

Methodology Report

Screening for Pregnancy Measure

April 25, 2018

This document was prepared by the Measure & Instrument Development and Support Contractor for the Inpatient Psychiatric Facility Outcome and Process Measure Development and Maintenance Task Order, under contract with the Centers for Medicare & Medicaid Services, an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.



PREPARED FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES BY HEALTH SERVICES ADVISORY GROUP, INC.

BETA TESTING – HEALTH SERVICES ADVISORY GROUP (HSAG)

Melissa Castora-Binkley, PhD, MA
Marie C. Hall, RN
Patti McKay, BA
Megan Keenan, MPH
Shannon Runge, PhD, MS
Kimberly Smuk, BS
Kristen Turner, MS
Suzanne Wright, MS
Tsu-Hsuan “Sherry” Yang, PharmD
Kyle Campbell, PharmD

ALPHA TESTING – UNIVERSITY OF FLORIDA

Almut G. Winterstein, RPh, PhD, FISPE, Department of Pharmaceutical Outcomes and Policy and Department of Epidemiology, University of Florida
Regina Bussing, MD, MS, Department of Psychiatry, University of Florida
Nakyung Jeon, PhD, Department of Pharmaceutical Outcomes and Policy, University of Florida
Xinyue Liu, PhD, Department of Pharmaceutical Outcomes and Policy, University of Florida
Ben Staley, PharmD, BCPS, Department of Pharmaceutical Outcomes and Policy and Department of Pharmacy, UF Health Shands Hospital
Gigi Lipori, MBA, Strategic Planning and Decision Support, UF Health and UF Health Sciences Center
Carl Henriksen, MS, Department of Pharmaceutical Outcomes and Policies, University of Florida

ACKNOWLEDGEMENTS

HSAG would like to thank the Inpatient Psychiatric Facility Measure Development and Maintenance Technical Expert Panel (TEP), who provided important insight and feedback during measure development and testing.

INPATIENT PSYCHIATRIC FACILITY MEASURE DEVELOPMENT AND MAINTENANCE TEP 2016-2018

Robert Cotes, MD
Medical Director, Inpatient Psychiatry at Grady Memorial Hospital

Kathleen Delaney, PhD, PMH-NP, FAAN
Professor, Rush College of Nursing

Vikas Duvvuri, MD, PhD
Medical Director, Fremont Hospital

Nola Harrison, ACSW, LSCW, LSW-A
Director, St. Anthony Hospital

Nora Lott Haynes, Med, EdS
Coordinator, NIMH Research Project, NAMI Savannah

Gayle Olano Hurt, MPA, CPHQ, PMC
Director Data Management, Outcomes Measurement, and Research Administration, Sheppard Pratt Health System

Mary Jane Krebs, FACHE
President, Spring Harbor Hospital

Kathleen McCann, RN, PhD
Director of Quality and Regulatory Affairs, National Association of Psychiatric Health Systems

Marsden McGuire, MD, MBA
Deputy Chief Consultant, Mental Health Services, Department of Veterans Affairs

Margaret Paccione-Dyszlewski, PhD
Director of Clinical Innovation, Bradley Hospital

Michael Peterson, MD, PhD
Director of Hospital Psychiatric Services, University Hospital

Nancy Purtell, MBA/HCM, RN
Assistant Vice President, Behavioral Health Services, Hospital Corporation of America (HCA)

Jessica Ross, MD, MS
Assistant Clinical Professor, Chief Informatics Officer, UCSF and Zuckerberg SF General Hospital, Department of Psychiatry

Elvira Ryan, MBA, BSN, RN
Associate Project Director, The Joint Commission

Lisa Shea, MD
Medical Director, Butler Hospital

Mary Kay Shibley, MSN, RN
Clinical Informaticist, Sharp Mesa Vista Hospital

Ann M. Sissler, MSW, LSW, ACSW
Senior Director, Quality and Patient Safety, Behavioral Health Services, Westchester Medical Center

Johan Smith, MBA
Vice President of Health Informatics, Universal Health Services, Horizon Health, Mental Health Outcomes

Julia Sullivan, MSN, RN-BC
Assistant Professor, Nursing, Santa Fe College

James D. Tew, Jr., MD
Medical Director, Quality and Clinical Pathways, Western Psychiatric Institute & Clinic

Michael Trangle, MD
Senior Medical Director, HealthPartners/Regions Hospital

CENTERS FOR MEDICARE & MEDICAID SERVICES

We would like to thank the following individuals from CMS for their continued guidance and support:

Jeffrey A. Buck, PhD
*Senior Advisor for Behavioral Health, Center for Clinical Standards and Quality
Program Lead, IPFQR Program*

Reena Duseja, MD
Director, Quality Measurement and Value-Based Incentives Group, Center for Clinical Standards and Quality

Kate Goodrich, MD, MHS
Director, Center for Clinical Standards and Quality

Vinitha Meyyur, PhD

Contracting Officer's Representative (COR), Measures Lead, Hospital Outpatient Quality Reporting and IPFQR

Cynthia Tourison, PhD

Deputy Director, Quality Measurement and Value-Based Incentives Group, Center for Clinical Standards and Quality

Pierre Yong, MD, MPH, MS

Director, Quality Measurement and Value-Based Incentives Group, Center for Clinical Standards and Quality

Table of Contents

List of Tables	6
List of Figures	7
Executive Summary	8
Background	8
Methods	8
Key Findings	8
Conclusion	9
1. Introduction	10
1.1 Importance	10
1.2 Measure Impact	11
2. Methods	13
2.1 Data Sources	13
2.1.1 Measure Testing.....	13
2.1.2 Site Training and Data Collection.....	13
2.2 Development of Denominator	13
2.2.1 Denominator Inclusion Criteria.....	13
2.2.2 Denominator Exclusion Criteria.....	13
2.3 Development of Numerator	14
2.4 Measure Scoring Methodology	14
2.4.1 Measure Calculation.....	14
2.4.2 Statistically Significant and Meaningful Differences in Performance.....	14
2.5 Reliability and Validity Testing	14
2.5.1 Reliability.....	14
2.5.1.1 Data Element Reliability.....	14
2.5.1.2 Performance Measure Score Reliability.....	15
2.5.2 Validity.....	16
2.6 Disparities Analyses	16
3. Results	17
3.1 Sample Characteristics	17
3.2 Denominator Results	17
3.2.1 Denominator Inclusion Analyses and Results.....	17
3.2.2 Denominator Exclusion Criteria Analysis and Results.....	18
3.3 Numerator Results	19
3.3.1 Numerator Analyses and Results.....	19
3.3.2 Definition of the Numerator.....	20
3.4 Measure Score Results	21
3.4.1 Measure Calculation Using the Proposed Measure Specifications.....	21
3.4.2 Statistically Significant and Meaningful Differences in Performance.....	22
3.5 Reliability and Validity Results	23
3.5.1 Reliability Results.....	23
3.5.1.1 Data Element Reliability Analysis and Results.....	23

3.5.1.2 AMA Exclusion Reliability Analysis and Results	24
3.5.1.3 Performance Measure Score Reliability Results and Interpretation	24
3.5.2 Validity Results	25
3.5.2.1 Systematic Assessment of Face Validity Results and Interpretation	25
3.6 Results of Disparities Analyses	25
4. Discussion	27
4.1 Summary	27
4.2 Measure Implementation	27
4.2 Measure Alignment	27
4.4 Limitations	28
5. Conclusion.....	29
6. References	30
Appendix A. Guideline Recommendations	33
Appendix B. Measure Information Form	37
Appendix C. Data Definitions and Abstraction Instructions.....	43
Data Dictionary	43
Data Element Name: <i>Admission Date</i>	43
Data Element Name: <i>Birthdate</i>	45
Data Element Name: <i>Discharge Date</i>	46
Data Element Name: Discharge Disposition	47
Data Element Name: Pregnancy Laboratory Test	50
Data Element Name: Documented Pregnancy Status	52
Data Element Name: <i>Sex</i>	54
Appendix D. Data Abstraction Tool.....	55

List of Tables

Table 1. Data Elements and Derived Scoring Elements used to Calculate the Measure Score and IRR.....	15
Table 2. Beta Testing Hospital Characteristics	17
Table 3. Percentage of females 15-44 who were discharged AMA	18
Table 4. Measure Score by Minimum Length of Stay Requirement.....	18
Table 5. Frequencies of Patients (age 15-44) with LOS > 2 Days by Type of Documented Pregnancy Screening	19
Table 6. Percentage of Patients (age 15-44) with LOS > 2 Days with a Resulted hCG Laboratory Test in the IPF, in the Emergency Department, or in a Transferring Facility	20
Table 7. Final Measure Scores Based on the Proposed Measure Specifications	22
Table 8. Distribution of Records Available for Inter-rater Reliability Analysis Across IPFs	23
Table 9. Percent of Agreement for Scoring Elements.....	24
Table 10. Reliability Using Signal-to-Noise for each IPF Final Measure Score	24
Table 11. Face Validity Results by Agreement Category	25
Table 12. Race/Ethnicity of Beta Testing Population (in percent; n=620)	25
Table 13. Final Measure Scores Stratified by Race and Ethnicity (n=420).....	25

List of Figures

Figure 1. Sample Cohort for Measure Score Calculation	22
Figure 2. Facility Measure Scores with 95% Confidence Intervals	23
Figure 3. Measure Algorithm	41

Executive Summary

Background

The Inpatient Psychiatric Facility Quality Reporting (IPFQR) program, which is a pay-for-reporting program mandated by section 1886(s)(4) of the Social Security Act, requires the Centers for Medicare & Medicaid Services (CMS) to develop measures that improve the quality of inpatient psychiatric care and to communicate quality information to consumers to help them make informed decisions about their healthcare options. Health Services Advisory Group, Inc. (HSAG) was contracted by CMS to identify new measures that could be considered for use in the IPFQR program and to maintain measures after they are implemented in the program.

Preventing harm caused by the delivery of healthcare was identified as a key measurement gap in the inpatient psychiatric facility (IPF) setting by patients and national experts. To identify specific areas that address this gap, the HSAG team reviewed clinical practice guidelines and drug labels for monitoring and screening activities that are recommended for medication classes commonly prescribed in the IPF setting. Screening female patients of childbearing age for pregnancy was identified as the highest priority measurement area because there was a demonstrated performance gap in preliminary test data; it would impact a significant portion of the IPF population; and was determined to have severe and preventable consequences if a screening was not conducted compared to other monitoring activities reviewed. Therefore, the *Screening for Pregnancy* measure was prioritized for development to address the CMS Meaningful Measures objective of Making Care Safer in the area of Preventable Healthcare Harm.

Methods

Measure development and testing were informed by an expert workgroup and a Technical Expert Panel (TEP) composed of patient representatives, psychiatrists, nurses, quality improvement specialists, and informaticists. Alpha testing was conducted in two IPFs located in the southeast United States. Beta testing was conducted in nine freestanding and unit-based IPFs from different regions of the country, with bed sizes ranging from 15 to 133, and various types of medical records including electronic, paper-based, and hybrid. Beta testing data were collected on a total of 913 admissions across the test sites. The importance of the measure was evaluated empirically by assessing the performance gap and number of female patients of childbearing age who were administered medications that carry risks during pregnancy. The reliability of scoring elements used to calculate the measure scores was evaluated based on percent agreement between two abstractors and a pooled Cohen's Kappa. Measure score reliability was evaluated based on a signal-to-noise analysis. The TEP reviewed the final measure specifications and testing results to assess the validity of the measure as an indicator of differences in facility quality. The feasibility of implementing the measure was assessed by confirming that all scoring elements could be abstracted from medical records with minimal burden. Alignment of scoring elements was achieved to the extent possible by examining whether they could be operationalized in the same way as similar scoring elements in measures in the IPFQR program.

Key Findings

- Importance
 - On average, across nine testing facilities, nearly one in five females of childbearing age was not screened for pregnancy, which is a performance gap of almost 20%. The average screening rate was 80.7%, with a range among facilities of 59.3% – 93.8%.
 - Screening female patients of childbearing age for pregnancy during the inpatient psychiatric hospitalization is important to reduce adverse pregnancy outcomes and integrate risk versus benefit considerations relevant to pregnancy into treatment decisions by clinicians and patients.
 - 96.1% of female patients of childbearing age admitted to nine beta testing IPFs received medications which can be harmful to fetal development and obstetrical outcomes.¹⁻¹⁴ By

identifying pregnancy during the inpatient psychiatric stay, providers and patients can engage in a discussion of the risks and benefits of various treatment options which may include dosage adjustments, monitoring serum levels of medications, changing to medications that carry fewer risks, or exploring non-pharmaceutical forms of treatment like psychotherapy for patients with depression.^{1,5-9,12-16} Providers and patients can consider that the risks of abruptly discontinuing psychiatric medications may outweigh the risks of continuing the medications during pregnancy.^{5,14,17}

- Identification of a pregnancy can help to inform discharge planning by including referrals to prenatal care, providing additional resources or instructions for women who may be at increased risk for postpartum depression, and making referrals to drug treatment programs for pregnant women with substance use disorders.^{1,12,14,18,19}
- Several psychiatric medications interact with oral contraceptives and decrease their efficacy.¹⁴ The screening for pregnancy provides an opportunity for providers to discuss these medication interactions with the patients who do not screen positive for pregnancy.
- Female patients and caregivers of female patients who reviewed the measure indicated that it assesses an aspect of care that is important to them.
- Scientific Acceptability
 - The measure specifications are precisely defined.
 - The scoring elements were highly reliable with an average agreement between abstractors of 98.3% and a Pooled Cohen's Kappa of 0.97, which indicates substantial agreement.
 - Measure performance scores had a high degree of reliability (range = 0.72 – 0.94) based on signal-to-noise analysis, which indicates that the measure can differentiate performance between facilities.
 - Among 18 voting TEP members, 17 agreed that the measure scores represent a valid assessment of facility quality.
- Usability
 - The measure was determined to be highly feasible to implement with minimal burden to facilities. The scoring elements were readily identified in the medical records during testing and the average abstraction time was 4.6 minutes per record.
 - Patients and caregivers interviewed about the measure indicated that measure scores were easy to interpret.
 - CMS can use the measure in pay-for-reporting programs to achieve the goal of high-quality and efficient healthcare.
- Alignment/Harmonization
 - The measure is aligned with existing endorsed measures where feasible.

Conclusion

In summary, if the *Screening for Pregnancy* measure were implemented in the IPFQR program, it would add to the suite of measures that improve the quality of inpatient psychiatric care by preventing healthcare harm. Improving the rates of screening would reduce the likelihood of adverse pregnancy outcomes among patients who are pregnant and provide an opportunity to discuss the importance of family planning while on psychiatric medications among patients who are not pregnant. As specified, the measure addresses a clear performance gap in the IPF setting, can be reliably calculated by facilities with minimal burden, and is a valid measurement of facility performance. Both providers and patients agree that the measure addresses an important aspect of care.

1. Introduction

This report describes the *Screening for Pregnancy* measure, which was developed for potential inclusion in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program. The IPFQR program is a pay for reporting program that was mandated by section 1886(s)(4) of the Social Security Act. The program was implemented on October 1, 2012 with goals to improve the quality of inpatient psychiatric care and to communicate information to consumers to help them make informed decisions about their healthcare options. Health Services Advisory Group, Inc. (HSAG) developed the *Screening for Pregnancy* measure under contract to the Centers for Medicare & Medicaid Services (CMS) and in collaboration with the University of Florida to improve quality by reducing harm caused by the delivery of care.

This report provides a description of the measure development process, the results of beta testing, and the final measure specifications. *Section 1* summarizes the literature that supports the measure focus and delineates the anticipated impact of measure implementation in the IPF setting. *Section 2* describes the methodology for the development and testing of the measure. *Section 3* presents results of beta testing. *Sections 4 and 5* provide a discussion of the measure findings and a concluding statement. For reference, *Appendix A. Guideline Recommendations* summarizes the clinical practice guidelines that support the measure focus and *Appendix B. Measure Information Form* provides detailed specifications for the measure.

1.1 Importance

Preventing harm caused by the delivery of healthcare was identified as a key measurement gap in the inpatient psychiatric facility (IPF) setting by patients and national experts. To identify specific areas that address this gap, the HSAG team reviewed clinical practice guidelines and drug labels for screening and monitoring activities that are recommended for medication classes commonly prescribed in the IPF setting. Examples of activities include screening for pregnancy and monitoring for abnormal blood pressure; heart rhythms; electrolyte levels; body mass index; bowel movements; thyroid, renal, or liver function; facial or body movements; or blood dyscrasia. Screening female patients of childbearing age for pregnancy was identified as the highest priority for quality measurement because preliminary test data demonstrated a performance gap; it would impact a significant portion of the IPF population; and was determined to have severe and preventable consequences if a screening were not conducted compared to the other monitoring activities reviewed.

Screening for pregnancy is standard practice in many settings but is particularly important in the inpatient psychiatric setting because many psychiatric medications commonly administered during inpatient psychiatric stays have important treatment considerations for women who are pregnant and some psychiatric medications that patients may have taken prior to the stay can reduce the efficacy of oral contraceptives.¹⁴ If a pregnancy is identified during the inpatient psychiatric stay, providers and patients can engage in a discussion of the risks and benefits of various treatment options and select treatments that best align with the patient's preferences. For example, providers can inform patients of the risks of their psychiatric medications to fetal development which can include congenital malformations; acute neonatal complications like intoxication and abstinence syndromes; intrauterine fetal death; altered fetal growth; higher rates of pre-term deliveries; and long-term central nervous system defects.¹⁻¹⁴ Providers can also inform patients of risks to their health from taking psychiatric medications during pregnancy, which can include higher risk for cesarean sections, venous thromboembolism, gestational diabetes, and pre-eclampsia.^{1,4,5,12}

For pregnant patients who are already taking psychiatric medications, providers can inform them of the risks of abruptly discontinuing their medications, which can include a relapse that would impact their ability to care for themselves or their other children.^{1,3,5,14,17,20} If the risks of discontinuation outweigh the risks associated with the medications, providers and patients can consider ways to mitigate risks like adjusting dosages, monitoring serum levels, or changing to medications that carry fewer risks.^{1,5-9,12-16} If the risks of discontinuation do not outweigh

the risks associated with the medications, patients may choose other forms of treatment like psychotherapy during their pregnancy.

In addition to engaging patients in treatment decisions to reduce harm caused by pharmacotherapy, identification of pregnancy in an inpatient psychiatric setting can have several other important benefits to reduce harm caused by the delivery of healthcare. For example, identification of a pregnancy provides an opportunity to discuss other risks with the patient like the development of pre- and postpartum depression and adverse pregnancy outcomes that can result from comorbid substance use disorder.^{1,12,14,18,19} The inpatient admission may be the patient's first contact with the healthcare system during their pregnancy and provides an opportunity to initiate prenatal care by referring the patient to an obstetrician at discharge.

Screening for pregnancy has the potential to benefit patients who are not pregnant during the inpatient psychiatric admission as well. It can provide an opportunity to discuss the importance of family planning while on psychiatric medications that pose risks during pregnancy and especially among those who are on psychiatric medications that reduce the efficacy of oral contraceptives.¹⁴

The importance of screening patients for pregnancy in the IPF setting is supported by clinical practice guidelines and feedback on the measure from providers and patients. Clinical practice guidelines from the American College of Obstetricians and Gynecologists (ACOG), American Psychiatric Association (APA), International Society for Bipolar Disorders (ISBD), US Department of Veteran Affairs and the US Department of Defense, and the American Academy of Pediatrics support the need to consider pregnancy status when treating females for psychiatric conditions.^{1,8,12,14,15,21,22} More information on each of the clinical practice guidelines is provided in *Appendix A. Guideline Recommendations*. The Technical Expert Panel (TEP), which provides input on the development of measures under this project, agreed that screening for pregnancy in the IPF setting has the potential to inform care to prevent adverse pregnancy outcomes and improve other aspects of care. Female patients and caregivers of female patients agreed that the measure addressed an issue that was important to them. One patient consultant shared a personal story about working with someone who suffered multiple disabilities as a result of the teratogenicity of a pharmacotherapeutic agent. This patient consultant stated the belief that screening for pregnancy should be a standard practice in the psychiatric setting because of the severity of the adverse outcomes.

1.2 Measure Impact

The *Screening for Pregnancy* measure has the potential to improve care for a large number of patients admitted to IPFs. In 2016, there were approximately 1.7 million admissions to IPFs for patients between the ages of 13 and 64. While data are not available on the exact number of IPF admissions that were for females of childbearing age, there are data which indicate that females make up approximately 42% of the inpatient mental health population.²³ Therefore, approximately 700,000 admissions to IPFs were for female patients between the ages of 13 and 64. Assuming an even distribution of admissions across the age range and defining childbearing age as between the ages of 15 and 44, it is estimated that the measure would impact approximately 400,000 females of childbearing age per year. Data on the exact number of pregnancies that could be identified by a screening in the inpatient psychiatric setting are not available. However, based on the 2015 fertility rate for the general population, which was 62.5 births per 1,000 women aged 15–44,²⁴ it is estimated that approximately 16,000 women per year are pregnant when they are treated by IPFs.

Empirical evidence from the nine facilities which conducted the beta testing for this project found that there is a large performance gap in screening for pregnancy in the IPF setting. This gap indicates a potential for harm to patients. Nearly one in five females of childbearing age did not have pregnancy status documented in their medical record during the inpatient stay. More than 95% of those females were administered a medication during the stay that was within the U.S. Food and Drug Administration (FDA) categories of “risk not ruled out” (C), “positive evidence of risk” (D), “contraindicated in pregnancy” (X), or “not classified” (N).²⁵ Therefore,

medications in these categories could have been administered to some women without informed discussion with the provider to determine the most appropriate treatment plan in the context of their pregnancy.

Data are not available to estimate the number of adverse outcomes that could be prevented by screening for pregnancy given the vast number of outcomes and various factors that contribute to those outcomes. However, screening females of childbearing age for pregnancy is a relatively low burden process that is critical for safe treatment of psychiatric inpatients. The burden of conducting the screening will vary by patient. For example, many patients who are far enough along in their pregnancy will self-report that they are pregnant, so the provider would just need to document pregnancy status in the record. If the patient is unable or unwilling to report a pregnancy, facilities can obtain the results of pregnancy screening tests from transferring facilities or conduct the screening test during the inpatient stay, which could incur some additional cost if the provider was not already collecting and submitting samples for other laboratory tests.

In summary, implementation of this measure will address the CMS Meaningful Measures area of Preventable Healthcare Harm through careful medication selection, education, and monitoring; treatment of comorbid conditions like depression and substance use disorder; and connection to prenatal care. The results of the measure will be important and informative to both providers and patients and are anticipated to lead to improvements in the quality of care provided to patients admitted to IPFs.

2. Methods

This section of the report describes the approach to developing and operationalizing the measure specifications and scoring methodology. This section also includes the approach to assessing the reliability and validity of the measure and determining whether disparities exist between different subpopulations of patients.

2.1 Data Sources

2.1.1 Measure Testing

The *Screening for Pregnancy* measure uses chart-abstracted data to calculate the measure score. Preliminary testing to identify the measure concept was conducted in two IPFs. Nine additional IPFs were solicited to participate in further testing of the measure through an email distributed in January 2017 to IPFQR program participants and other key stakeholders. Varying site characteristics were sought, such as, free standing facilities and hospital-based units.

2.1.2 Site Training and Data Collection

At the start of testing, each test site received a one-hour group training on the abstraction instructions and process. The Measure Developer provided a structured medical record abstraction tool developed in Microsoft Access to collect the elements used to define the measure and to calculate the measure score. Test sites were asked to have paired abstractors independently collect data on the same 10 medical records, which served as practice cases. A preliminary inter-rater reliability (IRR) was calculated for each test site for the practice cases to ensure that abstraction questions were interpreted correctly and consistently across abstractors. The two trained abstractors at each beta testing site then collected data from 50 admissions each for a total of 100 unique patient records. In addition, 30% of each abstractor's records were randomly selected and reviewed by the other abstractor to reassess the IRR. Demographic information was collected on a subsample of 620 cases for testing purposes only. A subsample was used to ensure that the burden of data collection and the calculated time for abstraction of the measure data elements were not influenced by collection of additional demographic data that would not be included in the final measure.

2.2 Development of Denominator

2.2.1 Denominator Inclusion Criteria

The proposed denominator includes all female patients of childbearing age who are admitted to an IPF. To determine the appropriate definition of childbearing age, the Measure Developer conducted a review of childbearing age definitions from a variety of sources which included: 1) clinical practice guidelines; 2) a review of drug label information for commonly administered psychiatric medications that have different FDA pregnancy risk categories; 3) existing National Quality Forum (NQF)-endorsed measures that assess a similar measure focus; and 4) recently published literature and surveillance data.

2.2.2 Denominator Exclusion Criteria

The Measure Developer explored instances where females of childbearing age may not require a screening for pregnancy and determined whether those instances necessitated measure exclusions. This was carefully considered to reduce provider burden and ensure that the measure would not lead to inappropriate screening. When data were available from the nine test sites, potential exclusions were tested empirically. When data were not available from the nine test sites, the Measure Developer reviewed findings from the literature and other NQF-endorsed measures with similar data elements.

2.3 Development of Numerator

The proposed numerator measures the total number of eligible patients in the denominator who were screened for pregnancy during their inpatient admission. A screening is defined as documentation of pregnancy status in the medical record for the IPF stay. To determine acceptable types of documentation, the Measure Developer considered the various ways a provider might confirm that a patient is either pregnant or not pregnant, collected data from the nine test sites on how frequently these assessments were documented in the medical record, and reviewed the results with the expert workgroup. To determine whether there was a specific timeframe that the screening should occur during the IPF stay, timestamps were collected for the documentation of pregnancy status when available and results were reviewed with the expert workgroup.

2.4 Measure Scoring Methodology

2.4.1 Measure Calculation

The measure is calculated by dividing the number of female patients of childbearing age who have documentation of pregnancy status in the medical record for the IPF stay by the total number of female patients of childbearing age in the denominator. The details and definitions for each aspect of this calculation are described in the denominator and numerator descriptions in *Appendix B. Measure Information Form*.

2.4.2 Statistically Significant and Meaningful Differences in Performance

To determine differences across testing facilities, the Measure Developer calculated the 95% confidence intervals for each facility using the following formulae:

Denominator= n .

Measure rate= $S_{\text{final score}} = 100 * p$, where p represents the proportion of patients meeting the denominator and numerator criteria in the study population and follows a binomial distribution.

Standard error of Measure rate= $Se_{\text{final score}} = 100 * \sqrt{\frac{p(1-p)}{n}}$.

The 95% confidence interval for the final score (Measure rate) is: $S_{\text{final score}} \pm 1.96 * Se_{\text{final score}}$.

A visual examination of a forest plot depicting measure scores and 95% confidence intervals for each facility was used to illustrate whether there are statistically significant differences in measure scores.

2.5 Reliability and Validity Testing

2.5.1 Reliability

2.5.1.1 Data Element Reliability

Data element reliability was calculated using the subset of records that were reviewed by both abstractors at each facility. Given that the final measure specifications were not known at the beginning of testing, the test sites were asked to collect more granular data than will be required for the final measure. Therefore, several data elements in the test data were combined into a more parsimonious set of five scoring elements to better reflect how they would be used to calculate the final measure score. The scoring elements are listed in Table 1.

Table 1. Data Elements and Derived Scoring Elements used to Calculate the Measure Score and IRR

Data Element from Test Data	Scoring Elements	Corresponding Data Elements in Final Measure and Data Dictionary
Sex	Was the patient female?	Sex
Admission Date Birthdate	Was the patient age between 15-44 on admission?	Admission Date Birthdate
Admission Date Discharge Date	Is the length of stay greater than 2 days?	Admission Date Discharge Date
Documentation of a Reason Human Chorionic Gonadotropin (hCG) Test Not Performed in IPF	Was there documentation that the patient was pregnant or could not become pregnant in the medical record?	Documented Pregnancy Status
Admission Date hCG Laboratory Test Result Documented hCG Test Performed in Emergency Department hCG Test Result Date	Was the hCG laboratory test documented in the medical record and resulted by end of Day 2?	Pregnancy Laboratory Test

IRR was evaluated as the percent agreement between the paired abstractors. Percent agreement refers to the degree to which the two abstractors provide consistent answers to the same data element question. Perfect agreement is 100%. IRR was also evaluated using Cohen’s Kappa that accounts for the possibility that abstractors’ agreement is due to chance alone. It is standardized on a scale of -1 to 1, where 1 is perfect agreement, 0 is exactly what would be expected by chance, and negative values indicate systematic disagreement between abstractors.^{26,27} A common scale is used to interpret Kappa statistics where 0.01–0.20 is considered slight agreement; 0.21–0.40 is fair agreement; 0.41–0.60 is moderate agreement; 0.61–0.80 is substantial agreement; and 0.81–0.99 is almost perfect agreement.

To calculate Cohen’s Kappa, the scoring element questions were organized into four categories (P₁₁: (1, 1), P₁₀: (1, 0), P₀₁: (0, 1) and P₀₀: (0, 0) with 0/1 indicating presence or absence of a scoring element) for each facility. Cohen’s Kappa was calculated based on the following formula:

$$\text{Cohen's Kappa} = \frac{P_o - P_e}{1 - P_e}$$

where P_o is the observed proportion of agreement and P_e is the expected proportion of agreement.

$$P_o = P_{11} + P_{00}$$

$$P_e = (P_{11} + P_{10}) * (P_{11} + P_{01}) + (P_{00} + P_{10}) * (P_{00} + P_{01})$$

Pooled Kappa is reported as aggregate across facilities to account for different rater pairs for each facility.

$$\text{Pooled Kappa} = \frac{\bar{P}_o - \bar{P}_e}{1 - \bar{P}_e}$$

\bar{P}_o is the mean of the P_os and \bar{P}_e is the mean of the P_es across the nine IPFs (or across a measure component). The 95% confidence interval of the pooled kappa is $K \pm 1.96 * SE_k$, in which $SE_k = \sqrt{\frac{\bar{P}_o(1-\bar{P}_o)}{n(1-\bar{P}_e^2)}}$, and n is the average number of questions across the nine IPFs. The confidence intervals for the pooled Cohen’s Kappa may generate limits smaller than -1.00 or greater than 1.00, which were truncated to -1.00 and 1.00, respectively.

2.5.1.2 Performance Measure Score Reliability

In order to assess measure precision in the context of the observed variability across IPFs, the team used the signal-to-noise approach which determines how well one can confidently distinguish the performance of one IPF

from another.²⁸ The signal-to-noise ratio was calculated as a function of the variance between IPFs (signal) and the variance within an IPF (noise). Measure score reliability was estimated using a beta-binomial model.

Reliability scores can range from 0.0 to 1.0. A score of zero implies that all variation is completely attributable to measurement error (i.e., noise or the IPF variance), whereas a reliability of 1.0 implies that all variation is caused by a real difference in performance across IPFs. In a simulation, Adams showed that differences between providers can be seen at a reliability of 0.7 and significant differences could be seen at a reliability of 0.9.²⁸ The rationale for the reliability analysis was based on Adams' work, and thus, a minimum reliability score of 0.7 was used to indicate sufficient signal strength to discriminate performance between IPFs.

The Measure Developer used the following formula to calculate the reliability of the measure rate for each IPF, reflecting a signal-to-noise ratio.

$$\text{Reliability} = \frac{\sigma_{\text{Between-IPFs}}^2}{\sigma_{\text{Between-IPFs}}^2 + \sigma_{\text{Within-IPFs}}^2}$$

In which $\sigma_{\text{Between-IPFs}}^2$ is the variance of scores between IPFs and $\sigma_{\text{Within-IPFs}}^2$ is the variance within IPFs.

2.5.2 Validity

Face validity was used to assess the validity of the measure. Face validity is a subjective assessment by experts of whether the measure results reflect the intent of the measure. In this context, the purpose of evaluating face validity is to determine whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality of care. Face validity of the measure score was obtained by a TEP vote on February 26, 2018. Prior to the vote, the TEP was provided with the final measure specifications and presented the results of beta testing. After review and discussion, the TEP agreed to vote on the face validity of the measure with the stipulation that the measure is specified to exclude patients who are discharged AMA. HSAG asked the TEP members to vote on whether they agree, disagree, or are unable to rate the following face validity statement:

“The performance scores resulting from the Screening for Pregnancy measure, as specified, can be used to distinguish good from poor facility-level quality related to the screening of female patients for pregnancy during the inpatient psychiatric facility hospitalization.”

2.6 Disparities Analyses

In order to assess whether disparities in measure performance exist between subpopulations of the measure cohort, the team used the method employed by the Agency for Healthcare Research and Quality (AHRQ) for the National Healthcare Quality and Disparities Report.²⁹ Two criteria were applied to determine meaningful differences between the performance for a reference group and another population group. A group's results may be interpreted as:

- Better than the reference group by at least a 10% relative difference and with a $p < 0.05$
- Worse than the reference group by at least a 10% relative difference and with a $p < 0.05$
- Same as the reference group with less than a 10% relative difference and with a p -value < 0.05 or > 0.05

Relative differences were calculated by subtracting the reference group from each demographic group and dividing it by the reference group. Statistical significance of the difference between two proportions was determined using a chi-square test of associations with continuity correction.

3. Results

This section provides the results of analyses that informed the final measure specifications. This section also provides the results of the assessments of the reliability and validity of the measure and disparities between subpopulations of patients.

3.1 Sample Characteristics

The measure was developed and tested using data obtained from retrospective chart reviews of female patients admitted to an IPF. A total of nine IPFs from eight states were used to perform the beta testing of the measure. The facilities varied in characteristics like type, bed size, and medical record system. Table 2 shows the characteristics of the IPFs included in the beta testing.

Table 2. Beta Testing Hospital Characteristics

IPF ID	Location	Type	Bed Size	Data Source
1	KS	Unit	15	Paper/EHR
2	MI	Freestanding	90	Paper
3	IN	Unit	30	EHR
4	SD	Unit	56	EHR
5	OK	Unit	86	EHR
6	MO	Unit	24	EHR
7	NJ	Unit	16	Paper/EHR
8	MO	Unit	42	EHR
9	NY	Unit	133	EHR

To test the measure, each of the nine IPFs were asked to retrospectively abstract clinical information from closed medical records using a random selection of female patient admissions, regardless of payer source, who were between the ages of 12 and 50 years. The average age of the sample population was 29.3 years with a range from 12 to 50 years. The total number of medical records used for testing was 913. The date of the admissions ranged from November 19, 2015, and February 16, 2017.

3.2 Denominator Results

3.2.1 Denominator Inclusion Analyses and Results

To determine the appropriate definition of childbearing age, the Measure Developer conducted a review of childbearing age definitions from four key sources. First, the team reviewed the clinical practice guidelines from the American College of Obstetricians and Gynecologists (ACOG), American Psychiatric Association (APA), International Society for Bipolar Disorders (ISBD), and US Department of Veteran Affairs and the US Department of Defense, which are described in *Appendix A. Guideline Recommendations*, and found that none specifically defined childbearing age. The second key source reviewed was drug label information for commonly administered psychiatric medications identified in alpha testing that have different FDA pregnancy risk categories. These FDA pregnancy risk categories include: “risk not ruled out” (C), “positive evidence of risk” (D), “contraindicated in pregnancy” (X), and “not classified” (N). The review found that none of the drug label information for any of these drugs provided an age range to define childbearing age.

Third, the team explored whether there were any existing NQF-endorsed measures that assess females of childbearing age. Although there were no existing NQF-endorsed measures, there were three claims-based measures, stewarded by the US Office of Population Affairs, which focused on contraceptive care and were endorsed by the NQF in 2016 (NQF #2902, NQF #2903, and NQF #2904). Each of these measures evaluates women age 15 to 44 years at risk of having an unintended pregnancy who are provided appropriate methods of

contraception. The Measure Developer contacted the US Office of Population Affairs in January 2018 to determine the rationale used for specifying the contraceptive care measures for women in the age range of 15 to 44 years. The US Office of Population Affairs clarified that the age range was aligned with the National Survey of Family Growth, which collects data on women of reproductive age 15 through age 44.

Fourth, the team considered the childbearing age range used in recently published literature and surveillance data. One 2017 study, which was conducted by the Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration (SAMHSA) evaluated opioid misuse and treatment among women of childbearing age and defined them as being between the ages of 15 to 44 years.³⁰ Surveillance data are collected by the 2016 U.S. Census Bureau on fertility rates of women in the United States and report rates for women between the ages of 15 and 50 years.³¹ The 2015 Center for Disease Control and Prevention (CDC) National Vital Statistics Reports include birth rates for women under the age of 15 years and between the ages of 15 and 54 years.²⁴

While the sources examined used varying age thresholds, all of the definitions of childbearing age included the ages of 15 to 44 years at a minimum. Therefore, the *Screening for Pregnancy* measure defines females of childbearing age as those between the ages of 15 and 44 years, which aligns with both the published literature and existing NQF-endorsed measures that focus on childbearing age. Using a conservative age range ensures that the measure does not lead to inappropriate screening and allows providers the discretion to determine when screening is appropriate for adolescents under age 15 or adults over age 44.

3.2.2 Denominator Exclusion Criteria Analysis and Results

The measure specifies two exclusion criteria to ensure that IPFs can feasibly complete the pregnancy screening for all patients in the denominator. The first exclusion applies to patients who are discharged from the IPF Against Medical Advice (AMA). The TEP members who advise this project recognized that patients who are discharged AMA represent patients who are generally more likely to refuse to be screened for pregnancy.

To evaluate the impact of the exclusion of patients who were discharged AMA, the Measure Developer conducted an analysis of Medicare fee-for-service claims data from IPF admissions that occurred between October 1, 2016 and September 30, 2017. Table 3 shows the percentage of females between the ages of 15 and 44 who were discharged AMA. Results show that across all IPFs only 1.8% of females were discharged AMA and, across the nine testing facilities included in beta testing, only 0.7% of females were discharged AMA. These results demonstrate minimal impact of the exclusion on the measure denominator.

Table 3. Percentage of females 15-44 who were discharged AMA

AMA Exclusion	Denominator	Numerator	Percent
National	49,233	868	1.8
Total for 9 IPFs	417	3	0.7

The second exclusion applies to the length of stay. The measure was tested with the exclusion specified as patient admissions with a length of stay of less than or equal to two days. This was selected to ensure that the duration of each stay is long enough to allow facilities an adequate amount of time to perform the pregnancy screening. Table 4 shows the impact of this exclusion on the measure scores, which is minimal.

Table 4. Measure Score by Minimum Length of Stay Requirement

LOS	Denominator	Numerator	Measure Score
Overall with any LOS	728	589	80.9%
Overall with LOS > 2 days	621	503	81.0%

3.3 Numerator Results

3.3.1 Numerator Analyses and Results

The development team analyzed medical records to identify the different types of screenings which could be used to determine pregnancy status. The results in Table 5 show the frequencies of the types of documentation of pregnancy status that were collected during testing. Acceptable types of documentation include self-reported pregnancy, history that would preclude the patient from becoming pregnant, or the results of an hCG laboratory test to detect pregnancy. The majority (63.3%) of acceptable documentation of pregnancy status was from hCG laboratory tests conducted in the emergency department (ED), medical unit within the same facility, or an acute care transfer. The results also showed that an hCG laboratory test was conducted in the IPF during 14.7% of stays. It should be noted that a patient could have more than one type of documentation in their medical record. Therefore, the sum of the frequencies of acceptable pregnancy screenings exceeds the Total (Numerator), which represents the number of patients with at least one acceptable type of pregnancy screening.

The expert workgroup reviewed all types of pregnancy screenings and considered which types of documentation should not qualify for the numerator criteria because they cannot confirm the pregnancy status of the patient. If a pregnancy is not identified, the provider and patient are not able to make informed decisions about the risks and benefits of different treatment options and it is a missed opportunity to initiate connections to prenatal care. Table 5 lists the types of unacceptable documentation, which include self-reported abstinence, contraceptive use, active menstruation, menopause, post-partum, or patient refusal of screening. The decision to require additional screening for patients using contraceptives is supported by published literature describing the failure rates of many contraceptive methods³² and because several psychiatric medications interact with oral contraceptives which may decrease their efficacy.¹⁴ The decision to require additional screening for patients who are menstruating or in the post-partum or post-menopausal periods is supported by the fact that women can be pregnant during these periods and may be less likely to know that they are pregnant.

Documentation that the patient refused the screening is not acceptable to meet the measure numerator because providers are encouraged to educate the patient about the importance of the screening over the course of the stay. Patient refusal was rare in the testing data (0.3%). However, the Measure Developer recognizes that some patients may be more likely to refuse the screening and those patients may not be evenly distributed across facilities. Based on the advice of the TEP, the measure adopted a denominator exclusion to remove patients who are discharged AMA from the measure to account for patients who are less likely to be compliant with treatment.

Table 5. Frequencies of Patients (age 15-44) with LOS > 2 Days by Type of Documented Pregnancy Screening

Pregnancy Screening	IPF 1	IPF 2	IPF 3	IPF 4	IPF 5	IPF 6	IPF 7	IPF 8	IPF 9	Total	% of Patients N = 621
Acceptable Documentation to Meet the Numerator											
Self-reported Pregnancy	2	0	3	2	1	0	1	0	0	9	1.4%
History of hysterectomy	5	2	1	0	0	0	0	6	0	14	2.3%
History of tubal ligation	6	1	2	2	0	0	0	14	0	25	4.0%
History of other clinical causes of sterility	0	0	0	0	0	0	0	0	0	0	0%
Result of a hCG laboratory test in IPF	19	0	23	12	10	10	2	7	8	91	14.7%
Result of hCG test from ED, medical unit, or acute transfer	28	49	33	23	44	25	73	50	68	393	63.3%
Total (Numerator)	54	52	60	38	54	35	73	61	76	503	81.0%

Pregnancy Screening	IPF 1	IPF 2	IPF 3	IPF 4	IPF 5	IPF 6	IPF 7	IPF 8	IPF 9	Total	% of Patients N = 621
Unacceptable Documentation to Meet the Numerator											
Abstinence/Contraception Use (of any form)	0	0	1	0	0	0	0	0	0	1	0.2%
Active Menstruation	4	1	1	0	0	0	1	2	4	13	2.1%
Post-menopausal	0	0	0	0	0	0	0	0	0	0	0%
Post-partum	0	1	0	0	0	0	0	0	0	1	0.2%
Patient Refusal	0	1	1	0	0	0	0	0	0	2	0.3%

Given that the intent of the measure is to determine pregnancy status to inform treatment decisions during the inpatient stay, screening activities should be conducted as close to the admission as possible. To reduce the abstraction burden of the measure, the Measure Developer decided to only apply a time constraint on the hCG laboratory test result because the expert workgroup noted that the IPF would likely check for self-reported pregnancy, history precluding pregnancy, or test results from a transferring facility prior to conducting a laboratory test. To establish an appropriate timeframe for the completion of the hCG laboratory tests, the Measure Developer evaluated various timeframes in one day increments from pre-admission, admission, and subsequent days following the admission. The admission day is counted as Day 0.

Table 6 shows the percentage of female patients between the ages of 15 and 44 years who had a blood or urine hCG laboratory test result date within one day increments from admission. Of note, IPF 2 did not conduct any hCG laboratory tests during the IPF stay so 100% of the blood or urine hCG laboratory tests results were conducted during the pre-admission period at transferring facilities. Beta testing results show that of those who had an hCG laboratory test, more than 98% of patients were screened for pregnancy by the end of Day 2. In other words, if a pregnancy screening laboratory test was performed during the inpatient hospitalization, the turn-around time rarely exceeded two calendar days from admission (or beyond the end of Day 2). This analysis confirms the appropriateness of the 2-day timeframe from admission to complete the pregnancy screening process of blood or urine laboratory test.

Table 6. Percentage of Patients (age 15-44) with LOS > 2 Days with a Resulted hCG Laboratory Test in the IPF, in the Emergency Department, or in a Transferring Facility

Timing of hCG test	IPF 1 n=47	IPF 2 n=49	IPF 3 n=56	IPF 4 n=35	IPF 5 n=52	IPF 6 n=35	IPF 7 n=72	IPF 8 n=57	IPF 9 n=76	% Across Records	Cumulative % Across Records
Pre-admission	59.6	100	57.9	65.7	76.4	67.6	94.6	87.7	89.5	79.7	79.7
Day 0	25.5	0	15.8	31.4	10.9	13.5	0	10.5	5.3	10.9	90.6
Day 1	12.8	0	21.1	2.9	7.3	13.5	0	1.8	3.9	6.6	97.2
Day 2	2.1	0	3.5	0	0	0	2.7	0	1.3	1.2	98.4
Day 3	0	0	1.7	0	1.8	2.7	0	0	0	0.6	99.0
≥ Day 4	0	0	0	0	3.6	2.7	2.7	0	0	1.0	100

3.3.2 Definition of the Numerator

The proposed numerator is defined as the total number of eligible patients in the denominator who have acceptable documentation in their medical record of pregnancy status. Acceptable documentation is defined as either of the following:

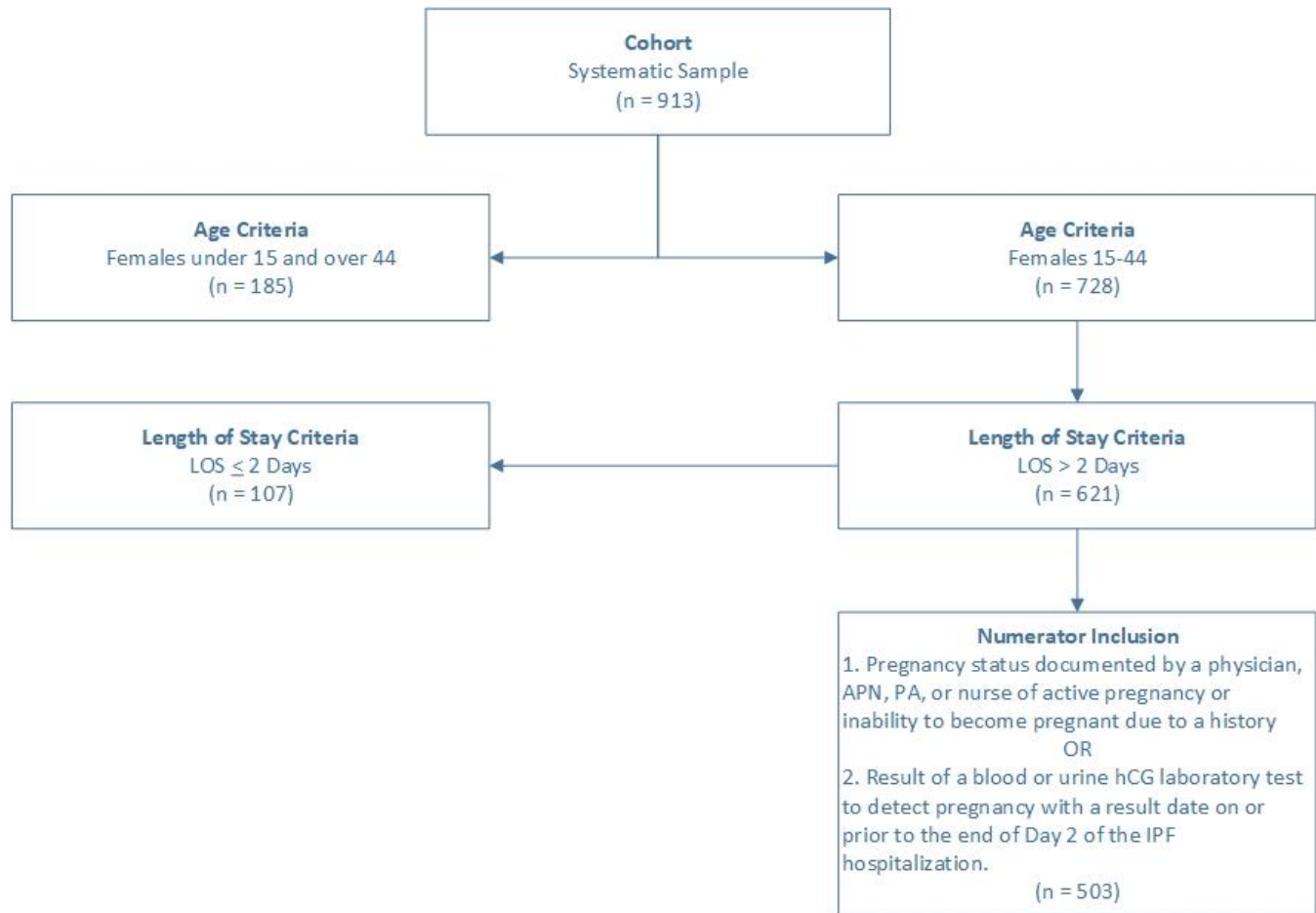
1. Pregnancy status documented by a physician, advanced practice nurse (APN), physician assistant (PA), or nurse of:
 - Active pregnancy as identified from auscultation of positive fetal heart tones or self-report by the patient
 - Inability to become pregnant due to a history of hysterectomy (total, radical or partial), tubal ligation, genetic disorder, or birth defect
2. Result of a blood or urine hCG laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization.
 - The hCG laboratory test result can be from a test performed during the IPF hospitalization or prior to the hospitalization at a transferring facility.

3.4 Measure Score Results

3.4.1 Measure Calculation Using the Proposed Measure Specifications

The details and definitions for each aspect of the measure calculation are described in the denominator and numerator descriptions in *Appendix B. Measure Information Form*. Figure 1 shows the sample size starting with the number of records abstracted by the test sites and shows how many records were excluded at each phase. Of note, the exclusion of patients who are discharged AMA could not be calculated using data from the beta testing sample and is not shown in Figure 1. However, based on testing results derived from Medicare claims data, the discharged AMA exclusion is estimated to impact less than 1.8% of the sample.

Figure 1. Sample Cohort for Measure Score Calculation



The measure scores for each of the test sites are shown in Table 7. The percentage of patients in the cohort who were screened for pregnancy across the nine facilities ranged from 59.3% to 93.8%. The average measure score was 80.7% with a standard deviation of 12.2, which indicates that approximately one in five females of childbearing age are not screened for pregnancy during their IPF hospitalization. Therefore, there is a significant gap in the quality of care for females of childbearing potential admitted to IPFs.

Table 7. Final Measure Scores Based on the Proposed Measure Specifications

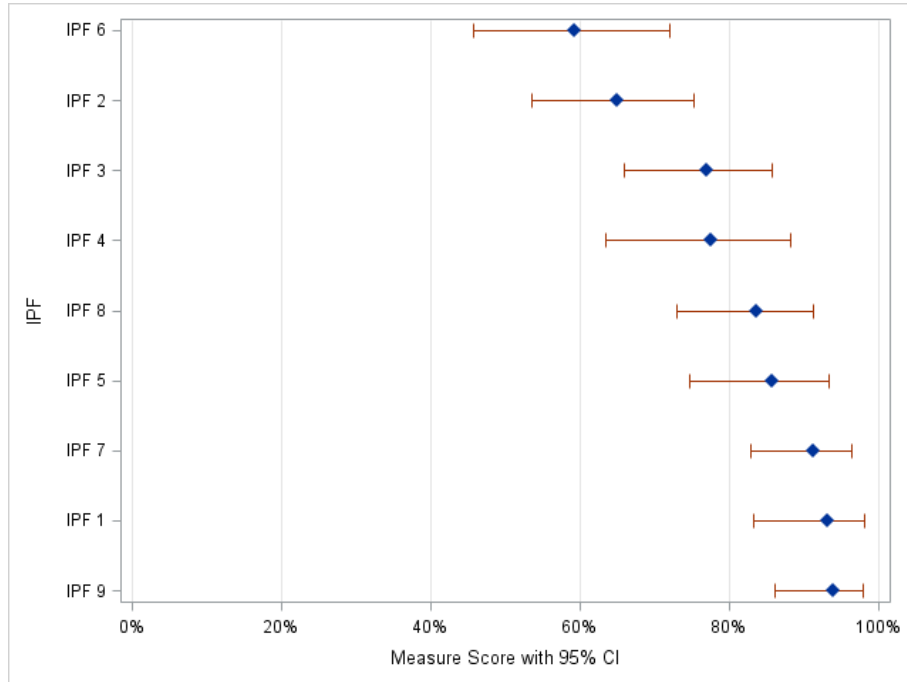
Ages 15-44	IPF 1 n=58	IPF 2 n=80	IPF 3 n=78	IPF 4 n=49	IPF 5 n=63	IPF 6 n=59	IPF 7 n=80	IPF 8 n=73	IPF 9 n=81
Measure Score	93.1	65.0	76.9	77.6	85.7	59.3	91.3	83.6	93.8
95% CI	(86.6, 99.6)	(54.6, 75.5)	(67.6, 86.3)	(65.9, 89.2)	(77.1, 94.4)	(46.8, 71.9)	(85.1, 97.4)	(75.1, 92.1)	(88.6, 99.1)

3.4.2 Statistically Significant and Meaningful Differences in Performance

Figure 2 displays facility scores with 95% confidence intervals (CIs) sorted by score. The results indicate differences in performance between the highest and lowest performers. Significant differences are indicated by confidence intervals that do not overlap. Of note, testing chart-based measures often results in smaller denominators compared to the testing of other types of measures (e.g., claims-based). Smaller sample sizes

produce larger standard errors and wider confidence intervals as are seen in Figure 2. Nevertheless, the measure was able to distinguish differences in performance between highest and lowest performing facilities of 34.5%.

Figure 2. Facility Measure Scores with 95% Confidence Intervals



3.5 Reliability and Validity Results

3.5.1 Reliability Results

3.5.1.1 Data Element Reliability Analysis and Results

To determine the extent to which the measure, as specified, produces consistent results, two trained abstractors at each IPF independently completed data ascertainment for the measure score data elements using a random subset of approximately 30 patient records per facility for a total subsample of 266 patient records. The number of records for each IPF is shown in Table 8.

Table 8. Distribution of Records Available for Inter-rater Reliability Analysis Across IPFs

	IPF 1	IPF 2	IPF 3	IPF 4	IPF 5	IPF 6	IPF 7	IPF 8	IPF 9	Total
IRR cases	31	30	29	26	29	30	30	30	31	266

The data collected by two independent abstractors at each IPF for the scoring elements were examined for reliability using percent agreement and Cohen’s Kappa. Results shown in Table 9 indicate that percentage of agreement across all five scoring elements was high with an average percentage of agreement of 98.3%. The scoring element with the lowest percent agreement (94.7%) was, *Was the hCG laboratory test resulted by end of Day 2?* These results may be due to variation in the documentation of the pregnancy screening as defined by the measure. However, the percent agreement for this scoring element high and indicates strong agreement. The pooled Cohen’s Kappa score for the scoring elements across all nine facilities was 0.97 (95% CI: 0.92, 1.00), indicating substantial agreement. Of note, a pooled Cohen’s Kappa score for the data element, *Was the patient*

female? could not be calculated because there were cases with missing data where the abstractors did not record the data element. This is indicated in Table 9 as N/A.

Table 9. Percent of Agreement for Scoring Elements

Scoring Elements	All Records	Agreed	% Agreement	Pooled Cohen's Kappa
Was the patient female?	265	259	97.7%	N/A
Was the patient between the ages of 15-44?	266	266	100%	1 (1.0, 1.0)
Is the length of stay greater than 2 days?	266	266	100%	1 (1.0, 1.0)
Was there documentation that the patient was pregnant or could not become pregnant in the medical record?	266	263	98.9%	0.89 (0.81, 0.97)
Was the hCG laboratory test resulted by end of Day 2?	266	252	94.7%	0.83 (0.73, 0.93)
Total Score	1,329	1,306	98.3%	0.97 (0.92, 1.0)

3.5.1.2 AMA Exclusion Reliability Analysis and Results

The Discharge Disposition data element for patients who are discharged AMA was not collected during the beta testing of the *Screening for Pregnancy* measure. The discharge disposition is a standard data element included in the Uniform Billing (UB04) form for institutional providers and allows for the collection of information about patients who are discharged AMA. The Measure Developer contacted The Joint Commission (TJC) to obtain testing results to evaluate the reliability of abstracting the AMA allowable value as part of the Discharge Disposition data element. Reliability testing results conducted in 2012 by the TJC for the *TOB-3: Tobacco Use Treatment Provided or Offered at Discharge* (NQF #1656) measure showed that of the 90 records reviewed, only two records had an AMA value for the Discharge Disposition data element. Of these two records where the AMA value was identified, both abstractors were in 100% agreement with the abstracted value. Of note, the Discharge Disposition data element has been used by several NQF-endorsed, chart-abstracted measures that use AMA as a denominator exclusion. Therefore, it was determined that the Discharge Disposition data element for patients who are discharged AMA is reliable and the measure excludes those patients from the denominator. For additional details on each of the data elements in the final measure construct, refer to *Appendix C. Data Definitions and Abstraction Instructions* and *Appendix D. Data Abstraction Tool*.

3.5.1.3 Performance Measure Score Reliability Results and Interpretation

To assess variability across IPFs, the signal-to-noise approach was used to determine how well one can confidently distinguish the performance of one IPF from another. The variance within and between IPFs and the reliability scores for each IPF measure score are shown Table 10. With a score of 1.0 indicating that all variation is caused by a real difference in performance across IPFs, the results show that the measure has a high degree of reliability (ranging from 0.72 to 0.94) and that scores can be considered different across facilities due to performance rather than due to measurement error.

Table 10. Reliability Using Signal-to-Noise for each IPF Final Measure Score

	IPF 1	IPF 2	IPF 3	IPF 4	IPF 5	IPF 6	IPF 7	IPF 8	IPF 9
Between IPFs σ^2	0.0105	0.0105	0.0105	0.0105	0.0105	0.0105	0.0105	0.0105	0.0105
Within IPF σ^2	0.0011	0.0028	0.0023	0.0036	0.0019	0.0041	0.0010	0.0019	0.0007
Reliability	0.90	0.79	0.82	0.75	0.84	0.72	0.91	0.85	0.94

3.5.2 Validity Results

3.5.2.1 Systematic Assessment of Face Validity Results and Interpretation

The Measure Developer obtained a face validity vote during the TEP meeting on February 26, 2018. The 18 TEP members in attendance at the meeting with voting privileges were asked to vote on whether the performance scores resulting from the *Screening for Pregnancy* measure, as specified, can be used to distinguish good from poor facility-level quality related to the screening of female patients for pregnancy admitted to an inpatient psychiatric facility. The results of the votes are reported in Table 11.

Table 11. Face Validity Results by Agreement Category

Agreement Category	Number of Votes	Percent
Agree	17	94.4%
Disagree	0	0%
Abstain	1	5.6%

3.6 Results of Disparities Analyses

A sub-sample of 620 cases out of 913 was used to test sociodemographic variables, including patient race and ethnicity. Table 12 shows the percent of cases by race and ethnicity in the sub-sample. Nearly two-thirds (63.9%) of the sub-sample was White and 20.8% of the sub-sample was Black.

Table 12. Race/Ethnicity of Beta Testing Population (in percent; n=620)

Race Ethnicity	White/ Caucasian	Black/ African American	American Indian/ Alaska Native	Asian	Unable to Determine/ Not Stated	Overall
Non-Hispanic	56.5	20.1	8.5	0.8	3.1	89.0
Hispanic	4.4	0.2	0.7	0.2	1.9	7.3
Not Abstracted	3.0	0.5	0	0	0.2	3.7
Overall	63.9	20.8	9.2	1.0	5.2	100

Of the 620 cases that included abstraction of demographic information, there were 420 cases that met the final denominator criteria. Table 13 shows the measure scores stratified by race and ethnicity. To determine if there were significant differences between races, the chi-square test was performed using the measure scores of three groupings of race: White, Black, and Other. The results indicate that there were statistically significant differences in the rate of pregnancy screening by race in this sample. Based on the methodology to determine disparities in care used by the Agency for Healthcare Research and Quality (AHRQ) for the National Healthcare Quality and Disparities Report,²⁹ disparities exist when there is a significant difference as well as a 10% relative difference. Using White race as the reference group, pregnancy screenings for Black race was significantly less ($p = 0.02$) with a relative difference of 12.7%, and pregnancy screenings for those in the Other category (American Indian/Alaska Native, Asian, and those whose race was unable to be determined or not stated) was not significantly less ($p = 0.05$) with a relative difference of 13.9%. These results, which suggest disparities in care by race, underscore the need to encourage pregnancy screenings for all women of childbearing age in the IPF setting.

Table 13. Final Measure Scores Stratified by Race and Ethnicity (n=420)

Race/ Ethnicity	White/ Caucasian	Black/ African American	American Indian/ Alaska Native	Asian	Unable to Determine/ Not Stated	Overall Measure Score
Non-Hispanic	86.0	76.8	74.1	100	68.8	82.2

Race/ Ethnicity	White/ Caucasian	Black/ African American	American Indian/ Alaska Native	Asian	Unable to Determine/ Not Stated	Overall Measure Score
Hispanic	85.0	100	50.0	0	85.7	80.7
Not Abstracted	75.0	0	N/A	N/A	100	58.3
Overall Measure Score	85.6	74.8	72.4	75.0	75.0	81.4

4. Discussion

4.1 Summary

The *Screening for Pregnancy* measure assesses whether female patients of childbearing age are screened for pregnancy during the inpatient psychiatric hospitalization. Both providers and patients agree that the measure addresses an important aspect of care. If the measure were implemented in the IPFQR program, it would add to the suite of measures that improve the quality of inpatient psychiatric care by preventing healthcare harm. Improving the rates of screening would reduce the likelihood of adverse pregnancy outcomes among patients who are pregnant and provide an opportunity to discuss the importance of family planning while on psychiatric medications among patients who are not pregnant.

As specified, the measure addresses a clear performance gap in the IPF setting. The average measure score was 80.7%. Measure performance rates from nine test facilities showed variation in performance with a range from 59.3% for the lowest performing facility to 93.8% for the highest performing facility. The data required to calculate the measure can be reliably abstracted and measure rates were highly reliable indicating ability to confidently distinguish performance across facilities.

4.2 Measure Implementation

Implementation of the *Screening for Pregnancy* measure can improve detection of pregnancy to inform discussion between providers and patients of the risks and benefits of various treatment options during pregnancy, which can lead to a reduction in preventable adverse pregnancy outcomes. Screening for pregnancy also provides an opportunity to discuss the importance of family planning while on certain psychiatric medications, which can reduce the efficacy of oral contraceptives. Therefore, it is anticipated that the measure would improve care for all women of childbearing age admitted to IPFs.

Screening females of childbearing age for pregnancy is a relatively low burden process that is critical for safe treatment of psychiatric inpatients. The burden of conducting the screening will vary by patient. For example, many patients who are far enough along in their pregnancy will self-report that they are pregnant, so the provider would just need to document pregnancy status in the record. If the patient is unable or unwilling to report a pregnancy, facilities can obtain the results of pregnancy screening tests from transferring facilities or conduct the screening test during the inpatient stay, which could incur some additional cost if the provider was not already collecting and submitting samples for other laboratory tests.

If implemented, this measure will rely on the abstraction of a sample of closed medical records by each IPF. The sampling approach will be determined by the IPFQR program if adopted and has the potential to align with the sampling approach used for existing measures in the IPFQR program to minimize the burden of data collection for facilities. The average time to abstract the required data elements of the measure during beta testing was 4.6 minutes.

4.2 Measure Alignment

Throughout the development process, the Measure Developer aligned the measure specifications, to the extent possible, with existing measures that contain similar data elements. Measures with the same focus or target population that have disparate specifications can create confusion among healthcare consumers and providers with not only the interpretation of the measure results across settings or patient populations, but also with how the measure scores are calculated. For example, the Measure Developer used the same data definitions for the

Admission Date, Birthdate, Discharge Date, Discharge Disposition and Sex data elements, which are used in other chart-based measures.

To align definitions with other measures that establish a length of stay requirement, the Measure Developer aligned the *Screening for Pregnancy* measure with the technical specifications of *SUB-1 Alcohol Use Screening* (NQF #1661), *TOB-1 Tobacco Use Screening* (NQF #1651), and the *Medication Reconciliation on Admission* (NQF #3317) measures. Each of these measures specify the length of stay in calendar days and define the admission day as Day 0 and the next hospitalization day as Day 1, and so forth.

The *Screening for Pregnancy* measure is aligned with the *Medication Reconciliation on Admission* (NQF #3317) measure, which establishes a designated timeframe by which the process must be completed from admission. Like the specifications used in the *Medication Reconciliation on Admission* (NQF #3317) measure, one aspect of the *Screening for Pregnancy* measure requires that the hCG laboratory test to detect pregnancy is resulted by the end of Day 2 of the hospitalization.

The Measure Developer conducted a review of the current landscape of measures to determine whether the *Screening for Pregnancy* measure would compete with existing measures. As of January 2018, there were no current NQF-endorsed measures that specifically evaluate pregnancy screening for women of childbearing age admitted to an inpatient psychiatric facility. However, there were three claims-based contraceptive care measures (NQF #2902, NQF #2903, and NQF #2904) that evaluate women among the ages of 15 and 44 at risk of unintended pregnancy who are provided appropriate methods of contraception, but none of these measures compete with the *Screening for Pregnancy* measure.

4.4 Limitations

A limitation of testing is that the sample was a convenience sample and therefore is not necessarily representative of the IPF population. However, the testing sample contained diversity in the type of facility, facility location, and bed size, and was diverse at the patient level in terms of ages and racial/ethnic composition.

Some data elements, such as whether the patient was discharged AMA, were not collected during testing. However, based on data obtained from other sources it is not anticipated to have a large impact on measure scores.

5. Conclusion

The *Pregnancy Screening* measure addresses a gap in the quality of care received by females of childbearing age who are admitted to an IPF. The measure addresses the Meaningful Measures area of Making Care Safer by preventing healthcare harm. As demonstrated by the analyses conducted in the testing of this measure, approximately one in five females of childbearing age who are admitted to an IPF are not screened for pregnancy. Improving the rates of screening would reduce the likelihood of adverse pregnancy outcomes among patients who are pregnant and provide an opportunity to discuss the importance of family planning while on psychiatric medications among patients who are not pregnant. The TEP, patients, and caregivers indicated that the measure addressed an issue that was important to them. Finally, the measure aligns with other measures focused on women of childbearing age and meets the scientific standards for quality measures established by CMS and NQF. In summary, implementation of this measure will be informative to both providers and patients and is anticipated to lead to improvements in the quality of care provided to patients admitted to IPFs.

6. References

1. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. 2010.
http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed November 20, 2017.
2. Calderon-Margalit R, Qiu C, Ornoy A, Siscovick DS, Williams MA. Risk of preterm delivery and other adverse perinatal outcomes in relation to maternal use of psychotropic medications during pregnancy. *Am J Obstet Gynecol*. 2009;201(6):579 e571-578. doi: 10.1016/j.ajog.2009.06.061.
3. Petersen I, McCrea RL, Sammon CJ, et al. Risks and benefits of psychotropic medication in pregnancy: cohort studies based on UK electronic primary care health records. *Health Technol Assess*. 2016;20(23):1-176. doi: 10.3310/hta20230.
4. Raimondi A, Sheiner E. Pregnant women with schizophrenia are at higher risk of pre-eclampsia, venous thromboembolism and adverse neonatal outcomes. *Evid Based Nurs*. 2015;18(2):39-40. doi: 10.1136/eb-2014-101902.
5. Scrandis DA. Bipolar disorder in pregnancy: a review of pregnancy outcomes. *J Midwifery Womens Health*. 2017;62(6):673-683. doi: 10.1111/jmwh.12645.
6. Ornoy A, Weinstein-Fudim L, Ergaz Z. Antidepressants, Antipsychotics, and Mood Stabilizers in Pregnancy: What Do We Know and How Should We Treat Pregnant Women with Depression. *Birth Defects Res*. 2017;109(12):933-956. doi: 10.1002/bdr2.1079.
7. Tanoshima M, Kobayashi T, Tanoshima R, Beyene J, Koren G, Ito S. Risks of congenital malformations in offspring exposed to valproic acid in utero: a systematic review and cumulative meta-analysis. *Clin Pharmacol Ther*. 2015;98(4):417-441. doi: 10.1002/cpt.158.
8. American Academy of Pediatrics. *Use of psychoactive medication during pregnancy and possible effects on the fetus and newborn*. Committee on Drugs; 2000.
<http://pediatrics.aappublications.org/content/105/4/880>.
9. Kohen D. Psychotropic medication in pregnancy. *Advances in Psychiatric Treatment*. 2004;10(1):59-66. doi: 10.1192/apt.10.1.59.
10. Terrana N, Koren G, Pivovarov J, Etwel F, Nulman I. Pregnancy Outcomes Following In Utero Exposure to Second-Generation Antipsychotics: A Systematic Review and Meta-Analysis. *J Clin Psychopharmacol*. 2015;35(5):559-565. doi: 10.1097/JCP.0000000000000391.
11. Malm H, Sourander A, Gissler M, et al. Pregnancy Complications Following Prenatal Exposure to SSRIs or Maternal Psychiatric Disorders: Results From Population-Based National Register Data. *Am J Psychiatry*. 2015;172(12):1224-1232. doi: 10.1176/appi.ajp.2015.14121575.
12. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia, 2nd ed. 2010.
http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Accessed November 20, 2017.
13. Tomson T, Battino D, Perucca E. Valproic acid after five decades of use in epilepsy: time to reconsider the indications of a time-honoured drug. *Lancet Neurol*. 2016;15:210-218. doi: 10.1016/S1474-4422(15)00314-2.
14. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder, Second edition. American Psychiatric Association; 2002.
http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf. Accessed November 20, 2017.
15. US Department of Veterans Affairs, US Department of Defense. *Management of Major Depressive Disorder*. 2016.

- <http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDDCPGFINAL82916.pdf>. Accessed February 14, 2017.
16. Gold KJ, Marcus SM. Effect of maternal mental illness on pregnancy outcomes. *Expert Rev Obstet Gynecol*. 2008;3(3):391-401. doi: 10.1586/17474108.3.3.391.
 17. Cohen LS, Altshuler LL, Harlow BL, et al. Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. *JAMA*. 2006;295(5):499-507. doi: 10.1001/jama.295.5.499.
 18. Kirkham C, Harris S, Grzybowski S. Evidence-based prenatal care: Part I. General prenatal care and counseling issues. *Am Fam Physician*. 2005;71(7):1307-1316.
 19. American College of Obstetricians and Gynecologists. *Perinatal Care Clinical Practice Guidelines 2016*. 2016. <http://passporthealthplan.com/wp-content/uploads/2016/07/HLTH62565-updated-Perinatal-CPG.pdf>. Accessed February 7, 2018.
 20. Einarson A, Selby P, Koren G. Abrupt discontinuation of psychotropic drugs during pregnancy: fear of teratogenic risk and impact of counselling. *J Psychiatry Neurosci*. 2001;26(1):44-48.
 21. American College of Obstetricians and Gynecologists. American College of Obstetricians and Gynecologists (ACOG) guidelines on psychiatric medication use during pregnancy and lactation. *Am Fam Physician*. 2008;78(6):772-778.
 22. Ng F, Mammen OK, Wilting I, et al. The International Society for Bipolar Disorders (ISBD) consensus guidelines for the safety monitoring of bipolar disorder treatments. *Bipolar Disord*. 2009;11(6):559-595. doi: 10.1111/j.1399-5618.2009.00737.x.
 23. Substance Abuse and Mental Health Services Administration. *National Mental Health Services Survey (N-MHSS): 2016. Data on Mental Health Treatment Facilities*. Rockville, MD: Department of Health and Human Services; 2017. https://www.samhsa.gov/data/sites/default/files/2016_National_Mental_Health_Services_Survey.pdf. Accessed March 12, 2018.
 24. Martin JA, Hamilton B, Osterman MJK, Driscoll AK, Mathews TJ. *Births: Final Data for 2015*. Hyattsville, MD: National Vital Statistics Reports; Vol 66, no 1; National Center for Health Statistics; 2017.
 25. 21 CFR Part 201. Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling; Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry; Availability; Final Rule and Notice; Final Rule. *Fed Regist*. 2014; 79(233).
 26. Tang W, Hu J, Zhang H, Wu P, He H. Kappa coefficient: a popular measure of rater agreement. *Shanghai Arch Psychiatry*. 2015;27(1):62-67. doi: 10.11919/j.issn.1002-0829.215010.
 27. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33(1):159-174.
 28. Adams J. *The reliability of provider profiling: a tutorial*. Santa Monica, CA: RAND; 2009. http://www.rand.org/pubs/technical_reports/TR653.html.
 29. Agency for Healthcare Research and Quality. *2014 National Healthcare Quality and Disparities Report*. Rockville, MD: US Department of Health and Human Services; 2015. <http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqdr/nhqdr14/2014nhqdr.pdf>. Accessed January 26, 2018.
 30. Smith K, Lipari RN. Women of Childbearing Age and Opioids. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration; 2017. https://www.samhsa.gov/data/sites/default/files/report_2724/ShortReport-2724.html. Accessed December 19, 2017.
 31. United States Census Bureau. Fertility of Women in the United States. 2016. <https://www.census.gov/data/tables/2016/demo/fertility/women-fertility.html>. Accessed 2/6/2018.

32. Winner B, Peipert JF, Zhao Q, et al. Effectiveness of long-acting reversible contraception. *N Engl J Med.* 2012;366(21):1998-2007. doi: 10.1056/NEJMoa1110855.

Appendix A. Guideline Recommendations

Clinical Practice Guideline	Recommendation	Grade of Evidence	Strength of Recommendation
<p>American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia, 2nd ed. 2010.</p>	<p>“A pregnancy test should be strongly considered for women with childbearing potential.”</p>	<p>No grade</p>	<p>APA grade II: Recommended with moderate clinical confidence</p>
<p>American College of Obstetricians and Gynecologists guidelines for use of psychiatric medications during pregnancy and lactation (reaffirmed 2016)</p>	<p>“The following recommendations and conclusions are based on good and consistent scientific evidence (Level A): Lithium exposure in pregnancy may be associated with a small increase in congenital cardiac malformations, with a risk ratio of 1.2 to 7.7. Valproate exposure in pregnancy is associated with an increased risk of fetal anomalies, including neural tube defects, fetal valproate syndrome, and long term adverse neurocognitive effects. It should be avoided in pregnancy, if possible, especially during the first trimester. Carbamazepine exposure in pregnancy is associated with fetal carbamazepine syndrome. It should be avoided in pregnancy, if possible, especially during the first trimester. Maternal benzodiazepine use shortly before delivery is associated with floppy infant syndrome.</p> <p>The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B): Paroxetine use in pregnant women and women planning pregnancy should be avoided, if possible. Fetal echocardiography should be considered for women who are exposed to paroxetine in early pregnancy. Prenatal benzodiazepine exposure increased the risk of oral cleft, although the absolute risk increased by 0.01%. Lamotrigine is a potential maintenance therapy option for pregnant women with bipolar disorder because of its protective effects against bipolar depression, general tolerability, and a growing reproductive safety profile relative to alternative mood stabilizers. Maternal psychiatric illness, if inadequately treated or untreated, may result in poor compliance with prenatal care, inadequate nutrition, exposure to additional medication or herbal remedies, increased alcohol and tobacco use, deficits in</p>	<p>No grade</p>	<p>Level A—based on good and consistent scientific evidence; Level B—based on limited or inconsistent scientific evidence; Level C—based primarily on consensus and expert opinion</p>

Clinical Practice Guideline	Recommendation	Grade of Evidence	Strength of Recommendation
	<p>mother–infant bonding, and disruptions within the family environment.</p> <p>The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C): Whenever possible, multidisciplinary management involving the patient's obstetrician, mental health clinician, primary health care provider, and pediatrician is recommended to facilitate care. Use of a single medication at a higher dose is favored over the use of multiple medications for the treatment of psychiatric illness during pregnancy.</p> <p>The physiologic alterations of pregnancy may affect the absorption, distribution, metabolism, and elimination of lithium, and close monitoring of lithium levels during pregnancy and postpartum is recommended.</p> <p>For women who breastfeed, measuring serum levels in the neonate is not recommended.</p> <p>Treatment with all selective serotonin reuptake inhibitors (SSRIs) or selective norepinephrine reuptake inhibitors or both during pregnancy should be individualized.</p> <p>Fetal assessment with fetal echocardiogram should be considered in pregnant women exposed to lithium in the first trimester.”</p>		
<p>International society for bipolar disorder</p> <p>Ng F, Mammen OK, Wilting I, et al. The International Society for Bipolar Disorders (ISBD) consensus guidelines for the safety monitoring of bipolar disorder treatments. <i>Bipolar Disord.</i> 2009;11(6):559-595. doi: 10.1111/j.1399-5618.2009.00737.x</p>	<p>“In women of childbearing age, the possibility of pregnancy should be considered, and a pregnancy test performed if clinically indicated.”</p>	No grade	N/A
<p>US Department of Veterans Affairs, US Department of Defense. <i>Management of Major Depressive Disorder.</i> 2016.</p>	<p>“Laboratory testing is performed as clinically indicated. Useful tests may include thyroid studies (thyroid-stimulating hormone [TSH]), complete blood count (CBC), chemistry profile, pregnancy screen, and/or toxicology panel.”</p>	No grade	N/A

Clinical Practice Guideline	Recommendation	Grade of Evidence	Strength of Recommendation
<p>American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder, Second edition. American Psychiatric Association; 2002</p>	<p>“Laboratory measures and other diagnostic tests are generally recommended on the basis of pathophysiological knowledge and anticipated clinical decisions rather than on empirical evidence of their clinical utility. The decision to recommend a test is based on the probability of detecting a finding that would alter treatment as well as the expected benefit of such alterations in treatment. Recommended tests fall into three categories: 1) baseline measures to facilitate subsequent interpretation of laboratory tests (e.g., ECG, CBC); 2) tests to determine conditions requiring different or additional treatments (e.g., pregnancy, thyroid-stimulating hormone level); and 3) tests to determine conditions requiring alteration of the standard dosage regimen of lithium (e.g., creatinine level). On the basis of these considerations, the following procedures are generally recommended before beginning lithium therapy: a general medical history, a physical examination, BUN, and creatinine level measurement, a pregnancy test, thyroid function evaluation, and, for patients over age 40, ECG monitoring with rhythm strip. Some authorities also suggest a CBC.”</p>	<p>No grade</p>	<p>N/A</p>
<p>American Psychiatric Association Practice Guideline for the Treatment of Patients With Major Depressive Disorder , 3rd ed. 2010.</p>	<p>“The treatment of major depressive disorder in women who are pregnant or planning to become pregnant requires a careful consideration of the benefits and risks of available treatment options for the patient and the fetus [I]. For women who are currently receiving treatment for depression, a pregnancy should be planned, whenever possible, in consultation with the treating psychiatrist, who may wish to consult with a specialist in perinatal psychiatry [I]. In women who are pregnant, planning to become pregnant, or breast-feeding, depression-focused psychotherapy alone is recommended [II] and should always be considered as an initial option, particularly for mild to moderate depression, for patients who prefer psychotherapy, or for those with a prior positive response to psychotherapy [I]. Antidepressant medication should be considered for pregnant women who have moderate to severe major depressive disorder as well as for those who are in remission from major depressive disorder, are receiving maintenance medication, and are deemed to be at high risk for a recurrence if the medication is discontinued [II]. When antidepressants are prescribed to a</p>	<p>Body of evidence not graded</p>	<p>[I] Recommended with substantial clinical confidence [II] Recommended with moderate clinical confidence [III] May be recommended on the basis of individual circumstances</p>

Clinical Practice Guideline	Recommendation	Grade of Evidence	Strength of Recommendation
	<p>pregnant woman, changes in pharmacokinetics during pregnancy may require adjustments in medication doses [I]. Electroconvulsive therapy may be considered for the treatment of depression during pregnancy in patients who have psychotic or catatonic features, whose symptoms are severe or have not responded to medications, or who prefer treatment with ECT [II]."</p>		
<p>American Academy of Pediatrics. Use of psychoactive medication during pregnancy and possible effects on the fetus and newborn. Committee on Drugs; 2000.</p>	<p>"Because of the potential for teratogenesis and other adverse events in the fetus or newborn, varying degrees of concern exist when any drug is prescribed during pregnancy. Avoidance of pregnancy and avoidance of drug therapy during pregnancy are commonly suggested strategies to prevent fetal drug exposure. However, these strategies are often not possible."</p> <p>"To minimize the risk of fetal and neonatal toxicity, including abstinence syndrome, the physician should prescribe the lowest dosage that provides adequate control of the woman's illness. The neonate must be monitored for evidence of persistent drug effect or development of an abstinence syndrome."</p> <p>"It is advisable to monitor the effectiveness of treatment throughout pregnancy to achieve the lowest effective dose of any agent."</p>	<p>No grade</p>	<p>N/A</p>

Appendix B. Measure Information Form

Performance Measure Name: Screening for Pregnancy

Description: Percentage of female patients of childbearing age (15-44 years) admitted to an inpatient psychiatric facility (IPF) who have documentation in their medical record of a pregnancy status.

Rationale: Screening female patients of childbearing age for pregnancy during the inpatient psychiatric hospitalization is important to reduce adverse outcomes and integrate risk versus benefit considerations relevant to pregnancy into treatment decisions by both clinicians and patients. Screening for pregnancy is standard practice in many settings but is particularly important in the inpatient psychiatric setting because many psychiatric medications commonly administered during inpatient psychiatric stays have important treatment considerations for women who are pregnant and some psychiatric medications that patients may have taken prior to the stay can reduce the efficacy of oral contraceptives (American Academy of Pediatrics, 2000; American Psychiatric Association, 2002; American Psychiatric Association, 2010a; American Psychiatric Association, 2010b; Gold & Marcus, 2008; Kohen, 2004; Ornoy, Weinstein-Fudim, & Ergaz, 2017; Scrandis 2017; Tanoshima, et al., 2015; Tomson, Battino, & Perucca, 2016; US Department of Veterans Affairs, 2016). Psychotropic medications can also adversely affect obstetrical outcomes, for instance, risk for cesarean sections, venous thromboembolism, gestational diabetes, and pre-eclampsia (American Academy of Pediatrics, 2000; American Psychiatric Association, 2002; American Psychiatric Association, 2010a; American Psychiatric Association, 2010b; Calderon-Margalit, Qui, Ornoy, Siscovick, & Williams, 2009; Kohen, 2004; Malm, Sourander, & Gissler, 2015; Ornoy, Weinstein-Fudim, & Ergaz, 2017; Petersen, et al., 2016; Raimondi & Sheiner, 2015; Scrandis 2017; Tanoshima, et al., 2015; Terrana, Koren, Pivovarov, Etwel, Nulman, 2015; Tomson, Battino, & Perucca, 2016). If a pregnancy is identified during the inpatient psychiatric stay, providers and patients can engage in a discussion of the risks and benefits of various treatment options and select treatments that best align with the patient's preferences.

In addition to avoiding potential adverse fetal and obstetrical outcomes and engaging the patient in treatment decisions, screening for pregnancy can have several other important benefits in an inpatient psychiatric setting related to ensuring best practices of prenatal care. For example, identification of a pregnancy can help to inform discharge planning by including referrals to prenatal care; providing additional resources or instructions for women who may be at increased risk for postpartum depression; and making referrals to drug treatment programs for pregnant women with substance use disorders (American Psychiatric Association, 2002; American Psychiatric Association, 2010a; American Psychiatric Association, 2010b; Einarson, Selby, & Koren, 2001; Kirkham, Harris, Grzybowski, 2005). For pregnant patients who are already taking psychiatric medications, providers can inform them of the risks of abruptly discontinuing their medications, which can include a relapse that would impact their ability to care for themselves or their other children (American College of Obstetricians and Gynecologists, 2016; American Psychiatric Association; 2002; American Psychiatric Association, 2010a; Cohen, et al., 2006; Petersen et al., 2016; Scrandis, 2017). If the risks of discontinuation outweigh the risks associated with the medications, providers and patients can consider ways to mitigate risks like adjusting dosages, monitoring serum levels, or changing to medications that carry fewer risks (American Academy of Pediatrics, 2000; American Psychiatric Association; 2002; American Psychiatric Association, 2010a; American Psychiatric Association, 2010b; Gold and Marcus, 2008; Kohen, 2004; Ornoy et al., 2017; Scrandis, 2017; Tanoshima et al., 2015; Tomson et al., 2016; US Department of Veterans Affairs, 2016). If the risks of discontinuation do not outweigh the risks associated with the medications, patients may choose other forms of treatment like psychotherapy during their pregnancy.

Screening for pregnancy has the potential to benefit patients who are not pregnant during the inpatient psychiatric admission as well. It can provide an opportunity to discuss the importance of family planning while on psychotropic medications that pose risks during pregnancy and especially among those who are on psychotropic medications that reduce the efficacy of oral contraceptives (American Psychiatric Association; 2002).

The risks of not identifying a pregnancy outweigh the potential burden associated with screening because of the severity of the preventable adverse outcomes to both fetal development and obstetrical outcomes. Screening females of childbearing age for pregnancy is a relatively low burden process. Clinical practice guidelines from the American College of Obstetricians and Gynecologists (ACOG), American Psychiatric Association (APA), International Society for Bipolar Disorders (ISBD), US Department of Veteran Affairs and the US Department of Defense and the American Academy of Pediatrics support the need to consider pregnancy status when treating females for psychiatric conditions (American Academy of Pediatrics, 2000; American College of Obstetricians and Gynecologists, 2008; American Psychiatric Association, 2002; American Psychiatric Association, 2010a; American Psychiatric Association, 2010b; Ng, et al., 2009; US Department of Veterans Affairs, 2016).

Type of Measure: Process

Improvement Noted As: Increase in the rate/proportion

Numerator Statement: Total number of eligible patients in the denominator who have documentation in their medical record of pregnancy status.

Numerator Details:

Acceptable documentation is defined as either of the following:

1. Pregnancy status documented by a physician, advanced practice nurse (APN), physician assistant (PA), or nurse of:
 - Active pregnancy as identified from auscultation of positive fetal heart tones or self-report by the patient
 - Inability to become pregnant due to a history of hysterectomy (total, radical or partial), tubal ligation, genetic disorder, or birth defect
2. Result of a blood or urine hCG laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization.
 - The hCG laboratory test result can be from a test performed during the IPF hospitalization or prior to the hospitalization at a transferring facility.

Data Element(s):

- Documented Pregnancy Status
- Pregnancy Test Result

Denominator Statement: The number of female patients who are between the ages of 15 and 44 on admission to an IPF.

Included Populations: Female patients of childbearing age (15 to 44 years)

Excluded Populations: Patient admissions with lengths of stay shorter than or equal to two days or who were discharged AMA

Data Elements:

- Admission Date
- Birthdate
- Discharge Date
- Sex
- Discharge Disposition

Risk Adjustment: No

Data Collection Approach: Retrospective data sources for required data elements include medical record documents. Some hospitals may prefer to gather data concurrently. This approach provides opportunities for improvement at the point of care/service.

Data Accuracy: Data accuracy is enhanced if all definitions are used without modification. The data dictionary should be referenced for definitions and abstraction notes when questions arise during data collection.

Sampling: The sampling approach will be determined by the IPFQR program if the measure is implemented.

Data Reported As: Aggregate rate generated from count data reported as percentage.

Selected References:

- American Academy of Pediatrics. (2000). *Use of psychoactive medication during pregnancy and possible effects on the fetus and newborn*. Retrieved from <http://pediatrics.aappublications.org/content/105/4/880>
- American College of Obstetricians and Gynecologists. (2008). American College of Obstetricians and Gynecologists (ACOG) guidelines on psychiatric medication use during pregnancy and lactation. *Am Fam Physician*, 78(6), 772-778.
- American College of Obstetricians and Gynecologists. Perinatal Care Clinical Practice Guidelines 2016. 2016. <http://passporthealthplan.com/wp-content/uploads/2016/07/HLTH62565-updated-Perinatal-CPG.pdf>. Accessed February 7, 2018.
- American Psychiatric Association. (2002). Practice guideline for the treatment of patients with bipolar disorder, Second edition. Retrieved from http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf
- American Psychiatric Association. (2010a). Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. Retrieved from http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf
- American Psychiatric Association. (2010b). Practice guideline for the treatment of patients with schizophrenia, 2nd ed. Retrieved from http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf
- Calderon-Margalit R, Qiu C, Ornoy A, Siscovick DS, Williams MA. Risk of preterm delivery and other adverse perinatal outcomes in relation to maternal use of psychotropic medications during pregnancy. *Am J Obstet Gynecol*. 2009;201(6):579 e571-578. doi: 10.1016/j.ajog.2009.06.061.
- Cohen, L. S., Altshuler, L. L., Harlow, B. L., Nonacs, R., Newport, D. J., Viguera, A. C., . . . Stowe, Z. N. (2006). Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. *JAMA*, 295(5), 499-507. doi:10.1001/jama.295.5.499
- Einarson A, Selby P, Koren G. Abrupt discontinuation of psychotropic drugs during pregnancy: fear of teratogenic risk and impact of counselling. *J Psychiatry Neurosci*. 2001;26(1):44-48.
- Gold, K. J., & Marcus, S. M. (2008). Effect of maternal mental illness on pregnancy outcomes. *Expert Rev Obstet Gynecol*, 3(3), 391-401. doi:10.1586/17474108.3.3.391
- Kirkham C, Harris S, Grzybowski S. Evidence-based prenatal care: Part I. General prenatal care and counseling issues. *Am Fam Physician*. 2005;71(7):1307-1316.
- Kohen, D. (2004). Psychotropic medication in pregnancy. *Advances in Psychiatric Treatment*, 10(1), 59-66. doi:10.1192/apt.10.1.59
- Malm H, Sourander A, Gissler M, et al. Pregnancy Complications Following Prenatal Exposure to SSRIs or Maternal Psychiatric Disorders: Results From Population-Based National Register Data. *Am J Psychiatry*. 2015;172(12):1224-1232. doi: 10.1176/appi.ajp.2015.14121575.
- Ng, F., Mammen, O. K., Wilting, I., Sachs, G. S., Ferrier, I. N., Cassidy, F., . . . International Society for Bipolar, D. (2009). The International Society for Bipolar Disorders (ISBD) consensus guidelines for the safety monitoring of bipolar disorder treatments. *Bipolar Disord*, 11(6), 559-595. doi:10.1111/j.1399-5618.2009.00737.x

- Ornoy, A., Weinstein-Fudim, L., & Ergaz, Z. (2017). Antidepressants, Antipsychotics, and Mood Stabilizers in Pregnancy: What Do We Know and How Should We Treat Pregnant Women with Depression. *Birth Defects Res*, 109(12), 933-956. doi:10.1002/bdr2.1079
- Petersen, I., McCrea, R. L., Sammon, C. J., Osborn, D. P., Evans, S. J., Cowen, P. J., . . . Nazareth, I. (2016). Risks and benefits of psychotropic medication in pregnancy: cohort studies based on UK electronic primary care health records. *Health Technol Assess*, 20(23), 1-176. doi:10.3310/hta20230
- Raimondi A, Sheiner E. Pregnant women with schizophrenia are at higher risk of pre-eclampsia, venous thromboembolism and adverse neonatal outcomes. *Evid Based Nurs*. 2015;18(2):39-40. doi: 10.1136/eb-2014-101902.
- Scrandis, D. A. (2017). Bipolar disorder in pregnancy: a review of pregnancy outcomes. *J Midwifery Womens Health*, 62(6), 673-683. doi:10.1111/jmwh.12645
- Tanoshima, M., Kobayashi, T., Tanoshima, R., Beyene, J., Koren, G., & Ito, S. (2015). Risks of congenital malformations in offspring exposed to valproic acid in utero: a systematic review and cumulative meta-analysis. *Clin Pharmacol Ther*, 98(4), 417-441. doi:10.1002/cpt.158
- Terrana N, Koren G, Pivovarov J, Etwel F, Nulman I. Pregnancy Outcomes Following In Utero Exposure to Second-Generation Antipsychotics: A Systematic Review and Meta-Analysis. *J Clin Psychopharmacol*. 2015;35(5):559-565. doi: 10.1097/JCP.0000000000000391.
- Tomson, T., Battino, D., & Perucca, E. (2016). Valproic acid after five decades of use in epilepsy: time to reconsider the indications of a time-honoured drug. *Lancet Neurol*, 15, 210-218. doi:10.1016/S1474-4422(15)00314-2
- US Department of Veterans Affairs, & US Department of Defense. (2016). *Management of Major Depressive Disorder*. Retrieved from <http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf>

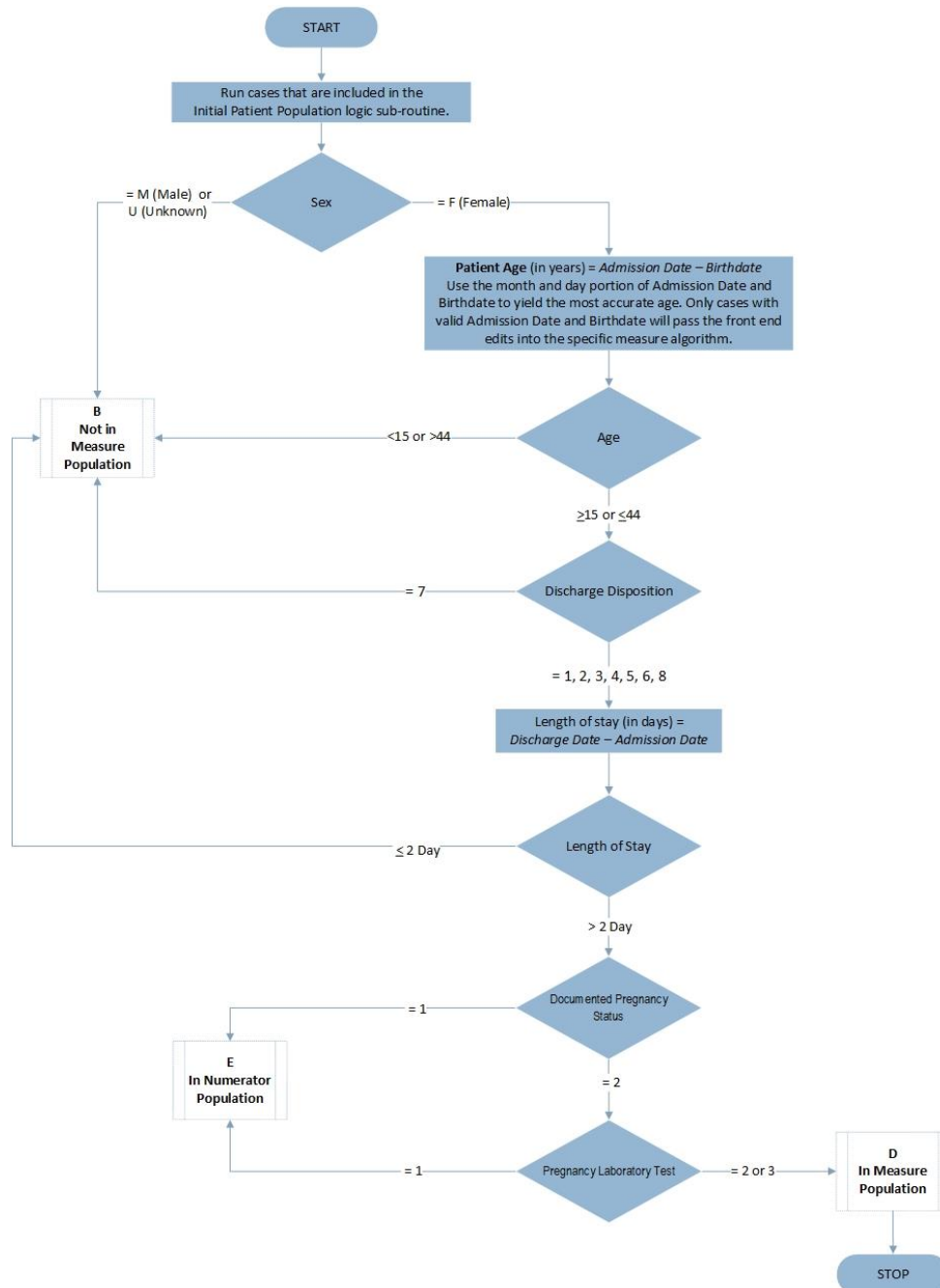
Measure Algorithm

Screening for Pregnancy

Numerator Statement: Total number of eligible patients in the denominator who have documentation in their medical record of pregnancy status.

Denominator Statement: The number of female patients who are between the ages of 15 and 44 on admission to an IPF.

Figure 3. Measure Algorithm



Measure Narratives:

1. Start processing. Run cases that are included in the Initial Patient Population as follows:
 - a. Find the patients that the performance measure is designed to address (all female patients between the ages of 15 and 44 years old, who were admitted to the inpatient facility with a length of stay greater than two days).
2. Check *Sex*.
 - a. If the *Sex* is equal to Female, continue processing and proceed to *Patient Age*.
 - b. If the *Sex* is equal to Male or Unknown, the record will proceed to Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
3. Calculate and Check *Patient Age*.
 - a. Calculate *Patient Age*, in years, as equal to the *Admission Date* minus the *Birthdate*. Use the month and day portion of admission date and birthdate to yield the most accurate age.
 - b. Check *Patient Age*.
 - i. If the *Age* is greater than or equal to 15 or less than or equal to 44, continue processing and proceed to *Length of Stay*.
 - ii. If the *Age* is less than 15 or greater than 44, the record will proceed to Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
4. Check the *Discharge Disposition*.
 - a. If the *Discharge Disposition* is equal to 1, 2, 4, 4, 5, 5, or 8, continue processing and proceed to *Length of Stay*.
 - b. If the *Discharge Disposition* is equal to 7, the record will proceed to Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
5. Calculate and Check *Length of Stay*.
 - a. Calculate *Length of Stay*, in days, as equal to the Discharge Date minus the Admission Date.
 - b. Check Length of Stay.
 - i. If the *Length of Stay* is greater than two days, continue processing and proceed to *Documented Pregnancy Status*.
 - ii. If the *Length of Stay* is less than or equal to two days, the record will proceed to Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
6. Check *Documented Pregnancy Status*.
 - a. If the *Documented Pregnancy Status* is equal to 1, the record will proceed to Measure Category Assignment of E and will be in the Numerator Population. Stop processing.
 - b. If the *Documented Pregnancy Status* is equal to 2, continue processing and proceed to *Pregnancy Laboratory Test*.
7. Check *Pregnancy Laboratory Test*.
 - a. If the *Pregnancy Laboratory Test* is equal to 1, the record will proceed to Measure Category Assignment of E and will be in the Numerator Population. Stop processing.
 - b. If the *Pregnancy Laboratory Test* is equal to 2 or 3, the record will proceed to Measure Category Assignment of D and will be in the Measure Denominator Population. Stop processing.

Appendix C. Data Definitions and Abstraction Instructions

Data Dictionary

Data Element Name: *Admission Date*

Definition: The month, day, and year of admission to an inpatient facility.

Suggested Data Collection Question: What was the date the patient was admitted to the inpatient psychiatric facility?

Format:

Length: 10 – MM-DD-YYYY (includes dashes)

Type: Date

Occurs: 1

Allowable Values:

Date:

MM = Month (01-12)

DD = Day (01-31)

YYYY = Year (20xx)

Notes for Abstraction:

- The intent of this data element is to determine the date that the patient was admitted to an inpatient facility, as evidenced by an admission order. Because this data element is critical in determining the population for the measure, the abstractor should NOT assume that the billing or claim information for the admission date is correct. If the abstractor determines through chart review that the date from billing is incorrect, for purposes of abstraction, she/he should enter the correct admission date and time documented in the admission order. Admission dates from billing information should only be considered if the admission order is not available or does not include a date.
- For patients who are admitted to Observation status and subsequently admitted to inpatient care, abstract the date that the order was made to admit to inpatient care. Do not abstract the date that the patient was admitted to Observation.

Example: Medical record documentation reflects that the patient was admitted to observation on 04-05-20xx. On 04-06-20xx, the physician writes an order to admit to inpatient care effective 04-05-20xx. The Admission Date would be abstracted as 04-06-20xx, the date the determination was made to admit to inpatient care and the order was written.

- If there are multiple inpatient admission orders, use the order that most accurately reflects the date that the patient was admitted, based on other documentation in the record.
- For interrupted stays, where the patient is readmitted to the facility, use the admission order that most accurately reflects the admission date that corresponds to the stay that is being reviewed.

Suggested Data Sources:

Note: The physician order is the priority data source for this data element.

Only Allowable Sources:

1. Physician order
2. Face sheet
3. UB-04

Excluded Data Sources:

UB-04 “From” and “Through” dates

Inclusion Guidelines for Abstraction:

None

Exclusion Guidelines for Abstraction:

- Admit to observation
- Arrival date
- Emergency department (ED) admission date
- ED admission date

Data Element Name: *Birthdate*

Definition: The month, day, and year the patient was born.

Note: Patient's age (in years) is calculated by Admission Date minus Birthdate. The algorithm to calculate age must use the month and day portion of admission date and birthdate to yield the most accurate age.

Suggested Data Collection Question: What is the patient's date of birth?

Format:

Length: 10 – MM-DD-YYYY (includes dashes)

Type: Date

Occurs: 1

Allowable Values:

MM = Month (01-12)

DD = Day (01-31)

YYYY = Year (1880-Current Year)

Notes for Abstraction:

- Because this data element is critical in determining the population for the measure, the abstractor should NOT assume that the claim information for the birthdate is correct. If the abstractor determines through chart review that the date is incorrect, she/he should correct and override the downloaded value. If the abstractor is unable to determine the correct birthdate through chart review, she/he should default to the date of birth on the claim information.

Suggested Data Sources:

- Emergency Department record
- Face sheet
- Registration form
- UB-04
- Scanned copy of photo identification (driver's license or state identification card)

Excluded Data Sources:

None

Inclusion Guidelines for Abstraction:

None

Exclusion Guidelines for Abstraction:

None

Data Element Name: *Discharge Date*

Definition: The month, day, and year of discharge from an inpatient facility.

Suggested Data Collection Question: What was the date the patient was discharged from the inpatient psychiatric facility?

Format:

Length: 10 – MM-DD-YYYY (includes dashes)

Type: Date

Occurs: 1

Allowable Values:

Date:

MM = Month (01-12)

DD = Day (01-31)

YYYY = Year (20xx)

Notes for Abstraction:

Because this data element is critical in determining the population for the measure, the abstractor should NOT assume that the claim information for the discharge date is correct. If the abstractor determines through chart review that the date is incorrect, she/he should correct and override the value. If the abstractor is unable to determine the correct discharge date through chart review, she/he should default to the discharge date on the claim information.

Only Allowable Sources:

1. Physician orders
2. Death certificate
3. Discharge summary
4. Nursing discharge notes
5. Transfer note
6. Face sheet
7. UB-04

Inclusion Guidelines for Abstraction:

None

Exclusion Guidelines for Abstraction:

None

Data Element Name: Discharge Disposition

Definition: The final place or setting to which the patient was discharged on the day of discharge.

Suggested Data Collection Question: What was the patient’s discharge disposition on the day of discharge?

Format:

Length: 1
Type: Alphanumeric
Occurs: 1

Allowable Values:

1. Home
2. Hospice - Home
3. Hospice – Health Care Facility
4. Acute Care Facility
5. Other Health Care Facility
6. Expired
7. Left Against Medical Advice/AMA
8. Not Documented or Unable to Determine (UTD)

Notes for Abstraction:

- Only use documentation written on the day prior to discharge through 30 days after discharge when abstracting this data element.

Example:

Documentation in the Discharge Planning notes on 04-01-20xx state that the patient will be discharged back home. On 04-06-20xx the physician orders and nursing discharge notes on the day of discharge reflect that the patient was being transferred to skilled care. The documentation from 04-06-20xx would be used to select Value “5” (Other Health Care Facility).

- The medical record must be abstracted as documented (taken at “face value”). Inferences should not be made based on internal knowledge.

If there is documentation that further clarifies the level of care that documentation should be used to determine the correct value to abstract. If documentation is contradictory, use the latest documentation.

Examples:

- Discharge summary dictated 2 days after discharge states patient went “home.” Physician note on day of discharge further clarifies that the patient will be going “home with hospice.” Select Value “2” (“Hospice - Home”).
 - Discharge planner note from day before discharge states “XYZ Nursing Home.” Discharge order from day of discharge states “Discharge home.” Contradictory documentation, use latest. Select Value “1” (“Home”).
 - Physician order on discharge states “Discharge to ALF.” Discharge instruction sheet completed after the physician order states patient discharged to “SNF.” Contradictory documentation, use latest. Select Value “5” (“Other Health Care Facility”).
- If documentation is contradictory, and you are unable to determine the latest documentation, select the disposition ranked highest (top to bottom) in the following list. See Inclusion lists for examples.
 - Acute Care Facility
 - Hospice – Health Care Facility

- Hospice – Home
- Other Health Care Facility
- Home

- Hospice (Values “2” and “3”) includes discharges with hospice referrals and evaluations.
- If the medical record states only that the patient is being discharged to another hospital and does not reflect the level of care that the patient will be receiving, select Value “4” (“Acute Care Facility”).
- If the medical record states the patient is being discharged to assisted living care or an assisted living facility (ALF) and the documentation also includes nursing home, intermediate care or skilled nursing facility, select Value “1” (“Home”).
- If the medical record states the patient is being discharged to nursing home, intermediate care or skilled nursing facility without mention of assisted living care or assisted living facility (ALF), select Value “5” (“Other Health Care Facility”).
- If the medical record identifies the facility the patient is being discharged to by name only (e.g., “Park Meadows”), and does not reflect the type of facility or level of care, select Value “5” (“Other Health Care Facility”).
- If the medical record states only that the patient is being “discharged” and does not address the place or setting to which the patient was discharged, select Value “1” (“Home”).
- When determining whether to select Value “7” (“Left Against Medical Advice/AMA”):
 - Explicit “left against medical advice” documentation is not required. E.g., “Patient is refusing to stay for continued care” – Select Value “7.”
 - Documentation suggesting that the patient left before discharge instructions could be given does not count.
 - A signed AMA form is not required, for the purposes of this data element.
 - Do not consider AMA documentation and other disposition documentation as “contradictory.” If any source states the patient left against medical advice, select Value “7,” regardless of whether the AMA documentation was written last. E.g., AMA form signed and discharge instruction sheet states “Discharged home with belongings” – Select “7.”

Suggested Data Sources:

- Discharge instruction sheet
- Discharge planning notes
- Discharge summary
- Nursing discharge notes
- Physician orders
- Progress notes
- Social service notes
- Transfer record

Excluded Data Sources:

- Any documentation prior to the last two days of hospitalization
- Coding documents
- UB-04

Inclusion Guidelines for Abstraction:

Home (Value 1):

- Assisted Living Facilities (ALFs) – Includes ALFs and assisted living care at: nursing home, intermediate care, and skilled nursing facilities
- Court/Law Enforcement – includes detention facilities, jails, and prison
- Home – includes board and care, foster or residential care, group or personal care homes, retirement communities, and homeless shelters
- Home with Home Health Services
- Outpatient Services including outpatient procedures at another hospital, Outpatient Chemical Dependency Programs and Partial Hospitalization

Hospice – Home (Value 2):

Hospice in the home (or other “Home” setting as above in Value 1)

Hospice – Health Care Facility (Value 3):

- Hospice - General Inpatient and Respite
- Hospice - Residential and Skilled Facilities
- Hospice - Other Health Care Facilities

Acute Care Facility (Value 4):

- Acute Short Term General and Critical Access Hospitals
- Cancer and Children’s Hospitals
- Department of Defense and Veteran’s Administration Hospitals
- Other Health Care Facility (Value 5):
- Extended or Intermediate Care Facility (ECF/ICF)
- Long Term Acute Care Hospital (LTACH)
- Nursing Home or Facility including Veteran’s Administration Nursing Facility
- Psychiatric Hospital or Psychiatric Unit of a Hospital
- Rehabilitation Facility including Inpatient Rehabilitation Facility/Hospital or Rehabilitation Unit of a Hospital
- Skilled Nursing Facility (SNF), Sub-Acute Care or Swing Bed
- Transitional Care Unit (TCU)
- Veterans Home

Exclusion Guidelines for Abstraction:

None

Data Element Name: Pregnancy Laboratory Test

Definition: Documentation of a result of a Human Chorionic Gonadotropin (hCG) laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization.

Suggested Data Collection Question: Was there documentation in the medical record of a result of a blood or urine hCG laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization?

Format:

Length: 1

Type: Alphanumeric

Occurs: 1

Allowable Values:

- 1 There was documentation in the medical record of a result of a blood or urine hCG laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization.
- 2 There was documentation in the medical record of a result of a blood or urine hCG laboratory test to detect pregnancy, but the result date was not on or prior to the end of Day 2 of the IPF hospitalization.
- 3 There was no documentation in the medical record of a result of a blood or urine hCG laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization.

Notes for Abstraction:

- To answer “1” there must be a result of a blood or urine hCG laboratory test documented with a result date on or prior to the end of Day 2 of the IPF hospitalization. This includes the day of admission, which is defined as Day 0 and the next hospitalization day is Day 1, and so forth.
- If the result of a blood or urine hCG laboratory test is documented, but the result date is not on or prior to the end of Day 2 of the IPF hospitalization, answer “2.”
- Documentation of the result of a blood or urine hCG laboratory test to detect pregnancy may be obtained from tests performed either during the IPF stay or performed at the transferring facility (emergency department, medical unit within the same facility, or another acute care facility) prior to the IPF admission.
- Blood or urine hCG laboratory test results to detect pregnancy obtained from any other setting are not acceptable.
- If more than one result of a blood or urine hCG laboratory test to detect pregnancy is documented in the record, use the date of the first conclusive test closest to the admission date.
- If the physician/APN/PA documented the blood or urine hCG laboratory test result in his/her progress notes, the date of the test result must accompany the documented result.
- If the test was resulted and was inconclusive or could not be calculated, select “3.”
- If the patient refused the blood or urine hCG laboratory test to detect pregnancy, answer “3”

Suggested Data Sources:

- Consultation notes

- Emergency Department record
- History and physical
- Initial (admission) assessment form
- Laboratory report
- Nursing notes
- Physician progress notes
- Psychiatrist assessment/admission form
- Transfer record

Excluded Data Sources:

None

Inclusion Guidelines for Abstraction:

- Point-of-care urine hCG laboratory tests

Exclusion Guidelines for Abstraction:

None

Data Element Name: Documented Pregnancy Status

Definition: Acceptable documentation of pregnancy status by a physician, advanced practice nurse (APN), physician assistant (PA), or nurse.

Suggested Data Collection Question: Was there documentation in the medical record by the physician/APN/PA or nurse of an acceptable type of pregnancy status?

Format:

Length: 1

Type: Alphanumeric

Occurs: 1

Allowable Values:

- | | |
|---------|--|
| 1 (Yes) | There was documentation in the medical record by the physician/APN/PA or nurse of an acceptable type of pregnancy status. |
| 2 (No) | There was no documentation in the medical record by the physician/APN/PA or nurse of an acceptable type of pregnancy status. |

Notes for Abstraction:

- Acceptable types of pregnancy status can be documented at any time during the IPF hospitalization or prior to the IPF hospitalization at a transferring facility (emergency department, medical unit within the same facility, or another acute care facility).
- Refer to the Inclusion Guidelines for Abstraction section for acceptable types of documented pregnancy status.

Suggested Data Sources:

- Consultation notes
- Emergency Department record
- History and physical
- Initial (admission) assessment form
- Nursing notes
- Physician progress notes
- Psychiatrist assessment/admission form
- Transfer record

Excluded Data Sources:

Laboratory Reports

Inclusion Guidelines for Abstraction:

Acceptable Types of Pregnancy Status Documentation:

The following are the only acceptable types of pregnancy status documentation allowed:

- The patient was pregnant on admission (as identified through patient self-report or auscultation of positive fetal heart tones)
- The patient has a documented history of hysterectomy (total, radical or partial) and/or has a history of tubal ligation

- The patient has a documented history of other clinical causes of sterility such as the patient is unable to conceive due to a genetic disorder or birth defect that specifically prevents the patient from becoming pregnant. Examples of genetic disorders include Mayer-Rokitansky-Küster-Hauser syndrome and Turner Syndrome.

Exclusion Guidelines for Abstraction:

Unacceptable Types of Pregnancy Status Documentation:

The following types of pregnancy status documentation are not acceptable because these types of documentation cannot confirm the pregnancy status of the patient:

- The patient is post-partum (regardless of timeframe)
- The patient is post-menopausal (regardless of timeframe)
- The patient is sexually inactive/abstinent
- The patient is taking hormonal, mechanical, or chemical contraception (birth control pill, patch, injection, sponge, ring, implant/intrauterine device (IUD), cervical cap, condom, diaphragm, spermicide, etc.), including fertility awareness-based methods and withdrawal

Data Element Name: Sex

Definition: The patient's documented sex on arrival at the hospital.

Suggested Data Collection Question: What was the patient's sex on arrival?

Format:

Length: 1
Type: Character
Occurs: 1

Allowable Values:

M = Male
F = Female
U = Unknown

Notes for Abstraction:

- Collect the documented patient's sex at admission or the first documentation after arrival.
- Consider the sex to be unable to be determined and select "Unknown" if:
 - The patient refuses to provide their sex.
 - Documentation is contradictory.
 - Documentation indicates the patient is a Transgender or Transsexual.
 - Documentation indicates the patient is a Hermaphrodite.
- If the sex is M = Male or U = Unknown, the case will not be included in the measure population. Stop abstraction and select another case.

Suggested Data Sources:

- Consultation notes
- Emergency Department record
- Face sheet
- History and physical
- Nursing admission notes
- Progress notes
- UB-04

Inclusion Guidelines for Abstraction:

None

Exclusion Guidelines for Abstraction:

None

Appendix D. Data Abstraction Tool

Question #	Data Element Name	Abstraction Question and Instructions	Abstraction Answers
Demographic Information			
1.	Sex	<p>What was the patient's sex on arrival?</p> <p>Select the letter that corresponds with the option from the Allowable Values that best represents the patient's sex.</p> <p>Allowable Values M = Male F = Female U = Unknown</p> <p>If M or U, stop abstraction and select another case</p>	
2.	Birthdate	<p>What is the patient's date of birth?</p> <p>Enter the date in the following format: (MM/DD/YYYY)</p>	
3.	Admission Date	<p>What was the date the patient was admitted to the inpatient psychiatric facility?</p> <p>Enter the date in the following format: (MM/DD/YYYY)</p>	
4.	Discharge Date	<p>What was the date the patient was discharged from the inpatient psychiatric facility?</p> <p>Enter the date in the following format: (MM/DD/YYYY)</p>	
Pregnancy Status Information			
5.	Documented Pregnancy Status	<p>Was there documentation in the medical record by the physician/APN/PA or nurse of an acceptable type of pregnancy status? Select the appropriate option from the Allowable Values.</p> <p>Allowable Values:</p> <p>1 (Yes) There was documentation in the medical record by the physician/APN/PA or nurse of an acceptable type of pregnancy status.</p> <p>2 (No) There was no documentation in the medical record by the physician/APN/PA or nurse of an acceptable type of pregnancy status</p> <p><u>Acceptable Types of Screening Documentation:</u> The following documentation are the only acceptable types of pregnancy screenings allowed:</p> <ul style="list-style-type: none"> The patient was pregnant on admission (as identified through patient self-report or auscultation of positive fetal heart tones) The patient has a documented history of hysterectomy (total, radical or partial) and/or has a history of tubal ligation The patient has a documented history of other clinical causes of sterility such as the patient is unable to conceive due to a genetic disorder or birth defect that specifically prevents the patient from becoming pregnant. Examples of genetic disorders include Mayer-Rokitansky-Küster-Hauser syndrome and Turner Syndrome. 	

Question #	Data Element Name	Abstraction Question and Instructions	Abstraction Answers
		<p><u>Unacceptable types of documented pregnancy screenings:</u> The following documentation are not acceptable types of pregnancy screenings because these types of documented pregnancy screenings cannot confirm the pregnancy status of the patient:</p> <ul style="list-style-type: none"> • The patient is post-partum (regardless of timeframe) • The patient is post-menopausal (regardless of timeframe) • The patient is sexually inactive/abstinent • The patient is taking hormonal, mechanical, or chemical contraception (birth control pill, patch, injection, sponge, ring, implant/intrauterine device (IUD), cervical cap, condom, diaphragm, spermicide, etc.), including fertility awareness-based methods and withdrawal. 	
6.	Pregnancy Laboratory Test	<p>Was there documentation in the medical record of a result of a blood or urine hCG laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization?</p> <p>Select the appropriate option from the Allowable Values.</p> <p><u>Allowable Values</u></p> <ol style="list-style-type: none"> 1. There was documentation in the medical record of a result of a blood or urine hCG laboratory test to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization. 2. There was documentation in the medical record of a result of a blood or urine hCG laboratory test to detect pregnancy, but the result date was not on or prior to the end of Day 2 of the IPF hospitalization. 3. There is was no documentation in the medical record of a blood or urine hCG laboratory test result to detect pregnancy with a result date on or prior to the end of Day 2 of the IPF hospitalization. <p>If 1, include in the numerator population and stop abstraction. If 2 or 3, include in the measure population and stop abstraction.</p>	