of experts in topics related to MMM – including patient stakeholders – to develop a roadmap for accelerating patient-centered MMM research using PCORnet. As part of building this roadmap, the workgroup developed an exploratory query of pregnancy-related events in support of future national-scale research on MMM. The query demonstrates the utility of the PCORnet infrastructure to identify and characterize the cohort of patients with pregnancy-related health events served by health systems participating in PCORnet.

Background on PCORnet:

PCORnet is a large, distributed "network of networks" (Figure 1) funded by PCORI to improve the nation's capacity to efficiently conduct definitive health research, particularly patient-centered comparative clinical effectiveness research (CER).

At the time of this query report, PCORnet Clinical Research Networks (CRNs) included 63 data contributing CRN sites, in addition to patient partners and a Coordinating Center. Collectively, CRN data-contributing partners consist of more than thirteen thousand clinical sites connected to

[1] Roosa Tikkanen et al., Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries (Commonwealth Fund, Nov. 2020). DOI: https://.org/10.26099/411v-9255

more than 34 million unique patients receiving care across the U.S. each year, including care delivered at large academic health systems, hospitals, federally qualified health centers, and community clinics.

In August 2023, PCORI awarded supplemental funding to support the addition of 16 new partners to PCORnet; the data from these sites are not reflected in this query report. A unique feature of PCORnet is that all data contributing partners store a version of their clinical data in the same standardized data model, the PCORnet® Common Data Model (CDM). In this distributed network, data holders (e.g., health systems, clinics) maintain physical control, use, and manage the transfer of their data to the CRNs, the Coordinating Center for PCORnet® and data requestors.

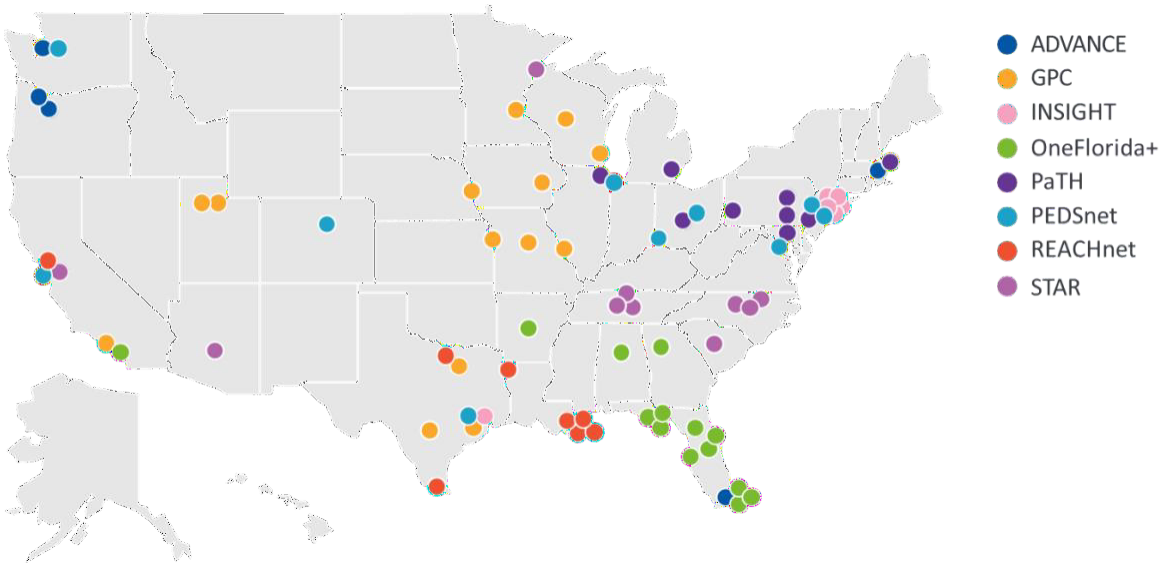

Figure 1. Clinical Research Networks (CRNs) (right) and their participating network sites in PCORnet, August 2023. Each CRN site comprises numerous clinical sites of care. Source: Developed by the Duke Clinical Research Institute (DCRI) with funding through a PCORI Award (RI-DCRI-01-PS3).

Query Description:

This query of PCORnet data resources describes the sociodemographic and clinical characteristics of a population of patients with a pregnancy-related event that had a healthcare encounter at a partner site between October 1, 2016 – January 1, 2022. The query results will inform how PCORnet can be used for patient-centered CER studies and trials on MMM and to inform opportunities to enhance PCORnet data resources for MMM research.

In addition, the query aims to demonstrate the utility of PCORnet to:

- Describe the sociodemographic and clinical characteristics of the population experiencing pregnancy-related events served by PCORnet participants
- Report the extent of pregnancy-related events in a large cohort

Query Methodology, Criteria and Engagement:

The query of PCORnet data resources includes a cohort of patients with a pregnancy-related event at a partner site participating in PCORnet during a 5-year query period (October 1, 2016, to January 1, 2022). The query identified individuals aged 10 years or older who experienced one pregnancy-related health event across any health care setting. Women experiencing one pregnancy-related health event were stratified into two cohorts: 1) delivery events only and 2) delivery or pregnancy interruption events.

To minimize misidentifying a delivery, the delivery date had to be followed by a 150-day window without delivery codes (i.e. Current Procedural Terminology (CPT) codes). For identification of women who experienced an interruption of pregnancy event, the date of that event must be followed by a 45-day window without relevant codes. These 150-day and 45-day windows are applied to reduce over-counting events where codes on multiple dates are associated with a single event. The Coordinating Center for PCORnet® programmed and distributed this descriptive query to all 63 data contributing partners.

As with all PCORI topics, the development process included a review of the relevant literature and engagement with stakeholders such as subject matter experts and patient partners. Patient partners and subject matter experts were engaged early in the query development to help identify the range of pregnancy-related conditions and important characteristics to describe the cohort.

The cohort criteria for the query are provided below:

- A pregnancy-related event at a partner site between October 2016 through January 1, 2022; and
- Female; and
- 10 years or age or older;
- Experienced a health event of interest during or after pregnancy.
- The following characteristics were also examined:
    - Demographics:
        - Race
        - Ethnicity
        - Location of residence
        - Area Deprivation Index
    - Delivery type
    - Severe maternal morbidity at pregnancy-related event
    - Pregnancy-related/associated mortality
    - Prenatal morbidities
    - Peripartum morbidities among deliveries
    - Postpartum morbidities among deliveries

A comprehensive list of all diagnosis and procedure codes used to define the cohorts and comorbidities is available in Appendix A.

Results:

Fifty-eight data contributing partners participating in PCORnet responded to the query request (92%).

Table 1 provides details of the counts and demographic characteristics of the two cohorts explored through this query of pregnancy-related events: 1) delivery events only and 2) delivery or pregnancy interruption events. For the delivery only cohort, there were 1,318,639 unique patients that experienced 1,528,414 delivery events during the 5-year query period.

The average age of patients experiencing only delivery events was 29.7 years old (SD ± 6.2 years), and the majority of patients were white (56%) and non-Hispanic (73%). For the delivery or interruption cohort, there were 1,874,673 unique events across 1,517,421 unique patients. For both cohorts, Table 1 also includes socioeconomic status for patients defined by zip code and the Area Deprivation Index (ADI). Approximately 17-18% of patients were in the lowest socioeconomic status group of ADI scores at the time of their pregnancy-related event; although, address data at the health care encounter date were missing for 37% of patients in both cohorts.

The majority of delivery events were vaginal deliveries (56%) followed by cesarean (28%) deliveries.

Table 2 provides details of severe maternal morbidities that occurred during delivery events for the delivery-only cohort. All severe maternal morbidities were observed to be 1% or below for the cohort. The most common maternal morbidity was receipt of blood transfusion (1%). Pregnancy-associated or pregnancy-related mortality occurred in <1% (n=657) of patients which was identified through EHR data in the 365 days post-delivery in the delivery-only cohort.

Table 3 provides counts of prenatal, perinatal, and postpartum morbidities observed in the delivery-only cohort.

Limitations:

Data and analyses presented are descriptive and derived from diagnosis and procedure codes collected during healthcare encounters in the EHR. Rows and percentages may not round due to missing values and/or if counts are less than 10. If counts are less than10, then they are reported as such to protect patient privacy and risk of identification from aggregate values as outlined in the Data Privacy Statement for PCORnet®.

No inferential analyses were conducted to compare populations or test hypotheses, as these are descriptive data only. Limitations with any EHR data analysis are applicable to this data, such as the possibility for misclassification due to imperfect algorithms and lack of consistent definition of enrollment to define cohorts. Specific to this query, the use of procedure codes is the preferred method to identify events, yet there was high variability in their use, ranging from 21% to 98% at other sites. Additionally, after a delivery event, patient care may resume at other care settings (e.g., primary care) resulting in discontinuity of the availability of data both prenatally and postnatally. Therefore, results should be interpreted with these limitations in mind.

To ensure PCORnet data resources are of high quality for research, activities in preparation for research (e.g., network query requests), and to mitigate the limitations above, all PCORnet-

accessible data resources undergo rigorous quality curation and screening as part of quarterly coordinated data quality assessment. For more information on data curation activities and strategies to improve data quality for PCORnet please contact frontdoor@pcornet.org.

Conclusion:

The results presented in this query report provide researchers and patient/caregiver partners with information about the capacity of the PCORnet infrastructure to identify pregnancy-related health events across any health care setting at a national scale to support future studies related to MMM. Researchers and patients/caregivers can use the information in this report to identify study questions and plan research about MMM that leverage the data found through this query. This cohort experiences a range of physical and mental health conditions in the prenatal and postpartum periods. The large numbers of women in the query cohorts enables identification of relatively rare occurrences such as severe maternal morbidity and pregnancy- associated or related mortality. This query provides basic information to stimulate future study planning in MMM using the PCORnet infrastructure.

Disclaimer:

PCORnet® is intended to improve the nation's capacity to efficiently conduct patient-centered health research, particularly CER, by providing a large, highly representative network of health data, research expertise, and patient insights. PCORnet has been developed with funding from the Patient-Centered Outcomes Research Institute® (PCORI®).

Network queries that return only aggregate or limited data sets are covered by the PCORnet® Master Data Sharing Agreement (version 4.0), and site-level blanket Institutional Review Board approvals.

The statements presented in this report do not necessarily represent the views of PCORI or other organizations participating in, collaborating with, or funding PCORnet.

For questions, comments or suggestions related to this PCORnet® Front Door query or other PCORnet queries, please contact frontdoor@pcornet.org.

Tables

Table 1. Demographic characteristics of the two maternal cohorts across data-contributing partners participating in PCORnet (October 2016 – January 2022).

	Delivery Only	Delivery or Interruption
Unique Patient Records	1,318,639	1,517,421
Unique Events	1,528,414	1,874,673
Mean Age (SD)	29.7 (6.0)	30.0 (6.2)
Female	100%	100%
Race		
White	56%	55%
Black or African American	19%	20%
American Indian or Alaska Native	0%	0%
Asian	6%	5%
Native Hawaiian or Other Pacific Islander	0%	0%
Multiple Races	1%	1%
Missing	<1%	<1%
Other	18%	18%
Hispanic		
Yes	21%	21%
No	73%	73%
Missing	<1%	<1%
Other	5%	6%
Area Deprivation Index (ADI)[1]		
SES Q1	18%	18%
SES Q2	13%	13%
SES Q3	15%	15%
SES Q4	17%	18%
Missing	37%	37%
Delivery Type		
Vaginal delivery	65%	56%
Cesarean section	33%	28%
Normal spontaneous vaginal delivery	22%	19%
Operative delivery	3%	3%

[1]Area Deprivation Index (ADI): Patient 5-Digit Zip Codes are mapped to socioeconomic status by normalized Area Deprivation Index (ADI) value (0-100). Lower values are associated with lower deprivation and higher values are associated with higher deprivation. A ranking of 1 indicates the highest level of socioeconomic status within the nation and an ADI with a ranking of 100 indicates the lowest level of socioeconomic status. In this table, values are grouped into quartiles using the count of zip codes. Quartile 1 (SES Q1) represents the lowest range of ADI values and Quartile 4 (SES Q4) represents the highest range of ADI values (Q1=0-38, Q2=39-43, Q3=44-49, and Q4=50-100). For additional information regarding the ADI index, see the Neighborhood Atlas here: https://www.neighborhoodatlas.medicine.wisc.edu/. Note that the Area Deprivation Index (ADI) is designed for validity at the 9-digit zip or census block group level rather than the 5-digit zip level.

Table 2. Severe maternal morbidity in delivery-only cohort for data-contributing across partners participating in PCORnet (October 2016 – January 2022).

	Delivery (n)	Delivery (%)
Pregnancy-Associated or Pregnancy-Related Mortality		
Within 365 days of delivery as collected in the electronic health record	657	<1%
Severe Maternal Morbidity		
Blood products transfusion	16,090	1%
Acute renal failure	4,175	<1%
Disseminated intravascular coagulation (DIC)	3,750	<1%
Sepsis	3,306	<1%
Pulmonary edema/acute heart failure	2,575	<1%
Adult respiratory distress syndrome (ARDS)	2,568	<1%
Hysterectomy	2,048	<1%
Eclampsia	1,544	<1%
Shock	1,439	<1%
Puerperal cerebrovascular disorders	1,250	<1%
Air and thrombotic embolism	1,066	<1%
Ventilation	964	<1%
Sickle cell disease with crisis	470	<1%
Acute myocardial infarction (MI)	276	<1%
Cardiac arrest, ventricular fibrillation	186	<1%
Conversion of cardiac rhythm	167	<1%
Aneurysm	148	<1%
Amniotic fluid embolism	139	<1%
Severe anesthesia complications	111	<1%
Temporary tracheostomy	74	<1%
Heart failure or arrest	39	<1%

Table 3. Prenatal, peripartum, and postpartum comorbidities in the delivery-only cohort (October 2016 – January 2022).

	Delivery (n)	Delivery (%)
Prenatal		
Diabetes (pre-pregnancy or gestational)	100,776	8 %
Depression/Anxiety	92,532	7 %
Preeclampsia and other hypertensive disorders of pregnancy	89,052	7 %
Preterm premature rupture of membranes	76,831	6 %
Tobacco and other substance use	62,676	5 %
Placental abruption	26,243	2 %
Preexisting hypertension (prior to pregnancy)	21,958	2 %
Peripartum		
Laceration: 3rd or 4th degree	22,117	2%
Intrauterine fetal demise (IUFD)/Stillbirth	16,484	1%
Preterm birth (<37 weeks gestational age)	969	<1%
Low birth weight (<2500g)	209	<1%
Low birth weight (<1500g)	72	<1%
Postpartum		
Postpartum hemorrhage	114,365	9%
Postpartum depression (0 to 180 days)	13,343	1%
Postpartum depression (181 to 365 days)	2,841	<1%
Endometritis	1,292	<1%
Postpartum PTSD	0	0%