NQF #0743 In-hospital Maternal Deaths

National Quality Forum

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF’s measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

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**BRIEF MEASURE INFORMATION**

De.1 Measure Title: In-hospital Maternal Deaths

Co.1.1 Measure Steward: Beth Israel Deaconess Medical Center

De.2 Brief Description of Measure: All pregnant women who die during the same hospital admission as their delivery

2a1.1 Numerator Statement: All women who fit the description

2a1.4 Denominator Statement: All pregnant women who deliver during the specified timeframe

2a1.8 Denominator Exclusions: None

1.1 Measure Type: Outcome

2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record

2a1.33 Level of Analysis: Clinician: Team, Facility

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed): Adverse Outcome Index, Weighted Adverse Outcome Score, Severity Index

**STAFF NOTES (issues or questions regarding any criteria)**

Comments on Conditions for Consideration:

Is the measure untested? Yes □ No □ If untested, explain how it meets criteria for consideration for time-limited endorsement:

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5):

5. Similar/related endorsed or submitted measures (check 5.1):

Other Criteria:

Staff Reviewer Name(s):

**1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT**

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.

1a. High Impact: □ H □ M □ L □ I □

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)
De.4 Subject/Topic Areas (Check all the areas that apply): Perinatal
De.5 Cross Cutting Areas (Check all the areas that apply): Care Coordination, Population Health, Safety : Complications

1a.1 Demonstrated High Impact Aspect of Healthcare: Severity of illness, Patient/societal consequences of poor quality, Other

1a.2 If “Other,” please describe: Addresses NPP Goals of Population Health and Safety

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):
Hospitalization for a delivery is one of the most frequent reasons for hospital admissions. A preventable maternal death is the most adverse outcome that can occur during delivery and has an enormous impact on the family and society. The maternal death rate is relatively low (~0.7/10,000 live births), but the impact is high.

1a.4 Citations for Evidence of High Impact cited in 1a.3: ACOG Quality and Safety in Women’s Health Care, Second Edition 2010

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
It has been estimated that up to 50% of maternal deaths are preventable. Further, specific patient safety interventions have been shown to decrease maternal morbidity. Using this measure can help assess the impact of patient safety and quality improvement measures.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):
[For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]
Maternal death is a rare but devastating outcome. It negatively impacts the mother, and the rest of the family and social structure. A large percent of these deaths are associated with sub-standard care and are thus preventable. Measurement of the maternal mortality rate can help assess the impact of quality improvement efforts in obstetrics.

1b.3 Citations for Data on Performance Gap: [For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]


1b.4 Summary of Data on Disparities by Population Group: [For Maintenance – Descriptive statistics for performance results for this measure by population group]
Racial differences in maternal mortality clearly exist. The extent to which they are due to differences in underlying medical conditions is not completely understood.

1b.5 Citations for Data on Disparities Cited in 1b.4: [For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities]
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1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.)

Is the measure focus a health outcome? Yes □ No □

If not a health outcome, rate the body of evidence.


Does the measure pass subcriterion 1c?

M-H □ M-H □ M-H □ Yes □


L □ M-H □ M-H □ M □ Yes □


M-H □ L □ M-H □ Yes □


L-M-H □ L-M-H □ L □ No □

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion 1c?

Yes □

1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process-health outcome; intermediate clinical outcome-health outcome):

Health Outcome; process-health outcome

1c.2-3 Type of Evidence (Check all that apply):

Other, Selected individual studies (rather than entire body of evidence), Systematic review of body of evidence (other than within guideline development)

This measure is one of 10 adverse events that make up the Adverse Outcome Index (AOI). There are at least 10 studies that have used this composite as the primary outcome measure since its introduction in 2006. It has also, been used in numerous QI initiatives at the hospital level, system level and in state-wide collaboratives and was recently identified by the ACOG publication “Quality and Safety in Women’s Health Care” 2nd edition, 2010 as one of several quality monitoring tools currently available. We will site reports/articles from these initiatives.

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

As stated above, poor care is identified in approximately 50% of maternal deaths. Most of these data come from observational studies, and thus it is not clear whether poor care causes these deaths, or simply fails to prevent them.

It is clear that improvements in the use of thromboprophylaxis decreases maternal death after cesarean delivery and better response to maternal hemorrhage also appears to decrease death.

Maternal death is a major component of the Adverse Outcomes Index (AOI). The references below all used the AOI as a main outcome measure in a research setting:


OBJECTIVE: To evaluate the effect of teamwork training on the occurrence of adverse outcomes and process of care in labor and delivery.

METHODS: A cluster-randomized controlled trial was conducted at seven intervention and eight control hospitals. The intervention was a standardized teamwork training curriculum based on crew resource management that emphasized communication and team
structure. The primary outcome was the proportion of deliveries at 20 weeks or more of gestation in which one or more adverse maternal or neonatal outcomes or both occurred (Adverse Outcome Index). Additional outcomes included 11 clinical process measures.

RESULTS: A total of 1,307 personnel were trained and 28,536 deliveries analyzed. At baseline, there were no differences in demographic or delivery characteristics between the groups. The mean Adverse Outcome Index prevalence was similar in the control and intervention groups, both at baseline and after implementation of teamwork training (9.4% versus 9.0% and 7.2% versus 8.3%, respectively). The intracluster correlation coefficient was 0.015, with a resultant wide confidence interval for the difference in mean Adverse Outcome Index between groups (−5.6% to 3.2%). One process measure, the time from the decision to perform an immediate cesarean delivery to the incision, differed significantly after team training (33.3 minutes versus 21.2 minutes, P=.03).

CONCLUSION: Training, as was conducted and implemented, did not transfer to a detectable impact in this study. The Adverse Outcome Index could be an important tool for comparing obstetric outcomes within and between institutions to help guide quality improvement.


The original randomized control study conducted by the Department of Defense (DoD) and Beth Israel Deaconess Medical Center (BIDMC) was an analysis of the impact of team training on adverse events occurring in L&D. The Adverse Outcome Index was developed by an expert panel including representatives from each participating hospital, ACOG, ASOAP, AF Institute of Pathology, US Navy BUMED, Office of Surgeon General and TRICARE. The expert panel identified the 10 adverse events and work with the ACOG Quality Committee to assign the weights. All of the original 10 events and assigned weights are included in the current AOI.


The authors, clinicians at Yale New Haven Hospital (YNHH) and their malpractice carrier, MCIC Vermont INC created a partnership from 2004-2006 to review and improve their patient safety climate. There were multiple interventions that included: review from outside experts, protocol standardization, implementing a patient safety nurse and patient safety committee, team training, and fetal heart monitoring training. The use of the AOI was used to track specific obstetrical adverse outcomes; the events were compiled on a monthly basis. YNHH was able to see a significant decrease in their AOI rate.

Other studies:


1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): A PubMed search of “English[Language] AND maternal mortality NOT infant” identified 254 clinical trials

In addition, maternal death is a major component of the Adverse Outcomes Index (AOI). The AOI has been used in collaboratives in Maryland, Greater NY Hospital Association, North Bronx Healthcare Network, North Shore-LIJ Health System, a network of Premier hospitals and at many individual hospitals across the US. The AOI has been cited in at least 40 references

1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): Maternal death is a major component of the Adverse Outcomes Index (AOI).

The original DoD/BIDMC study relied on abstracted data and included a Baseline period of two months before team training (intervention) and 5 months post team training. The study found a significant change in only one process measure and while there was a decline in the AOI from the Baseline to Follow-up period, the change was not significant. The study concluded that the time frame to assess the true impact of team training may have been too brief; current experience with the AOI has shown that there is generally a 6-9 month period required to realize the full impact of team training and movement in the AOI. Using administrative data to calculate the AOI, allows hospitals to look at a longer baseline period (1-2 years) and begin follow-up monitoring when the entire team is fully trained and continue monitoring indefinitely.

The references cited above indicate that the AOI consistently tracks with quality improvement efforts across a broad range of practice environments.

In subsequent use of AOI in conjunction with QI/team training initiatives, the evidence for the measure to stimulate improved communication and teamwork, measure outcomes before and after an intervention and demonstrate reduction in adverse events has been strong.


   In 2007, Wyoming Medical Center in partnership with Marsh adopted three quality improvement tools: AOI, WAOS, and the SI. The obstetrical data collected is used for benchmarking purposes within the hospital and the hospital’s Captive (17 other western hospitals insured by Marsh). The average score for the first two quarters of 2007 were: AOI- 5.7%, WAOS- 0.62, and SI-11. They were compared to the benchmark scores: AOI- 9.2%, WAOS- 3.0, and SI- 25, and against the captive hospital scores.

CM Pettker, MD "Clinical: Patient Safety in Obstetrics." MedPedia : Safety can be tested by outcome measures by tracking events and comparing them to evidence-based practices. Some adverse outcomes have been suggested for tracking, which include: maternal death, fetal/neonatal death, fetal injury/trauma, cord pH<700, shoulder dystocia, and hysterectomy. The most common outcome measure is the adverse outcome index.... Pettker noted that a safety effort with a majority of the above elements showed a decrease in adverse events on an OB unit. The mean quarterly AOI decreased by 40-60%, and the change in quarterly AOI showed a significant decrease over time.

measure that is attractive due to its ability to collect a wide range of obstetric outcomes. However, it requires widespread data collection, which may be difficult for some organizations to implement. The AOI’s scoring system may favor cesarean deliveries, driving up C-section rates. The nulliparous C-section rate is a compelling quality measure, but it does not take into account complications or outcomes. The only way to improve obstetrical quality is to measure it, and then work at refining the measures.

Pettiker MD, Christian M., and Edmund F. Funai MD. “Managing Obstetric Risk: Is Your Labor and Delivery Team Ready?” Modern Medicine. 1 Feb. 2011. The authors, physicians and professors at Yale University School of Medicine and Yale-New haven Hospital, reported that insufficient communication between providers and patients was the main cause of 60-70% of investigated sentinel events in all areas of medicine, and for obstetrics that percent was even higher at 72%. 55% of cases studied had a culture that prevented effective teamwork and communication.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Maternal death is the most severe adverse event that can occur during parturition. A large percent of these deaths are preventable by improvement in the quality or safety of the medical care.

Use of the AOI has shown remarkable consistency with most facilities improving between Baseline and Follow-up. Beginning performance often shows notable variation and often the hospitals with the highest Baseline AOI will improve the most. Hospitals without strong leadership or experience a change in leadership often have difficulty moving their rates. A number of hospitals will usually improve their rates by improving the accuracy of their coding or through changes in practice patterns (NICU admits). The studies/articles published using the AOI as a measure of quality have consistently demonstrated that the AOI is responsive to quality improvement efforts, and tracks with other quality measures.

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):
In the United States, the Maternal Mortality rate is approximately 0.7 deaths per 10,000 live births. A 50% reduction in the preventable deaths (~50 of all deaths) would decrease this to 0.6 deaths per 10,000 live births, or a total reduction of 80 maternal deaths per year.

Maternal death is a major component of the Adverse Outcomes Index (AOI). Reducing the frequency of any of the adverse events is a net benefit and improvement in quality. Hospitals with high AOI rates due to documentation and/or coding issues rather than quality issues have the opportunity to easily correct their administrative data to more accurately reflect the quality of their care—a potential benefit to the hospital under review. If the frequency of adverse events is too high, it will guide the hospital to focus their resources and process improvement activities on those events that are the most serious and/or have the highest volume. Measurement of the AOI over time demonstrates the impact of those improvements and comparison to an external comparative benchmark allows the hospital to see their improvement relative to the benchmark.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: Consensus panels were developed for the identification of measures to be included in the composite measure (AOI). This included vetting each of the individual measures. Peter E. Nielsen, MD; Marlene B. Goldman, ScD; Susan Mann, MD; David E. Shapiro, Ph.D.; Ronald G. Marcus, MB,BCh.; Stephen D. Pratt,MD; Penny Greenberg, RN; Munish Gupta, MD; Patricia McNamee, RN, MS; Mary Salisbury, RN, MSN; David J. Birnbach, MD; Paul A. Gluck, MD; Mark D. Pearlman, MD; Heidi King, MS; David N.Tornburg, MD, MPH; Benjamin P. Sachs, MB, BS.; Lauren BAles, MD; Naval Medical Center Camp Pendleton; Ronald Burkman, MD, Baystate Medical Center; Cynthia Brumfield,MD University of Alabama at Birmingham; Peter Cherouny, MD, University of Vermont- Fletcher Allen Health Care; Jack Cooley, MD, National Naval Medical Center; Harold Fox, MD, Johns Hopkins Medical Center; Elizabeth Golladay, MD, Tripler Army Medical Center; Lynn Leventis, MD, Naval Medical Center San Diego; Robert Lorenz, MD, William Beaumont Hospital; William Lucky, MD, Baptist Hospital of Miami; Patrick Nugent, MD, South Shore Hospital; Spike Lipschitz, MD, South Shore Hospital; Chris
Stolle, MD, Naval Medical Center of Portsmouth; Cosmas van DeVen, MD, University of Michigan Medical Center; Frank Witter, MD, Johns Hopkins Medical Center, Eileen Hemman, EdD. and Tom Bennedetti, MD, Suznne Walker, RN, MPH and Thomas Strandjord, MD from the University of Washington. In addition, representatives from the American Congress of Obstetrics and Gynecology, the American Society for Obstetric Anesthesia and Perinatology, the American Society of Anesthesiologists, the Association of Women’s Health, Obstetric and Neonatal Nurses, the Armed Forces Institute of Pathology, the U.S. Navy Bureau of Medicine and Surgery, the Office of the Surgeon General, U.S. Army and TRICARE were present.

1c.13 Grade Assigned to the Body of Evidence: No prospective, randomized trial has demonstrated that changes in healthcare services improve maternal mortality rates. However, many large cohort studies have demonstrated that improvements in the quality of care decrease maternal morbidity and Skupski demonstrated a decrease in maternal mortality after the implementation of a maternal hemorrhage protocol.

1c.14 Summary of Controversy/Contradictory Evidence: There is no controversy that maternal death is a catastrophic and largely preventable complication. The degree of preventability varies for 25 to > 50%.

1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):


1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):
No specific guideline exist for the prevention of maternal death. However, guidelines for the management or prevention of cases of maternal death (thromboprophylaxis, Hemorrhage) do exists


1c.18 National Guideline Clearinghouse or other URL:

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: Expert panel from original study and current workgroup
Consensus panels were developed for the identification of measures to be included in the composite measure (AOI). This included vetting each of the individual measures.

Peter E. Nielsen, MD; Marlene B. Goldman, ScD; Susan Mann, MD; David E. Shapiro, Ph.D.; Ronald G. Marcus, MB,BCh.; Stephen D. Pratt, MD; Penny Greenberg, RN; Munish Gupta, MD; Patricia McNamee, RN, MS; Mary Salisbury, RN, MSN; David J. Birnbach, MD; Paul A. Gluck, MD; Mark D. Pearlman, MD; Heidi King, MS; David N. Tornburg, MD, MPH; Benjamin P. Sachs, MB, BS.; Lauren Bales, MD; Naval Medical Center Camp Pendleton; Ronald Burkman, MD, Baystate Medical Center; Cynthia Brumfield, MD University of Alabama at Birmingham; Peter Cherouny, MD, Univesity of Vermont- Fletcher Allen Health Care; Jack Cooley, MD, National Naval Medical Center; Harold Fox, MD, Johns Hopkins Medical Center; Elizabeth Golladay MD, Tripler Army Medical Center; Lynn Leventis, MD, Naval Medical Center San Diego; Robert Lorenz, MD, William Beaumont Hospital; William Lucky, MD, Baptist Hospital of Miami; Patrick Nugent, MD, South Shore Hospital; Spike Lipschitz, MD, South Shore Hospital; Chris Stolle, MD, Naval Medical Center of Portsmouth; Cosmas van DeVen, MD, University of Michigan Medical Center; Frank Witter, MD, Johns Hopkins Medical Center, Eileen Hemman, EdD. and Tom Bennedetti, MD, Suznne Walker, RN, MPH and Thomas Strandjord, MD from the University of Washington. In addition, representatives from the American Congress of Obstetrics and Gynecology, the American Society for Obstetric Anesthesia and Perinatology, the American Society of Anesthesiologists, the Association of Women’s Health, Obstetric and Neonatal Nurses, the Armed Forces Institute of Pathology, the U.S. Navy Bureau of Medicine and Surgery, the Office of the Surgeon General, U.S. Army and TRICARE were present.

National Perinatal Information Center, Providence Rhode Island assisted with translating the AOI into administrative data specifications.

1c.23 Grade Assigned to the Recommendation:
1c.24 Rationale for Using this Guideline Over Others:

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: High 1c.26 Quality: Moderate 1c.27 Consistency: Moderate

Was the threshold criterion, Importance to Measure and Report, met? (1a & 1b must be rated moderate or high and 1c yes) Yes No

Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: www.npic.org Sample AOI Report

2a. RELIABILITY. Precise Specifications and Reliability Testing: H□ M□ L□ I□

2a1. Precise Measure Specifications. (The measure specifications precise and unambiguous.)

2a1.1 Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome):
All women who fit the description

2a1.2 **Numerator Time Window** *(The time period in which the target process, condition, event, or outcome is eligible for inclusion):*
During the delivery admission/discharge

2a1.3 **Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses:)*
DRG 370-375 or MS DRG 765-768 and 774-775 and discharge disposition = died

2a1.4 **Denominator Statement** *(Brief, narrative description of the target population being measured):*
All pregnant women who deliver during the specified timeframe

2a1.5 **Target Population Category** *(Check all the populations for which the measure is specified and tested if any):* Maternal Care

2a1.6 **Denominator Time Window** *(The time period in which cases are eligible for inclusion):*
During the delivery admission/discharge

2a1.7 **Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):*
DRG 370-375 or MS DRG 765-768 and 774-775

2a1.8 **Denominator Exclusions** *(Brief narrative description of exclusions from the target population):*
None

2a1.9 **Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):*
None

2a1.10 **Stratification Details/Variables** *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses ):*
N/A

2a1.11 **Risk Adjustment Type** *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13):* No risk adjustment or risk stratification  2a1.12 If "Other," please describe:

2a1.13 **Statistical Risk Model and Variables** *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):*
n/a

2a1.14-16 **Detailed Risk Model Available at Web page URL** *(or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. **Type of Score:** Rate/proportion

2a1.19 **Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score):* Better quality = Lower score

2a1.20 **Calculation Algorithm/Measure Logic** *(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating...*
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data; risk adjustment; etc.):
1) Identify all women who delivered during the specified time frame
2) Identify their discharge disposition
3) If expired, they are in the numerator

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
Attachment
AOI_V2.2-634564526842497333.docx

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
n/a

2a1.25 Data Source (Check all the sources for which the measure is specified and tested). If other, please describe:
Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

2a1.26 Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): Administrative data, UB 04

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
www.npic.org

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
www.npic.org   Sample AOI Report

2a1.33 Level of Analysis (Check the levels of analysis for which the measure is specified and tested):   Clinician : Team, Facility

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested):   Hospital/Acute Care Facility

2a2. Reliability Testing. (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)

2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
Administrative data for Beth Israel Deaconess Medical Center for the period Q 3, 2005- Q2 2006 was reconciled with abstracted data for the same period. In addition, all maternal deaths from a cohort of eight hospitals that contract with NPIC and had validated data over a three year period were reviewed.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):
Case by case review.

2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):
All maternal deaths identified through manual abstraction of data were present on the administrative data set.

2b. VALIDITY. Validity, Testing, including all Threats to Validity:   H☐ M☐ L☐ I☐

2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence:
Maternal death is an objective outcome that is 100% consistent with the supporting evidence

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
Beth Israel Deaconess Medical Center has been tracking this adverse event as part of their Adverse Outcome Index since early 2001.

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment): Chart review and analysis of the administrative data set for all deliveries during the period.

2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment): Maternal death is a very rare event yet tracking and measuring the rate of maternal deaths is critical to measuring the quality and safety of perinatal care.

POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)

2b3. Measure Exclusions. (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)

2b3.1 Data/Sample for analysis of exclusions (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): The original DoD/BIDMC study identified categories of patients where adverse events were not preventable and therefore need to be excluded from the AOI calculations. When the AOI was being translated into an algorithm to be used with administrative data, BIDMC cases identified using the algorithm were matched against cases identified during the study period and the differences reconciled.

2b3.2 Analytic Method (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference): Reconciling each case with an adverse event resulted in a fairly strong overlap between the administrative cases and abstracted study cases. There were some cases on the administrative list that were not on the abstracted case and vice versa. Each case was reviewed by analysts at BIDMC and NPIC/QAS resulting in refinement to the algorithm as well as improved identification of exclusions.

2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses): In the case by case review there was rarely significant variance in the total count of cases included in the original study count and identified using the administrative files indicating the exclusions were appropriately identified.

Some measure categories, especially those with very rare events (maternal/neonatal mortality, uterine rupture), pose a greater risk of missed exclusions or false inclusions. Providing total count of cases by review period and medical record numbers to hospitals under review, allow the hospital and team to correct the inaccuracies and use the AOI as a tool to accurately report and assess quality of labor and delivery care.

2b4. Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)

2b4.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

2b4.2 Analytic Method (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):

2b4.3 Testing Results (Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):
### 2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:

The AOI measure excludes cases that are not likely to be impacted by team training and are generally beyond the control of the clinician/team. The remaining cases are deemed to be able to be decreased regardless of the risk of the presenting patient. There are plans to look at risk adjustment in more detail but at this point the AOI is not risk adjusted.

### 2b5. Identification of Meaningful Differences in Performance.

*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*

<table>
<thead>
<tr>
<th>Data/Sample</th>
<th>Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2b5.1</strong></td>
<td>This measure has been individually tracked as part of a composite measure (AOI). It has been used in multiple published reports (see selected references), totaling more than 50,000 deliveries. In addition, the National Perinatal Information center has tracked this across a wide range of clinical settings, totally nearly 300,000 deliveries.</td>
</tr>
</tbody>
</table>


There are two Collaboratives and approximately 30-40 individual hospitals that are using or have used the AOI in their QI programs, a total of ~ 100 hospitals (through NPIC/QAS). Total deliveries/inborns analyzed is greater than 300,000. Each hospital identified a Baseline period of 1-2 years, starting with discharges as early as 2006; for some hospitals the follow-up analysis is still on-going. Each hospital submits their administrative data set (UB 04) for all mothers and neonates 0-28 days old admission. The hospitals included all levels of care (OB Level I-III), teaching and non-teaching, urban and rural.

#### 2b5.2 Analytic Method

*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance.*

Maternal death is a major component of the Adverse Outcomes Index (AOI). Baseline and Follow-up calculations are made for the AOI, WAOS and SI for each hospital. The Baseline period is usually 4-8 quarters prior to an QI initiative- team training, simulation, NICHD common language, IHI bundle compliance training etc and a Follow-up period after the intervention. Percent change in each rate, test of statistically significant of trend and in comparison to a Baseline comparative rate and target benchmark are all calculated.

#### 2b5.3 Results

*Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance.*

Maternal death is a major component of the Adverse Outcomes Index (AOI). Summary data for 61 hospitals participating in a collaborative or team training program show the Baseline ranges for the AOI, WAOS and SI of .031-.130 , .51-7.86 and 12.11-41.24 respectively. Follow-up ranges for the AOI were: .028-.088; for WAOS of .55-2.42 and the SI of 13.27-42.22.

For one collaborative of 16 hospitals, 5 improved on all 3 scores, 6 improved at least two scores. The overall rate of improvement for the AOI and WAOS was a decrease by 6.3% and .7 % respectively. The SI showed an increase of 2.7%.

The second collaborative of 20 hospitals had an average decrease for the AOI and WAOS of 2.08 % and 1.8% respectively; the SI improved by 2.9%. 6 of the 20 showed improvement on all three scores; 5 improvement on 2 scores, 5 on 1 score and 4 declined.

### 2b6. Comparability of Multiple Data Sources/Methods.

*If specified for more than one data source, the various approaches result in comparable scores.*

#### 2b6.1 Data/Sample

*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included:

When the AOI was being translated into an algorithm to be used with administrative data, BIDMC cases identified using the algorithm were matched against cases identified during the study period and the differences reconciled. Hospitals currently using the AOI receive numerator case lists so they reconcile their adverse event counts with chart review.

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**See Guidance for Definitions of Rating Scale:**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>H</td>
<td>High</td>
</tr>
<tr>
<td>M</td>
<td>Moderate</td>
</tr>
<tr>
<td>L</td>
<td>Low</td>
</tr>
<tr>
<td>I</td>
<td>Insufficient</td>
</tr>
<tr>
<td>NA</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
2b6.2 **Analytic Method** *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):*

Chart review validation or data from other sources (pharmacy, blood bank) shows a high degree of correlation with administrative data. We have used the administrative data algorithm exclusively since the original study allowing hospitals to submit supplemental data from other files when necessary. Other than in the first review with BIDMC we have not tested the comparability of scores using data exclusively from other sources.

2b6.3 **Testing Results** *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):*

In the original review with BIDMC data, the overlap was very strong. Hospitals currently using the AOI, perform chart review comparisons regularly and find there is little discrepancy. As hospitals move toward a more integrated EHR, any discrepancy should be largely removed.

2c. **Disparities in Care: H M L I NA** *(If applicable, the measure specifications allow identification of disparities.)*

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts): NA*

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

Maternal mortality is clearly higher in African American and Latino women, and in under served areas in the United States. The degree to which this is due to poor care (failure to prevent or to treat conditions that lead to death, or failure to rescue) and the degree to which this is due to increased underlying risk is not well established.

2.1-2.3 **Supplemental Testing Methodology Information:**

**Steering Committee:** Overall, was the criterion, **Scientific Acceptability of Measure Properties, met?** *(Reliability and Validity must be rated moderate or high)* Yes No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

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### 3. **USABILITY**

**Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.** *(evaluation criteria)*

**C.1 Intended Purpose/ Use** *(Check all the purposes and/or uses for which the measure is intended):** Public Reporting, Quality Improvement (Internal to the specific organization)

**3.1 Current Use** *(Check all that apply; for any that are checked, provide the specific program information in the following questions):** Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

**3a. Usefulness for Public Reporting:** H M L I

*(The measure is meaningful, understandable and useful for public reporting.)*

3a.1. **Use in Public Reporting - disclosure of performance results to the public at large** *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: **[For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]**

The CDC reports maternal deaths *(http://www.cdc.gov/nchs/data/series/sr_03/sr03_033.pdf), as do individual states.
3a.2 **Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting.** If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: Maternal death is the most severe adverse event in obstetrics. Evidence suggests that approximately 50% of maternal deaths are preventable. In addition, sub-standard care is often provided to parturients are increased risk of death (e.g. Pre-eclampsia), and during maternal resuscitation efforts.

Many large cohort studies have demonstrated that improvements in both quality and safety efforts have led to improved care and lower maternal mortality.

### 3.2 Use for other Accountability Functions (payment, certification, accreditation)

If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This measure is part of the AOI Composite measure and has a weight of 750, the highest of all the measures. The AOI is being used by all Team Performance Plus (TPP) contracted hospitals, a subset of NPIC hospitals, all the hospitals participating in the Maryland Perinatal Patient Safety Initiative and the Premier Perinatal Patient Safety Initiative.

### 3b. Usefulness for Quality Improvement: H [ ] M [ ] L [ ] I [ ]

(The measure is meaningful, understandable and useful for quality improvement.)

#### 3b.1. Use in QI

If used in quality improvement program, provide name of program(s), locations, Web page URL(s): [For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

Maternal death is the most severe adverse event in obstetrics. Evidence suggests that approximately 50% of maternal deaths are preventable. In addition, sub-standard care is often provided to parturients are increased risk of death (e.g. Pre-eclampsia), and during maternal resuscitation efforts.

Large cohort studies have demonstrated that improvements in both quality and safety efforts have led to improved care and lower maternal mortality.

In addition, it has been used as part of the AOI in the following studies and collaboratives.


In 2007, Wyoming Medical Center I in partnership with Marsh adopted three quality improvement tools: AOI, WAOS, and the SI. The obstetrical data collected is used for benchmarking purposes within the hospital and the hospital’s Captive (17 other western hospitals insured by Marsh). The average score for the first two quarters of 2007 were: AOI- 5.7%, WAOS- 0.62, and SI-11. They were compared to the benchmark scores: AOI- 9.2%, WAOS- 3.0, and SI- 25, and against the captive hospital scores.


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See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:

Maternal death is easily understandable by clinician and patient/families. It has devastating impact on the lives of the surviving family members.

Maternal death is the most severe adverse event in obstetrics. Evidence suggests that approximately 50% of maternal deaths are preventable. In addition, sub-standard care is often provided to parturients are increased risk of death (e.g. Pre-eclampsia), and during maternal resuscitation efforts.

Many large cohort studies have demonstrated that improvements in both quality and safety efforts have led to improved care and lower maternal mortality.

Overall, to what extent was the criterion, **Usability**, met?  H M L I

Provide rationale based on specific subcriteria:

### 4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? **(Check all that apply).**

Data used in the measure are:
- generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition,
- Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically **(Elements that are needed to compute measure scores are in defined, computer-readable fields):** Yes

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:

Miscoding maternal death occurring during the delivery discharge is extremely rare. If the death occurs as a result of a non-obstetric
event (car accident; violent act etc) then the case would not and should not be included in the numerator.

Identification of case counts for the analytic period allows the hospital to confirm the validity of the maternal death through chart review.

These were audited during testing; no cases requiring exclusion were found.

4d. Data Collection Strategy/Implementation: H □ M □ L □ I □

A.2 Please check if either of the following apply (regarding proprietary measures):

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures):

Administrative data has improved greatly over the years such that it is a very reliable source for calculating quality measure/indicator rates. It is a standard data set across all health care facilities, maintains patient confidentiality, is cost effective to collect and analyze, and can be collected at reasonable intervals (monthly, quarterly etc) so as to identify improvements or deterioration in patient safety. As with any measuring system, facilities being measured should have the opportunity to review and validate their data prior to their final rate calculations. Numerator case lists can be generated using medical record numbers present on most administrative data sets. Chart review to confirm or correct numerator cases has proven very effective in validating measure rates.

Overall, to what extent was the criterion, Feasibility, met? H □ M □ L □ I □

Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes □ No □

Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures (either same measure focus or target population) or competing measures (both the same measure focus and same target population), list the NQF # and title of all related and/or competing measures:

0347 : Death Rate in Low-Mortality Diagnosis Related Groups (PSI 2)

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? No

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

This measure includes all deaths in DRGs with <.5% mortality including MDC 14. In-hospital maternal death includes all maternal deaths and denominator is all deliveries.

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):

It specifically measures mortality during the delivery hospitalization and can be tracked directly to the hospital of care as compared...
to patients that are transferred out to another facility post delivery or readmitted for a post partum complication death resulting.

It also excludes post-discharge causes of death that may not be related to the quality of care provided during the delivery hospitalization.

**CONTACT INFORMATION**

Co.1 Measure Steward (Intellectual Property Owner): Beth Israel Deaconess Medical Center, 330 Brookline Ave, Depart of OB/GYN; Dept of Anesthesia, Boston, Massachusetts, 02215

Co.2 Point of Contact: Janet, Muri, MBA, jmuri@npic.org, 401-274-0650-105

Co.3 Measure Developer if different from Measure Steward: Beth Israel Deaconess Medical Center, 330 Brookline Ave, Depart of OB/GYN; Dept of Anesthesia, Boston, Massachusetts, 02215

Co.4 Point of Contact: Stephen, Pratt, MD, spratt@bidmc.harvard.edu, 641-667-3353-105

Co.5 Submitter: Janet, Muri, MBA, jmuri@npic.org, 401-274-0650-105, National Perinatal Information Center

Co.6 Additional organizations that sponsored/participated in measure development:

Consensus panels were developed for the identification of measures to be included in the composite measure (AOI). This included vetting each of the individual measures.

Peter E. Nielsen, MD; Marlene B. Goldman, ScD; Susan Mann, MD; David E. Shapiro, Ph.D.; Ronald G. Marcus, MB, BCh.; Stephen D. Pratt, MD; Penny Greenberg, RN; Munish Gupta, MD; Patricia McNamee, RN, MS; Mary Salisbury, RN, MSN; David J. Birnbach, MD; Paul A. Gluck, MD; Mark D. Pearlman, MD; Heidi King, MS; David N. Tornburg, MD, MPH; Benjamin P. Sachs, MB, BS.; Lauren Bales, MD; Naval Medical Center Camp Pendleton; Ronald Burkman, MD, Baystate Medical Center; Cynthia Brumfield, MD University of Alabama at Birmingham; Peter Cherouny, MD, Univesity of Vermont- Fletcher Allen Health Care; Jack Cooley, MD, National Naval Medical Center; Harold Fox, MD, Johns Hopkins Medical Center; Elizabeth Golladay, MD, Tripler Army Medical Center; Lynn Leventis, MD, Naval Medical Center San Diego; Robert Lorenz, MD, William Beaumont Hospital; William Lucky, MD, Baptist Hospital of Miami; Patrick Nugent, MD, South Shore Hospital; Spike Lipschitz, MD, South Shore Hospital; Chris Stolle, MD, Naval Medical Center of Portsmouth; Cosmas van DeVen, MD, University of Michigan Medical Center; Frank Witter, MD, Johns Hopkins Medical Center, Eileen Hemman, EdD. and Tom Benedetti, MD, Suznne Walker, RN, MPH and Thomas Strandjord, MD from the University of Washington. In addition, representstatives from the American Congress of Obstetrics and Gynecology, the American Society for Obstetric Anesthesia and Perinatology, the American Society of Anesthesiologists, the Association of Women’s Health, Obstetric and Neonatal Nurses, the Armed Forces Institute of Pathology, the U.S. Navy Bureau of Medicine and Surgery, the Office of the Surgeon General, U.S. Army and TRICARE were present.

National Perinatal Information Center, Providence Rhode Island assisted with translating the AOI into administrative data specifications.

Co.7 Public Contact: Janet, Muri, MBA, jmuri@npic.org, 401-274-0650-105, National Perinatal Information Center

**ADDITIONAL INFORMATION**

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development.

Consensus panels were developed for the identification of measures to be included in the composite measure (AOI). This included vetting each of the individual measures.

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NQF #0743 In-hospital Maternal Deaths

Medical Center; Lynn Leventis, MD, Naval Medical Center San Diego; Robert Lorenz, MD, William Beaumont Hospital; William Lucky, MD, Baptist Hospital of Miami; Patrick Nugent, MD, South Shore Hospital; Spike Lipschitz, MD, South Shore Hospital; Chris Stolle, MD, Naval Medical Center of Portsmouth; Cosmas van DeVen, MD, University of Michigan Medical Center; Frank Witter, MD, Johns Hopkins Medical Center, Eileen Hemman, EdD. and Tom Bennedetti, MD, Suznne Walker, RN, MPH and Thomas Strandjord, MD from the University of Washington. In addition, representatives from the American Congress of Obstetrics and Gynecology, the American Society for Obstetric Anesthesia and Perinatology, the American Society of Anesthesiologists, the Association of Women’s Health, Obstetric and Neonatal Nurses, the Armed Forces Institute of Pathology, the U.S. Navy Bureau of Medicine and Surgery, the Office of the Surgeon General, U.S. Army and TRICARE were present.

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<table>
<thead>
<tr>
<th>Measure Developer/Steward Updates and Ongoing Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:</td>
</tr>
<tr>
<td>Ad.3 Year the measure was first released: 2007</td>
</tr>
<tr>
<td>Ad.4 Month and Year of most recent revision: 09, 2011</td>
</tr>
<tr>
<td>Ad.5 What is your frequency for review/update of this measure? On-going; last update was 09/2011-</td>
</tr>
<tr>
<td>Ad.6 When is the next scheduled review/update for this measure? 09, 2013</td>
</tr>
</tbody>
</table>

| Ad.7 Copyright statement: N/A |
| Ad.8 Disclaimers: |
| Ad.9 Additional Information/Comments: |
| Date of Submission (MM/DD/YY): 05/21/2010 |