- TO: Consensus Standards Approval Committee (CSAC)
- FR: Reva Winkler, Suzanne Theberge, and Nadine Allen
- RE: Perinatal and Reproductive Health
- DA: September 13, 2016

The CSAC will review recommendations from the Perinatal and Reproductive Health project at its September 13 conference call.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

Member voting on these recommended measures ended on August 18.

Accompanying this memo are the following documents:

- 1. <u>Perinatal and Reproductive Health Draft Report</u>. The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
- 2. <u>Comment table</u>. Staff has identified themes within the comments received. This table lists 178 comments received and the NQF/Standing Committee responses.

BACKGROUND

Despite the fact that the United States spends more on perinatal healthcare than any other health sector (\$111 billion in 2010) the US is ranked 61st in the world for maternal health. In 2014, there were nearly 4 million births in the US. In 2011, of the 7.6 million hospital stays with Medicaid as the primary payer, 29% (or 3 of the top 5 conditions) were related to pregnancy and childbirth: newborn infant, trauma to the perineum and vulva caused by childbirth, and delivery following a Cesarean section. For the 61 million women of reproductive age in the US, access to high-quality care before and between pregnancies, including pregnancy planning, contraception, and preconception care, can reduce the risk of pregnancy-related complications, including maternal and infant mortality.

The National Quality Forum's (NQF) portfolio of measures for Perinatal and Reproductive Health includes measures for reproductive health; pregnancy, labor and delivery; high-risk pregnancy; newborn, premature, or low birthweight newborns; and postpartum patients.

For this project, the 27-member <u>Perinatal and Reproductive Health Standing Committee</u> evaluated 9 newly submitted measures and 15 measures undergoing maintenance of endorsement review against NQF's standard evaluation criteria. The Committee recommended 18 measures for endorsement, did not reach consensus on 1 measure, and did not recommend 5 measures. Evaluated measures are listed by topic in the draft report.

DRAFT REPORT

The Perinatal and Reproductive Health Draft Report presents the results of the evaluation of 24 measures considered under the CDP. Eighteen are recommended for endorsement as voluntary

consensus standards suitable for accountability and quality improvement, one did not achieve consensus, and five were not recommended. The measures were evaluated against the 2015 version of the <u>measure evaluation criteria</u>.

	MAINTENANCE	NEW	TOTAL
Measures considered	15	9	24
Withdrawn from consideration	7	0	7
Recommended	13	5	18
Consensus is not yet reached	1	0	1
Not recommended	1	4	5
Reasons not	Importance- 1	Importance- 2	
Recommended	Scientific Acceptability- 0	Scientific Acceptability- 1	
	Overall- 0	Overall- 1	
	Competing Measure- 0	Competing Measure- 0	

CSAC ACTION REQUIRED

1. Consensus Not Reached by the Perinatal Committee

CSAC must determine a resolution for a measure where consensus was not reached by the Perinatal and Reproductive Health Committee. On June 25, 2016, the Committee considered comments received and developer responses in further evaluation of one measure for which the Committee did not reach consensus on a recommendation during the May 2-3 in-person meeting. On re-vote the Committee again did not reach consensus on the following measure:

<u>1517</u>: Prenatal & Postpartum Care (PPC) – This measure has two parts, assessing the timeliness of prenatal and post-partum care. The Committee noted most concerns with the timeframe for the post-partum visit, defined as on or between 21 and 56 days after delivery. The timing specified in the measure is based on consensus opinion rather than empirical evidence, however, the Committee granted an exception to the evidence criteria. The Committee was concerned about the validity of the measures as a reflection of quality of care. Some Committee members found the time range specified in the postpartum measure to be problematic as patients receiving postpartum care a few days on either side of the window are not necessarily receiving poor care. A two-week postpartum visit (14 days) also may be appropriate for some patients. Other Committee members were reluctant to removed endorsement because this is the only measure for prenatal and post-partum care, though all agreed better measures are urgently needed.

The ten public comments were also split with some supporting removal of endorsement and others not. Committee discussion after reviewing the public comments again focused on concerns for the timeframe, the fact the measure is based on expert consensus, not empirical evidence, and the emphasis on timing, not content of visits. Committee members disagreeing noted the lack of measures in this area, the large gap in performance, the unlikelihood that randomized controlled trials (RCTs) will be conducted on this topic, and the fact that if patients are not receiving care, it is definitely poor quality. During the Post-

Comment Call, the Committee re-voted and was unable to reach consensus on validity (Moderate-11 (52%); Low-7; Insuffient-3) and Overall Suitability (Y-12 (46.2%); N-14). The NQF Membership voted not to recommend measure #1517 for endorsement; three voting comments were submitted:

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	0	1	0	1	0%
Health Plan	0	1	1	2	0%
Health Professional	2	1	0	3	67%
Provider Organizations	0	1	0	1	0%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	2	3	1	6	40%
QMRI	1	1	0	2	50%
Supplier/Industry	0	0	0	0	
All Councils	5	8	2	15	38%
Percentage of councils approving (>60%)					17%
Average council percentage app	proval				26%

Measure #1517 Prenatal & Postpartum Care (PPC)[Consensus Not Reached]

*equation: Yes/ (Total -

Abstain)

Voting Comments:

- American College of Nurse Midwives: ACNM is in support of this measure. The endorsed measure portfolio is anemic with regard to primary prevention and outpatient measures. While ACNM agrees with the commentary that this is not a perfect measure, there is well documented evidence that institutional and systemic inequity decreases systems level performance. We are in support of this measure as a population health measure.
- Pacific Business Group on Health: We are concerned about this measure because it does not
 provide any information about the content, quality, outcomes and experience of care provided.
 Removing this measure from the inventory of existing endorsed perinatal measures will
 encourage measure developers to develop a high value measure to fill this gap area; we
 envision measures of prenatal and postpartum care that have a strong evidence base and
 indicate quality of care provided. Moreover, we are concerned about the validity of this
 measure. Focusing on a period of between 21 to 56 days is not supported by empirical
 evidence and creates a disincentive for more timely care, such as breastfeeding support or
 post-cesarean wound care. To truly seize opportunities for improving the quality of maternity
 care and closing pervasive disparities in care and outcomes, we must prioritize measures that
 will have a significant impact in driving improvement.
- Florida Health Care Coalition: Our perspective is that removing #1517 from the inventory of existing endorsed perinatal measures due to its limitations would better encourage measure developers to fill this gap area.

2. Approval of the Perinatal Committee Recommendations

Pursuant to the CDP, the CSAC may consider approval of the Perinatal and Reproductive Health Committee's recommendation on 23 candidate consensus standards (details of the evaluation are available via the number links):

Perinatal and Reproductive Health Measures Recommended for Endorsement:

- <u>0033</u>: Chlamydia Screening in Women (CHL) Overall Suitability for Endorsement: Y-27; N-0
- <u>0304</u>: Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted) Overall suitability for Endorsement: Y-21, N=3
- <u>0469</u>: PC-01 Elective Delivery Overall suitability for endorsement: Y=25, N=0
- <u>0469:2829</u>: PC-01 Elective Delivery [eMeasure]
 Overall suitability for endorsement: Y=22, N=3
- <u>0470</u>: Incidence of Episiotomy Overall suitability for endorsement: Y=27, N=0
- <u>0471</u>: PC-02 Cesarean Birth Overall suitability for endorsement: Y=26, N=1
- <u>0475</u>: Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Center Discharge
 - Overall suitability for endorsement: Y=27, N=0
- <u>0476</u>: PC-03 Antenatal Steroids Overall suitability for endorsement: Y=26, N=0
- <u>0478</u>: Neonatal Blood Stream Infection Rate (NQI #3) Overall suitability for endorsement: Y=22, N=1
- <u>0480</u>: PC-05 Exclusive Breast Milk Feeding Overall suitability for endorsement: Y=21, N=2
- <u>0480:2830</u>: PC-05 Exclusive Breast Milk Feeding [eMeasure] Overall suitability for endorsement: Y=18, N=2
- <u>0483</u>: Proportion of infants 22 to 29 weeks gestation screened for retinopathy of prematurity Overall suitability for endorsement: Y=24, N=2
- <u>0716</u>: Unexpected Complications in Term Newborns Overall suitability for endorsement: Y=25, N=0
- <u>1382</u>: Percentage of low birthweight births Overall suitability for endorsement: Y=26, N=0
- <u>1731</u>: PC-04 Health Care-Associated Bloodstream Infections in Newborns Overall suitability for endorsement: Y=23, N=0
- <u>2902</u>: Contraceptive Care Postpartum Overall suitability for endorsement: Y=24, N=3
- <u>2903</u>: Contraceptive Care Most & Moderately Effective Methods Overall suitability for endorsement: Y=20, N=5
- <u>2904</u>: Contraceptive Care Access to LARC (Long Acting Reversible Contraception) Overall suitability for endorsement: Y=20, N=5

Perinatal and Reproductive Health Measures Not Recommended (See <u>Appendix A</u> for the Committee's votes and rationale)

- <u>1391</u>: Frequency of Ongoing Prenatal Care (FPC) This measure was withdrawn from consideration by the developer after the NQF Member and Public Comment period.
- <u>2892</u>: Birthrisk Cesarean Birth Measure
- <u>2893</u>: Neonatal Intensive Care All-Condition Readmissions
- <u>2895</u>: Thermal Condition of Low Birthweight Neonates Admitted to Level 2 or Higher Nurseries in the First 24 Hours of Life: A PQMP Measure
- <u>2896</u>: Structural Attributes of Facility in which High Risk Women Deliver Newborns: A PQMP Measure

COMMENTS AND THEIR DISPOSITION

NQF received 178 comments from 10 member organizations and 35 members of the public (organizations and individuals) pertaining to the general draft report and to the measures under consideration.

A <u>table of comments</u> submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the <u>Perinatal and</u> <u>Reproductive Health project page</u> under the Public and Member Comment section.

Comment Themes and Committee Responses

Three general themes were identified in the post-evaluation comments, including support for harmonization and consolidation of competing measures; concern around patient choice - particularly for contraception and breastfeeding measures; and suggestions for measure gaps. At its review of all comments, the Standing Committee had the benefit of developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Measure Specific Comments

<u>2903 Contraceptive Care – Most & Moderately Effective Methods</u> <u>2902 Contraceptive Care – Postpartum</u> <u>2904: Contraceptive Care – Access to LARC</u>

These three new measures addressing contraception received a large number of comments. Almost all of the comments were supportive but highlighted the importance of ensuring that women are not coerced into using contraceptives and the need for a women-reported contraceptive access measure. The developer outlined plans to monitor the use of the measure as well as the educational materials available to support patient-centered contraceptive counseling. The developer also reported the ongoing development of a patient reported outcome for contraceptive services.

0471: PC-02 Cesarean Birth

The developer has updated specification for this endorsed measure that removes the age adjustment. This measure received 25 comments during the post comment period. Of these, seven organizations

commented in support of the Committee's recommendation, noting continued disparities in care, the risks associated with cesarean sections, and evidence-based processes to reduce Cesarean birth rates safely.

The measure received 17 comments from 11 individuals disagreeing with the Committee's recommendation. The concerns raised focused on two issues: the lack of risk adjustment in the measure and concerns over the Healthy People 2020 target rate of 23.9%. During the in-person meeting, the developer shared data demonstrating the lack of association of maternal age at the time of the first pregnancy with hospital performance.

During the post-comment call, the Committee reaffirmed that they recommend the measure with the age adjustment removed. The Committee agreed they did not have any concerns with the measure with the updated specifications. Committee members noted that measure #0716, Unexpected Complications in Term Newborn, is a balancing measure for this measure and could provide a signal for overzealous reductions in Cesarean birth rates. The Committee noted that the target rate mentioned in the comments is set by Healthy People 2020 and is not in the control of either The Joint Commission or NQF.

NQF MEMBER VOTING RESULTS

All 18 of the recommended measures were approved with 67 % approval or higher. Complete voting results are detailed in <u>Appendix B</u>.

Representatives of 15 member organizations voted; no votes were received from the Public & Community Health Agency and Supplier/Industry Councils. (Links are provided to the full measure summary evaluation tables in <u>Appendix C.</u>)

REMOVE ENDORSEMENT OF MEASURES

Six measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement. One additional measure was withdrawn after the comment period.

Measure	Description	Reason for removal of
0472 Appropriate Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision – Cesarean section	Percentage of patients undergoing cesarean section who receive appropriate prophylactic antibiotics within 60 minutes of the start of the cesarean delivery, unless the patient is already receiving appropriate antibiotics.	Unable to continue as steward. Would be willing to transfer ownership to another willing steward. No other steward yet identified.
0477 Under 1500g infant Not Delivered at Appropriate Level of Care	The number per 1,000 livebirths of <1500g infants delivered at hospitals not appropriate for that size infant.	The developer indicated that resubmission was too much work for a measure that the steward themselves are not using, uncertainty that others were truly using it as a quality measure, and

Measure	Description	Reason for removal of
		endorsement
		the best role seemed to be as a
		population level measure rather
		than a hospital level measure,
		which is the steward's main
		interest.
0567 Appropriate Work up	To ensure that all women have	No reason provided.
Prior to Endometrial Ablation	endometrial sampling performed	
Procedure	before undergoing an endometrial	
	ablation.	
0651 Ultrasound	Percentage of pregnant patients	No reason provided.
determination of pregnancy	who present to the ED with a chief	
location for pregnant patients	complaint of abdominal pain and	
with abdominal pain	or vaginal bleeding who receive a	
	trans-abdominal or trans-vaginal	
	ultrasound.	
1391 Frequency of Ongoing	The percentage of Medicaid	NCQA has opted to remove the
Prenatal Care (FPC)	deliveries that had the following	Frequency of Prenatal Care
	number of expected prenatal	(#1391) measure from
	visits:	consideration for re-
	 less than 21 percent of expected 	endorsement.
	visits.	
	 21 percent–40 percent of 	
	expected visits.	
	 41 percent–60 percent of 	
	expected visits.	
	 61 percent–80 percent of 	
	expected visits.	
	 greater than or equal to 81 	
	percent of expected visits.	
1395 Chlamydia Screening	The percentage of female	NCQA is not currently using this
and Follow Up	adolescents 18 years of age who	measure in other major programs
	had a chlamydia screening test	to the extent that the level of
	with proper follow-up.	effort required to maintain
		endorsement.
1746 Intrapartum Antibiotic	Percentage of pregnant women	Unable to continue as steward.
Prophylaxis for Group B	who are eligible for and receive	Would be willing to transfer
Streptococcus (GBS)	appropriate intrapartum antibiotic	ownership to another willing
	prophylaxis (IAP) for Group B	steward. No other steward yet
	Streptococcus (GBS).	identified.

Appendix A – Measure Not Recommended for Endorsement

Measure	Voting Results	Rationale
<u>1391</u> : Frequency of Ongoing Prenatal Care (FPC)	Evidence H-1; M-1; L-9; I- 15	Measure failed on evidence – the frequency of visits is an expert opinion only. This measure was withdrawn from consideration by the developer after the NQF Member and Public Comment period.
<u>2892</u> : Birthrisk Cesarean Birth Measure	Evidence Y-26, N-1 Gap H-3; M-7; L-13; I-5	This fee-based, proprietary method of risk adjustment using cohort comparisons uses a novel approach to measuring Cesarean birth rates. The Committee had no reference data to evaluate the results calculated by the developer, which was completed using birth certificate data from New York 2005-2007 (now 10 years old.)
2893: Neonatal Intensive Care All-Condition Readmissions	Evidence Y-26, No-1 Gap H-14; M-11; L-1; I-0 Reliability H-1; M-7; L-17; I-2;	Many NICUs do not readmit neonates and it will be hard to track outcomes. The developer indicated that "accurate implementation of this metric will require new data collection linkage with birth certificates or more widespread and standardized use of the EHR for publicly reported measures." The Committee recommended further development of this important measure.

The table below lists the Committee's vote and rationale for measures not recommended for endorsement. Additional details are available via the number links.

Measure	Voting Results	Rationale
2895: Thermal Condition of Low Birthweight Neonates Admitted to Level 2 or Higher Nurseries in the First 24 Hours of Life: A PQMP Measure	Evidence Y-25, No-0 Gap H-14; M-10; L-2; I-0 Reliability H-0; M-13; L-8; I-4; Validity H-3; M-8; L-4; I-10 (CNR) Feasibility H-3; M-15; L-5; I-2 Usability and Use H-2; M-13; L-9; I-1 Overall Suitability for Endorsement Y-7; N-18	This measure is reported using a distribution graph or table rather than a single number. The Committee was not clear how this construct could be used for public reporting or accountability. The temperature strata were determined by expert consensus rather than evidence and the validity testing was performed on a variant of the measure.
2896: Structural Attributes of Facility in which High Risk Women Deliver Newborns: A PQMP Measure	Evidence H-1; M-6; L-3; I-15 Insufficient Evidence with Exception Y-11; N-14	This composite measure has four structural components. The evidence for the components is expert opinion rather than empirical evidence. The developers noted that this is a "population measure de-linked from individual patient care." The Committee noted that the information may be important as a designation of care provision, but did not agree that this is a measure of quality or accountability for providers.

Appendix B - NQF Member Voting Results

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community					
Health Agency	0	0	0	0	
Purchaser	5	1	0	6	83%
QMRI	1	1	0	2	50%
Supplier/Industry	0	0	0	0	
All Councils	13	2	0	15	87%
Percentage of councils approving (>60%)					83%
Average council percentage	approval				89%

Measure #0033 Chlamydia Screening in Women (CHL)

*equation: Yes/ (Total -

Abstain)

<u>Measure #0304 Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted)</u>

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	1	0	1	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	0	1	1	2	0%
Supplier/Industry	0	0	0	0	
All Councils	12	1	2	15	92%
Percentage of councils approving (>60%)					83%
Average council percentage app	oroval				83%

*equation: Yes/ (Total -

Abstain)

Measure #0469 PC-01 Elective Delivery

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	14	0	1	15	100%
Percentage of councils approving (>60%)					100%
Average council percentage app	oroval				100%

*equation: Yes/ (Total

Abstain)

Measure #0470 Incidence of Episiotomy

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	14	0	1	15	100%
Percentage of councils approving (>60%)					100%
Average council percentage ap	proval				100%
*equation: Yes/ (Total -					
Abstain)					

Measure #0471 PC-02 Cesarean Birth

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	1	0	3	67%

Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	13	1	1	15	93%
Percentage of councils approving (>60%)					100%
Average council percentage app	oroval				94%

*equation: Yes/ (Total -

Abstain)

Measure #0475 Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	1	0	1	2	100%
Health Professional	3	0	0	100%	
Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	13	0	2	15	100%
Percentage of councils approving (>60%)					100%
Average council percentage app	oroval				100%

*equation: Yes/ (Total -

Abstain)

Measure #0476 PC-03 Antenatal Steroids

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%

Supplier/Industry	0	0	0	0	
All Councils	14	0	1	15	100%
Percentage of councils approving (>60%)					100%
Average council percentage app	proval				100%
*equation: Yes/ (Total -					

Abstain)

APPROVE DISAPPROVE ABSTAIN

Measure #0478 Neonatal Blood Stream Infection Rate (NQI 03)

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	1	0	1	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	0	1	0	1	0%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	0	1	1	2	0%
Supplier/Industry	0	0	0	0	
All Councils	11	2	2	15	85%
Percentage of councils approving (>60%)					67%
Average council percentage app	proval				67%

*equation: Yes/ (Total -

Abstain)

Measure #0480 PC-05 Exclusive Breast Milk Feeding

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	13	1	1	15	93%
Percentage of councils approving (>60%)					100%
Average council percentage app	oroval				94%

*equation: Yes/ (Total -

Abstain)

prematurity						
Maaguna Caurai	Var	Ne	A hatain	Total Voter	% 4	
Measure Council	res	NO	Abstain	votes	Approval*	
Consumer	1	0	0	1	100%	
Health Plan	1	0	1	2	100%	
Health Professional	3	0	0 0 3			
Provider Organizations	0	1	0	1	0%	
Public/Community Health						
Agency	0	0	0	0		
Purchaser	6	0	0	6	100%	
QMRI	1	0	1	2	100%	
Supplier/Industry	0	0	0	0		
All Councils	12	1	2	15	92%	
Percentage of councils approving (>60%)					83%	
Average council percentage app	proval				83%	

<u>Measure #0483 Proportion of infants 22 to 29 weeks gestation screened for retinopathy of prematurity</u>

*equation: Yes/ (Total -

Abstain)

Micasure norio enexpected e	omplications in re				
Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	0	1	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	1	0	0	1	100%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	12	1	2	15	92%
Percentage of councils approving (>60%)				100%	
Average council percentage app	oroval				94%

Measure #0716 Unexpected Complications in Term Newborns

*equation: Yes/ (Total -

Abstain)

Voting Comment:

• Society for Maternal-Fetal Medicine: Numerator has multiple complications that are not severe and may differ only due to practice patterns (e.g., length of stay longer than mother-which also may have to do with how quickly moms discharged). Good concept, but not truly getting at consistent measure.

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	1	0	1	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	0	1	0	1	0%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	11	2	2	15	85%
Percentage of councils approving (>60%)					83%
Average council percentage app	oroval				78%

Measure #1382 Percentage of low birthweight births

*equation: Yes/ (Total -

Abstain)

Abstani)

Voting Comment:

Society for Maternal-Fetal Medicine: Largely not within control of hospital system (e.g., is quite dependent upon social determinants, and no true treatment to prevent SGA, while the treatments we have to reduce PTB are expected to reduce it by <1% even if used with fidelity). Important measure of the health of a society, but I don't think of abilities of a health care system.

STAFF NOTE: The level of analysis for this measure is a population, not a hospital system.

Measure #17511C-04 meanin Care-Associated Diodustream milections in New Jorns						
				Total	%	
Measure Council	Yes	No	Abstain	Votes	Approval*	
Consumer	1	0	0	1	100%	
Health Plan	1	0	1	2	100%	
Health Professional	3	0	0	3	100%	
Provider Organizations	1	0	0	1	100%	
Public/Community Health						
Agency	0	0	0	0		
Purchaser	6	0	0	6	100%	
QMRI	1	0	1	2	100%	
Supplier/Industry	0	0	0	0		

Measure #1731 PC-04 Health Care-Associated Bloodstream Infections in Newborns

All Councils	13	0	2	15	100%
Percentage of councils approving (>60%)					100%
Average council percentage app	proval				100%
*equation: Yes/ (Total -					

Abstain)

Measure #2829 PC-01 Elective Delivery

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	0	1	0	1	0%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	13	1	1	15	93%
Percentage of councils approving (>60%)					83%
Average council percentage app	proval				83%
*					

*equation: Yes/ (Total -

Abstain)

Measure #2830 PC-05 Exclusive Breast Milk Feeding

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	2	1	0	3	67%
Provider Organizations	0	1	0	1	0%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	1	0	1	2	100%
Supplier/Industry	0	0	0	0	
All Councils	11	3	1	15	79%
Percentage of councils approving (>60%)					67%
Average council percentage app	proval				69%

*equation: Yes/ (Total -

Abstain)

Voting Comment:

American College of Nurse Midwives: ACNM is in strong support of this measure. This is a • preference sensitive measure. Unwarranted variations exist across health care settings demonstrating that facilities are driving variation, not patient preferences. -

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	0	1	0	1	0%
Public/Community Health					
Agency	0	0	0	0	
Purchaser	4	2	0	6	67%
QMRI	0	1	1	2	0%
Supplier/Industry	0	0	0	0	
All Councils	9	5	1	15	64%
Percentage of councils approving (>60%)		67%			
Average council percentage approval		56%			

Measure #2902 Contracentive Care - Postpartum

*equation: Yes/ (Total -

Abstain)

Voting Comment:

Society for Maternal-Fetal Medicine: Agree about its importance, but should be dependent • upon women's choice and whether it was offered/documented, not upon uptake (given potential for coercion)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	0	1	0	1	0%
Public/Community Health Agency	0	0	0	0	
Purchaser	5	1	0	6	83%
QMRI	0	1	1	2	0%
Supplier/Industry	0	0	0	0	
All Councils	10	4	1	15	71%

Measure #2903 Contraceptive Care – Most & Moderately Effective Methods

Percentage of councils approving (>60%)	67%
Average council percentage approval	58%

*equation: Yes/ (Total - Abstain)

Voting Comment

• Society for Maternal-Fetal Medicine: Agree about its importance, but should be dependent upon women's choice and whether it was offered/documented, not upon uptake (given potential for coercion)

				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	0	1	0	1	0%
Public/Community Health	0	0	0	0	
Agency	0	0	0	0	
Purchaser	5	1	0	6	83%
QMRI	0	1	1	2	0%
Supplier/Industry	0	0	0	0	
All Councils	10	4	1	15	71%
Percentage of councils approving (>60%)		67%			
Average council percentage approval		58%			

Measure #2904 Contraceptive Care - Access to LARC

*equation: Yes/ (Total -

Abstain)

Voting Comment

• Society for Maternal-Fetal Medicine: Agree about its importance, but should be dependent upon women's choice and whether it was offered/documented, not upon uptake (given potential for coercion)

Appendix C: Measure Evaluation Summary Tables

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

Measures Recommended

0033 Chlamydia Screening in Women (CHL)

Submission | Specifications

Description: The percentage of women 16–24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement year.

Numerator Statement: Females who were tested for chlamydia during the measurement year.

Denominator Statement: Females 16-24 years who had a claim or encounter indicating sexual activity.

Exclusions: Females who received a pregnancy test to determine contraindications for medication (isotretinoin) or x-ray.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Imaging/Diagnostic Study, **Electronic Clinical Data**: Laboratory, Electronic Clinical Data: Pharmacy

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [May 02 2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-21; M-6; L-0; I-0** <u>Rationale</u>:

- The developer provided updated US Preventative Services Task Force (USPSTF) (2014) recommendations for screening for chlamydia in sexually active females aged 24 years or younger and in older women who are at increased risk for infection. Evidence synthesis concluded, "Chlamydia screening in young women may reduce pelvic inflammatory disease." USPSTF notes "the studies it reviewed on the direct effects of screening for chlamydia, including one new good-quality RCT, showed mixed results. This led to the change in grade for screening for chlamydia, which is now based on "moderate" certainty of a moderate net benefit rather than "high certainty" of a substantial net benefit."
- Although the USPSTF recommendation has been changed to a "B" level, the Committee agreed that the underlying evidence presented appears to be directionally the same since the last NQF endorsement review.
- The Committee highlighted that only 38% of the visits in one cohort in 2014 had appropriate testing, signaling a significant gap in care.
- The Committee expressed concerns about the exclusive focus on women and the unintended consequences for not including men in the measure. The developer clarified that the Task Force evaluated this before this measure was originally approved and the evidence for a direct health benefit was limited to women. The Committee highlighted that the USPSTF recommendation acknowledged the importance of men in this population, citing extensively the CDC recommendations in screening and treating men but recognized the limitation of data.
- The Committee noted that even though the developer presents evidence from the literature that describes racial/ethnic differences in screening rates (higher in African-Americans and Hispanics) and

0033 Chlamydia Screening in Women (CHL) prevalence of the disease (higher in African-Americans and Mexican-Americans), the developer did not collect performance data stratified by race, ethnicity, or language. The developer explained that they are very interested in having data that would help propel the improvement and elimination of disparities and the release of the Medicare Advantage data by race and ethnicity is a huge step forward, and one that they are closely tracking to leverage into opportunities for displaying data in stratified ways to push improvement. The developer also noted that health plans are able to stratify the data by race/ethnicity or any other variables they desire. 2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) 2a. Reliability: Previous Reliability Evaluation Accepted 2b. Validity: Previous Validity Evaluation Accepted Rationale: The developer noted several updates to the specification codes (HCPCS, LOIN, ICD-10 diagnosis codes) • since the prior evaluation. The Committee noted the specifications state a patient only needs to be identified in 2 methods (i.e., pharmacy data and claim/encounter data indicating sexual activity) to be eligible for this measure. The Committee questioned how this measure would account for transgender individuals and females between 16 and 24 who are using some types of contraception for non-contraceptive benefits. • The developer clarified that the teenagers in that age group sometimes state that they are using oral contraceptives for non-contraceptive reasons, but because of confidentiality and privacy concerns, may not disclose that they are in fact sexually active. The developer found that the algorithm was a reasonable proxy and that the false negative rates were quite low. There was no updated testing for reliability and validity. The developer previously conducted empirical testing at the measure score level and face validity. The prior testing demonstrated high reliability and adequate validity. The Committee agreed the measure was reliable and valid. 3. Feasibility: H-21; M-5; L-1; I-0 (3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale: The Committee agreed the measure is feasible, since it is based on administrative claims data for which • data collection is generally considered to be feasible and low burden. No concerns regarding feasibility were noted. 4. Usability and Use: H-13; M-14; L-0; I-0 (Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. *Benefits outweigh evidence of unintended consequences)* Rationale: This measure is publicly reported and used in the Medicaid Adult and Child Core Sets and California's • Value Based Pay for Performance Program. The Committee had no concerns about unintended consequences of continued use. 5. Related and Competing Measures No related or competing measures noted. • Standing Committee Recommendation for Endorsement: Y-27; N-0 Rationale The Committee agreed that this measure meets all the NQF criteria for continued endorsement.

0033 Chlamydia Screening in Women (CHL)

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• This measure received 6 comments, generally supporting continued endorsement, but also raising some concerns focused around the exclusions and suggestions for updates, as well as how "sexually active" is defined. Comments recommended improvements such as expanding the age range, including males, and establishing appropriate benchmarks.

Developer Response

- The measure's age range aligns with the US Preventive Services Task Force screening recommendation and corresponds to the age groups with highest chlamydia prevalence. In females, the highest chlamydia infection rates occur in those aged 20-24 years, followed by those 15-19 years (CDC. 2012 Sexually Transmitted Diseases Surveillance. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2014. Accessed at www.cdc.gov/std/stats12/default.htm).
- The measure uses two administrative methods to identify sexual activity: claims/encounters that suggest sexual activity (pregnancy codes, sexual activity codes) and pharmacy data (contraceptives). For those who qualify based on a pregnancy test alone, if the test was used to rule out pregnancy for x-rays or retinoid prescription, those females are excluded. This method to assess sexual activity using an administrative algorithm was tested and found to reasonably identify sexually active females. Women who have sex with women and meet any of the criteria specified would be included in the denominator.

Committee Response

• The Committee agreed they were comfortable with the age range in the measure because that is the range of the data provided. Committee members agreed that screening men is crucial to stopping transmission of chlamydia, but since the Committee is not able to change the measure to include men, they did not want to not recommend it for that reason alone. The Committee has added a new gap to the measure gaps list, a chlamydia screening measure for men.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0304 Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted) Submission | Specifications Description: Standardized morbidity ratio and observed minus expected measure for nosocomial bacterial infection after day 3 of life in very low birth weight infants Numerator Statement: Eligible infants with one or more of the following criteria: Criterion 1: Bacterial Pathogen. A bacterial pathogen is recovered from a blood and/or cerebral spinal fluid culture obtained after Day 3 of life. OR Criterion 2: Coagulase Negative Staphylococcus. The infant has all 3 of the following: 1. Coagulase negative staphylococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain. 2. One or more signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability). 3. Teatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days. **Denominator Statement**: Eligible infants who are in the reporting hospital after day 3 of life. Exclusions: Infants who do not meet eligibility criteria for birth weight, gestational age or hospital admission, or if the infant is discharged home, is transferred or dies prior to day 3 of life. Adjustment/Stratification: Statistical risk model Level of Analysis: Facility Setting of Care: Hospital/Acute Care Facility Type of Measure: Outcome Data Source: Electronic Clinical Data : Registry Measure Steward: Vermont Oxford Network STANDING COMMITTEE MEETING [05/02/2016] 1. Importance to Measure and Report: The measure meets the Importance criteria (1a. Evidence, 1b. Performance Gap) 1a. Evidence: Previous Evidence Evaluation Accepted; 1b. Performance Gap: H-15; M-9; L-1; I-0 Rationale: The Committee noted the evidence was updated with 11 observational and guasi-experimental studies • and one clinical guideline further supporting the evidence of this measure, and that there are specific things that providers can do to reduce infections. The developer noted that the measure looks at bacterial infections in blood or cerebral spinal fluid, and it is based on clinical data, not claims. While members of Vermont Oxford Network have made improvements, some hospitals still have high rates. The developer is working creating an eMeasure

version.
The mean rate of infection has been reduced (2006 mean rate =0.192; 2014 mean rate = 0.108) but there

continues to be variation between the minimum and maximum performance, and disparities remain.

NQF REVIEW DRAFT—Comments due by July 6, 2016 by 6:00 PM ET.

0304 Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted)

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-2; M-21; L-2; I-0; 2b. Validity: M-20; L-4; I-0 Rationale:

- The developer provided additional reliability testing using split-half analysis to assess signal-to-noise. The result of 0.63 was lower than expected.
- The Committee had some questions about the definition of infection, and noted that the measure was tested for babies weighing between 500-1,500 grams, but is being implemented for babies 400-1,500 grams.
- The Committee asked why meningitis had been added and how many cases it contributed, since this is the only one of the three infection measures that included it. The developer said they do not distinguish how many were meningitis as the definition includes positive blood culture or positive CSF.

3. Feasibility: H-4; M-20; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

• This measure is collected by the Vermont Oxford Network (VON) registry. The proprietary risk-adjustment method is available only to members. Members must pay a fee to belong to VON.

4. Usability and Use: H-2; M-12; L-10; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is currently in use, but only within the VON Network. While it does capture 85% of birth hospital NICUs, 25% of neonatal care is provided by freestanding children's hospitals, not all of which are part of Vermont Oxford Network. Babies may be born at a VON center and then transferred out to a specialized hospital for further care, which would not be counted in this measure.
- The developer stated that they were looking into producing a publically reported panel that a hospital could put out if they would like, and which would include this measure. Further, while they will not publically report results (as per their member contract), they will make it easier for their members to publically report results if they would like to. They are working with AAP, CDC, NQF, Leapfrog, and other organizations to report on the data without reporting results from a particular hospital.
- Clarification was provided that the measure includes all admissions before day 28, and that the data includes which hospital the infant developed the infection at, if they are later admitted to a second hospital.
- The measure did not achieve consensus on usability and use.

5. Related and Competing Measures

- This measure competes with 0478: Neonatal Blood Stream Infection Rate (NQI 03) (AHRQ) and #1731: PC-04 Health Care-Associated Bloodstream Infections in Newborns (The Joint Commission).
- The Committee had an extensive discussion on the 3 competing measures. NQF provided guidance on the related/competing measure process.
- The Joint Commission and AHRQ have done some work on harmonization. The Joint Commission (TJC) compared the 2 measures, #1731, which uses partial chart review and administrative data, and #0478, which only uses administrative data, and found the measure using chart review was able to identify more cases that had not been included in the other measure due to coding issues. In addition, #0478 excludes cases diagnosed 7 days or less after birth and #1731 measure excludes only 2 days or less, which they thought accounted for about 10% of the difference. (#0478 is now 3 days or less.) The Joint Commission stated that while the measures are similar, since codes are not uniformly assigned, their measure, which

0304 Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted)

also uses chart review is able to identify more cases. This comparison was done using ICD-9 CM codes, and they think that there will be less discrepancy between the two measures with the use of ICD-10 CM codes.

- AHRQ noted that they had made changes to #0478 based in part on the analysis done with TJC, and that the measure will also change with ICD-10 CM, and that the current versions are more aligned. In addition, #0478 looks at all causes and cases of sepsis, while #1731 focuses on those associated with central lines. In addition, the AHRQ measure is not reported at a hospital level.
- A Committee member related some of the history of this measure, noting that the AHRQ measure was
 originally endorsed and brought into The Joint Commission's core set, and then turned into a clinical data
 measure. During the previous review and discussion of competing measures, Medicaid programs stated
 that they could not collect the data unless it was administrative, and that is why there were 2 endorsed
 measures.
- Committee members requested more information on the change to ICD-10 CM, in particular wondering if this would now have less chart review burden, and the developer stated it was too soon to tell, especially with the learning curve associated with changing coding guidelines. It was also noted that with ICD-10 CM, "suspected" or "probable" is no longer included (cases are yes/no) which should reduce gaming.
- For the chart review Committee members who are using the measure did not think it was a large burden due to the very small number of charts that have to be reviewed, and that hospitals would be reviewing all of these charts anyway due as they work to reduce infection rates. Coding for neonatal sepsis is complicated and the chart review is used to make the measure more accurate. In addition, the developer noted, hospitals like to be able to exclude false positives. It was noted that false negatives are a larger issue.
- After discussion, the Committee felt there is not yet enough data on the performance of either measure under ICD-10 CM and that ICD-10 CM has the potential to reduce a lot of the burden associated with manual chart review. In addition, many new, smaller facilities (300 deliveries) are just beginning to report on this measure so current performance rates are not yet available (although these very small facilities are unlikely to be caring for these babies, who would be transferred).
- The Committee noted that EHRs are not yet to the point where this data can be automatically pulled out.
- The Committee then discussed the ways in which the VON measure, #0304, differs from the other 2 measures. Measure #0304 does not include babies more than 1,500 grams, and does include meningitis; however, it is not clear how big the group of babies with meningitis actually is. Currently the measure requires either a positive blood or CSF culture and is not collected separately, although the developer agreed that might be a good idea. The VON measure is risk adjusted, which allows for more even comparisons across facilities. However, the major issue with the VON measure is that it is not publically reported and requires a registration fee.
- The Committee noted they were struggling with the question of whether one was best, especially with the changes to the measures. Committee members using the measures noted they focus on slightly different populations. For example, there are about 40,000 VLBW babies born in each year and bloodstream infections are most prevalent in this population, but there are many more, larger babies born each year even if the infection rates are smaller. One Committee member stated that to actually move the needle, the VLBW babies are the target population, but only about a quarter of the NICUs in the country treat these babies, with the remaining three-fourths of NICUs treating LBW and premature babies. Another Committee member noted that focusing on the smaller, high-prevalence population misses the opportunity to improve processes and reduce infections in many facilities.
- Ultimately, due to the changes in the AHRQ measure, the update to ICD-10, the expanded number of facilities reporting, and the slightly different populations included, the Committee agreed that for the time being all 3 measures should remain endorsed, since they are being used for different things. In terms of burden, it was noted that the high-level NICUs are all already reporting to VON; that almost everyone has to report to the Joint Commission; and that there is no burden for hospitals for the AHRQ measure since it comes out of billing data and is reported by the state data organizations.

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- The Committee requested that, for the next year, a specific effort be made to get the data from those facilities that collect and report on 2 or 3 of the measures in order to allow a more accurate comparison. VON noted that they do a member survey and they will ask members that are collecting on the other measures as well. They also offered to work with The Joint Commission to compare the data.
- Committee members highlighted that while it is easy for them to understand the differences between the measures and rates, it may not be so clear to the public, and they reiterated the need for a single measure.
- The Committee requested that the developers provide more information and new data in 18 months for the Committee to relook at the measures during an off-cycle review. They further requested that the developers work together toward a single future measure.

Standing Committee Recommendation for Endorsement: Y-21; N-3

<u>Rationale</u>

The Committee agreed that this measure meets all the NQF criteria for continued endorsement.

6. Public and Member Comment: June 7 - July 6, 2016

Comments Received

• One commenter submitted 1 comment on each of the 3 measures agreeing with the Committee's decision to recommend, but urging the developers to coordinate or combine measures.

Developer Responses

- Agency for Healthcare Research and Quality: AHRQ appreciates the suggestion to compare the AHRQ, The Joint Commission (TJC), and Vermont Oxford Network's measures of neonatal blood stream infection, AHRQ's NQI 03 Neonatal Blood Stream Infection Rate (NQF 0478), TJC's PC-04 Health Care-Associated Bloodstream Infections in Newborns (NQF 1731), and Vermont Oxford Network's Late Sepsis or Meningitis in Very Low Birth Weight (VLBW) Neonates (NQF 0304). These three NQF endorsed measures were each developed for specific and different purposes and for different data sources, which has led to deviations in specifications. As noted in the NQF submission materials to the Perinatal Committee, AHRQ engaged with TJC to harmonize the measures NQF 0478 (AHRQ) and NQF 1731 (TJC) where possible. In some cases, differences in the data source or intended purpose of the measures favor measures that are not fully harmonized. In other cases, harmonization is feasible while maintaining the integrity of the measure for the intended use and data source. As suggested by the committee, AHRQ will continue to explore the feasibility and desirability of further harmonization of the measures.
- *The Joint Commission:* Thank you for your feedback. We have done extensive work and these measures have been harmonized to the extent possible at this time.
- Vermont Oxford Network: Thank you for your comment. The developers of the three infection measures agreed to work together to harmonize these measures before the next submission period. This measure is specific to Vermont Oxford Network members, but we do work with health systems and plans to provide reports of our measures with appropriate permissions from our members.

Committee Response

• The Committee agrees that harmonization of these 3 measures is important to reduce the burden of reporting. The developers have been directed to work together over the next 18 months to arrive at a single measure with supporting data, to be presented to the Committee during an off-cycle review.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0469 PC-01 Elective Delivery

Submission | Specifications

Description: This measure assesses patients with elective vaginal deliveries or elective cesarean births at >= 37 and < 39 weeks of gestation completed. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-02: Cesarean Birth, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns, PC-05: Exclusive Breast Milk Feeding)

Numerator Statement: Patients with elective deliveries with ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for one or more of the following:

• Medical induction of labor as defined in Appendix A, Table 11.05 available at:

http://manual.jointcommission.org/releases/TJC2016A/ while not in Labor prior to the procedure

• Cesarean birth as defined in Appendix A, Table 11.06 and all of the following:

- o not in Labor
- no history of a Prior Uterine Surgery available at: http://manual.jointcommission.org/releases/TJC2015B2/

Denominator Statement: Patients delivering newborns with >= 37 and < 39 weeks of gestation completed with ICD-10-PCS Principal or Other Procedure Codes for delivery as defined in Appendix A, Table 11.01.1 available at: http://manual.jointcommission.org/releases/TJC2016A/ and with ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for planned cesarean birth in labor as defined in Appendix A, Table 11.06.1 available at: http://manual.jointcommission.org/releases/TJC2016A/

Exclusions: • ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for conditions possibly justifying elective delivery prior to 39 weeks gestation as defined in Appendix A, Table 11.07

• Less than 8 years of age

- Greater than or equal to 65 years of age
- Length of Stay >120 days
- Gestational Age < 37 or >= 39 weeks or UTD

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [05/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-10; M-13; L-2; I-0** <u>Rationale</u>:

- The developer did not submit new evidence during this maintenance review, but Committee members noted that ACOG recently reaffirmed the practice bulletin for timing of elective induction of labor at >39 weeks.
- While performance is improving, there is still a gap in care in this area (2014 data in 1388 hospital national mean= 3.3%, range 0-8.7%.) Committee members noted that as of January 2016, more hospitals are reporting on this measure (now 80% of all birthing hospitals), so they expect more variation to appear. Committee members noted that one of the major drivers of morbidity was repeat elective C-sections at 37 weeks, and that number had dropped significantly.
- There was some discussion about whether this measure is "topped out" but Committee members agreed the change was very new, and that it was too soon to retire this measure, both because there are many outliers and because the improvement is too recent to ensure it will continue. In addition, it was noted this is a very good measure to educate people outside of healthcare about quality improvement. Further,

NQF REVIEW DRAFT—Comments due by July 6 2016 by 6:00 PM ET.

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it is relatively newly recognized that babies born at 37-39 weeks do, in fact, have more problems and much education remains to be done for parents and other stakeholders.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: M-25; L-1; I-0 2b. Validity: Previous Validity Evaluation Accepted Rationale:

- The measure has recently been converted to ICD-10 CM, and it was noted that it is not yet clear how this may affect the measure.
- Some changes have been made to the specifications to further clarify and refine the measure, including now excluding patients with no prenatal care (since gestational age cannot be determined). Committee members noted that sampling for small populations can be problematic and that the measure is more reliable when the full population is used.
- Some Committee members questioned the appropriateness of some of the exclusions, i.e. "Patients with ICD-10-CM Principal Diagnosis Code or Other Diagnosis Codes for conditions for possibly justifying elective delivery are excluded" including poor obstetric history, biliary disease, pregnancy after miscarriage, etc.

3. Feasibility: H-15; M-10; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Committee members noted that while the measure does require some manual chart review, it has been used for several years and the new codes should reduce the burden.
- The developer clarified that gestational age is based on best obstetric estimate, generally ultrasound, and that it should be counted from gestational age at delivery (not the date the baby leaves the hospital). Electronic records should reduce the possibility of gaming if the wrong date is written at the time of delivery.

4. Usability and Use: H-21; M-4; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is in widespread use in Quality Check, Hospital Compare, accreditation, and hospital and patient quality reporting. In addition, it is measure easily understood by the public.
- It was noted some of the improvements to the measure made it more usable.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-25; N-0

<u>Rationale</u>

• The Committee agreed that this measure meets all the NQF criteria for continued endorsement.

6. Public and Member Comment: June 7 - July 6, 2016

Comments Received

• A total of 12 comments were received on both the electronic and paper versions of the measure. Generally, the comments were in support, and several noted that while rates have improved, much remains to be done. However, a pair of comments noted concerns with the measure exclusions. A second pair of comments noted that elective delivery/induction may be preferable in very rural areas that lack access to secondary and tertiary facilities.

Developer Response

0469 PC-01 Elective Delivery

- Over the last several years The Joint Commission has responded to suggestions from the obstetrics community to adjust the specifications for PC-01: Elective Delivery to allow for a wider array of exclusions. Some of these have resulted in new ICD codes being added and others have required the addition of new exclusions that can only be determined by chart reviews (an unfortunate but currently needed situation). The Joint Commission continues to receive numerous requests for "appeals" and new exclusions which are uncommon or rare conditions justifying the need for an early-term elective delivery. While many of these conditions have been incorporated into the current PC-01 specifications, medical issues are varied enough that it is impossible to enumerate 100% of the potential circumstances that could justify an early-term elective delivery. For example, a mother with a malignancy and need to start chemotherapy might require a delivery before 39 weeks. Although these cases are rare their occurrence can be such to generate an early-term elective delivery rate of 2-4%. This supports the rationale for not expecting this measure to consistently reach 0% elective deliveries. The Joint Commission has worked closely with a technical advisory panel (TAP) since the inception of this project. The TAP is comprised of leading national perinatal care experts including obstetricians, pediatricians, neonatologists and nurse clinicians. Recently, the TAP reaffirmed the goal of 5% which is supported by the 2013 study by Clark, et. al, validating the denominator exclusion criteria for PC-01.
- There are currently 2 sets of ICD-10-CM diagnosis codes on Table 11.07 which should be used for pre-labor (preterm) rupture of membranes: the first set is 042.011, 042.012, 042.013, 042.02, 042.911, 042.912, 042.913 and 042.92 and for prolonged rupture: the second set is 042.111, 042.112, 042.113 and 042.12. The coders should be applying these codes when there is appropriate documentation that SROM occurred without commencement of labor. As a result the case would be excluded from the measure. Documentation of spontaneous rupture of membranes without onset of labor should be taken at face value according to ACOG. The 2013 ACOG definition of Preterm Rupture of Membranes (PROM is rupture of membranes before the onset of labor. Membrane rupture that occurs before 37 weeks of gestation is referred to as preterm PROM. Membrane rupture that occurs at 37 weeks of gestation or later is referred to as term PROM. In 2014, ACOG re-named premature rupture of membranes to pre-labor rupture of membranes in order to further clarify the meaning of PROM. We consider ACOG an authoritative source. Based on the ACOG definition one of the codes from the first set applies to all cases with SROM regardless of gestational age, and only the absence of labor should be required to use this code. If the ruptured membranes are >24 hours then one of the codes from the second set applies."
- Requiring gestational age and careful scrutiny (chart reviews) for exclusions does preclude the use of claims data but there is progress in creating an eMeasure version. However, because of the small sample size for this measure for a given health plan within a given hospital it will unlikely be a practical measure at the plan level.
- While this has been proposed as a potential concern, rural hospitals in general have done very well on this measure. In general there are few logistical reasons that truly need elective delivery prior to 39 weeks of gestation. In any case, the federal mandate for reporting of this measure for MediCare P4P specifically excludes Critical Access Hospitals.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0470 Incidence of Episiotomy

Submission | Specifications

Description: Percentage of vaginal deliveries (excluding those coded with shoulder dystocia) during which an episiotomy is performed.

Numerator Statement: Number of episiotomy procedures (ICD-9 code 72.1, 72.21, 72.31, 72.71, 73.6; ICD-10 PCS:0W8NXZZ performed on women undergoing a vaginal delivery (excluding those with shoulder dystocia ICD-10; O66.0) during the analytic period- monthly, quarterly, yearly etc.

Denominator Statement: All vaginal deliveries during the analytic period- monthly, quarterly, yearly etc. excluding those coded with a shoulder dystocia ICD-1: 066.0).

Exclusions: Women who have a coded complication of shoulder dystocia. In the case of shoulder dystocia, an episiotomy is performed to free the shoulder and prevent/mitigate birth injury to the infant.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Administrative claims, Paper Medical Records

Measure Steward: Christiana Care Health System

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-20; M-4; L-0; I-0** <u>Rationale</u>:

- The evidence has not changed from the Cochrane Review and ACOG bulletins cited in the original submission that report an increased risk of perineal trauma with episiotomy.
- Committee members noted while there has been a 33% decrease in episiotomies, there is still great variation in performance between hospitals (0.8 22%) and much room remains for improvement.
 Committee members shared their experience with providing individual clinician results and peer teaching as effective in changing behavior to reduce episiotomies.

• A Committee member suggested that episiotomy and vacuum deliveries should be linked.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Previous Reliability Evaluation Accepted**; 2b. Validity: **Previous Validity Evaluation Accepted** Rationale:

- The measure has been recently converted to ICD-10 CM.
- No changes to the specifications have been made and no new testing data was offered. Data element validity had been tested comparing the coded data to medical record "gold standard" and face validity.

3. Feasibility: H-25; M-2; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

- Committee members noted that because this is a procedure, it is easy to code (yes/no). It is included in discharge data and administrative data sets.
- The developer noted that updating to ICD-10 CM codes helps make the measure more feasible by addressing some coding issues that had come up in the past.

0470 Incidence of Episiotomy
4. Usability and Use: H-25; M-2; L-0; I-0
(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)
Rationale:
• The Leapfrog Group has been publically reporting this measure for close to 1,000 hospitals.
 Several Committee members have had experience using this measure to educate providers and hospitals and reduce rates, and all commented favorably about the usability. It was also noted that peer-to-peer education is the most effective way of changing performance.
5. Related and Competing Measures
No related or competing measures noted.
Standing Committee Recommendation for Endorsement: Y-27; N-0
Rationale
The Committee agreed that this measure meets all the NQF criteria for continued endorsement.
6. Public and Member Comment: June 7 – July 6, 2016
Comments Received
 This measure received 4 comments, all in support of endorsement. One comment suggested the additional exclusion of fetal distress requiring more rapid delivery.
Developer Response
 Fetal distress requiring more rapid delivery should NOT be an exclusion for this measure. This is a hospital level measure and the inclusion of these cases will not have a material impact on a hospital's rate and runs the risk of over coding fetal distress.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X

Submission | Specifications

Description: This measure assesses the number of nulliparous women with a term, singleton baby in a vertex position delivered by cesarean birth. This measure is part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns, PC-05: Exclusive Breast Milk Feeding).

Numerator Statement: The outcome being measured is: Patients with cesarean births with ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for cesarean birth as defined in Appendix A, Table 11.06 available at:

http://manual.jointcommission.org/releases/TJC2016A/

Denominator Statement: The outcome target population being measured is: Nulliparous patients delivered of a live term singleton newborn in vertex presentation ICD-10-PCS Principal or Other Diagnosis Codes for delivery as defined in Appendix A, Tables 11.01.1 available at:

http://manual.jointcommission.org/releases/TJC2016A /

Exclusions: • ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for multiple gestations and other presentations as defined in Appendix A, Table 11.09

- Less than 8 years of age
- Greater than or equal to 65 years of age
- Length of Stay >120 days
- Gestational Age < 37 weeks or UTD

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [May/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-23; M-3; L-0; I-0** <u>Rationale</u>:

- The prior maintenance evaluation noted that "ACOG says this is the "optimal measure" for Cesarean section (C-section) because it focuses on first-time, uncomplicated pregnancy. The measure looks at the outcome of labor management. The developer reported that, "Among primary cesarean deliveries, more subjective indications (non-reassuring fetal status and arrest of dilation) contributed larger proportions than more objective indications (malpresentation, maternal-fetal, and obstetric conditions)." Cesarean sections are associated with increased risk of obstetric hemorrhage, uterine infection, and increased costs to the healthcare system.
- The Committee questioned whether this measure should be classified as an intermediate outcome measure instead of an outcome measure.
- The Committee highlighted that the Healthy People2020 target is 23.9%, and the 2014 data with 1,388 hospitals reporting is 26.8%. Additionally, the Committee noted that the variation for this measure is quite large since the performance was 14% at the 10th percentile and 40% at the 90th percentile.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-23; M-3; L-0; I-0; 2b. Validity: H-10; M-14; L-2; I-0 Rationale:

- The developer has changed the specifications since the last NQF endorsement review. The specifications have been updated to ICD-10 CM and the initial patient population is now identified with ICD-10-PCS-Principal or Other Procedure Codes for delivery instead of diagnosis codes for pregnancy, since the ICD-10-CM Principal or Other Diagnosis Codes do not indicate whether the delivery took place during the hospitalization. Additionally, cases with a gestational age of "unable to be determined (UTD)" are excluded, since UTD is highly correlated with no prenatal care.
- The Committee expressed concerns about the exclusions, including babies in clinical trials. The developer stated that clinical trials have been removed as an exclusion.
- The measure was tested using inter-rater reliability (IRR) by the ORYX vendor, for 108 hospitals with 13,279 records. IRR is an appropriate method of assessing data element reliability for chart abstraction. The agreement rate for the data element "Gestational age" was 89.75% and the data element "Parity" was 97.43%. The Committee agreed the reliability of the measure was demonstrated, with the developer providing reliability testing at data element levels (2012).
- The developer reported that continued face validity was determined through feedback from measure users as well as a website that picks up questions and issues from the field, and addresses them in a continuous process of clarification and refinement.
- The measure received a pre-meeting comment regarding adjustment for various demographic variables. To address this, the developer provided data from 231 California hospitals showing that hospitals with a higher concentration of older moms (over 35 years) were distributed across hospitals with higher, medium, and lower range measure results. This finding suggested that age is not a significant factor and performance is driven by other factors of labor management.
- The developer noted that they are eliminating the age stratification effective July 1, 2016.
- The Committee requested that the developer consider a balancing measure that monitors potential unintended adverse consequences. The developer noted that *NQF#0716 Unexpected Complications in the Term Newborn* is being used in this manner in California, Oregon, and Washington.
- The Committee expressed concerns that lowering C-section rates too much can be as bad as higher Csection rates. There may be variations based on medical issues that affect whether the babies tolerate labor and whether labor goes smoothly in a timely fashion that does not exhaust the baby or the placental reserve.
- The Committee cautioned that tying payment to certain percentage of Cesarean birth rate (i.e., Healthy People 2020 target of 23.9%) might lead to bad outcomes.
- The Committee discussed possibilities for risk-adjustment and questioned whether contraindications for a vaginal delivery should be excluded from the measure moving forward. The developer clarified that they looked extensively at other diagnoses that could be contraindications for vaginal delivery such as placenta previa and HIV +, which are both included in the coding. The developer found only 56 cases in all of California that were coded as HIV with the several codes for HIV in pregnancy nulliparous to term, suggesting they were under coded. Additionally, only a few hospitals reported 2% 3% of their patients had placenta previa; half of those were delivered vaginally -- the coding was indicative of a placenta previa being present on ultrasound in the first or second trimester that was coded on the delivery chart. The developer emphasized that adding other diagnoses may result in coding issues that may or may not be real, which is one of the reasons why they decided to keep this measure simple with the highest quality codes.

3. Feasibility: H-15; M-11; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• The Committee noted that the developer is working on an eMeasure that will be tested this year, which would be a good addition.

• The Committee agreed all data elements are in defined fields in electronic sources. No concerns regarding feasibility were noted.

4. Usability and Use: H-21; M-6; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is in use in The Joint Commission's Hospital Accreditation Program, is publically reported in the Joint Commission's Annual Report, America's Hospitals: Improving Quality and Safety, and is used for internal quality improvement via the Perinatal Care Certification program run by the Joint Commission. This measure is also included in the Medicaid Child Core Set.
- The Committee expressed the need to have this measure publicly reported beyond what is done
 voluntarily. The developer stated that their public reporting system is set up for process measures and
 they are trying to figure out how to accurately report this outcome measure publicly as well as some
 others, so that they make sense to the public.
- The Committee noted some challenges with reporting outcome measures such as determining the expected rate versus the actual rate and reporting that in a way that makes sense to people.

5. Related and Competing Measures

• This measure is similar to the newly submitted measure #2892: Birthrisk Cesarean Birth Measure. The Committee did not discuss the competing measure issue since NQF #2892 was not recommended.

Standing Committee Recommendation for Endorsement: Y-26; N-1

<u>Rationale</u>

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment

Comments Received

- This measure received 25 comments during the post comment period. Of these, 7 organizations commented in support of the Committee's recommendation, noting continued disparities in care, the risks associated with cesarean sections, and evidence-based processes to reduce Cesarean birth rates safely.
- The measure received 17 comments from 11 individuals disagreeing with the Committee's decision to recommend the measure. The concerns raised focused on two issues: the lack of risk adjustment in the measure and concerns over the Healthy People 2020 target rate of 23.9%. While this target rate was not set by the measure developer or NQF, a number of commenters indicated that without risk adjustment, this may not be an appropriate target. Commenters urged the measure to include risk adjustment for patient factors that impact the likelihood of Cesarean birth, including patient characteristics such as age or obesity, or medical factors such as diabetes, hypertensive disorders, LGA or SGA fetuses with/without growth restriction, etc.
- One commenter noted the need for more exclusions to cover cases where Cesarean births are medically indicated, such as "mal-presentation that could not be corrected, placenta previa, contracted pelvis, previous perineal reconstruction, fetal anomalies incompatible with vaginal birth, or other contraindications to vaginal birth."

Developer Responses

The Joint Commission has had numerous, detailed communications with the commenter on this subject, and is of the opinion that current evidence contradicts his contentions. The final decision to remove all risk-adjustment from this measure was made after submitting the measure to NQF and is based on evidence from two recent studies ¹,² which have shown that hospitals with a high maternal age population also have a low body mass index (BMI) and conversely, those with low maternal age have a high BMI (at the time of the first birth). Because when tested against a more robust risk adjusted model

(age, BMI, race, hypertension, diabetes), the studies found differences limited to 1-2%, the Joint Commission's Perinatal Care Technical Advisory Panel has recommended using the simple cesarean birth rates without further risk adjustment. Therefore, effective with discharges beginning July 1, 2016, The Joint Commission has removed all risk adjustments until such time as data are available demonstrating the need for risk adjustment and the feasibility of collecting any risk factors required.

¹ Caceres IA, Arcaya M, Declercq E, Belanoff CM, Janakiraman V, et al. (2013) Hospital Differences in Cesarean Deliveries in Massachusetts (US) 2004–2006:The Case against Case-Mix Artifact. PLoS ONE 8(3): e57817. doi:10.1371/journal.pone.0057817

² Main E. (2014) Nuliparous, Term, Singleton, Vertex (NTSV) Cesarean Birth Rates: extreme hospital variation is not changed by adjustment for case-mix. Oral Presentation: Pacific Coast Obstetrics and Gynecology Society

- The Cesarean Birth measure (PC-02) is designed to measure the rates of cesarean births among a subset of the general obstetric population of women while also keeping the burden of data collection to a minimum. The measure focuses on mothers having their first birth who are at the highest risk of primary cesarean birth when compared to mothers who have experienced a previous vaginal birth. By setting aside twins, breech presentations, and premature births, this measure focuses on a more homogeneous group of women where the greatest improvement opportunity exists. Because the measure focuses on nulliparous women with a term, singleton baby in a vertex position, the only exclusions to the denominator population are multiple gestations and presentations other than a vertex position, which are realized through the use of specific ICD-10-CM diagnosis codes found on Table 11.09 in Appendix A of the Specifications Manual for Joint Commission National Quality Core Measures. Extensive testing by The Joint Commission made it clear that there is no need to exclude for all known indications for performing cesareans, since these types of medical conditions are less common and would not significantly increase a hospital's adjusted cesarean rates. Maternal age, race, and weight are known cesarean risk factors for individuals but do not impact hospital PC-02 rates. Thus, including a comprehensive set of maternal medical exclusions would add data collection burden without commensurate benefit.
- There are also no ideal target rates for this outcome measure. Instead, the measure is designed to be an accurate way for leaders to identify whether a hospital's rate of cesarean births for women included in this select population is consistent with the rate of cesareans within this same population at another hospital. Hospitals whose cesarean birth measure rates are higher than they wish them to be are encouraged to explore and evaluate differences in the medical and nursing management of women in labor.
- Since there is currently no risk adjustment for this measure, inclusion of expected versus observed results is not indicated.
- The Joint Commission has not set this as a target for cesarean birth rates, nor does it establish benchmarks for any of its measures. The intent of this measure is for hospitals to understand their baseline rate of performance in order to determine if performance improvement efforts are indicated and, when they are, effective over time.

Committee Response

- During the post-comment call, the Committee reaffirmed that they recommend the measure with the age adjustment removed. The Committee agreed they did not have any concerns with the measure with the updated specifications. Committee members noted that measure #0716, Unexpected Complications in Term Newborn, is a balancing measure for this measure and could provide a signal for overzealous reductions in Cesarean birth rates.
- The Committee noted that the target rate mentioned in the comments is set by Healthy People 2020 and is not in the control of either The Joint Commission or NQF.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0475 Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

Submission | Specifications

Description: Percent of live newborn infants that receive Hepatitis B vaccination before discharge (or within 1 month of life, if the infant had an extended hospital stay) at each single hospital/birthing facility during given time period (one year).

Numerator Statement: The number of live newborn infants administered Hepatitis B vaccine prior to discharge (or within 1 month of life, if the infant had an extended hospital stay) from the hospital/birthing facility ("birth dose" of Hepatitis B vaccine).

Denominator Statement: The number of live newborn infants born at the hospital/birthing facility during the reporting window (one calendar year).

Exclusions: a. Determine number of live newborn infants born at the hospital/birthing facility whose parent/guardian refused Hepatitis B birth dose and exclude from the denominator. ICD-10 code for this information will include the following (link: http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z28/Z28-/#Z28):

i. Z28.82 Immunization not carried out because of caregiver refusal

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Other, Paper Medical Records, Electronic Clinical Data : Pharmacy, Electronic Clinical Data : Registry

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-18; M-8; L-0; I-0** <u>Rationale</u>:

- The developer submitted new evidence during this review, which includes 4 systematic reviews, that agree and demonstrate that hepatitis B vaccine administered shortly after birth effectively prevents perinatal hepatitis B transmission.
- Data from the 2014 National Immunization Survey shows the national Hepatitis B vaccine birth dose coverage overall was 72.4%.
- The developers provided disparities literature for the measure, that in the 22 states evaluated, approximately 16,500 births were estimated to be from HBV-infected women; 80.6% of these were foreign-born women.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-26; M-1; L-0; I-0; 2b. Validity: Previous Validity Evaluation Accepted <u>Rationale</u>:

- The developer removed the exclusion for parent refusal from the measure that was in the previous version of this measure. The CDC wants to measure the babies protected by vaccination. The Committee agreed with the change in specifications.
- The Committee found the specifications to be detailed and consistent with the evidence. The measure is specified for electronic clinical data, registry and abstraction from electronic health records with all the codes necessary to calculate the measure presented (ICD-9 CM and ICD-10 CM and CPT II codes).
- Reliability testing was conducted at the performance measure score. For measure score reliability, the

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score ranged from 0.981 and 1.000, indicating very high reliability, indicating that variability between hospitals regarding the Hepatitis B vaccine birth dose is due to actual performance differences rather than measurement error. The Committee agreed the reliability testing provided was sufficient.

- Face validity of the measure score was assessed by a 22 member expert panel, with a 63.6% response rate, who agreed that the measure could distinguish quality of care.
- The Committee stressed that by excluding refusals to vaccinate within the denominator of the measure, the health community would have a more accurate vision of challenges facing vaccination. This would also encourage better communication and shared decision making between providers and patients. Members highlighted that while some facilities might have a measure performance score of 90%, they could potentially be excluding 50% of the measurement population.

3. Feasibility: H-20; M-7; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• The Committee agreed the measure is well specified and is in use by the New York City Department of Health and Mental Hygiene. Data elements are in defined fields in a combination of electronic sources and also in paper medical records, including EHRs.

4. Usability and Use: H-24; M-3; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• The measure is currently used by the New York City Department of Health and Mental Hygiene. The developer presented data from the National Immunization Survey, demonstrating that Hepatitis B birth dose coverage has improved from 64.1% (+/-1.3) in 2010 to 72.4% (+/-1.5) in 2014.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-27; N-0

Rationale

• The Committee recommended measure 0475: Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge for continued endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• This measure received 4 comments, generally supporting endorsement. One comment noted that the measure as specified does not adequately reflect the immunization of infants who had deferred vaccination until the infant's first visit to the pediatrician. Another comment raised the issue that babies who are transferred for a higher level of care are often transferred prior to the birthing facility having the opportunity to administer the vaccine; the comment urged the exclusion of newborns who are transferred to a tertiary care facility. One of the supportive comments suggested that the measure be modified to "recommend educational material be provided to parents regarding efficacy of vaccines since some parents decide to not vaccinate".

Developer Response

• We thank you for your response and agree that educational materials for parents are helpful. Vaccine Information Statements are required (by federal law) to be given to the patient, parent, or legal representative prior to administration of certain vaccines, including HepB vaccine. The Vaccine Information Statements provide information about the benefits and risks of specific vaccines, and include general information on vaccine efficacy (note that Vaccine Information Statements are generally written at a 10th grade reading level). Hospitals or birthing facilities may elect to provide 0475 Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

additional information to parents regarding HepB vaccine efficacy.

- While we are open to excluding newborns who are transferred to a tertiary care facility from the denominator, we feel that this is unnecessary. Overall, the number of infants transferred out of a hospital (compared to the total number of infants born at a hospital) is low. The numerator specifies number of infants administered HepB vaccine prior to discharge, or within 1 month of life if the infant had an extended hospital stay. The majority of infants needing a transfer will have an extended hospital stay, and therefore have ample opportunity to receive the birth dose at the receiving hospital. The birthing hospital could obtain records regarding HepB vaccine receipt from the receiving hospital and/or an immunization registry. As such, this issue should not affect the measure in any meaningful way.
- We agree that the measure would not reflect immunization of infants who had deferred vaccination until the infant's first visit to the pediatric office. However, delay of the HepB birth dose should occur only in very rare circumstances. The Advisory Committee on Immunization Practices states "on a case-by-case basis and only in rare circumstances, the first dose may be delayed until after hospital discharge for an infant who weighs greater than or equal to 2,000 grams and whose mother is HBsAg negative." Administration of a birth dose in the hospital (even without HBIG) serves as a safety net to prevent perinatal infection among infants born to positive mothers who are not identified because of errors in testing or reporting. Administration of a birth dose has also been associated with higher rates of on-time completion of the HepB vaccine series and improved completion rates for other vaccines.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

0476 PC-03 Antenatal Steroids

Submission | Specifications

Description: This measure assesses patients at risk of preterm delivery at >=24 and <34 weeks gestation receiving antenatal steroids prior to delivering preterm newborns. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Birth, PC-04: Health Care-Associated Bloodstream Infections in Newborns, PC-05: Exclusive Breast Milk Feeding).

Numerator Statement: Patients with antenatal steroids initiated prior to delivering preterm newborns (refer to Appendix C, Table 11.0, antenatal steroid medications available at:

http://manual.jointcommission.org/releases/TJC2016A/)

Denominator Statement: Patients delivering live preterm newborns with >=24 and <34 weeks gestation completed with ICD-10-PCS Principal or Other Procedure Codes for delivery as defined in Appendix A, Table 11.01.1 available at: http://manual.jointcommission.org/releases/TJC2016A/

Exclusions: • Less than 8 years of age

- Greater than or equal to 65 years of age
- Length of Stay >120 days
- Documented Reason for Not Initiating Antenatal Steroids

• ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for fetal demise as defined in Appendix

A, Table 11.09.1 available at: http://manual.jointcommission.org

• Gestational Age < 24 or >= 34 weeks or UTD

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [05/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Previous Evidence Evaluation Accepted; 1b. Performance Gap: H-7; M-14; L-5; I-0

<u>Rationale</u>:

- The developer reports that the measure has been changed to reflect the 2013 ACOG Practice Bulletin for Premature Rupture of Membranes that recommends antenatal steroids up to 34 weeks (change from 32 weeks).
- In January 2014, the measure became mandatory for all hospitals with more than 1,100 births per year. The measure performance increased from 54% in 2011 to 82% in 2014.
- The developer provides literature references rather than data from use of this measure. A 2011 report on births in California found that Hispanic mothers (25.6%), mothers younger than age 20 (27.6%), and those without prenatal care (52.2%) were less likely to receive antenatal steroids. Mothers giving birth vaginally (26.8%) and mothers with a diagnosis of fetal distress (26.5%) were also less likely to receive antenatal steroids.
- The Committee acknowledged that there is still a significant gap in performance.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: M-22; L-3; I-0; 2b. Validity: H-14; M-11; L-0; I-0

Rationale:

• The specifications were detailed and consistent with the evidence. The measure is specified for paper medical records, Vital Records reports, and delivery logs and clinical information systems. All the codes

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necessary to calculate the measure are presented (ICD-9 CM and ICD-10 CM and CPT II codes).

- The developer made the following updates to the measure specifications: The single numerator data
 element "Antenatal Steroids Administered" was changed to "Antenatal Steroids Initiated" to capture
 initiation of antenatal steroids instead of a full course. The denominator statement was changed from
 patients delivering live preterm newborns with >=24 and <32 weeks gestation completed to patients
 delivering live preterm newborns with >=24 and <34 weeks gestation based on the 2013 ACOG Practice
 Bulletin on Premature Rupture of Membranes (PROM).
- Reliability testing was conducted at the data element level. For data element reliability, the developer performed inter-rater reliability by ORXY vendor re-abstraction for 108 hospitals comprising 13,279 records. The agreement rate for the data element "Antenatal steroids administered" was 99.16%.
- Empirical validity of the measure score was assessed using the Spearman rank-order correlation to correlate the results from this measure with other measures in the Joint Commission's perinatal set. The correlation of PC-03 with the other PC measures in the PC measure set indicates that the correlations with two other PC measures are moderate and statistically significant.
- The developer confirmed that clinical trials will be removed as an exclusion.

3. Feasibility: H-15; M-10; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee agreed the measure is well specified for public reporting and accountability programs. According to the developer, "Hospitals using this performance measure generally collect measure data via manual review of the paper medical record, the EMR or a combination of both."
- The Committee did caution that data collection might be burdensome for smaller facilities.

4. Usability and Use: H-22; M-4; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently used in public reporting and accountability programs such as Quality Check[®] and The Joint Commission's Hospital Accreditation Program. The Joint Commission presented ORYX performance measurement data demonstrating that the rate of patients receiving antenatal steroids prior to premature deliveries has improved from 63.3% in 2010 with 114 hospitals reporting to 91.6% in 2014 with 1,133 hospitals reporting.
- The developer reports on three unexpected findings during measure implementation:
 - Cases failed when the repeat dose of antenatal steroids was not given due to the delivery
 occurring prior to the routinely scheduled repeat dose being ordered. In response to this
 problem, the developer changed the data element "Antenatal Steroids Administered" to
 "Antenatal Steroids Initiated" to capture initiation of antenatal steroids instead of a full course.
 - Patients who did not receive prenatal care were inappropriately included in the measure denominator, as the gestational age data element was abstracted as "UDT." In response to this, the developer removed "undetermined cases" from the measure denominator.
 - Hospitals have reported lower rates due to small denominator populations as a result of sampling. In response to this, the developer added Vital Records reports, delivery logs, and clinical information systems as acceptable data sources to help hospitals identify all cases with at least 24 and less than 34 weeks gestation, so that 100% of these cases could be reviewed to increase the denominator population size.

5. Related and Competing Measures

• No related or competing measures noted.

0476 PC-03 Antenatal Steroids

Standing Committee Recommendation for Endorsement: Y-26; N-0

<u>Rationale</u>

• The Committee recommends measure 0476: PC-03 Antenatal Steroids for continued endorsement.

6. Public and Member Comment: June 7 - July 6, 2016

Comments Received

• Of the 5 comments received on this measure, 4 were fully in support. One comment raised concerns with the measure's numerator and denominator: first, with the denominator exclusion of "a documented reason for not giving steroids", pointing out that this could allow exclusions for facility structural issues, knowledge deficiencies on the part of the provider, or an "improper attitude" on the part of the provider or hospital unit. The comment also raised the issue of potential gaming, noting that the numerator captures use of steroids at any time, but they are optimally effective if given 24 hours to 7 days prior to early preterm birth.

Developer Response

The purpose of the measure is to evaluate that patients at risk of preterm delivery at >=24 and <34 weeks
gestation receive antenatal steroids prior to delivering preterm newborns. The measure is not
constructed to evaluate other aspects of established guidelines. Hospitals would need to use other
measures or evaluation methods to determine adherence to additional guidelines.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

Submission | Specifications

Description: Discharges with healthcare-associated blood stream infection per 1,000 discharges for newborns and outborns with birth weight of 500 grams or more but less than 1,500 grams; with gestational age between 24 and 30 weeks; or with birth weight of 1,500 grams or more and death, an operating room procedure, mechanical ventilation, or transferring from another hospital within two days of birth. Excludes discharges with a length of stay less than 3 days and discharges with a principal diagnosis of sepsis, sepsis or bacteremia, or newborn bacteremia.

Numerator Statement: Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with either:

- any secondary ICD-9-CM or ICD-10 CM diagnosis codes for other septicemia; or
- any secondary ICD-9-CM or ICD-10 CM diagnosis codes for newborn septicemia or bacteremia and

• any secondary ICD-9-CM or ICD-10 CM diagnosis codes for staphylococcal or Gram-negative bacterial infection

Denominator Statement: All newborns and outborns with either:

- a birth weight of 500 to 1,499 grams (Birth Weight Categories 2, 3, 4 and 5); or
- any-listed ICD-9-CM or ICD-10 CM diagnosis codes for gestational age between 24 and 30 weeks; or
- a birth weight greater than or equal to 1,500 grams (Birth Weight Category 6, 7, 8, or 9) and death (DISP=20); or
- a birth weight greater than or equal to 1,500 grams (Birth Weight Category 6, 7, 8, or 9) and any-listed ICD-9-CM or ICD-10 PCS procedure codes for operating room procedure; or
- a birth weight greater than or equal to 1,500 grams (Birth Weight Category 6, 7, 8, or 9) and any-listed ICD-9-CM or ICD-10 PCS procedure codes for mechanical ventilation; or
- a birth weight greater than or equal to 1,500 grams (Birth Weight Category 6, 7, 8, or 9) and transferring from another health care facility within two days of birth

See Pediatric Quality Indicators Appendices:

- Appendix A Operating Room Procedure Codes
- Appendix I Definitions of Neonate, Newborn, Normal Newborn, and Outborn
- Appendix L Low Birth Weight Categories

Exclusions: Exclude cases:

• with a principal ICD-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission⁺) for sepsis

• with a principal ICD-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission⁺) for sepsis or bacteremia

- with a principal ICD-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission⁺) for staphylococcal or Gram-negative bacterial infection
- with birth weight less than 500 grams (Birth Weight Category 1)
- with length of stay less than 3 days
- with missing gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1=missing)

⁺ Only for cases that otherwise qualify for the numerator.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

NATIONAL QUALITY FORUM

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Previous Evidence Evaluation Accepted; 1b. Performance Gap: H-14; M-9; L-0; I-0 Rationale:

- The developer reports that the evidence supporting this measure consists of 11 nonrandomized studies that demonstrate that effective preventive measures for decreasing blood infection "range from simple hand-washing protocols or closed medication delivery systems to more elaborate multidisciplinary quality improvement plans involving hand-washing, nutrition, skin care, respiratory care, vascular access, and diagnostic practices".
- The average hospital neonatal blood stream infection rate decreased from 11.53 per 1,000 in 2011 to 9.15 per 1,000 in 2013. The Committee acknowledged that there is still a significant gap in performance, noting that there are disparities between urban and rural populations, and between Medicaid, private insurance and the uninsured.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: Previous Reliability Evaluation Accepted; 2b. Validity: Previous Validity Evaluation Accepted Rationale:

- The specifications were detailed and consistent with the evidence. The measure is specified for administrative claims. All the codes necessary to calculate the measure are presented (ICD-9 CM and ICD-10 CM and CPT II codes).
- The developer updated the measure by adding data from the AHRQ 2013 Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID).
- Reliability testing was conducted at the measure score level. Signal to noise was utilized to assess the reliability of the measure. In 2013 for 943 hospitals comprising on average 72.3 discharges per hospital, reliability testing found a signal-to-noise average of 0.63.
- Face validity was assessed using a multi-specialty panel with a rating scale from 1 9. The panel agreed that the measure would be useful for rating the usefulness for internal QI improvement and for comparative purposes.
- This measure is risk adjusted. The developer utilized a multivariable model with covariates grouped into four categories, then estimated on the pediatric analytic data using a backward stepwise bootstrap approach. C-statistic = 0.752.

3. Feasibility: Previous Feasibility Evaluation Accepted

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee agreed the measure is well specified for public reporting and accountability programs.
- The Committee did not raise concerns about the feasibility of this measure.

4. Usability and Use: H-16; M-7; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently used in public reporting and accountability programs including the Wisconsin • Hospital Association (WHA) Information Center and the Wisconsin Hospital Association (WHA) Quality Indicators Report.
- The developer presented data exhibiting improved performance. The average hospital neonatal blood

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stream infection rate decreased from 11.53 per 1,000 in 2011 to 9.15 per 1,000 in 2013.

5. Related and Competing Measures

- This measure competes with #1731: PC-04 Health Care-Associated Bloodstream Infections in Newborns and #0304: Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates.
- The Committee had an extensive discussion on the 3 competing measures. NQF provided guidance on the related/competing measure process.
- The Joint Commission (TJC) and AHRQ have done some work on harmonization. TJC compared measures #1731, which uses partial chart review and administrative data, and #0478, which only uses administrative data, and found the measure using chart review was able to identify more cases that had not been included in #1731 due to coding issues. In addition, the #0478 measure excludes cases diagnosed 7 days or less after birth and measure #1731 excludes only 2 days or less, which they thought accounted for about 10% of the difference. (#0478 is now three days or less.) The Joint Commission stated that the measures are similar; however, since codes are not uniformly assigned, their measure, which also uses chart review, is able to identify more cases. However, this comparison was done using ICD-9 CM codes, and they think that there will be less discrepancy between the two measures with the use of ICD-10 CM codes.
- AHRQ noted that they had made changes to #0478 based in part on the analysis done with TJC, that the measure will change with ICD-10 CM, and that the current versions are more aligned. In addition, #0478 looks at all causes and cases of sepsis, while #1731 focuses on those associated with central lines. In addition, the AHRQ measure is not reported at a hospital level.
- A Committee member related some of the history of this measure, noting that the AHRQ measure was
 originally endorsed and brought into The Joint Commission's core set, and then turned into a clinical data
 measure. During the previous review and discussion of competing measures, Medicaid programs stated
 that they could not collect the data unless it was administrative, and that is why there were 2 endorsed
 measures.
- Committee members requested more information on the change to ICD-10 CM, in particular whether this
 would now have less chart review burden. The developer stated it was too soon to tell, especially with the
 learning curve associated with changing coding guidelines. It was also noted that with ICD-10 CM,
 "suspected" or "probable" is no longer included (cases are yes/no), which should reduce gaming.
- Committee members who are using the measure did not think chart review was a large burden due to the very small number of charts that have to be reviewed, and that hospitals would already be reviewing all of these charts as they work to reduce infection rates. Coding for neonatal sepsis is complicated and the chart review is used to make the measure more accurate. In addition, the developer noted, hospitals like to be able to exclude false positives. It was noted that false negatives are a larger issue.
- After discussion, the Committee felt there is not yet enough data on the performance of either measure under ICD-10 CM and that ICD-10 CM has the potential to reduce a lot of the burden associated with manual chart review. In addition, many new, smaller facilities (> 300 deliveries per year) are just beginning to report on this measure so current performance rates are not yet available (although these very small facilities are unlikely to be caring for these babies since they would be expected to be transferred).
- The Committee noted that EHRs are not yet to the point where this data can be automatically pulled out.
- The Committee then discussed the ways in which the VON measure, #0304, differs from the other 2 measures. Measure #0304 does not include babies more than 1,500 grams, and does include meningitis; however, the number of meningitis cases is not clear. Currently the measure requires either a positive blood or CSF culture and is not collected separately, although the developer agreed that might be a good idea. The VON measure is risk adjusted, which allows for more even comparisons across facilities. However, the major issue with the VON measure is that it is not publically reported and requires a registration fee.
- The Committee noted they were struggling with the question of whether one was best, especially with the changes to the measures. Committee members using the measures noted they focus on slightly

different populations. For example, there are about 40,000 VLBW babies born each year and bloodstream infections are most prevalent in this population, but there larger babies at risk for infection though the rates are lower. One Committee member stated that to actually move the needle, the VLBW babies are the target population, but only about a quarter of the NICUs in the country treat these babies, with the remaining three-fourths of NICUs treating LBW and premature babies. Another Committee member noted that focusing on the smaller, high-prevalence population misses the opportunity to improve processes and reduce infections in many facilities.

- Ultimately, due to the changes in the AHRQ measure, the update to ICD-10 CM, the expanded number of facilities reporting, and the slightly different populations included, the Committee agreed that for the time being all three measures should remain endorsed, since they are being used for different things. In terms of burden, it was noted that all high-level NICUs are already reporting to VON; that almost everyone has to report to The Joint Commission; and that there is no burden for hospitals for the AHRQ measure since it comes out of billing data and is reported by the state data organizations.
- The Committee requested that, for the next year, a specific effort be made to get the data from those facilities that collect and report on two or three of the measures in order to allow a more accurate comparison. VON noted that they do a member survey and will ask members that are collecting on the other measures as well. They also offered to work with The Joint Commission to compare the data.
- Committee members highlighted that while it is easy for them to understand the differences between the measures and rates, it may not be so clear to the public, and they reiterated the need for a single measure.
- The Committee requested that the developers provide more information and new data in 18 months for the Committee to relook at the measures during an off-cycle review. They further requested that the developers work together toward a single future measure.

Standing Committee Recommendation for Endorsement: Y-22; N-1 Rationale

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• One commenter submitted a comment on each of the 3 competing measures agreeing with the Committee's decision to recommend, but urging the developers to coordinate or combine measures.

Developer Response

 AHRQ appreciates the suggestion to compare the AHRQ, The Joint Commission (TJC), and Vermont Oxford Network's measures of neonatal blood stream infection, AHRQ's NQI 03 Neonatal Blood Stream Infection Rate (NQF 0478), TJC's PC-04 Health Care-Associated Bloodstream Infections in Newborns (NQF 1731), and Vermont Oxford Network's Late Sepsis or Meningitis in Very Low Birth Weight (VLBW) Neonates (NQF 0304). These three NQF endorsed measures were each developed for specific and different purposes and for different data sources, which has led to deviations in specifications. As noted in the NQF submission materials to the Perinatal Committee, AHRQ engaged with TJC to harmonize the measures NQF 0478 (AHRQ) and NQF 1731 (TJC) where possible. In some cases, differences in the data source or intended purpose of the measures favor measures that are not fully harmonized. In other cases, harmonization is feasible while maintaining the integrity of the measure for the intended use and data source. As suggested by the committee, AHRQ will continue to explore the feasibility and desirability of further harmonization of the measures.

Committee Response

• The Committee agrees that harmonization of these 3 measures is important to reduce the burden of reporting. The developers have been directed to work together over the next 18 months to arrive at a single measure with supporting data, to be presented to the Committee during an off-cycle review.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-22; N-1

0480 PC-05 Exclusive Breast Milk Feeding

Submission | Specifications

Description: PC-05 assesses the number of newborns exclusively fed breast milk during the newborn's entire hospitalization. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Birth, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns).

Numerator Statement: Newborns that were fed breast milk only since birth

Denominator Statement: Single term liveborn newborns discharged alive from the hospital with ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table 11.20.1 available at: http://manual.jointcommission.org/releases/TJC2016A/

Exclusions: • Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization

• ICD-10-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21

• ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22

- Experienced death
- Length of Stay >120 days
- Patients transferred to another hospital

• Patients who are not term or with < 37 weeks gestation completed

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [05/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-X=18; M-5; L-1; I-0** Rationale:

- The goal for performance of the measure is 70%, and in over half of The Joint Commission hospitals that reported this measure, rates are less than 50%. In the 10th percentile, hospitals are at 22%.
- More hospitals are reporting now (1,400, up from 166), so there are more opportunities for improvement.
- Committee members noted concerns around patient choice, and that an issue with this measure is that it puts pressure on patients to breastfeed when it may not be appropriate due to circumstances outside the control of the hospital (for example, work circumstances that do not allow pumping).
- Committee members discussed the resources available for hospitals as they work to improve performance on this measure, such as toolkits, and that one key focus is training staff to ensure they are counseling patients appropriately.
- The Committee discussed the potential for a balancing measure.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: M-21; L-2; I-0; 2b. Validity: H-8; M-12; L-2; I-0

Rationale:

• The measure was updated to ICD-10 CM. The sub-measure, exclusion of mothers who declined to breastfeed, was removed because stakeholders felt it was too much burden to get the data.

0480 PC-05 Exclusive Breast Milk Feeding

- Committee members discussed validity extensively, with one noting the measure reflects what patients chose to do, not the actual action or quality of care provided, and another stating that almost all measures can be said to reflect patient choices (for example, the choice to take medicine, have a procedure, etc.).
- One Committee member noted doubts about the validity of results when facilities report more than 95% rates, but the developer stated only one hospital reported rates that high, and reiterated the goal of 70%, noting that due to both choice and medical conditions, 100% is not the goal; however, many hospitals are at 70%. One Committee member noted that she audits hospitals and is confident in the data, even those reporting at high rates.
- Committee members were interested in the possibility of measures that report on percent still breastfeeding longer-term. Despite many limitations in women's ability to breastfeed long-term, Committee members noted that circumstances are improving and that this measure can be used to improve accommodations that allow more mothers to breastfeed for longer.
- A Committee member summarized the issue as the tension between pressure on mothers whose circumstances do not allow breastfeeding (such as women who have less than four weeks leave or who have jobs where they cannot pump) and keeping the threshold at 70% to move the nation forward.
- This is a population health measure with lifetime benefits. A Committee member stated that pressure on women has to do with a lack of process, and that in Baby-Friendly Hospitals it is easy to opt-out; therefore, pressure is a system issue that can be improved. Other Committee members agreed there are many process issues that can be addressed within the healthcare system.

3. Feasibility: H-18; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• The measure is used by Quality Check, The Joint Commission, the Hospital Inpatient Reporting Program; the Committee felt it was quite feasible.

4. Usability and Use: H-14; M-8; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• As the measure is in use, there were no usability concerns.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-21; N-2

<u>Rationale</u>

The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• A total of 13 comments were received on both the paper and electronic version of this measure. Comments were generally supportive of both the electronic and paper versions of the measure, but a number of concerns were raised, including issues around maternal choice, exclusions for the measure, and the need for implementation within a family-centered decision making process. Commenters also encouraged the development of a measure on longer-term breastfeeding.

Developer Response

• This measure was designed as an in-patient quality measure. The Joint Commission has no means of tracking this post-discharge activity. Much evidence has now focused on the prenatal and intrapartum period as critical for the success of exclusive (or any) breastfeeding. (Centers for Disease Control and

0480 PC-05 Exclusive Breast Milk Feeding

Prevention [CDC], 2007; Petrova et al., 2007; Shealy et al., 2005; Taveras et al., 2004).

- PC-05 does not exclude maternal medical conditions. These conditions are unusual (~2% of patients), and they cannot be modeled in the electronic Clinical Quality Measure (eCQM) version of PC-05. The removal of measure exclusions will also significantly reduce the burden of data abstraction. The revised measure is similar in construct to PC-02: Cesarean Birth, which reports the cesarean birth rate with no exclusions. As a result of some mothers declining exclusive breast milk feeding and by removing exclusions, The Joint Commission does not anticipate or expect that measure rates for PC-05 will reach near 100% as has been the case for many other measures. Available evidence suggests that a 70% threshold may be a more reasonable target for many organizations.
- It is important to note that The Joint Commission does not establish benchmarks for any of the core measures. The goal is for hospitals to understand their baseline rate of performance for each measure in order to determine if performance improvement efforts are effective over time when their baseline is higher or lower than the national performance (depending on the desired direction for improvement).

Committee Response

• The Committee agrees that measures of continued breastfeeding after hospital discharge are important and this has been added to the measure gaps list.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

0483 Proportion of infants 22 to 29 weeks gestation screened for retinopathy of prematurity

Submission | Specifications

Description: Proportion of infants born from 22 weeks, 0 days to 29 weeks, 6 days gestational age who were in the reporting hospital at the postnatal age recommended for screening for retinopathy of prematurity (ROP) by the American Academy of Pediatrics (AAP) and who received a retinal examination for ROP prior to discharge.

Numerator Statement: Number of infants born from 22 weeks, 0 days to 29 weeks, 6 days gestational age who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP and who received a retinal exam for ROP prior to discharge

Denominator Statement: All eligible infants born from 22 weeks, 0 days to 29 weeks, 6 days gestational age who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP

Exclusions: 1. Infants outside the gestational age range of 22 to 29 weeks

2. Outborn infants admitted to the reporting hospital more than 28 days after birth

3. Outborn infants who have been home prior to admission

4. Infants who die in the delivery room or initial resuscitation area prior to admission to the neonatal intensive care unit

5. Infants not in the reporting hospital at the postnatal age recommended for ROP screening by the AAP

Adjustment/Stratification: Stratification by risk category/subgroup

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: Vermont Oxford Network

STANDING COMMITTEE MEETING [May/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-12; M-12; L-2; I-0** <u>Rationale</u>:

- This previously endorsed process measure from the Vermont Oxford Network (VON) assesses whether premature infants who are at risk for eye complications due to prematurity have had an eye evaluation prior to hospital discharge in alignment with guidelines from American Academy of Pediatrics.
- For the 916 hospitals in the VON network, average performance on this measure improved slightly, from 90.1% in 2006 to 91.8% in 2014.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-8; M-16; L-2; I-0; 2b. Validity: Previous Validity Evaluation Accepted <u>Rationale</u>:

- The Committee noted that the data collected is a simple yes/no and does not include the date or gestational age.
- The Committee discussed alternative methods for the eye evaluation because of shortages of pediatric ophthalmologists in some areas.
- Reliability testing of the measure scores indicates higher reliability for larger sample sizes.

0483 P	roportion	of infants	22 to 29	weeks	gestation	screened i	for retin	opathy of	f prematurity
		01 111001100			Bestation	001001100		opacity of	prematarity

3. Feasibility: H-4; M-20; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• For VON members, this measure requires chart abstraction and submission to VON, but the measure specifications can be used by any hospital to calculate their own performance.

4. Usability and Use: H-5; M-15; L-6; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently used only for internal QI within the membership of VON.
- The Committee was concerned that this measure is not publicly reported.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-24; N-2

<u>Rationale</u>

• Due to the importance of preventing eye problems for premature babies, the Committee recommended this measure for continued endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received:

• This measure received one comment supporting endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

0716 Unexpected Complications in Term Newborns

Submission | Specifications

Description: This is a hospital level performance score reported as the percent of infants with Unexpected Newborn Complications among full term newborns with no preexisting conditions, typically calculated per year. **Numerator Statement**: Numerator: The numerator is divided into two categories: Severe complications and

moderate complications.

Severe complications include neonatal death, transfer to another hospital for higher level of care, extremely low Apgar Scores (=3 at either 5 or 10 minutes of life), severe birth injuries such as intracranial hemorrhage or nerve injury, neurologic damage, severe respiratory and infectious complications such as sepsis. Parents of such babies may often worry about short or long term infant outcomes.

Moderate complications include diagnoses or procedures that raise concern but at a lower level than the list for severe (e.g. use of CPAP or bone fracture). For inclusion in the numerator, most require an infant length of stay that exceeds that of the mother, validating that these are indeed significant complications. Examples include less severe respiratory complications (e.g. Transient Tachypnea of the Newborn), or infections with a longer length of stay not including sepsis. As a "safety net" to capture cases who were under-coded, the numerator also includes infants who have a prolonged length of stay of over 5 days to capture the "seemingly normal" infants with neither any form of jaundice nor a social reason for staying in the hospital (e.g. family disruption or adoption).

Denominator Statement: The denominator is comprised of singleton, live born babies who are at least 37.0 weeks of gestation, and over 2500g in birth weight. The denominator excludes most serious fetal conditions that are "preexisting" (present before labor), including prematurity, multiple gestations, poor fetal growth, congenital malformations, genetic disorders, other specified fetal and maternal conditions and infants exposed to maternal drug use in-utero. The final denominator population consists of babies who are expected to do well following labor and delivery and go home routinely with their mothers.

Exclusions: a) Babies not born in hospitals are excluded as this is a hospital quality performance measure

b) Babies who are part of multiple gestation pregnancies are excluded.

c) Premature infants (babies born before 37 weeks gestational age) are excluded

d) Low birth weight babies (<=2500g) are excluded

e) Babies with congenital malformations and genetic diseases are excluded

f) Babies with pre-existing fetal conditions such as IUGR are excluded

g) Babies who were exposed to maternal drug use in-utero are excluded

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Integrated Delivery System, Population : Regional, Population : State

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: California Maternal Quality Care Collaborative

STANDING COMMITTEE MEETING [May/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-16; M-8; L-0; I-0** Rationale:

- This maintenance measure was originally endorsed in 2012 as a measure titled Healthy Term Newborn. It has since been inverted to report on the unexpected outcomes for healthy, full-term newborns. The revised measure reports the same information in a different format. The developer noted that performance rates on the previous measure were 94-97% and while this reflects strong performance, they wanted to focus attention on the 3-6% of babies that have unexpected complications, so they reversed the measure.
- Committee members reviewed the 2013 and 2014 data submitted by the developer and noted there is

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0716 Unexpected Complications in Term Newborns

still room for improvement, although the rate is not expected to be zero. Committee members discussed some of the reasons for variation, including how neonatal sepsis is handled. It was also noted that African American women have slightly higher rates.

• They also noted the need for a measure that looks at healthy pregnancies.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Previous Reliability Evaluation Accepted**; 2b. Validity: **H-18; M-7; L-0; I-0** <u>Rationale</u>:

- The Committee had questions about the exclusions and risk adjustment, noting that outcomes can be affected by the patient's health as opposed to provider actions. The developer explained they had reviewed adjusting for hypertension, diabetes, birth weight, and a variety of other factors, but they found that only insulin-requiring, pre-gestational diabetics were at risk.
- The developer noted that this measure is most useful as a balancing measure: a measure used for following a hospital over time as they change practices, to ensure that outcomes are worsened, rather than comparing a performance of 5% vs. 4% to rank hospitals.
- Committee members noted the new reliability testing was useful but requested more information on the
 number of deliveries cutoff. The developer explained that less than 200 births annually was too small to
 provide accurate information; that 200-500 births is a "grey zone" in that the reliability is lower, but the
 measure is still useful for comparing performance over time. The Committee and developer agreed that
 in hospitals with small numbers the measure is a "case finding tool" and that most deliveries are
 happening in hospitals with more than 500 births annually, where the measure is reliable.
- New empirical validity testing compared the results of this measure to a similar measure from the National Perinatal Information Center (admissions to NICU) and found similar results. Also, in 3 hospital quality improvement projects trying to reduce the Cesarean birth rate, this measure declined thus offering reassurance that there were not unintended consequences for the baby.
- The data source is administrative claims linked to Vital Statistics; unlike the underused ICD codes for gestational age, the birth certificate data fields for "Best Obstetric Gestational Age" and "Birthweight" have high degrees of completeness and accuracy.

3. Feasibility: H-16; M-8; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- This measure has complicated numerators and denominators and the Committee had some questions about how it was implemented, especially at small hospitals. The developer explained that it was easier to implement at higher levels of analysis using state data.
- Committee members who are currently using the measure in large systems noted that it was feasible to use and not too difficult to set up.

4. Usability and Use: H-21; M-4; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently in use in several states, including California, Washington, Oregon, Alaska, and Montana.
- The Committee noted the addition of birth certificate data makes the measure easier to use.
- It was also noted that the reframing makes it a more consumer-friendly measure.

5. Related and Competing Measures

• No related or competing measures noted.

0716 Unexpected Complications in Term Newborns

Standing Committee Recommendation for Endorsement: Y-25; N-0 Rationale

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• This measure received one comment supporting endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

1382 Percentage of low birthweight births

Submission | Specifications

Description: The percentage of births with birthweight <2,500 grams

Numerator Statement: The number of babies born weighing <2,500 grams at birth in the study population

Denominator Statement: All births in the study population

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Population : County or City, Population : National, Population : Regional

Setting of Care: Hospital/Acute Care Facility, Other

Type of Measure: Outcome

Data Source: Patient Reported Data/Survey

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE MEETING [May/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Previous Evidence Evaluation Accepted; 1b. Performance Gap: H-15; M-9; L-1; I-0 <u>Rationale</u>:

- This is a population-level measure monitored by the National Center for Health Statistics.
- The Committee noted that there is little variability at any moment in time, but that in the US there has been a downward trend in the incidence of low birthweight, suggesting that incidence of low birthweight is modifiable, as well as the fact that US levels are very different from those seen in other countries.
- The Committee highlighted that there is substantial opportunity for improvement in this measure since rates have edged down only slightly over the last few years, and there are substantial variations across race and ethnicity.
- The Committee questioned whether the developer considered gestational age since the US ranks very low among industrial countries in terms of infant mortality rate and maternal mortality rate.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Previous Reliability Evaluation Accepted**; 2b. Validity: **Previous Validity Evaluation Accepted** <u>Rationale</u>:

- The Committee agreed the underlying method and results for the measure had not significantly changed since the last NQF endorsement review. Data element validity was assessed by direct comparison of birth certificate data to medical records. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were computed.
- Data element validity tested against a "gold standard" such as the medical record also counts for reliability. The Committee accepted the validity testing conducted at the data element level for the last NQF endorsement review.
- The Committee accepted the prior evaluation of the reliability and validity criteria without further discussion.

3. Feasibility: H-24; M-1; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• The Committee agreed the measure is feasible since the data are collected by law and is universally available.

1382 Percentage of low birthweight births

4. Usability and Use: H-18; M-7; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is publicly reported by the CDC National Vital Statistics System.
- The Committee noted that this measure assesses perinatal healthcare in general rather than specific providers, yet it is important to measure and track. For example, from a public health and planning point of view, it is helpful to know how many babies are going to need NICU follow up and potentially, future support services; this measure can assist in predicting that need.
- Some Committee members noted that birth certificate data are not very reliable for many of the maternal indicators. However, birthweight and gestational age are quite accurate on the birth certificate.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-26; N-0

Rationale

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• This measure received 4 comments, 2 of which were fully supportive. One comment suggested replacing birthweight with gestational age, as that is now widely available. The fourth comment did not agree with the recommendation for endorsement, noting "this measure has not influenced outcome over the past several years in US", and that "Additional maternal and neonatal info would be necessary to provide any meaningful outcomes."

Developer Response

• Agree, gestational age is now a better measure of outcome and should replace this measure.

Committee Response

• The Committee agrees with the commenter and developer that a measure of gestational age would be a better outcome measure, and this has been added to the measure gaps list. However, since that measure does not currently exist and is not development, the Committee elected to continue to recommend this measure as they agreed it is an important topic.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

Submission | Specifications

Description: This measure assesses the number of staphylococcal and gram negative septicemias or bacteremias in high-risk newborns. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Birth, PC-03: Antenatal Steroids, PC-05: Exclusive Breast Milk Feeding).

Numerator Statement: The outcome being measured is: Newborns with septicemia or bacteremia with ICD-10-CM Other Diagnosis Codes for newborn septicemia or bacteremia as defined in Appendix A, Table 11.10 with a Bloodstream Infection Confirmed OR ICD-10-CM Other Diagnosis Codes for sepsis as defined in Appendix A, Table 11.10.1 with a Bloodstream Infection Confirmed available at:

http://manual.jointcommission.org/releases/TJC2016A/

The only national hospital quality measure currently requiring patient-level risk adjustment is the Health Care-Associated Bloodstream Infections in Newborns (PC-04) outcome measure in the perinatal care measure set.

Denominator Statement: The outcome target population being measured is: Liveborn newborns with ICD-10-CM Other Diagnosis Codes for birth weight between 500 and 1499g as defined in Appendix A, Table 11.12, 11.13 or 11.14 OR Birth Weight between 500 and 1499g OR ICD-10-CM Other Diagnosis Codes for birth weight = > 1500g as defined in Appendix A, Table 11.15 or 11.16 OR Birth Weight = > 1500g who experienced one or more of the following:

o Experienced death

o ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for major surgery as defined in Appendix A, Table 11.18

o ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for mechanical ventilation as defined in Appendix A, Table 11.19

o Transferred in from another acute care hospital or health care setting within 2 days of birth.

Exclusions: • ICD-10-CM Principal Diagnosis Code for septicemias or bacteremias as defined in Appendix A, Table 11.10.2

• ICD-10-CM Other Diagnosis Codes for septicemias or bacteremias as defined in Appendix A, Table 11.10.2 or ICD-10-CM Principal or Other Diagnosis Codes for newborn septicemia or bacteremia as defined in Appendix A, Table 11.10 with a Bloodstream Infection Present on Admission

• ICD-10-CM Other Diagnosis Codes for birth weight < 500g as defined in Appendix A, Table 11.20 OR Birth Weight < 500g

• Length of Stay < 2 days

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [May/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-17; M-5; L-1; I-0** <u>Rationale</u>:

• It was generally agreed there is still a significant opportunity for improvement on performance with this measure. The Committee noted the increase in the gap since 2011, and the developer explained that in 2014 this measure became mandatory for all hospitals with more than 1,100 births annually (as of 2016, it is now all hospitals with more than 300 births). With 1,000 more hospitals reporting, more cases are identified.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **M-22; L-1; I-0**; 2b. Validity: **H-14; M-9; L-0; I-0** Rationale:

- The measure has been updated to ICD-10 CM.
- There have been changes to the specifications. The numerator included population now requires a check to confirm that the bloodstream infection was health care-associated after the first 48 hours when infection codes are present on Table 11.10 or 11.10.1 with a new data element Bloodstream Infection Confirmed, since infection codes are also applied for infections resulting from other newborn medical conditions that are not health care-associated, i.e., necrotizing enterocolitis, pneumonia, urosepsis, etc. The exclusion for hospitalization greater than 120 days was removed and another exclusion was added to exclude newborns with bloodstream infection present on admission. The Committee had no concerns with the changes.
- The measure is risk-adjusted using 6 factors: two birthweight categories, transfers out or died, congenital anomalies of the GI or CV systems and transfers in. The C-statistic is 0.654.
- Race and ethnicity were SDS factors found to be statistically significant in the risk model, changing the c-statistic to 0.702. Race and ethnicity were not included in the final model.
- This measure does not correlate with the other measures in the Joint Commission perinatal core set, but the Committee agreed that would not be expected.

3. Feasibility: H-15; M-8; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

- <u>Rationale</u>:
 - The Committee had no concerns about the feasibility.

4. Usability and Use: H-15; M-8; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• Committee members noted the measure has been improved, with expanded data sources, and some changes to the specifications. The developer noted that the new version of the measure should be more accurate but they could not yet compare the newest data with data from the prior version.

5. Related and Competing Measures

- This measure competes with #0304: Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates and #0478: Neonatal Blood Stream Infection Rate (NQI 03) (AHRQ).
- The Committee had an extensive discussion on the 3 competing measures. NQF provided guidance on the related/competing measure process.
- The Joint Commission (TJC) and AHRQ have done some work on harmonization. TJC compared #1731, which uses partial chart review and administrative data, and #0478, which uses only administrative data. They found the measure using chart review was able to identify more cases that had not been included in the other measure due to coding issues. In addition, #0478 excludes cases diagnosed 7 days or less after birth and #1731 excludes only 2 days or less, which they thought accounted for about 10% of the difference. (#0478 is now three days or less.) The Joint Commission stated that the measures are similar; however, since codes are not uniformly assigned, their measure, which also uses chart review is able to identify more cases. This comparison was done using ICD-9 CM codes, and they think that that there will be less discrepancy between the two measures with the use of ICD-10 CM codes.
- AHRQ noted that they had made changes to #0478 based in part on the analysis done with TJC, that the measure will change with ICD-10 CM, and that the current versions are more aligned. In addition, #0478

looks at all causes and cases of sepsis, while #1731 focuses on those associated with central lines. In addition, the AHRQ measure is not reported at a hospital level.

- A Committee member related some of the history of this measure, noting that the AHRQ measure was
 originally endorsed and brought into The Joint Commission's core set, and then turned into a clinical data
 measure. During the previous review and discussion of competing measures, Medicaid program
 representatives stated that they could not collect the data unless it was administrative, and that is why
 there were two endorsed measures.
- Committee members requested more information on the change to ICD-10 CM, in particular questioning
 if this would now have less chart review burden. The developer stated it was too soon to tell, especially
 with the learning curve associated with changing coding guidelines. It was also noted that with ICD-10
 CM, "suspected" or "probable" is no longer included (cases are yes/no) which should reduce gaming.
- For the chart review, Committee members who are using the measure did not think it was a large burden due to the very small number of charts that have to be reviewed, and that hospitals would be reviewing all of these charts as they work to reduce infection rates. Coding for neonatal sepsis is complicated and the chart review is used to make the measure more accurate. In addition, the developer noted, hospitals like to be able to exclude false positives. It was noted that false negatives are a larger issue.
- After discussion, the Committee felt there is not yet enough data on the performance of either measure under ICD-10 CM and that ICD-10 CM has the potential to reduce burden associated with manual chart review. In addition, many new, smaller facilities (>300 deliveries per year) are just beginning to report on this measure so current performance rates are not yet available (although these very small facilities are unlikely to be caring for these babies, who would be transferred).
- The Committee noted that EHRs are not yet to the point where these data can be automatically pulled out.
- The Committee then discussed the ways in which the VON measure, #0304, differs from the other two. 0304 does not include babies more than 1,500 grams, and does include meningitis; however, it is not clear the size of that group. Currently the measure requires either a positive blood or CSF culture and is not collected separately, although the developer agreed that might be a good idea. The VON measure is risk adjusted, which allows for more even comparisons across facilities. However, the major issue with the VON measure is that it is not publically reported and requires a registration fee.
- The Committee noted they were struggling with the question of whether one was best, especially with the changes to the measures. Committee members using the measures noted they focus on slightly different populations. For example, there are about 40,000 VLBW babies born in each year and bloodstream infections are most prevalent in this population, but larger babies born are also at risk for infection even if the infection rates are smaller. One Committee member stated that to actually move the needle, the VLBW babies are the target population, but only about a quarter of the NICUs in the country treat these babies, with the remaining three-fourths of NICUs treating LBW and premature babies. Another Committee member noted that focusing on the smaller, high-prevalence population misses the opportunity to improve processes and reduce infections in many facilities.
- Ultimately, due to the changes in the AHRQ measure, the update to ICD-10 CM, the expanded number of facilities reporting, and the slightly different populations included, the Committee agreed that for the time being all three measures should remain endorsed, since they are being used for different things. In terms of burden, it was noted that the high-level NICUs are all already reporting to VON; that almost everyone has to report to the Joint Commission; and that there is no burden for hospitals for the AHRQ measure since it comes out of billing data and is reported by the state data organizations.
- The Committee requested that, for the next year, a specific effort be made to get the data from those facilities that collect and report on two or three of the measures in order to allow a more accurate comparison. VON noted that they do a member survey and they will ask members that are collecting on the other measures as well. They also offered to work with The Joint Commission to compare the data.
- Committee members highlighted that while it is easy for them to understand the differences between the measures and rates, it may not be so clear to the public, and they reiterated the need for a single

measure.

• The Committee requested that the developers provide more information and new data in 18 months for the Committee to relook at the measures during an off-cycle review. They further requested that the developers work together toward a single measure.

Standing Committee Recommendation for Endorsement: Y-23; N-0 Rationale

<u>Rationale</u>

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7- July 6, 2016

Comments Received

• One commenter submitted a comment on each of the 3 measures agreeing with the Committee's decision to recommend, but urging the developers to coordinate or combine measures.

Developer Response

• Thank you for your feedback. We have done extensive work and these measures have been harmonized to the extent possible at this time.

Committee Response

• The Committee agrees that harmonization of these 3 measures is important to reduce the burden of reporting. The developers have been directed to work together over the next 18 months to arrive at a single measure with supporting data, to be presented to the Committee during an off-cycle review.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

0469: 2829 PC-01 Elective Delivery

Submission | Specifications

Description: This measure assesses patients with elective vaginal deliveries or elective cesarean births at >= 37 and < 39 weeks of gestation completed. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns, PC-05: Exclusive Breast Milk Feeding). PC-01, Elective Delivery is one of two of the measures in this set that have been reengineered as eCQMs and are included in the EHR Incentive Program and Hospital Inpatient Quality Reporting Program.

Numerator Statement: Patients with elective deliveries by either:

- Medical induction of labor while not in labor prior to the procedure
- Cesarean birth while not in labor and with no history of a prior uterine surgery

Denominator Statement: The Denominator is patients who deliver newborns with >= 37 and < 39 weeks of gestation completed.

Exclusions: ICD-9-CM, ICD-10-CM, or SNOMED CT codes for conditions possibly justifying elective delivery prior to 39 weeks gestation.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Pharmacy

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [May/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-10; M-13; L-2; I-0** <u>Rationale</u>:

- This measure is the eMeasure version of NQF#480 and the information for evidence and opportunity for improvement is the same:
 - The developer did not submit new evidence during this review, but Committee members noted that ACOG recently reaffirmed the practice bulletin for timing of elective induction of labor.
 - While the performance is improving, there is still a gap in care in this area, and Committee members noted that as of January 2016, more hospitals are reporting on this measure (now 80% of all birthing hospitals), so they expect more variation to appear. Committee members noted that one of the major drivers of morbidity was repeat elective C-sections at 37 weeks, and that number had dropped significantly.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: M-22; L-2; I-1; 2b. Validity: M-23; L-1; I-1

Rationale:

- NQF eMeasure technical review found this eMeasure to have appropriate specifications and value sets, and an adequate feasibility assessment that addressed the data elements and measure logic.
- The developer explained that because this measure was tested using BONNIE simulated data set, the testing was looking to confirm that the measure specifications are accurately implemented and that the measure performs as it should.
- Since there is no sampling with the eMeasure and 100% of cases are used, performance should be more reliable.

0469: 2829 PC-01 Elective Delivery

• Actual performance information is not yet available to compare with the paper version of the measure. Thus far, 7 hospitals submitted data on 2015 performance in March 2016, and 69 hospitals will submit 2016 data in 2017. Committee members noted the importance of good training for coders as the measure is implemented.

3. Feasibility: H-2; M-16; L-0; I-7

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Pationalo:

Rationale:

• Given the limited use of the measure thus far, the Committee found it difficult to comment on feasibility. The developer noted that some of the major EHR vendors submit feedback on the eMeasures each year and they are using that feedback to improve the measure.

4. Usability and Use: H-21; M-4; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• The Committee thought the usability of the eMeasure would be similar to the medical record abstraction measure.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-22; N-3

<u>Rationale</u>

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• A total of 12 comments were received on both versions of the measure. Generally, the comments were in support, and several noted that while rates have improved, much remains to be done. However, a pair of comments noted concerns with the measure exclusions. A second pair of comments noted that elective delivery/induction may be preferable in very rural areas that lack access to secondary and tertiary facilities.

Developer Response

- Over the last several years The Joint Commission has responded to suggestions from the obstetrics community to adjust the specifications for PC-01: Elective Delivery to allow for a wider array of exclusions. Some of these have resulted in new ICD codes being added and others have required the addition of new exclusions that can only be determined by chart reviews (an unfortunate but currently needed situation). The Joint Commission continues to receive numerous requests for "appeals" and new exclusions which are uncommon or rare conditions justifying the need for an early-term elective delivery. While many of these conditions have been incorporated into the current PC-01 specifications, medical issues are varied enough that it is impossible to enumerate 100% of the potential circumstances that could justify an early-term elective delivery. For example, a mother with a malignancy and need to start chemotherapy might require a delivery before 39 weeks. Although these cases are rare their occurrence can be such to generate an early-term elective delivery rate of 2-4%. This supports the rationale for not expecting this measure to consistently reach 0% elective deliveries. The Joint Commission has worked closely with a technical advisory panel (TAP) since the inception of this project. The TAP is comprised of leading national perinatal care experts including obstetricians, pediatricians, neonatologists and nurse clinicians. Recently, the TAP reaffirmed the goal of 5% which is supported by the 2013 study by Clark, et. al, validating the denominator exclusion criteria for PC-01.
- There are currently 2 sets of ICD-10-CM diagnosis codes on Table 11.07 which should be used for prelabor (preterm) rupture of membranes: the first set is 042.011, 042.012, 042.013, 042.02, 042.911,

0469: 2829 PC-01 Elective Delivery

O42.912, O42.913 and O42.92 and for prolonged rupture: the second set is O42.111, O42.112, O42.113 and O42.12. The coders should be applying these codes when there is appropriate documentation that SROM occurred without commencement of labor. As a result the case would be excluded from the measure. Documentation of spontaneous rupture of membranes without onset of labor should be taken at face value according to ACOG. The 2013 ACOG definition of Preterm Rupture of Membranes (PROM is rupture of membranes before the onset of labor. Membrane rupture that occurs before 37 weeks of gestation is referred to as preterm PROM. Membrane rupture that occurs at 37 weeks of gestation or later is referred to as term PROM. In 2014, ACOG re-named premature rupture of membranes to pre-labor rupture of membranes in order to further clarify the meaning of PROM. We consider ACOG an authoritative source. Based on the ACOG definition one of the codes from the first set applies to all cases with SROM regardless of gestational age, and only the absence of labor should be required to use this code. If the runtured membranes are >24 hours then one of the codes from the
second set applies "
 Requiring gestational age and careful scrutiny (chart reviews) for exclusions does preclude the use of claims data but there is progress in creating an eMeasure version. However, because of the small sample size for this measure for a given health plan within a given hospital it will unlikely be a practical measure at the plan level.
 Thank you for the support. We agree that measures of patient engagement and documentation of consent would be an attractive next step but we don't have measures fully developed in those areas yet.
 While this has been proposed as a potential concern, rural hospitals in general have done very well on this measure. In general there are few logistical reasons that truly need elective delivery prior to 39 weeks of gestation. In any case, the federal mandate for reporting of this measure for MediCare P4P specifically excludes Critical Access Hospitals.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

480: 2830 PC-05 Exclusive Breast Milk Feeding

Submission | Specifications

Description: PC-05 assesses the number of newborns exclusively fed breast milk during the newborn's entire hospitalization. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns). PC-05, Exclusive Breast Milk Feeding, is one of two measures in this set that have been reengineered as eCQMs and are included in the EHR Incentive Program and Hospital Inpatient Quality Reporting Program.

Numerator Statement: Newborns that were fed breast milk only since birth

Denominator Statement: Single term newborns discharged from the hospital who did not have a diagnosis of galactosemia, were not subject to parenteral nutrition, and had a length of stay of less than or equal to 120 days **Exclusions**: - Newborns who were admitted to the Neonatal Intensive Care Unit (NICU)

- Newborns who were transferred to an acute care facility
- Newborns who expired during the hospitalization

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [May/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-0=18; M-5; L-1; I-0** <u>Rationale</u>:

- As this is the eMeasure version of measure 0480: Exclusive Breast Feeding, the information for evidence and gap are the same:
 - The goal for performance of the measure is 70%, and in over half of The Joint Commission hospitals that reported this measure, rates are less than 50%. In the 10th percentile, hospitals are at 22%.
 - More hospitals are reporting now (1,400, up from 166), so there are more opportunities for improvement.
 - Committee members noted concerns around patient choice, and that one issue with this measure is that it puts pressure on patients to breastfeed when it may not be appropriate due to circumstances outside the control of the hospital (for example, work circumstances that do not allow pumping).
 - Committee members discussed the resources available for hospitals as they work to improve performance on this measure, such as toolkits, and that one key focus is training staff to ensure they are counseling patients appropriately.
 - The Committee discussed the potential for a balancing measure.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: M-17; L-1; I-1; 2b. Validity: M-15; L-4; I-0

Rationale:

- NQF eMeasure technical review found this eMeasure to have appropriate specifications and value sets, and an adequate feasibility assessment that addressed the data elements and measure logic.
- This eMeasure has been tested through BONNIE and as such, the Committee noted similar concerns as

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with the other eMeasures. During the BONNIE testing, 528 cases passed at 100%.

• It has HQMF specifications, was vetted through USAC, and is used in meaningful use, so the Committee agreed the quality construct is present and the measure meets the scientific acceptability criteria.

3. Feasibility: H-18; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• Given the limited use of the measure thus far, the Committee found it difficult to comment on feasibility. The developer noted that some of the major EHR vendors submit feedback on the eMeasures each year and they are using that feedback to improve the measure.

4. Usability and Use: H-14; M-8; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• The Committee thought the usability of the eMeasure would be similar to the medical record abstraction measure.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-18; N-2

Rationale

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

A total of 13 comments were received on the paper and electronic version of these measures. Comments
were generally supportive of both the electronic and paper versions of the measure, but a number of
concerns were raised, including issues around maternal choice, exclusions for the measure, and the
need for implementation within a family-centered decision making process. Commenters also
encouraged the development of a measure on longer-term breastfeeding.

Developer Response

- This measure was designed as an in-patient quality measure. The Joint Commission has no means of tracking this post-discharge activity. Much evidence has now focused on the prenatal and intrapartum period as critical for the success of exclusive (or any) breastfeeding. (Centers for Disease Control and Prevention [CDC], 2007; Petrova et al., 2007; Shealy et al., 2005; Taveras et al., 2004).
- PC-05 does not exclude maternal medical conditions. These conditions are unusual (~2% of patients), and they cannot be modeled in the electronic Clinical Quality Measure (eCQM) version of PC-05. The removal of measure exclusions will also significantly reduce the burden of data abstraction. The revised measure is similar in construct to PC-02: Cesarean Birth, which reports the cesarean birth rate with no exclusions. As a result of some mothers declining exclusive breast milk feeding and by removing exclusions, The Joint Commission does not anticipate or expect that measure rates for PC-05 will reach near 100% as has been the case for many other measures. Available evidence suggests that a 70% threshold may be a more reasonable target for many organizations.
- It is important to note that The Joint Commission does not establish benchmarks for any of the core measures. The goal is for hospitals to understand their baseline rate of performance for each measure in order to determine if performance improvement efforts are effective over time when their baseline is higher or lower than the national performance (depending on the desired direction for improvement).

Committee Response

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 The Committee agrees that measures of continued breastfeeding after hospital discharge are important and this has been added to the measure gaps list. 						
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X						
8. Board of Directors Vote: Y-X; N-X						
9. Appeals						

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2902 Contraceptive Care – Postpartum

Submission | Specifications

Description: Among women ages 15 through 44 who had a live birth, the percentage that is provided:

1) A most effective (i.e., sterilization, implants, intrauterine devices or systems (IUD/IUS)) or moderately (i.e., injectables, oral pills, patch, ring, or diaphragm) effective method of contraception within 3 and 60 days of delivery.

2) A long-acting reversible method of contraception (LARC) within 3 and 60 days of delivery.

Two time periods are proposed (i.e., within 3 and within 60 days of delivery) because each reflects important clinical recommendations from the U.S. Centers for Disease Control and Prevention (CDC) and the American College of Obstetricians and Gynecologists (ACOG). The 60-day period reflects ACOG recommendations that women should receive contraceptive care at the 6-week postpartum visit. The 3-day period reflects CDC and ACOG recommendations that the immediate postpartum period (i.e., at delivery, while the woman is in the hospital) is a safe time to provide contraceptive care.

Numerator Statement: Primary measure: Women ages 15 through 44 who had a live birth and were provided a most (sterilization, intrauterine device, implant) or moderately (pill, patch, ring, injectable, diaphragm) effective method of contraception within 3 and 60 days of delivery.

Sub-measure: Women ages 15 through 44 who had a live birth and were provided a long-acting reversible method of contraception (LARC) within 3 and 60 days of delivery.

Denominator Statement: Women ages 15 through 44 who had a live birth in a 12-month measurement year.

Exclusions: The following categories are excluded from the denominator: (1) deliveries that did not end in a live birth (i.e., miscarriage, ectopic, stillbirth or induced abortion); and (2) deliveries that occurred during the last two months of the measurement year.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan, Population : Regional

Setting of Care:

Type of Measure: Intermediate Clinical Outcome

Data Source: Administrative claims

Measure Steward: US Office of Population Affairs

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Y-24; N-1; 1b. Performance Gap: H-21; M-6; L-0; I-0

Rationale:

- This measure assesses a subpopulation of measures #2903 and #2904: it covers the population of women who have given birth in the last 60 days.
- As with measures #2903 and #2904, the Committee noted a large body of evidence demonstrated a relationship between contraception and reducing unintended pregnancy, which is no different for the postpartum period.
- The Committee highlighted that the provision of most or moderately effective methods does not address patient preference.
- One Committee member questioned if the measure is excluding mothers who gave birth less than 60 days from the end of the year. The developer explained that they excluded women who delivered with only 2 months left in the measurement year as the developer wanted to make sure that providers had enough time after delivery to see the woman while ensuring that the measure aligns with ACOG's recommendations.
- The Committee requested that the developer clarify whether this is 2 different measures (within 3 days and within 60 days) or combined into one result. Conceptually, the developer explained, this is a

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stratification of a single measure into 2 different timeframes.

- One Committee member requested that the developer harmonize this measure with the HEDIS measure of postpartum visits to widen the timeframe since it is hard to get the timely postpartum visit. The developer stated that they would consider this in the next iteration of the measure.
- The Committee noted that the performance gap is actually larger for the postpartum population than the general population and has more room for improvement.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-8; M-14; L-2; I-0; 2b. Validity: M-17; L-6; I-1

Rationale:

- The Committee agreed that the reliability and validity for this measure was similar to NQF #2903: Contraceptive Care – Most & Moderately Effective Methods and #2904: Access to LARC. However, one Committee member asked that the developer clarify the reliability for this measure. The developer explained that for these measures in particular high numbers (several hundreds) were required to achieve a high reliability of 0.9, or 0.7 for a moderate level of reliability, which is acceptable or widely acceptable level of reliability.
- The Committee noted that, similar to the other measures, the same reasoning applies in terms of providers being responsible for their patients' decision-making regardless of the clinic process and counseling.

3. Feasibility: H-20; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

• The Committee acknowledged the measure is feasible.

4. Usability and Use: H-15; M-12; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• The Committee voiced no concerns regarding usability and use.

5. Related and Competing Measures

• This measure directly relates to NQF #2903: Contraceptive Care – Most & Moderately Effective Methods and #2904: Access to LARC. These measures are from the same developer and harmonized.

Standing Committee Recommendation for Endorsement: Y-24; N-3

<u>Rationale</u>

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• This measure received 25 comments, all supporting the endorsement of the measure. A number of the comments highlighted the gap in contraceptive measures, noting there are no currently endorsed in the NQF portfolio. Several of the comments also noted some concern with the measure, including: the need to ensure women's choices are informed and respected and the need for the balancing measure of woman-reported experience of contraceptive care currently under development; these comments reiterated that the performance should not be 100%. In addition, commenters submitted requests to align the timing for postpartum coverage with other measures of postpartum care and for minor changes to the age range. One commenter stated this is not appropriate for a health plan level measure "given that health care decisions are best made between the providers and their patients"; another noted "that the contraceptive measures as currently specified are most appropriately reported at a population level

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and are not appropriate for "pay for performance" programs."

Developer Responses

- We appreciate the reviewer's support for the measure. The reviewer has raised an important issue, which OPA will be delighted to consider over the coming years as we gain more experience using the measure and consider whether any changes are needed when it goes before NQF for maintenance review in 3 years. Our intention is to form and convene an Expert Work Group in the interim period to review the use of the measure in various settings (Medicaid, Title X, other programs) and give us advice on what changes may be justified.
- The reviewer is correct in noting that Medicaid and other health plans that rely on claims-based reporting of the measure would not capture 'free contraception' -- however, this is likely to be a very small number of patients. Programs such as OPA's Title X program that do provide 'free' contraception can adapt the measure to their own data systems so that the 'free' methods are identified. We will consider submitting a Title X adaptation of the contraceptive measure to NQF when we submit for measure maintenance in 3 years.
- We appreciate the reviewer's support for this measure, and share their concern that contraceptive care be offered in a client-centered manner. Of note, existing research has shown that method effectiveness is important to many women and, as such, is one of many aspects of client centered care. For example, a recent study showed that nearly 90% of women reported that method effectiveness was an 'extremely important' characteristic (Jackson 2016).
- We do not fully understand the context of the comment that the measure is appropriate for population level but not health plan level, and welcome additional information from the reviewer. The primary purpose of the measures is to encourage removal of barriers to contraceptive access in the provider- and systems-level so that women are offered a wide range of methods in a client-centered manner, preferably on a same-day, onsite basis. It seems to us that these barriers could exist in a health plan, and therefore could be addressed at a health plan level as well as at the population level. We agree that benchmarking for this measure will require careful consideration so that comparisons across reporting units are done in a fair manner that does not put undue pressure on providers to 'coerce' women; we intend to convene an Expert Work Group in the intervening period before measure maintenance review, to help us consider the issue of benchmarking. If we are overlooking some other important aspect, we welcome additional information from the reviewer.
- We can see the potential benefit of aligning the postpartum contraceptive measure with the HEDIS postpartum measure, and will be delighted to consult with the Expert Work Group about this as preparation for submitting for measure maintenance in 3 years. However, the 3 day window is important to ensure women have access to contraception in the immediate postpartum period. This is a period in which there have been a number of barriers to providing the full range of contraceptive methods.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

2903 Contraceptive Care – Most & Moderately Effective Methods

Submission | Specifications

Description: The percentage of women aged 15-44 years at risk of unintended pregnancy that is provided a most effective (i.e., sterilization, implants, intrauterine devices or systems (IUD/IUS)) or moderately effective (i.e., injectables, oral pills, patch, ring, or diaphragm) FDA-approved methods of contraception.

The proposed measure is an intermediate outcome measure because it represents a decision that is made at the end of a clinical encounter about the type of contraceptive method a woman will use, and because of the strong association between type of contraceptive method used and risk of unintended pregnancy.

Numerator Statement: Women aged 15-44 years of age at risk of unintended pregnancy who are provided a most (sterilization, intrauterine device, implant) or moderately (pill, patch, ring, injectable, diaphragm) effective method of contraception.

Denominator Statement: Women aged 15-44 years of age who are at risk of unintended pregnancy.

Exclusions: The following categories of women are excluded from the denominator: (1) those who are infecund for non-contraceptive reasons; (2) those who had a live birth in the last 2 months of the measurement year; or (3) those who were still pregnant or their pregnancy outcome was unknown at the end of the year.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Health Plan, Population : Regional, Population : State

Setting of Care:

Type of Measure: Intermediate Clinical Outcome

Data Source: Administrative claims

Measure Steward: US Office of Population Affairs

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Y-24; N-1; 1b. Performance Gap: H-13; M-10; L-1; I-0 Rationale:

- The Committee noted that the evidence demonstrated strong support for providing LARCs to demonstrate that clinics are providing greater access to a wide range of contraception options.
- The Committee highlighted that the evidence has shown that the type of counseling can be associated with the choice of method selected but did note that measuring the provision of most or moderately effective methods does not address patient preference. The Committee expressed concerns that this measure is assessing providers based on patients' clinical decision-making, which could lead to unintended consequences such as penalizing providers for patients' choices and preferences. Additionally, there might be resistance against contraception (e.g. Catholic systems or patient religious beliefs), which is not factored into the decision-making. The developer stated that the evidence is very strong that when counseling a woman about the range of options that most women will chose to use those most or moderately effective methods. In addition, the benchmark for this measure is 63%, so that patient preferences are respected.
- The developer also explained that this is a voluntary measure and it is possible that Catholic hospitals will
 not use this measure. However, 99% of women who identify a religious affiliation, including Catholic, have
 used birth control; 89% of Catholics report currently using contraception if they are at risk of unintended
 pregnancy; and 68% of Catholic women are using a highly effective method (i.e., sterilization, pill or other
 hormonal method, or IUD). Only 3% of Catholic women who are at risk of unintended pregnancy are
 using natural family planning.
- The Committee questioned why the focus is on actual provision of most or moderately effective methods and LARC versus offering other methods. The developer explained provision is the most reliable data available and can be captured in administrative data.
- The Committee asked the developer to explain the measure's postpartum exclusion, when those women

2903 Contraceptive Care – Most & Moderately Effective Methods

are often the highest risk of repeat pregnancy. The developer explained that they developed NQF #2902: Contraceptive Care - Postpartum specifically for that purpose. Additionally, ACOG's recommendation is to provide contraception at the six-week postpartum visit, so to be fair to providers, the developer excluded postpartum for this measure.

• The Committee highlighted that the percentage of women of reproductive age who are at risk of unintended pregnancy is 38 million and 51% of 6.7 million pregnancies each year are unintended. Additionally, there are gaps in unintended pregnancy especially for teens and unmarried women.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-8; M-14; L-2; I-0; 2b. Validity: M-17; L-6; I-1

Rationale:

- One Committee member noted the significant barriers to contraceptive care for adolescents, specifically limited access to birth control for adolescents under the age of 18. Therefore, it is unfair to penalize providers based on these access limitations. The developer explained that adolescents under the age of 18 were included to align with the Medicaid Adult and Child Core Sets, so the measure could be stratified differently to capture this particular subpopulation.
- The Committee noted that the definition for "at risk" is unclear and it is missing from the measure specifications, specifically the denominator statements. The developer defined "at risk" as having ever had sex, fecund/able to become pregnant, not pregnant, and seeking pregnancy.
- The Committee questioned if condoms for women who want to prevent STIs, vasectomy as a form of birth control, oral contraceptives for menstrual cramps, young people and parents of young people with developmental disabilities using contraceptive method to control menstruation, and same-sex relationships where birth control is not an issue were subpopulations that were excluded from this measure. The developer explained that they are considering a hybrid measure that will be better able to address these issues, but this measure relies on claims data, so they were unable to address those issues in this measure. The developer noted that there were some limitations using this strictly claims-based measure.
- The developer reported that the measure was tested with approximately 800,000 clients in Planned Parenthood across 25 affiliates, 3 state Medicaid programs, and Title X programs.
- Systematic assessment of face validity by 9 experts agreed that this measure would provide an accurate reflection of quality.
- One Committee member asked the developer to explain how the measure handles situations in which patients have access to multiple healthcare systems and would be included in the denominator for both: which provider system or specialty care would be responsible for the prescribing of the contraceptive, and who would be penalized if the other prescribed first. The developer explained that the measure was tested at the Medicaid plan level looking at performance overall but the measure has not been tested at other levels of analysis (e.g., medical groups, clinicians). The Committee stressed that this measure needs to explicitly state that it is not appropriate for hospital level or provider level comparison.
- The Committee questioned whether this measure would capture over-the-counter oral contraceptives and pharmacy claims since states like California and Oregon are allowing this.
- One Committee member suggested that a pure provision measure would be better, especially since the measure is not accounting for women who were provided LARC in a previous measurement year or discontinuation of other methods. The developer stated that they would consider this in the next iteration of the measure.

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3. Feasibility: H-20; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• The data source is administrative claims data, so the Committee agreed that this measure was feasible.

4. Usability and Use: H-10; M-12; L-3; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee expressed concern about how consumers and patients might perceive this measure, particularly since over the past 5 years there have been significant examples of coercion in contraception counseling (e.g., forced sterilization in the prison system in California). One Committee member referenced a particular study that demonstrated that contraceptive counseling differed for women of different races and providers were biased towards providing LARC methods to African-American patients.
- The developer noted that they are funding a study to develop a patient-reported outcome measure looking at possible coercion as one dimension of the entire client experience related to contraceptive care. Another Committee member stated that it is not always coercion but limitation of contraceptive choices. For example, the provider offers 1 or 2 methods out of the whole range of options, rather than offering comprehensive contraceptive counseling that explains all of the options and allows patients to choose from a full range.
- Committee members noted that contraceptive counseling for women is probably one of the most intimate services that providers offer, and unfortunately, many providers are unskilled at doing that well regardless of the available guidelines.

5. Related and Competing Measures

• This measure directly relates to NQF #2902: Contraceptive Care – Postpartum and #2904: Access to LARC. These measures are from the same developer and harmonized.

Standing Committee Recommendation for Endorsement: Y-20; N-5

<u>Rationale</u>

• The Committee agreed that this measure meets all the NQF criteria for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• This measure received 23 comments. As with measure #2902, the comments were all in favor, but highlighted the importance of ensuring that women are not coerced into using contraceptives and the need for a women-reported contraceptive access measure. In addition, commenters requested the exclusion of women who refuse contraceptives.

Developer Responses

- Our intention is to form and convene an Expert Work Group in the interim period to review the use of the measure in various settings (Medicaid, Title X, other programs) and give us advice on what changes may be justified.
- We do not fully understand the context of the reviewer's comment that the measure should exclude
 members that refuse listed contraceptives, and welcome additional information from the reviewer. If the
 member refused the listed contraceptive because their preferred method(s) were not available, then we
 think this may be a barrier that could be reduced by use of the measure over time. Some clients will
 choose to not use any contraception at all and the measure is designed to respect their right to do so –
 but those refusals would be captured by setting a benchmark below 100%. If there is some other nuance
 that we do not currently understand, we will be delighted to consider some other alternative.
- We share their concern that contraceptive care be offered in a client-centered manner. Of note, existing
2903 Contraceptive Care – Most & Moderately Effective Methods

research has shown that method effectiveness is important to many women and, as such, is one of many aspects of client centered care. For example, a recent study showed that nearly 90% of women reported that method effectiveness was an 'extremely important' characteristic (Jackson 2016).

- OPA is fully committed to doing everything it can to ensure that the performance measures are used in a manner that supports the delivery of client-centered care. As the measure steward, we will take every opportunity (e.g., on the steward's measure webpage, in presentations, in publications) to explain how the measures are intended to be used. Key messages will include: no specific benchmark has been set for the most/moderately effective method but OPA does not expect it to reach 100%; the interpretation of the LARC measure should be focused solely on identifying areas with extremely low levels of LARC provision and should not be used to encourage high rates of use; and it is not appropriate to use the LARC measure in a pay-for-performance context. We will also highlight the importance of following Federal recommendations, especially CDC-OPA's recommendations for how to provide quality family planning (QFP), for how to provide contraceptive care in a client-centered manner.
- We also agree with the reviewer's note of the need for a measure of client experience that will 'balance' the current measures focused on contraceptive provision. In fact, OPA recently awarded a 3-year cooperative agreement to the University of San Francisco to develop a patient-reported outcome performance measure (PRO-PM) for contraceptive care. The PRO-PM will focus on the client's experience with care and identify situations in which the woman's preference was not respected; it will serve to 'balance' the current measures that focus on what contraceptive methods were provided. A rigorous plan of testing and validation of the PRO-PM measure is planned, and we expect it will be ready for submission within 3 years. We look forward to learning more in the coming years about how to best use the two sets of measures in tandem so that women receive high quality, client-centered care.
- It seems to us that these barriers could exist in a health plan, and therefore could be addressed at a health plan level as well as at the population level. We agree that benchmarking for this measure should be voluntary; no specific benchmark has been set for the most/moderately effective method but OPA does not expect it to reach 100%; the interpretation of the LARC measure should be focused solely on identifying areas with extremely low levels of LARC provision and should not be used to encourage high rates of use; and it is not appropriate to use the LARC measure in a pay-for-performance context. We will be consulting with our Expert Work Group on this over the coming years, and welcome additional input.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals



2904 Contraceptive Care - Access to LARC

Submission | Specifications

Description: Percentage of women aged 15-44 years at risk of unintended pregnancy that is provided a long-acting reversible method of contraception (i.e., implants, intrauterine devices or systems (IUD/IUS).

It is an access measure because it is intended to identify situations in which women do not have access to the long-acting reversible methods of contraception (LARC), i.e., contraceptive implants and intrauterine devices.

Numerator Statement: Women aged 15-44 years of age at risk of unintended pregnancy who were provided a long-acting reversible method of contraception (LARC), i.e., intrauterine device or implant.

Denominator Statement: All women aged 15-44 years of age who are at risk of unintended pregnancy.

Exclusions: The following categories of women are excluded from the denominator: (1) those who are infecund for non-contraceptive reasons; (2) women who had a live birth in the last 2 months of the measurement year; or (3) women were still pregnant or their pregnancy outcome was unknown at the end of the year.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Health Plan, Population : Regional, Population : State

Setting of Care:

Type of Measure: Structure

Data Source: Administrative claims

Measure Steward: US Office of Population Affairs

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Y-24; N-1; 1b. Performance Gap: H-18; M-7; L-0; I-0

Rationale:

- This new measure is a subset of measure #2903, but has a different goal: to assess access to LARC methods of contraception. This measure focuses on the percentage of women at risk for unintended pregnancy that are provided a long-acting reversible method of contraception (i.e., implants, intrauterine devices or systems (IUD/IUS)).
- The Committee agreed that the overarching issues surrounding the evidence were addressed in the discussion of NQF #2903: Contraceptive Care – Most & Moderately Effective Methods. However, the Committee requested that, in the future, the developer include more evidence for adolescent and around issues relating to side effects particular to LARCs, patients' fear of having IUD/IUS, and the noncontraceptive benefits of LARCs.
- The Committee agreed there were gaps in terms of unintended pregnancy rates among women of reproductive age and opportunities for improvement.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-8; M-1; L-0; I-0; 2b. Validity: M-17; L-6; I-1

Rationale:

- This measure is used to identify women who do not have access to LARCs.
- The Committee discussed the use of the population denominator versus the encounters as the denominator. The developer explained that the reason they chose population versus encounter was primarily because attribution could not be made to one encounter or one type of provider.
- The Committee noted that this measure provides a good metric for access, not necessarily quality, since there are many different factors that contribute to quality of care.



2904 Contraceptive Care - Access to LARC

3. Feasibility: H-20; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• The Committee noted that the data required are routinely generated and/or used during care delivery, therefore data collection is feasible. This measure does not represent an undue burden to collect and can be implemented without much administrative burden.

4. Usability and Use: H-12; M-11; L-2; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• The Committee noted the potential for coercive practices in which women are not offered a complete choice of methods and are pressured into using a LARC method. The developer stated that they do not think this will be a concern since the measure focus is on ensuring access to these methods by monitoring very low rates (well below the median) and the measure is not intended to be used for benchmarking.

5. Related and Competing Measures

• This measure directly relates to NQF #2902: Contraceptive Care – Postpartum and #2903: Contraceptive Care – Most & Moderately Effective Methods. These measures are from the same developer and harmonized.

Standing Committee Recommendation for Endorsement: Y-20; N-5

Rationale

• The Committee agreed that this measure is useable as a marker of access to LARC methods.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

- This measure received 24 comments. Almost all of the comments were supportive, and many raised similar concerns as with #2902 and #2903. Concerns were raised for this measure, including the fact that some insurers and health systems restrict access to LARC. One comment noted that IUDs and implants require different insertion skills and the measure should differentiate between them. Commenters both agreed and disagreed that this is a measure of access; one noted a concern that it may be misinterpreted and encourage providers to provide LARCs without appropriate counseling.
- One comment noted continuing concerns such a measure has the "potential to encourage coercion, which remains an ongoing reality for many, including low-income women, women of color, young women, immigrant women, LGBT people, and incarcerated women. We request that this measure be paired with a woman-reported "balancing measure" of experience of receiving contraceptive care. Such a measure can be expected to help identify and/or check inappropriate pressure from the health care system. We understand that OPA is developing such a measure and encourage its rapid completion and submission for endorsement. We recommend that proposed measure #2904 be held back until the measure of the experience of receiving contraceptive care is in place."

Developer Responses

- For purposes of simplicity and because we did not want to imply one LARC method was preferred over the other, we combined both methods into a single LARC measure. However, there may be benefits to looking at the methods separately in the future as the measure is used more widely, to ensure that women are being given a choice of both IUDs and implants. We will consult with the Expert Work Group that will be considering the measure over the coming years, and welcome additional input.
- research has shown that method effectiveness is important to many women and, as such, is one of many aspects of client centered care. For example, a recent study showed that nearly 90% of women reported



2904 Contraceptive Care - Access to LARC

that method effectiveness was an 'extremely important' characteristic (Jackson 2016).

- OPA is fully committed to doing everything it can to ensure that the performance measures are used in a manner that supports the delivery of client-centered care. As the measure steward, we will take every opportunity (e.g., on the steward's measure webpage, in presentations, in publications) to explain how the measures are intended to be used. Key messages will include: no specific benchmark has been set for the most/moderately effective method but OPA does not expect it to reach 100%; the interpretation of the LARC measure should be focused solely on identifying areas with extremely low levels of LARC provision and should not be used to encourage high rates of use; and it is not appropriate to use the LARC measure in a pay-for-performance context. We will also highlight the importance of following Federal recommendations, especially CDC-OPA's recommendations for how to provide quality family planning (QFP), for how to provide contraceptive care in a client-centered manner.
- We also agree with the reviewer's note of the need for a measure of client experience that will 'balance' the current measures focused on contraceptive provision. In fact, OPA recently awarded a 3-year cooperative agreement to the University of San Francisco to develop a patient-reported outcome performance measure (PRO-PM) for contraceptive care. The PRO-PM will focus on the client's experience with care and identify situations in which the woman's preference was not respected; it will serve to 'balance' the current measures that focus on what contraceptive methods were provided. A rigorous plan of testing and validation of the PRO-PM measure is planned, and we expect it will be ready for submission within 3 years. We look forward to learning more in the coming years about how to best use the two sets of measures in tandem so that women receive high quality, client-centered care.
- It seems to us that these barriers could exist in a health plan, and therefore could be addressed at a health plan level as well as at the population level. We agree that benchmarking for this measure should be voluntary; no specific benchmark has been set for the most/moderately effective method but OPA does not expect it to reach 100%; the interpretation of the LARC measure should be focused solely on identifying areas with extremely low levels of LARC provision and should not be used to encourage high rates of use; and it is not appropriate to use the LARC measure in a pay-for-performance context. We will be consulting with our Expert Work Group on this over the coming years, and welcome additional input.

Committee Response

• The Committee agreed that the measure developer is making concerted efforts to ensure that the measure not be used for coercion. They reiterated that the benchmark should absolutely not be 100%. The Committee strongly encouraged the developer to continue work on the patient-reported outcome measure of contraceptive care.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

Measures Where Consensus Is Not Yet Reached

1517 Prenatal & Postpartum Care (PPC)

Submission | Specifications

Description: The percentage of deliveries of live births between November 6 of the year prior to the measurement year and November 5 of the measurement year. For these women, the measure assesses the following facets of prenatal and postpartum care:

Rate 1: Timeliness of Prenatal Care. The percentage of deliveries that received a prenatal care visit as a member of the organization in the first trimester or within 42 days of enrollment in the organization.



1517 Prenatal & Postpartum Care (PPC)

Rate 2: Postpartum Care. The percentage of deliveries that had a postpartum visit on or between 21 and 56 days after delivery.

Numerator Statement: This measure assesses whether pregnant women had timely prenatal and postpartum care visits. It has two rates, one assessing the timeliness of prenatal visits, and one assessing the timeliness of postpartum visits.

Denominator Statement: The percentage of deliveries of live births between November 6 of the year prior to the measurement year and November 5 of the measurement year.

Exclusions: Non-live births

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Paper Medical Records

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-0; M-3; L-2; I-21; Evidence Exception: Y-16; N-10

1b. Performance Gap: H-7; M-15; L-1; I-2

Rationale:

- The Committee that previously evaluated this maintenance measure during noted that this measure only assesses visits but not the content of those visits. The current Committee agreed that ACOG guidelines recommend a schedule of prenatal visits based primarily on expert opinion. The Committee acknowledged that data does show that patients who have no prenatal care have worse outcomes.
- The current Committee noted that there was no evidence for the timing of visits; however, the Committee agreed that empirical evidence is not needed to hold providers accountable for the measure. Therefore, the measure moved forward on Insufficient Evidence with Exception.
- The measure contains two rates: timeliness of prenatal care and postpartum care. The Committee noted the low adherence to the measure and missing care for women, which highlights that there is room for improvement:
 - o Timeliness of prenatal care: (2015) 85% Commercial plans; 82% Medicaid plans
 - Postpartum care (2015): 73% Commercial plans; 62% Medicaid plans

2. Scientific Acceptability of Measure Properties: <u>Consensus was not reached on the Scientific Acceptability</u> <u>criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Previous Reliability Votes Accepted** 2b. Validity: **M-14; L-10; I-2** Rationale:

- The measures has two rates: one for timeliness of prenatal care and one for postpartum care. The developer has changed the specifications since the last NQF endorsement review. The use of infant claims to identify deliveries was removed and the developer clarified the tests that must be included to meet criteria for an obstetric panel in the medical record specification. These are as follows: hematocrit, differential WBC count, platelet count, hepatitis B surface antigen, rubella antibody, syphilis test, RBC antibody screen, Rh, and ABO blood typing.
- The Committee agreed the reliability of the measure was demonstrated, with the developer providing reliability testing at the measure score level. Reliability for commercial plans is 0.99 and for Medicaid



1517 Prenatal & Postpartum Care (PPC)

plans 0.92-0.95.

• The Committee expressed major concerns about validity, specifically the limited number of codes and lack of information about the content of the visits.

3. Feasibility: H-4; M-14; L-7; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c .Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The developer states that, "To allow for widespread reporting across health plans and healthcare practices, this measure is collected through multiple data sources (administrative data, electronic clinical data, paper records)."
- The Committee noted that collecting this measure using administrative claims was feasible and the burden of paper medical record review is considerable.

4. Usability and Use: H-2; M-14; L-8; I-2

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>

- The measure is actively used in programs for both health plan and state reporting.
- The Committee noted that early prenatal care is important for peri-partum depression screening, contraception, and life planning.
- The Committee agreed that this measure is problematic because it discourages earlier care and it is unclear whether quality is improving.

5. Related and Competing Measures

• Related measure NQF #1391: Frequency of Ongoing Prenatal Care (FPC) has been withdrawn.

Standing Committee Recommendation for Endorsement: Y-12; N-14 CONSENSUS NOT REACHED Rationale

 Overall, the Committee did not reach consensus on this measure. Despite the various problems raised with the measure, several Committee members were reluctant to remove endorsement until better measures are available.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

- The measure received 10 comments; 6 were in support, 3 did not support, and 1 did not specify. Many of the comments noted that the quality of the visits is not being assessed and urged NQF to "raise the bar"; comments suggested issues that should be addressed within the visits. Of the comments in support of the measure, urging the Committee to recommend it, commenters noted the importance of the measure in ensuring access to both prenatal and postpartum care, and "it doesn't matter how high the quality of care is if women do not access care early enough to benefit from it". Other comments suggested that holding health systems at least partially responsible for access to prenatal care is crucial, and that to not do so "contradicts national efforts to reduce maternal morbidity and mortality." Noting the lack of measures in this area, commenters urged the Committee to recommend this measure in the interim while improved measures are developed.
- Comments urging the Committee not to recommend the measure noted that the schedule of both prenatal and postpartum visits is based on expert opinion, not evidence, and the content and quality are not evaluated. Several commenters suggested new timeframes, and noted the need for earlier postpartum visits for breastfeeding support or caesarean section wound care as well as the difficulty of gathering this data via billing codes.



1517 Prenatal & Postpartum Care (PPC)

• Commenters also recommended splitting the measure into two separate measures, one on prenatal care and one on postpartum care.

Developer Responses

- We agree that measures addressing the content of perinatal care are needed. We hope to develop better perinatal measures in the future in order to complement this current access/availability of care measure, which we believe is still useful in the meantime.
- There is variation in recommendations for timing of postpartum visits. Organizations have typically recommended a visit 4-6 weeks post-delivery unless there are specific complications or risk factors. Our advisory panels recommended a 3-8-week timeframe as appropriate for capturing timely postpartum care without inadvertently counting visits for post C-section wound checks, which they concluded did not meet the intent of the measure. ACOG notes that a comprehensive postpartum visit should include a full assessment of physical, social and psychological well-being, with guidance given on issues such as contraception and postpartum concerns.
- The measure is currently reported as two rates: timeliness of prenatal care and postpartum care. Results for each rate can be viewed separately in order to understand a plan's performance on each.

Committee Response

- The Committee continues to have similar concerns as were discussed at the in-person meeting, including the timeframe, the fact the measure is based on expert consensus, not empirical evidence, and the emphasis on quantity, not content of visits. This was contrasted with the lack of measures in this area, the large gap in performance, the unlikelihood that RCTs will be conducted on this topic, and the fact that if patients are not receiving care, it is definitely poor quality.
- The Committee again requested splitting the measure into 2 separate measures. The prenatal care measure was not a concern.
- The Committee found the time range specified in the postpartum measure to be problematic as patients receiving postpartum care a few days on either side of the window are not receiving poor care. A two-week postpartum visit (14 days) also may be appropriate for some patients.
- Committee members report that improving the results for the postpartum measures is difficult even in the face of payment penalties.
- Despite extensive discussions, the Committee was unable to achieve consensus on their re-votes on either validity or an overall recommendation:
 - Validity: Mod 11 (52%); Low 7; Insufficient 3
 - Overall: Yes 10 (48%) No 12 (52%)
- measure will move forward as "consensus not reached" to NQF Member Vote. CSAC will make the final recommendation for or against endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

Measures Not Recommended

1391 Frequency of Ongoing Prenatal Care (FPC)

Submission

Description: The percentage of Medicaid deliveries that had the following number of expected prenatal visits: • less than 21 percent of expected visits.



1391 Frequency of Ongoing Prenatal Care (FPC)

• 21 percent-40 percent of expected visits.

• 41 percent–60 percent of expected visits.

• 61 percent-80 percent of expected visits.

• greater than or equal to 81 percent of expected visits.

Numerator Statement: Women who had the appropriate number of expected prenatal visits

Denominator Statement: The percentage of deliveries of live births between November 6 of the year prior to the measurement year and November 5 of the measurement year.

Exclusions: Exclude non-live births

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Paper Medical Records

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-1; M-1; L-9; I-15; 1b. Performance Gap: H-0; M-0; L-0; I-0

Rationale:

- The Committee that previously evaluated this maintenance measure noted that this measure only assesses the number of visits but not the content of those visits. The Committee agreed that ACOG guidelines recommend a schedule of prenatal visits that are based primarily on expert consensus. The prior Committee questioned the relationship of the visit groups defined in this measure to patient outcomes. The current Committee acknowledged that data does show that patients who have no prenatal care have worse outcomes.
- The current Committee noted the deficiency of the evidence, specifically the frequency of visits being based on expert consensus and not empiric evidence. The Committee noted that there is no empiric evidence in terms of the visit schedule or the number of visits being associated with improvement in outcomes for mothers and babies.
- This measure is considered a proxy for access to care; however, the measure does not assess the capacity of a plan to provide prenatal care. The measure reflects the challenges women face in accessing care, such as taking time off work, transportation, and childcare.
- The Committee noted that frequency does not equal quality and that this measure inhibits innovative strategies and new models of care.
- The measure did not pass the Evidence criterion.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) 2a. Reliability: H-0; M-0; L-0; I-0 2b. Validity: H-0; M-0; L-0; I-0

Rationale:

3. Feasibility: H-0; M-0; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) <u>Rationale</u>:



1391 Frequency of Ongoing Prenatal Care (FPC)

4. Usability and Use: H-0; M-0; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences) Rationale:

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5. Related and Competing Measures

• Related measure NQF #1517: Prenatal & Postpartum Care (PPC).

Standing Committee Recommendation for Endorsement: Y-0; N-0 DID NOT PASS IMPORTANCE Rationale

• The Committee did not recommend this measure because the number/frequency of visits was not demonstrated to equal quality or improve outcomes.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

This measure received 3 comments agreeing with the Committee's concerns and their decision not to
recommend the measure for endorsement. The measure did not pass Evidence (H-1; M-1; L-9; I-15).
Two commenters disagreed with the Committee's recommendation. One comment agreed there are
shortcomings with the measure, but noted that it is considered a basic measure of appropriate
maternity care and there are no alternatives to replace it; this commenter urged the development of an
improved measure as soon as possible. The final commenter raised concerns stating that the measure
has been the basis for successful public health programs since the 1930s, and noting that gaps in care
remain. In addition, the commenter stated, the loss of the measure could "lead to further disregard of
PNC utilization in US healthcare plans, diminished primary and preventive care for women during
pregnancy, and exacerbate reproductive health and health care inequity in the US." This commenter
also suggested simplifications to improve the measure.

Developer Response

• NCQA has withdrawn the Frequency of Prenatal Care (#1391) measure from consideration for reendorsement.

NQF Response

• This measure has been withdrawn from consideration. Endorsement will be removed.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2892 Birthrisk Cesarean Birth Measure

Submission

Description: This is a measure of the effect that obstetrical care provider's labor management strategies have on their laboring patient's risk for cesarean birth. The target population is limited to women who attempt labor with a singleton vertex pregnancy without a history of a prior cesarean birth and give birth between 37 and 42 weeks of gestation.

Numerator Statement: Number of cesarean births.

Denominator Statement: Women without a history of a prior cesarean birth who attempted labor and gave birth



2892 Birthrisk Cesarean Birth Measure

to a single baby in vertex presentation between 37 and 42 weeks of gestation.

Exclusions: The denominator excludes women with any of the following:

- 1. Gestational age at birth of less than 37 weeks or greater than 42 weeks.
- 2. History of a prior cesarean birth.
- 3. Multiple gestation.
- 4. Not in vertex presentation.
- 5. Did not attempt to have a vaginal birth by attempting labor.

Adjustment/Stratification: Cohort comparison

Level of Analysis: Facility, Clinician : Individual

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Other

Measure Steward: Birthrisk.com, LLC.

STANDING COMMITTEE MEETING [May/03/2016]

1. Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Y-26; N-1; 1b. Performance Gap: H-2; M-7; L-13; I-5

Rationale:

- This new measure uses a novel approach to measuring Cesarean birth rates (as opposed to the currently endorsed measure, #0470) as this measure includes all mothers undergoing labor and is not limited to first time mothers.
- The Committee had no reference data to evaluate the results calculated by the developer, which was completed using birth certificate data from New York State in 2005-2007. This hospital and clinician-level measure also uses a fee-based, proprietary method of risk adjustment using cohort comparisons.
- The data presented was from 2005-2007 now 10 years old.
- The developer notes that efforts to have the method published have not been successful.
- The measure did not pass Performance Gap.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-0; M-0; L-0; I-0 2b. Validity: H-0; M-0; L-0; I-0

Rationale:

3. Feasibility: H-0; M-0; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

•

4. Usability and Use: H-0; M-0; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences) Rationale:

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2892 Birthrisk Cesarean Birth Measure

5. Related and Competing Measures

Standing Committee Recommendation for Endorsement: DID NOT PASS IMPORTANCE Rationale

• The Committee did not recommend this proprietary measure in which the only data presented was a decade old.

6. Public and Member Comment: June 7 – July 6, 2016

Comments Received

• This measure received 2 comments supporting the Committee's recommendation not to endorse.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2893 Neonatal Intensive Care All-Condition Readmissions

Submission

Description: The NICU Readmissions metric assess the hospital- or state-level readmission rate at 30 days after a stay in the Neonatal Intensive Care Unit.

Numerator Statement: Number of infants with a gestational age between 23-34 weeks who were readmitted to the hospital within 30 days of discharge. These time periods are assessed cumulatively, such that readmissions occurring within prior time periods are included. Reliability is strongest if each health care unit has at least 50 discharges per time unit studied.

Denominator Statement: Number of newborns with a gestational age between 23-34 weeks discharged from the NICU, based on gestational age field contained in the birth certificate record (best obstetrical estimate).

Exclusions: Infants with a specified congenital anomaly are excluded from the target population.

Infants with a missing gestational age are excluded from the primary analysis. Information about multiple imputation methods to allow for their inclusion are presented in the testing attachment, section 2b7.

Infants who expired during the neonatal intensive care period are not eligible for a hospital readmission and excluded.

The smallest level of measurement (i.e. hospital, state, etc.) must have a minimum of 50 patients eligible for readmission in a single calendar year.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility, Population : State

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data : Electronic Health Record, Other

Measure Steward: The Children's Hospital of Philadelphia

STANDING COMMITTEE MEETING [05/03/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Y-26; N-1; 1b. Performance Gap: H-14; M-11; L-1; I-0

Rationale:



2893 Neonatal Intensive Care All-Condition Readmissions

- The Committee agreed that transitions of care are important; that discharge planning and outpatient care coordination can influence the outcome; and there is significant variation in care.
- There are racial/ethnic disparities, particularly for African Americans.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-1; M-7; L-17; I-2 2b. Validity: H-0; M-0; L-0; I-0

Rationale:

- The Committee noted that there are numerous readmission measures for adults and children, however, newborns may be cared for in 2 types of NICUs: a maternity/birth hospital that does not readmit neonates and a general acute care facility that does readmit neonates (though the infants are typically readmitted to the general pediatrics floor rather than the NICU).
- This measure is specified for facilities/hospitals, and not all of these may be able to track readmissions to other facilities. Though health information exchanges may improve the ability to capture and share data in the future, the Committee noted that insurers, managed care organizations and Medicaid may be better able to track readmissions across facilities than the facilities themselves.
- The measure relies on hospital data linked to vital statistics, which may not be available in all locations. The Committee was concerned that the measure does not account for planned readmissions or planned transfers and does not differentiate between a hospitalization and an observation stay since both are included as readmissions.
- The developer indicated that "accurate implementation of this metric will require new data collection linkage with birth certificates or more widespread and standardized use of the EHR for publicly reported measures."
- The measure did not pass Reliability.

3. Feasibility: H-0; M-0; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

•

4. Usability and Use: H-0; M-0; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: DID NOT PASS RELIABILITY

Rationale

• The Committee did not recommend the measure because of the questions around reliability of data capture and recommends further development of this important measure. The Committee also suggested including larger babies, that may not have been in the NICU, but who experience a significant number of readmissions.

6. Public and Member Comment: June 7 – July 6, 2016

• This measure received one comment supporting the measure, but it did not provide any further data in support of the measure.



2893 Neonatal Intensive Care All-Condition Readmissions

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2895 Thermal Condition of Low Birthweight Neonates Admitted to Level 2 or Higher Nurseries in the First 24 Hours of Life: A PQMP Measure

Submission

Description: This measure describes in terms of admission temperature the status of live-born neonates less than 2,500 grams that are admitted to a Level 2 or higher nursery.

This measure reports on the temperature at admission. Temperatures are reported both in categorical terms and as a distribution. The distribution should be presented as a cumulative incidence curve with a chart to present key moments in the distribution. The categorization data may be presented in chart or graphical form, such as a pie chart, with parents. Each admission is categorized into one of five strata on the basis of their admission temperature. The strata, which were defined by our expert panel, are cold (<34.5), very cool (34.51-35.50), cool (35.51-36.50), about right (36.51-37.50) and overly warm (>37.5). All temperatures are analyzed using degrees Celsius and reported to one decimal place. The FIRST temperature taken in the nursery is to be recorded and used.

To avoid the potential for gaming the measure by delaying a recorded temperature after arrival, the results are stratified in three ways:

- Main Stratum: Time between arrival at Level 2 or higher nursery is between 0 and 15 minutes.

- Delayed stratum: Time between arrival at Level 2 or higher nursery is more than 15 minutes.

- Other: Inadequate documentation to determine timing of temperature

Numerator Statement: The metric of interest is the temperature upon arrival to the Level 2 or higher nursery that is being assessed. This measure does not have the form of numerator and denominator. It is a distribution. We ask for reporting of the distribution in terms of five categories across the distribution, in terms of key moments in the distribution, and as a graphical presentation of the distribution. This is an information rich measure. Accountability entities may choose to use any of various components for their emphasis (alone or in combination), including percent "about right," mean or median temperatures, or value of the 10th or 25th percentiles, and the inter-percentile range.

There is an eligible population of newborns, which could be considered the denominator.

In lieu of a numerator, this measure reports the distribution of temperatures, using both numbers and a graph. In order to allow for reporting of key factors of interest to the accountability entity, this measure is specified to report that distribution in a variety of ways. This measure offers users (the accountability entity) the option to focus on one or more key substantive aspects of thermal outcomes in the defined population.

Data Elements:

-- Temperature to first decimal place

-- Units of temperature (Celsius, Fahrenheit). Those measured in Fahrenheit should be converted to Celsius. Celsius=(Fahrenheit less 32) times 5 divided by 9.

-- Time that temperature was measured

-- Time of arrival to the nursery (not time that admission was done)

State and County of residence OR zip code of mother

-- Optional: Method of temperature measurement (axillary, rectal, skin, tympanic)

Denominator Statement: All newborn infants born in a medical facility with birthweights less than 2,500 grams



2895 Thermal Condition of Low Birthweight Neonates Admitted to Level 2 or Higher Nurseries in the First 24 Hours of Life: A PQMP Measure

and admitted to a level 2 or higher nursery within 24 hours of life, other than those excluded.

Exclusions: Neonates with an encephaly, who receive only comfort care in the Level 2 or higher nursery, or those who die or are placed intentionally on a pre-existing hypothermia protocol prior to the 15 minute after arrival specification time.

Adjustment/Stratification: Stratification by risk category/subgroup

Level of Analysis: Population : Community, Population : County or City, Facility, Health Plan, Integrated Delivery System, Population : Regional, Population : State

Setting of Care: Hospital/Acute Care Facility, Other

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data : Electronic Health Record, Other, Paper Medical Records

Measure Steward: University Hospitals Cleveland Medical Center

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: Y-25; N-0; 1b. Performance Gap: H-14; M-10; L-2; I-0

Rationale:

- This new, intermediate outcome measure for newborn temperature management reports the distribution of temperatures on arrival to the NICU for babies weighing less than 2,500 grams.
- Strong evidence has shown that low birthweight babies who are allowed to lose body heat are at increased risk for morbidity and mortality.
- Data from the test population in New York provided by the developer demonstrated variation in performance.

2. Scientific Acceptability of Measure Properties: <u>The measure did not reach consensus for the Scientific</u> <u>Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: M-13; L-8; I-4 2b. Validity: H-3; M-8; L-4; I-10

Rationale:

- The Committee did not reach consensus on the reliability and validity of the measure due to multiple concerns:
 - the temperature strata were determined by expert consensus rather than empirical evidence;
 - difficulty in interpreting the measure results that are intended to be displayed as a distribution in a table and cumulative distribution curve rather than a single numerical result;
 - o the validity testing was performed on a variant of the measure; and
 - o confusion as to how to interpret the measure results for accountability purposes.

3. Feasibility: H-3; M-15; L-5; I-2

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

• The Committee agreed that temperature data are readily collected in the medical record, however, extracting that data would be challenging for this measure. The developer reported that they are creating a web portal to submit data.



2895 Thermal Condition of Low Birthweight Neonates Admitted to Level 2 or Higher Nurseries in the First 24 Hours of Life: A PQMP Measure

4. Usability and Use: H-2; M-13; L-9; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

• Committee members were not clear as to how a distribution result recommended by the developer could be used for making comparisons and accountability.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-7; N-18 Rationale

• The Committee agreed that neonatal temperature management is an important topic but did not recommend this measure, as constructed, for endorsement.

6. Public and Member Comment: June 7 – July 6, 2016

• This measure received 1 comment supporting the Committee's decision not to recommend the measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2896 Structural Attributes of Facility in which High Risk Women Deliver Newborns: A PQMP Measure

Submission

Description: This measure characterizes the facility that is the site of delivery of newborn infants born to high risk women by four key structural characteristics. These four characteristics were identified as critical structures by a national expert panel who served CAPQuaM's 360 degree process for measure development. This work was undertaken in the context of developing innovative measures of the availability of High Risk Obstetrical (HROB) care as assigned by AHRQ and CMS.

The four key structures are:

(a) Level 3 or higher NICU services on campus. Level 3 NICU is defined as meeting either the American Academy of Pediatrics (AAP) criteria or a locally used set of explicit criteria recognized by that state's Department of Health.

(b) 24/7 on-site blood banking services/transfusion services that are always available for obstetrical patients. By 24/7 blood banking/transfusion services we mean that the following are always available to obstetrical patients: testing of blood group and Rh Type; cross matching; antibody testing; transfusion with on-site and available blood, either ABO specified or O-Rh-negative; transfusion with fresh frozen plasma; and transfusion with cryoprecipitate.

(c) 24/7 in - house physician dedicated to labor and delivery who is capable of safely managing labor and delivery, and of performing a cesarean section, including an emergent cesarean section.

(d) 24/7 in - house physician coverage dedicated to the obstetrical service by an anesthesiologist who is qualified to provide obstetrical anesthesia.

Numerator Statement: Number of eligible newborn deliveries that occur in facilities with:

(a) Level 3 or higher NICU services on campus. Level 3 NICU is defined as meeting either the American Academy of Pediatrics (AAP) criteria or a locally used set of explicit criteria recognized by that state's Department of Health.



2896 Structural Attributes of Facility in which High Risk Women Deliver Newborns: A PQMP Measure

(b) 24/7 on-site blood banking services/transfusion services that are always available for obstetrical patients. By 24/7 blood banking/transfusion services we mean that the following are always available to obstetrical patients: testing of blood group and Rh Type; cross matching; antibody testing; transfusion with on-site and available blood, either ABO specified or O-Rh-negative; transfusion with fresh frozen plasma; and transfusion with cryoprecipitate.

(c) 24/7 in - house physician dedicated to labor and delivery who is capable of safely managing labor and delivery, and of performing a cesarean section, including an emergent cesarean section.

(d) 24/7 in - house physician coverage dedicated to the obstetrical service by an anesthesiologist who is qualified to provide obstetrical anesthesia.

Measure: Meets all four criteria.

Stratifications:

- a. Meets none
- b. Includes a
- c. Includes b
- d. includes c
- e. includes d
- Numerator Elements:

Number of eligible deliveries

Maternal and infant ICD-9 codes

Response to survey question identified on technical specifications or Other valid self-report of structural characteristics as specified

No Numerator Exclusions

Denominator Statement: Overall number of newborn deliveries in health care facilities that are born to women whose pregnancy meets the criteria for high risk. While qualification for the denominator requires that the birth occur in a health care facility this measure is not specified to assess performance of individual facilities.

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Population : Community, Population : County or City, Health Plan, Integrated Delivery System, Population : National, Population : Regional, Population : State

Setting of Care: Hospital/Acute Care Facility, Other

Type of Measure: Composite

Data Source: Administrative claims, Healthcare Provider Survey

Measure Steward: University Hospitals Cleveland Medical Center

STANDING COMMITTEE MEETING [05/02/2016]

1. Importance to Measure and Report: The measure did not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-1; M-6; L-3; I-15; 1b. Performance Gap: H-0; M-0; L-0; I-0; Evidence Exception: Y-11; N-14 <u>Rationale</u>:

- This new composite measure includes 4 structural components of care delivery for high-risk mothers.
- The Committee did not agree that this is a measure of quality or accountability for providers. The Committee noted that the information may be important as a designation of care provision.
- The evidence provided for the 4 components is expert opinion, not empirical evidence.
- The developers stated that this is a "population measure de-linked from individual patient care" and "the measure does not make a distinction between good care and bad care."



2896 Structural Attributes of Facility in which High Risk Women Deliver Newborns: A PQMP Measure

- The Committee noted that the measure includes mothers with birth complications that are mostly unpredictable and care cannot be redirected to a different facility after birth.
- No measure results for any plans/systems were presented by the developer. The Committee agreed that directing high-risk mothers and high-risk babies to the facilities most capable of caring for them may impact outcomes but this measure needs further development to become an accountability measure.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-0; M-0; L-0; I-0; 2b. Validity: H-0; M-0; L-0; I-0

Rationale: •

3. Feasibility: H-0; M-0; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

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4. Usability and Use: H-0; M-0; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale: ٠

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: DID NOT PASS IMPORTANCE **Rationale**

• The Committee agreed that directing high-risk mothers and high-risk babies to the facilities most capable of caring for them may impact outcomes, but this measure needs further development to become an accountability measure.

6. Public and Member Comment: June 7 - July 6, 2016

• This measure received 1 comment supporting the Committee's decision not to recommend the measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals