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PROJECT REPORT

FINAL REPORT

FHIR Implementation Guide Assessment for Maternal Mental Health Data Extraction

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The Office of the Assistant Secretary for Planning and Evaluation (ASPE)
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by
NORC at the University of Chicago

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OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

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Table of Contents

Executive Summary	1
1. Introduction.....	3
1.1 Objectives and Structure of the Report	3
2. Methods	4
3. Gap Analysis Findings.....	5
3.1 Maternal Mental Health Use Case	6
3.2 Assessment of Research IG for Inclusion of the Maternal Mental Health Use Case	9
4. Recommendations for Research IG Enhancement	15
4.1 Update the Existing Research IG to Work with New Tools	15
4.2 Incorporate Maternal Mental Health Use Case	15
5. Implementation Plan.....	15
6. Conclusion	17
Appendix A. Targeted Review Methods	18
Appendix B. Candidate HIEs	19
Appendix C. Form to Assess HIE Capacity to Participate in the Pilot.....	20
References.....	22

Table of Exhibits

Exhibit 1. Data Sources and Resources for FHIR Research IG Assessment	5
Exhibit 2. Experts Engaged in FHIR Research IG Assessment	5
Exhibit 3. Clinical Data Elements for Capture in FHIR Research IG	7
Exhibit 4. FHIR Resources, Other Standards, and Terminologies in the Current Research IG.....	9
Exhibit 5. Gap Analysis: Data Elements to Include in the Research IG for the New Maternal Mental Health Use Case	11
Exhibit 6. Relevant Maternal Mental Health Standardized Data Classes	14
Exhibit 7. Pilot Activities Overview	16

Executive Summary

Introduction

To support improved maternal health patient-centered outcomes research (PCOR), the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) funded development of the *Longitudinal Maternal & Child Health Information for Research Fast Healthcare Interoperability Resources (FHIR) Implementation Guide*¹ v1.0.0 (Research IG). Currently, the Research IG covers two use cases: 1) pregnancy and subsequent death within a specific time frame, and 2) hypertensive disorders of pregnancy. Given that maternal mental health conditions are leading contributors to maternal morbidity and mortality in the United States, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) commissioned NORC at the University of Chicago to expand the Research IG to include a maternal mental health use case for researchers to extract data to study the outcomes of mothers with mental health diagnoses and their infants. The maternal mental health use case will focus on identifying patients who have experienced a delivery event and demonstrated evidence of mental health conditions during pregnancy and postpartum. ASPE identified International Classification of Disease, 10th Revision, codes representing a broad set of maternal mental health conditions. While this report and the current Research IG expansion focus on four initial mental health conditions of interest—depression, anxiety, bipolar disorder, and psychosis—future IG expansion may incorporate the broader set of maternal mental health conditions identified by ASPE. Once integrated into the Research IG, the maternal mental health use case will be piloted with a health information exchange (HIE) organization to extract data.

Research IG Assessment

We first conducted a gap analysis to review clinical guidelines, data standards for related data classes and elements, the existing Research IG, and other relevant FHIR IGs. Next, we sought feedback on the gap analysis findings from six subject-matter experts with relevant maternal mental health data expertise.

As a result of the gap analysis, we developed a table of data elements related to maternal mental health that the Research IG must support for capture, including diagnostic codes, screening tools and assessments, timing of screening, maternal health characteristics and indicators, treatment and interventions, follow-up monitoring, maternal outcomes, and infant outcomes. We then assessed the Research IG to determine the extent of modifications needed to include the new maternal mental health use case. Expanding the Research IG to include maternal mental health requires adding new profiles and value sets for the mental health conditions of interest, screening tools for these conditions, and treatments and interventions associated with these conditions (e.g., medication, therapy, and referrals). Specifications also are needed to support symptom monitoring, temporal context for screening timing, and outcome tracking for mothers and infants specific to maternal mental health. The Research IG has existing structures for capturing pregnancy status and linking mother-infant records.

Recommended Research IG Updates

To expand the Research IG, we will undertake the following key activities, leveraging existing data elements from established standards, including United States Core Data for Interoperability (USCDI) and other relevant FHIR IGs.

First, we will update the existing Research IG to work with current tools by converting Research IG artifacts into the FHIR Shorthand format using an available Health Level 7 International®-supported open-source IG publishing tool.

The Research IG will be updated to the new format and will include content for the maternal mental health use case, following the same approach as the existing use cases. Specifically, we will add the following artifacts to the Research IG:

- **Measure resource** to define the patient cohort and the data that should be exported.
- **Library resource** (included in the Measure resource) to retrieve patient data from the FHIR server.
- **ValueSet resources** for data such as the mental health conditions, medications, and procedures.
- **Example resources** that include examples of patient data in FHIR Release 4 format to supplement the existing resources.

Next Steps

To pilot test these updates, we will implement the Research IG with an HIE to conduct a comparative effectiveness research (CER) study using the extracted dataset and document lessons learned that could inform future Research IG enhancements. The ability to analyze data regarding maternal mental health across healthcare settings will support PCOR, CER, and policy development geared toward improving maternal mental health.

1. Introduction

Maternal mental health conditions, including but not limited to perinatal depression, anxiety, bipolar disorder, and psychosis, are leading contributors to maternal morbidity and mortality in the United States.² Mental health disorders are now recognized as the most frequent underlying cause of pregnancy-related deaths, underscoring the urgency of early detection and coordinated care.³ Despite increased awareness, maternal mental health conditions remain underdiagnosed and undertreated.⁴ Existing research on maternal mental health is constrained by a lack of standardized, comprehensive, and interoperable data.⁵

To support improved maternal health patient-centered outcomes research (PCOR), the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) funded development of the *Longitudinal Maternal & Child Health Information for Research Fast Healthcare Interoperability Resources (FHIR) Implementation Guide*⁶ v1.0.0 (Research IG). Released on December 8, 2022, the Research IG was developed by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH), in collaboration with the Centers for Disease Control and Prevention (CDC), Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC), and National Library of Medicine (NLM). The Research IG provides a framework for researchers to consistently aggregate, extract, and analyze electronic clinical information related to maternal health across different healthcare organizations and health IT systems that have adopted FHIR standards.

Currently, the Research IG covers two cohorts: 1) women who die within 365 days of a pregnancy, regardless of cause of death or pregnancy outcome and infant outcomes, and 2) women diagnosed with gestational hypertension and/or postpartum hypertension within six weeks of delivery and infant outcomes. The purpose of this project is to expand the Research IG by adding a maternal *mental health use case* to support patient-centered outcomes of the mother and child. Maternal mental health encompasses a broad set of conditions. While the Assistant Secretary for Planning and Evaluation (ASPE) conducted an analysis to identify a broad set of relevant International Classification of Disease, 10th Revision, (ICD-10) codes, the current Research IG expansion focuses on four maternal mental health conditions of interest—depression, anxiety, psychosis, and bipolar disorder. Once integrated into the Research IG, the maternal mental health use case will be pilot tested with a health information exchange (HIE) organization to extract the data.

The new use case will provide researchers with tools to extract data to study the outcomes of mothers with mental health diagnoses and their infants. These data can be used in patient-centered outcomes research (PCOR), comparative effectiveness research (CER), and policy analyses to answer key questions such as how pre- and postpartum depression screenings impact pregnancy outcomes and how treatment for mental health diagnoses influences maternal health postpartum. These analyses can inform both clinical care and policy approaches.

1.1 Objectives and Structure of the Report

This report describes findings from an assessment of the Research IG to determine the extent to which the Research IG can be used to extract maternal mental health data in its current form, identify gaps and limitations, and summarize how the gaps will be addressed to integrate the new use case. The report findings will be used to update the Research IG to include the maternal mental health use case to

support federal, academic, and independent researchers interested in maternal and infant health outcomes research. The report sections are organized as follows:

- The **Methods** section describes the process for assessing the Research IG and determining relevant data elements and standards needed to extract data on maternal mental health, including engaging with experts for guidance on these topics. **Appendix A** includes additional information regarding the methods.
- The **Gap Analysis** section provides information on the gaps and limitations of the current Research IG to support inclusion of the maternal mental health use case.
- The **Recommendations for Research IG Enhancement** section outlines the needed updates or modifications to the Research IG.
- The **Implementation Plan** section describes the project's next steps for implementing the updated Research IG with an HIE partner to pilot test data extraction and quality assessment. **Appendix B** includes the HIE candidates under consideration.
- The report ends with a **Conclusion** section that summarizes findings and potential impacts for the maternal mental health and infant health data infrastructure.

2. Methods

The methods were designed to ensure a systematic approach to expanding the Research IG for the maternal mental health use case. We aimed to 1) define the new maternal mental health use case to establish clear objectives and scope; 2) identify the data elements required to support this use case, ensuring completeness and relevance; and 3) assess necessary modifications to the current Research IG to incorporate the new use case effectively.

To achieve these objectives, we first used a snowball approach to conduct a gap analysis reviewing clinical guidelines and data standards. Next, we sought feedback on the gap analysis findings from maternal mental health subject-matter experts (SMEs) via email and through individual virtual discussions.

The gap analysis process included a web-based scan for maternal mental health data sources and standards, supplemented by additional resources recommended by SMEs. These included 1) clinical guidelines on evidence-based practices for maternal mental health screening, conditions, outcomes, data collection, and workflows from the American College of Obstetricians and Gynecologists (ACOG), the Alliance for Innovation on Maternal Health (AIM), the National Institute of Mental Health (NIMH), and the World Health Organization (WHO); 2) data standards, such as the United States Core Data for Interoperability (USCDI), for data classes and elements related to maternal health and/or behavioral health; and 3) the original Research IG along with other relevant FHIR IGs that could contain useful information on research data exchange. The full list of data sources is included in **Exhibit 1**. Information was abstracted into a spreadsheet that was collaboratively reviewed by all team members (**Appendix A**).

Exhibit 1. Data Sources and Resources for Research IG Assessment

SME Engagement		
Clinical Guidelines <ul style="list-style-type: none">•ACOG Summary of Perinatal Mental Health Conditions•ACOG Patient Screening•ACOG Assessment and Treatment of Perinatal Mental Health Conditions•AIM Perinatal Mental Health Conditions Patient Safety Bundle•NIMH Common Data Elements/Data Dictionary•WHO mhGAP Intervention	Data Standards <ul style="list-style-type: none">•Consolidated Clinical Document Architecture (v4.0.0)•Interoperability Standards Advisory (ISA)•USCDI (v3, v6)•USCDI+ Behavioral Health (v0.1.0)•USCDI+ Maternal Health (draft)•USCDI+ Public Health (draft)•USCDI+ Quality (draft)	Implementation Guides <ul style="list-style-type: none">•Bulk Data Access FHIR IG•Longitudinal Maternal & Infant Health Information for Research FHIR IG•Postpartum Transition of Care FHIR IG (draft)•Real World Data FHIR IG•US Behavioral Health Profiles FHIR IG•US Core FHIR IG

We engaged six SMEs from universities, health systems, and research organizations with relevant maternal mental health data expertise to provide guidance throughout the project. SMEs were identified through online searches related to maternal mental health data and ASPE recommendations. They were selected to ensure representation across clinical care, informatics, health services and policy research, and HIE data governance and privacy (**Exhibit 2**). For this Research IG assessment, we asked two SMEs with clinical informatics backgrounds to validate our gap analysis abstraction findings. In November 2025, we shared with them a table of clinical data elements identified as relevant for the maternal mental health use case. We requested they review the table for accuracy and completeness and provide feedback on data elements to include or remove based on electronic health record (EHR) data standardization and completeness. SMEs provided input by email and/or through individual virtual discussions to facilitate detailed review and incorporation of expert-specific feedback. The abstraction spreadsheet was updated based on their feedback.

Exhibit 2. Experts Engaged in Research IG Assessment

Expertise	Number of Experts (N=6)
Maternal Health Clinical Informatics/Data Infrastructure	3
Maternal Mental Health Research/Policy	2
Data Governance and Privacy	1

3. Gap Analysis Findings

This section describes the maternal mental health use case and summarizes needed changes to the Research IG to incorporate the new use case.

3.1 Maternal Mental Health Use Case

The use case focuses on high-priority maternal mental health conditions—depression, anxiety, bipolar disorder, and psychosis—based on clinical significance, prevalence, and relevance to maternal and infant outcomes. *Perinatal depression* is one of the most common obstetric complications and is frequently underdiagnosed.^{7,8} Prevalence estimates vary across studies, with some reporting rates as high as 26.3% and 27.6% for perinatal and postpartum depression, respectively. *Perinatal anxiety* is also common, affecting approximately 1 in 5 perinatal women.^{9,10,11} Both conditions are prioritized for structured screening and diagnosis during pregnancy and postpartum.¹² *Bipolar disorder* is critical for maternal mental health surveillance due to the high risk of relapse during pregnancy and postpartum.¹³ Although less common, *psychosis* is identified by ACOG as a severe perinatal mental health condition requiring immediate clinical assessment and management.¹⁴

The maternal mental health use case will focus on identifying patients who have experienced a delivery event and demonstrated evidence of the mental health conditions during pregnancy and postpartum. This cohort definition establishes the criteria for inclusion in the population targeted by the *Measure resource* (see textbox for definition).

To support the maternal mental health use case, standardized data should be collected for each condition, including screening and assessment results; clinical diagnoses recorded in the EHR; treatment and care plans (including pharmacologic and non-pharmacologic interventions); referrals and care coordination; longitudinal symptom monitoring; and maternal and infant (health) outcomes. Value sets and terminologies are needed to distinguish these conditions, incorporate pregnancy and postpartum timing context, and support longitudinal research. Inclusion of validated screening tools such as Edinburgh Postnatal Depression Scale (EPDS),¹⁵ Patient Health Questionnaire-9 (PHQ-9),¹⁶ and General Anxiety Disorder-7 (GAD-7)¹⁷ will ensure consistent capture of structured assessment data and facilitate comparison across settings and populations. According to SMEs and clinical guidelines, data for these conditions are typically collected during prenatal visits, postpartum checkups, pediatric well-child visits, and emergency department (ED) encounters. The data collection at these touchpoints should support comprehensive and longitudinal maternal mental health data collection, including cross-provider and cross-setting data exchange.

Maternal Mental Health Use Case Cohort Definition

Female patients who experienced a delivery event and had evidence of depression, anxiety, bipolar disorder, and/or psychosis, regardless of delivery outcome. These conditions are defined as meeting at least one of the following criteria during any time of their pregnancy through up to 12 months postpartum:

- A diagnosis of depression, anxiety, bipolar disorder, and/or psychosis based on the ICD-10 Clinical Modification codes.
- Prescription or active medication for treatment (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs], tricyclic antidepressants, mood stabilizers).
- Screening scores documented in the patient record.

Exhibit 3 provides an overview of the data elements that the Research IG must support for capture. These data elements were identified based on a review of clinical guidelines from professional organizations and were validated by clinical and research SMEs.

Exhibit 3. Clinical Data Elements for Capture in Research IG

Clinical Condition	Screening Tools/Assessments ¹⁸	Timing of Screening	Additional Maternal Health Indicators	Treatment/Intervention ^{19, 20}	Follow-up/Monitoring ^{21, 22}	Maternal Outcomes ^{23, 24}	Infant Outcomes ²⁵ 26 27
Depression	PHQ-9, ²⁸ EPDS ²⁹	Prenatal visit, Labor and delivery, Postpartum visit (up to 12 months following childbirth), Well-baby visit	Patient demographic information, healthcare utilization (ED visits, psychiatric hospitalizations), delivery type (e.g., emergency c-section), lab values, maternal weight gain, vitals, prenatal visit count, pain scores	Antidepressants (SSRIs, SNRIs, brexanolone, zuranolone), anxiolytics, or antipsychotics, psychotherapy, peer or group support, referral to behavioral health	Ongoing monitoring of depressive symptom scores; remission status tracking; medication adherence; suicide risk and repeat screening	Symptom remission, decreased recurrence, improved functioning	Pre-term birth, low birth weight, ³⁰ developmental delays, neonatal intensive care unit (NICU) admission, results of developmental screenings (e.g., Ages and Stages Questionnaire, Parents' Evaluation of Developmental Status, Modified Checklist for Autism in Toddlers), ED/urgent care visits
Anxiety	GAD-7, GAD-2, Perinatal Anxiety Screening Scale (PASS) ³¹	Prenatal visit, Labor and delivery, Postpartum visit, Well-baby visit	Patient demographic information, healthcare utilization (ED visits, psychiatric hospitalizations), delivery type (e.g., emergency c-section), lab values, maternal weight gain, vitals, prenatal visit count	Cognitive Behavioral Therapy (CBT), relaxation/mindfulness-based interventions, SSRIs, anxiolytics, behavioral health referral	Symptom severity over time (GAD-7 scores); remission status tracking; medication adherence	Improved anxiety symptomatology and functioning	Pre-term birth, low birth weight, ³² developmental delays, NICU admission, results of developmental screenings (e.g., Ages and Stages Questionnaire, Parents' Evaluation of Developmental Status, Modified Checklist for Autism in Toddlers), ED/urgent care visits

Clinical Condition	Screening Tools/Assessments ¹⁸	Timing of Screening	Additional Maternal Health Indicators	Treatment/Intervention ^{19, 20}	Follow-up/Monitoring ^{21, 22}	Maternal Outcomes ^{23, 24}	Infant Outcomes ^{25, 26, 27}
Bipolar Disorder	Mood Disorder Questionnaire (MDQ), ³³ structured clinical assessment	Prenatal visit, Labor and delivery, Postpartum visit, Well-baby visit	Patient demographic information, healthcare utilization (ED visits, psychiatric hospitalizations), delivery type (e.g., emergency c-section), lab values, maternal weight gain, vitals, prenatal visit count	Mood stabilizers (lithium, lamotrigine), psychotherapy, close psychiatric follow-up, referral coordination	Monitoring of relapse/recurrence, medication adherence, serum levels for mood stabilizers	Reduced relapse risk, mood stabilization	Pre-term birth, low birth weight, ³⁴ developmental delays, NICU admission ³⁵ , results of developmental screenings (e.g., Ages and Stages Questionnaire, Parents' Evaluation of Developmental Status, Modified Checklist for Autism in Toddlers), ED/urgent care visits
Psychosis	Clinical assessment (no standard screening tool; rapid evaluation for symptoms)	Labor and delivery, Postpartum (usually within the first six weeks after delivery) ³⁶	Patient demographic information, healthcare utilization (ED visits, psychiatric hospitalizations), delivery type (e.g., emergency c-section), lab values, maternal weight gain, vitals, prenatal visit count	Antipsychotic medication, hospitalization if indicated, urgent psychiatric referral	Psychiatric stabilization monitoring, relapse prevention planning ³⁷	Symptom stabilization, reduced risk of suicide or harm	Infant safety, custody, or protection concerns ³⁸ , results of developmental screenings (e.g., Ages and Stages Questionnaire, Parents' Evaluation of Developmental Status, Modified Checklist for Autism in Toddlers), ED/urgent care visits

3.2 Assessment of Research IG for Inclusion of the Maternal Mental Health Use Case

The Research IG was assessed to determine the extent of modifications needed to include the new maternal mental health use case. This included reviewing needed data elements and standards to extract data on maternal mental health screenings; diagnoses; treatments; and maternal, pregnancy, and infant outcomes in a FHIR-compatible format.

The Research IG is built on FHIR Release 4 (R4) and uses numerous FHIR resources, other FHIR IGs, and standards-based value sets and code systems (**Exhibit 4**). To support data aggregation and extraction, the Research IG leverages the FHIR Clinical Quality Framework and Quality Measure IG, which support data collection to calculate electronic clinical quality measures. In the Research IG, this approach is used to define a “cohort measure”: a population cohort (e.g., hypertensive pregnant or postpartum women) for which to extract data.

Exhibit 4. FHIR Resources, Other Standards, and Terminologies in the Current Research IG

FHIR Resources ³⁹	Dependencies ⁴⁰	Value Sets/Code Systems ⁴¹
<ul style="list-style-type: none"> • AllergyIntolerance • CarePlan • CareTeam • Composition • Condition • Coverage • Device • Diagnostic Report • DocumentReference • Encounter • FamilyMemberHistory • Goal • Immunization • Location • Measure • Medication • MedicationRequest • Observation • Organization • Patient • Practitioner • PractitionerRole • Procedure • Provenance • RelatedPerson 	<ul style="list-style-type: none"> • Health Level 7 International® (HL7) Terminology • US Core Implementation Guide • Vital Records Common Profiles Library • Vital Records Birth and Fetal Death Reporting • Clinical Quality Framework Common FHIR Assets • Quality Measure Implementation Guide (STU3) 	<ul style="list-style-type: none"> • Pregnancy value set: Grouping of 3 value sets – Pregnancy, Complications of Pregnancy, Childbirth and the Puerperium, and Complications of Pregnancy, Childbirth and the Puerperium (<i>ICD-9/10 and Systematized Nomenclature of Medicine – Clinical Terms [SNOMED CT] codes</i>) • ValueSet - Hypertensive Disorders of Pregnancy ICD • ValueSet - Hypertensive Disorders of Pregnancy SNOMED CT • ValueSet - Hypertensive Disorders of Pregnancy (<i>ICD-10 and SNOMED CT codes</i>) • Pregnancy Non-Live value set: Grouping of 2 value sets – Non Live Birth Diagnosis and Non Live Birth Current Procedural Terminology (CPT) Procedures (<i>ICD-10, SNOMED CT, and CPT codes</i>) • Pregnancy Procedure Delivery value set: Grouping of two value sets – Delivery and Live Births and Delivery Procedures (<i>ICD-10 PCDS and SNOMED CT codes</i>) • Pregnancy Procedure Delivery CPT: ValueSet containing all CPT concepts for pregnancy procedures

Exhibit 5 presents a gap analysis, outlining what is needed to expand the current Research IG to incorporate the new maternal mental health use case. For each concept area (e.g., clinical condition, pregnancy status), the table displays the data elements required to address maternal mental health. It then indicates whether the concept is currently included in the Research IG and identifies the FHIR resource(s) that can represent the concept. Finally, it provides additional notes on the gaps identified.

The narrative text of the Research IG describes a conceptual approach to linking mother and infant(s) records. However, the Research IG does not provide technical specifications for linking the records. Furthermore, the FHIR Library included with the Measure resource lacks Clinical Quality Language (CQL) expressions for linking the records. On testing the CQL library, it included resources from the mother's record where it should have included resources from the infant's record (e.g., head circumference).

In summary, to expand the Research IG to include the maternal mental health use case, a new cohort needs to be defined for the maternal health population of interest. This will require the addition of new profiles and value sets for the four mental health conditions of interest (depression, anxiety, bipolar disorder, and psychosis), screening tools for these conditions, and treatments and interventions associated with these conditions (e.g., medication, therapy, referrals). Specifications also are needed to support symptom monitoring, temporal context for screening, and outcomes tracking for mothers and infants specific to maternal mental health. Feasibility of linking a mother and infant(s) records using CQL and FHIR R4 will also need to be assessed. The Research IG has existing structures for capturing pregnancy status.

Exhibit 5. Gap Analysis: Data Elements to Include in the Research IG for the New Maternal Mental Health Use Case

Concept Area	Data Element	Currently Supported in Maternal FHIR IG	Source FHIR Resource(s) to Represent the Data Element	Notes/Gaps Identified
Clinical Condition	Mental health conditions during the peripartum period, e.g., maternal depression, anxiety, bipolar disorder, psychosis	Partially supported – needs mental health conditions	Condition	Includes maternal conditions but not specific mental health conditions; new or existing codes or value sets need to be included for maternal mental health.
Pregnancy Status	Current pregnancy, postpartum, interpregnancy status	Fully supported	Observation, Encounter, Condition	Need to link screening assessments and interventions to pregnancy stage.
Mental Health Screening Tool	EPDS, PHQ-9, GAD-7, clinical assessment	Not supported – not currently profiled for mental health screening	Questionnaire, Questionnaire Response, Observation	No defined profiles for mental health screening instruments.
Treatment/ Intervention	Pharmacotherapy, therapy, referral	Partially supported – structure supported, no maternal mental health-specific examples	Medication Request, Service Request, Procedure	Structure available for all FHIR resources but ServiceRequest. Additionally, there are no mental health-specific examples; IG could include sample workflows for medication management, therapy referral, and care coordination.

Concept Area	Data Element	Currently Supported in Maternal FHIR IG	Source FHIR Resource(s) to Represent the Data Element	Notes/Gaps Identified
Follow-up/ Monitoring of Symptoms	Symptom severity, recurrence, treatment response	Partially supported – structure supported, no maternal mental health-specific examples	Observation, Care Plan	Structure available but no mental health-specific examples; IG could define recommended Observation profiles and Care Plan elements to support symptom monitoring.
Screening Timing	Prenatal, labor, postpartum, pediatric visit	Not supported – timing context not defined	Encounter, Observation	Needs a temporal context to indicate the screening period.
Outcome Tracking	Remission, readmission, suicide risk, adverse event, pre-term birth, low birth weight	Partially supported – structure available, no mental health or infant outcomes defined	Observation, Condition, Care Plan	Outcome tracking exists but is not tailored for maternal mental health or linked to maternal outcomes.
Mother-Infant Linkage	Mother-Infant Linkage	Not supported	Related Person, Patient	Technical specifications or implementation in CQL are not included for linking the record.

To address the gaps identified in Exhibit 5, we will leverage existing data elements from established standards, including USCDI and other relevant FHIR IGs. **Exhibit 6** lists data classes that can be referenced for the Research IG updates found within USCDI, USCDI+ versions, and Consolidated Clinical Document Architecture (C-CDA).

USCDI,⁴² which defines the data classes and elements required for nationwide interoperable health information exchange, contains core clinical and demographic data. Expanded versions contain public health, care planning, and social functional data. USCDI Version 3,⁴³ which is required for adoption by the Health Data, Technology, and Interoperability (HTI-1) Final Rule,⁴⁴ includes a data class for pregnancy status. USCDI Version 6,⁴⁵ published in 2025, adds new maternal mental health data elements such as postpartum depression screening, alcohol use, and substance use; however, Version 6 has not been fully adopted and may require EHR customization to track information across the postpartum period.

Federal initiatives have expanded on USCDI by harmonizing more granular, standardized data elements for specific health priorities. USCDI+ Behavioral Health,⁴⁶ USCDI+ Maternal Health,⁴⁷ USCDI+ Public Health, and USCDI+ Quality all contain relevant information for maternal mental health, such as pregnancy information, screening instruments, risk assessments, and care interventions. For instance, depending on the dataset, the Health Status Assessment data class may contain elements related to anxiety, depression, mental trauma, mental/cognitive status, pregnancy status, psychological functioning, substance use, and screening type. ASTP/ONC is currently investigating strategies to encourage federal agencies and healthcare industry participants to adopt these standard-driven methodologies. For instance, current initiatives are focused on expanding the USCDI+ Maternal Health dataset and FHIR resources to support the postpartum transitions of care use case.

C-CDA Version 2.1⁴⁸ defines how to structure clinical documents. While there is not a widely adopted prenatal or antepartum C-CDA document with required key data elements, the HL7 CDA Maternal Health track has been exploring key data elements and developing new templates for Pregnancy Status Observation and Pregnancy Summary Organizer that track a patient's journey from the three trimesters of pregnancy to the three phases of postpartum (acute, subacute, and delayed phase).⁴⁹

Additional FHIR IGs offer templates and rules that can be applied when updating the Research IG. The HL7 FHIR US Core IG⁵⁰ provides technical specifications for using the FHIR standard to query for USCDI data elements, and there is a specific IG designed for the USCDI+ Behavioral Health data elements. The FHIR US Core IG v6.1.0 - STU6 is required for the [“Standardized API for patient and population services”](#) certification criteria as of December 31, 2025.⁵¹ The Bidirectional Services eReferral FHIR IG⁵² provides guidance on exchanging clinical and non-clinical referrals in the form of service requests to streamline communication between health care systems and community services organizations. The HL7 IG for CDA Release 2.1⁵³ provides templates and supporting materials for summary care records that would contain maternal mental health information and is the regulatory standard for the [“clinical quality measures \(CQMs\)—record and export”](#) certification criteria.⁵⁴

Exhibit 6. Relevant Maternal Mental Health Standardized Data Classes

Data Class	C-CDA	USCDI v3	USCDI v6	USCDI BH	USCDI MH	USCDI PH	USCDI Quality
Assessment and Plan of Treatment/Care Plan	✓	✓	✓	✓	✓	✓	✓
Behavioral Health (or Behavioral Health Status Screen)				✓	✓		
Clinical Notes	✓	✓	✓	✓	✓	✓	✓
Encounter Information	✓	✓	✓	✓	✓	✓	✓
Family Health History			✓	✓	✓		✓
Health Insurance		✓	✓	✓	✓		✓
Health Status/Assessments (may include Pregnancy Status and Mental Health Screen)	✓	✓	✓	✓	✓	✓	✓
High Risk Behavioral Health Indicators				✓			
High Risk Perinatal Care Referrals					✓		
Labor & Delivery					✓		
Laboratory	✓	✓	✓	✓	✓	✓	✓
Lactation					✓		
Medications	✓	✓	✓	✓	✓	✓	✓
Mortality					✓		
Newborn's Delivery Information					✓	✓	✓
Patient Demographics	✓	✓	✓	✓	✓	✓	✓
Postpartum					✓		
Pregnancy Information					✓	✓	✓
Problems	✓	✓	✓	✓	✓	✓	✓
Procedures	✓	✓	✓	✓	✓	✓	✓
Recovery Support Services				✓			
Referrals							✓
Social Determinants/Social History	✓		✓	✓		✓	
Vital Signs	✓	✓	✓	✓	✓	✓	✓

BH: Behavioral Health; MH: Maternal Health; PH: Public Health

4. Recommendations for Research IG Enhancement

To enhance the Research IG to include the maternal mental health use case, we will undertake the following key activities.

4.1 Update the Existing Research IG to Work with New Tools

The current version of the Research IG was developed using Trifolia-on-FHIR®, a tool developed by Lantana Consulting Group. Technical artifacts within the Research IG, such as profiles and definitional and example FHIR resources, were specified in the XML format with Trifolia. Lantana has since retired the Trifolia tool.⁵⁵

An available alternative tool is the HL7-supported open-source IG publishing tool. This tool uses a different format for the source artifacts, namely FHIR Shorthand (FSH).⁵⁶ Therefore, a preliminary task will be to convert the current Research IG artifacts to the FSH format using available tools like GoFSH.

4.2 Incorporate Maternal Mental Health Use Case

Once the Research IG is updated to the new format, we will include content for the maternal mental health use case. The new content will follow the same approach as the content for existing use cases. Specifically, we will add the following artifacts to the Research IG:

- **Measure resource.** This FHIR resource defines the patient cohort and the data that should be exported for the maternal mental health use case.
- **Library resource.** This resource (included in the Measure resource) contains CQL expressions to retrieve patient data from the FHIR server, assess patient inclusion in the cohort, and format the data to be included in the MeasureReport. The latter is produced when the Measure is evaluated by a FHIR server.
- **ValueSet resources.** Additional value sets will be included in the Research IG, such as for the four mental health conditions, medications, and procedures. To align with existing value sets, we will first look for and use value sets from the Value Set Authority Center (VSAC).⁵⁷ If a suitable value set is unavailable in VSAC, we will create a new value set.
- **Example resources.** As appropriate, we will create and include examples of patient data in FHIR R4 format to supplement the resources already in the Research IG.

CQL expressions will be developed using the Visual Studio Code plugin and validated with that tool. We will test the Measure and Library resources with the open-source HAPI FHIR server⁵⁸ to confirm that the correct output is being produced.

5. Implementation Plan

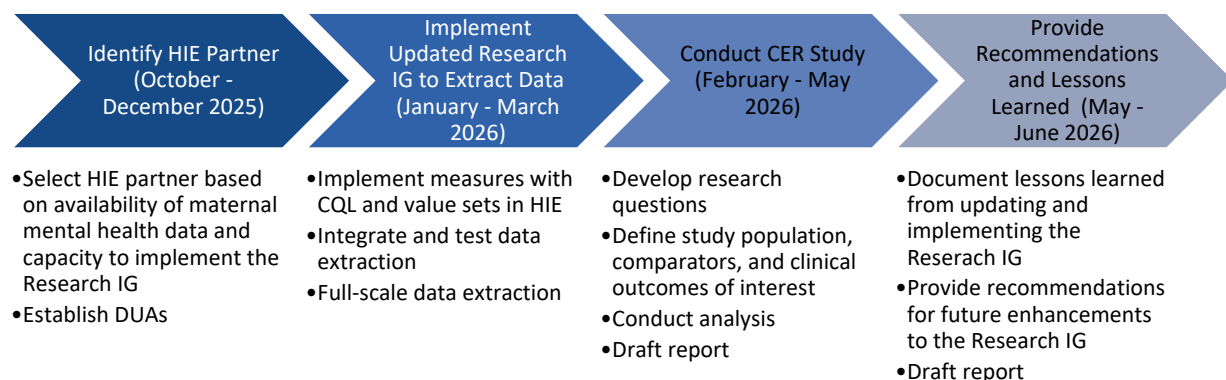
To pilot test Research IG updates, we will implement the maternal mental health related artifacts in the Research IG with an HIE (that is, use the IG specifications to guide data extraction from the HIE) and conduct a proof-of-concept CER study using the extracted dataset. We will use a phased approach (illustrated in **Exhibit 7**) in the pilot to ensure that we adhere to necessary data governance and regulatory requirements and document lessons learned to inform how the Research IG should be modified for broader adoption and use.

To select an HIE partner, we first aimed to identify and engage approximately 10 HIE organizations with a documented interest in advancing maternal and/or mental health through HIE. We also attempted to identify HIE organizations using FHIR, although public documentation of FHIR capacity was limited and therefore not used as an exclusion criterion. **Appendix B** provides a shortlist of HIE candidates. We conducted initial conversations with these HIE organizations to confirm that they 1) have identified maternal health as a priority; 2) possess the technical infrastructure to implement the Research IG; 3) compile Continuity of Care Documents; 4) collect data elements relevant for maternal mental health from relevant healthcare settings (e.g., hospital, outpatient); and 5) have experience with data extraction and secondary uses of HIE data. We then fielded a brief form to the HIE organizations to collect additional information on their technical capacity to implement the Research IG, data availability, and governance processes (**Appendix C**). Based on these responses and follow-up conversations (ongoing), we will select one HIE partner based on readiness and willingness to participate in the pilot, availability of desired data, and data governance committee approval.

To implement the updated Research IG pilot with the HIE partner, conduct the proof-of-concept CER study, and develop lessons learned we will:

- Establish data use agreements (DUAs) with the HIE organization and ensure privacy and security requirements are met for this patient population.
- Provide technical assistance to the HIE organization for implementing the Research IG to extract a dataset.
- Conduct the CER study using the extracted dataset to demonstrate the effectiveness and utility of the updated Research IG for maternal mental health research. This includes engaging with SMEs to develop relevant, high-priority research questions and define the study's population, comparators, and outcomes; and drafting a report detailing the findings from the data analysis and any limitations related to data quality.
- Iteratively document lessons learned and limitations in a table describing the issue encountered, context of the problem, resolutions to the problem, and recommendations for future refinements to the Research IG. This will culminate in a report to inform ways to modify the Research IG to ensure its scalability among EHR vendors.

Exhibit 7. Pilot Activities Overview



6. Conclusion

This report included a gap analysis with recommendations of how the Research IG can be expanded to support maternal mental health research. Expanding the Research IG to include maternal mental health conditions represents an important step toward improving the data infrastructure for studying maternal mental health using real-world, clinical data. While this report and the expanded Research IG focus on inclusion of four maternal mental health conditions, future work can include expanding the Research IG to include the broader set of maternal mental health conditions identified by ASPE. The ability to analyze maternal mental health data across healthcare settings will support PCOR, CER, and policy development geared toward improving maternal mental health.

Appendix A. Targeted Review Methods

Exhibit A1. List of Resources Reviewed and Abstraction Categories

Type of Resource	Abstraction Categories
USCDI and Common Data Elements	<ul style="list-style-type: none"> ■ Name of Source/Document ■ Version and Release Date ■ Relevant Data Classes/Elements (e.g., Problems, Medications, Observations, Assessments, Outcomes) ■ Maternal Mental Health Coverage ■ Maternal Health Coverage (generally, including postpartum) ■ Mental Health Coverage ■ Psychiatric Medication Coverage ■ Gaps Identified (e.g., Missing Data, Limited Granularity) ■ Other Notes/Considerations
FHIR IG Resources	<ul style="list-style-type: none"> ■ Resource/IG Name ■ Version/Release Date ■ FHIR Resource Types Used ■ Other FHIR Structures Referenced ■ Value Sets/Code Systems Referenced ■ Support for Screenings/Questionnaires ■ Support for Psychiatric Medications ■ Support for Mother-Infant Linkages ■ Support for Outcomes (and which) ■ Longitudinal Data Support ■ Constraints/Limitations ■ Alignment with USCDI ■ Gaps & Opportunities for Enhancement ■ Other Notes/Considerations
Clinical Guidelines	<ul style="list-style-type: none"> ■ Resource Name ■ Sponsoring Organization ■ Publication Date ■ Clinical Conditions Covered ■ Maternal Health Coverage ■ Mental Health Coverage ■ Maternal Mental Health Coverage ■ Tools/Measures Referenced ■ Recommended Interventions ■ Outcome Measures Identified ■ Mapping Potential ■ Other Notes/Considerations

Appendix B. Candidate HIEs

Exhibit B1. Health Information Exchange (HIE) Networks Reviewed for Pilot Partnership

HIE Name	State	Population
Connxus	Texas	Regional
Contexture	Arizona	Statewide
CyncHealth	Nebraska	Statewide
HealtheConnections	New York	Regional
MyHealth Access Network	Oklahoma	Statewide
OneHealthPort	Washington	Statewide
PelEx	Louisiana	Statewide

Appendix C. Form to Assess HIE Capacity to Participate in the Pilot

Maternal Mental Health Data Project HIE Background Form

Background

NORC at the University of Chicago has been contracted by the U.S. Office of the Assistant Secretary for Planning and Evaluation (ASPE) to improve data infrastructure for conducting perinatal and postpartum mental health research using data from electronic health records (EHRs) and health information exchanges (HIEs). Specifically, NORC will:

- Extend the [Longitudinal Maternal & Infant Health Information for Research](#) Fast Healthcare Interoperability Resources (FHIR®) Implementation Guide to include a new use case that supports the extraction of data on maternal mental health for use in research.
- Collaborate with an HIE to conduct a one-time data extract using the maternal mental health specifications in the updated Implementation Guide.

The data extract will pull HIE data related to four maternal mental health conditions—anxiety, depression, bipolar disorder, and psychosis—in the pre-natal, perinatal, and post-partum periods. It will also include data on pregnancy outcomes. The project will utilize existing HIE data; it will not require any new data collection. The data will be used to conduct a comparative effectiveness research study examining the relationship between maternal mental health and pregnancy outcomes.

Available Data Elements

1. From which of the following facility types does the HIE receive data? (select all that apply)
 - a. Hospital inpatient
 - b. Hospital ER
 - c. Hospital outpatient
 - d. Primary care
 - e. Pediatric care
 - f. Specialists (e.g., OBGYN)
 - g. Urgent care
 - h. Behavioral health providers
 - i. FQHCs
2. Does the HIE receive Continuity of Care Documents (CCDs)?
3. Which of the following data elements are currently available in the HIE related to maternal behavioral/mental health? (select all that apply)
 - a. Medications (e.g., antipsychotics, antidepressants, anxiolytics)
 - b. Diagnoses (e.g., postpartum depression, anxiety, psychosis, bipolar disorder)
 - c. Procedures (e.g., psychotherapy, psychiatric referral)
 - d. Healthcare utilization (e.g., hospitalizations, ED visits)
 - e. Maternal Mental Health Screenings (e.g., PHQ9, GAD7, EPDS)
4. Does the HIE have prior experience linking mother and infant records?

Data Exchange Capabilities

5. Does the HIE have prior experience using FHIR APIs to extract data?
6. Does the HIE use FHIR R4 APIs?
7. Do the FHIR R4 APIs support US Core?
8. Can the HIE support bulk data extraction?
9. The FHIR Implementation Guide uses the FHIR Clinical Quality Framework for Research, specifically relying on the Framework's measure model to define populations of interest and aggregate data (read more [here](#)). Does the HIE have the ability to run a FHIR Quality Measure (specifically, a cohort-type measure)?

Data Governance

10. Does the HIE need to obtain patient consent to share maternal mental health data?
11. Is the HIE prohibited from sharing maternal mental health data due to 42 CFR Part 2 requirements?
12. Can the HIE share a limited dataset?
13. Does the HIE have prior experience sharing limited datasets for secondary research purposes?

Timeline

14. Is the HIE available to work on this pilot project in the first quarter of next year (January-March 2026)?
15. Are there any other considerations you would like to share with us that are relevant to the proposed project?

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