

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](#).

NQF #: 0748 NQF Project: Perinatal and Reproductive Health Project
(for Endorsement Maintenance Review) Original Endorsement Date: Most Recent Endorsement Date:
BRIEF MEASURE INFORMATION
De.1 Measure Title: Third or fourth degree perineal laceration
Co.1.1 Measure Steward: Beth Israel Deaconess Medical Center
De.2 Brief Description of Measure: Number of women who suffer a 3rd or 4th degree laceration of the perineum during vaginal delivery.
2a1.1 Numerator Statement: All women who meet above criteria
2a1.4 Denominator Statement: As part of the AOI/WAOS/SI- all women who deliver.
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, Patient Reported Data/Survey 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 and Severity Index

STAFF NOTES (issues or questions regarding any criteria)
Comments on Conditions for Consideration:
Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> 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. (evaluation criteria)
1a. High Impact: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/>

NQF #0748 Third or fourth degree perineal laceration

(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, Disparities, Safety, Safety : Complications

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Other

1a.2 If "Other," please describe: Addresses NPP Goal: Safety

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Delivery hospitalization is one of the highest volume reasons for admission to a hospital. 3rd or 4th degree laceration is a serious OB injury with potential long term impact on the woman. The reported rate of 3rd/4th degree episiotomy ranges from 1-10%, and may be as high as 30% after operative vaginal delivery.

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1: Alperin M, Krohn MA, Parviainen K. Episiotomy and increase in the risk of

obstetric laceration in a subsequent vaginal delivery. *Obstet Gynecol.* 2008 Jun;111(6):1274-8. PubMed PMID: 18515508.

2: Lowder JL, Burrows LJ, Krohn MA, Weber AM. Risk factors for primary and subsequent anal sphincter lacerations: a comparison of cohorts by parity and prior mode of delivery. *Am J Obstet Gynecol.* 2007 Apr;196(4):344.e1-5. PubMed PMID: 17403415.

3: Angioli R, Gómez-Marín O, Cantuaria G, O'sullivan MJ. Severe perineal lacerations during vaginal delivery: the University of Miami experience. *Am J Obstet Gynecol.* 2000 May;182(5):1083-5. PubMed PMID: 10819834.

4: Bodner K, Bodner-Adler B, Wagenbichler P, Kaider A, Leodolter S, Husslein P, Mayerhofer K. Perineal lacerations during spontaneous vaginal delivery. *Wien Klin Wochenschr.* 2001 Oct 15;113(19):743-6. PubMed PMID: 11715753.

5: Sheiner E, Levy A, Walfisch A, Hallak M, Mazor M. Third degree perineal tears in a university medical center where midline episiotomies are not performed. *Arch Gynecol Obstet.* 2005 Apr;271(4):307-10. Epub 2004 Mar 16. PubMed PMID: 15024575.

6: Hudelist G, Gelle n J, Singer C, Ruecklinger E, Czerwenka K, Kandolf O, Keckstein J. Factors predicting severe perineal trauma during childbirth: role of forceps delivery routinely combined with mediolateral episiotomy. *Am J Obstet Gynecol.* 2005 Mar;192(3):875-81. PubMed PMID: 15746685.

7: Fenner DE, Genberg B, Brahma P, Marek L, DeLancey JO. Fecal and urinary incontinence after vaginal delivery with anal sphincter disruption in an obstetrics unit in the United States. *Am J Obstet Gynecol.* 2003 Dec;189(6):1543-9; discussion 1549-50. PubMed PMID: 14710059.

8: Borgatta L, Piening SL, Cohen WR. Association of episiotomy and delivery position with deep perineal laceration during spontaneous delivery in nulliparous women. *Am J Obstet Gynecol.* 1989

Feb;160(2):294-7. PubMed PMID: 2916609.

9: Landy HJ, Laughon SK, Bailit JL, Kominiarek MA, Gonzalez-Quintero VH, Ramirez M, Haberman S, Hibbard J, Wilkins I, Branch DW, Burkman RT, Gregory K, Hoffman MK, Learman LA, Hatjis C, Vanveldhuisen PC, Reddy UM, Troendle J, Sun L, Zhang J; Consortium on Safe Labor. Characteristics associated with severe perineal and cervical lacerations during vaginal delivery. *Obstet Gynecol.* 2011 Mar;117(3):627-35. PubMed PMID: 21343766; PubMed Central PMCID: PMC3132187.

10: Dandolu V, Chatwani A, Harmanli O, Floro C, Gaughan JP, Hernandez E. Risk factors for obstetrical anal sphincter lacerations. *Int Urogynecol J Pelvic Floor Dysfunct.* 2005 Jul-Aug;16(4):304-7. Epub 2005 Apr 5. PubMed PMID: 15809773.

11: Sheiner E, Walfisch A, Hallak M, Harlev S, Mazor M, Shoham-Vardi I. Length of the second stage of labor as a predictor of perineal outcome after vaginal delivery. *J Reprod Med.* 2006 Feb;51(2):115-9. PubMed PMID: 16572912.

12: Bodner-Adler B, Bodner K, Kaider A, Wagenbichler P, Leodolter S, Husslein P, Mayerhofer K. Risk factors for third-degree perineal tears in vaginal delivery, with an analysis of episiotomy types. *J Reprod Med.* 2001 Aug;46(8):752-6. PubMed PMID: 11547651.

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:

Third or fourth degree perineal tear is a commonly tracked adverse event in obstetric care (AHRQ, Joint Commission). Obstetric management, especially use of episiotomy and forceps delivery, strongly influences the rate of perineal tear. In addition, fetal macrosomia, and prolonged second stage of labor, both influenced by obstetric decision making, are also associated with increased rates of perineal tears. Thus, this complication is frequently preventable.

1) http://www.qualitymeasures.ahrq.gov/summary/summary.aspx?doc_id=12735.

2) <http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/Pregnancy+and+Related+Conditions+Core+Measure+Set.htm>

3) Ogunyemi D, Manigat B, Marquis J, Bazargan M. Demographic variations and clinical associations of episiotomy and severe perineal lacerations in vaginal delivery. *J Natl Med Assoc.* 2006 Nov;98(11):1874-8.

4) Dandolu V, Chatwani A, Harmanli O, et al. Risk factors for obstetrical anal sphincter lacerations. *Int Urogynecol J Pelvic Floor Dysfunct.* 2005;16:304-7.

5) Mikolajczyk RT, Zhang J, Troendle J, Chan L. Risk factors for birth canal lacerations in primiparous women. *Am J Perinatol.* 2008 May;25(5):259-64.

6) Kudish B, Blackwell S, Mcneeley SG, et al. Operative vaginal delivery and midline episiotomy: a bad combination for the perineum. *Am J Obstet Gynecol.* 2006 Sep;195(3):749-54.

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.]

Several controllable factors are associated with 3rd/4th degree perineal laceration, including episiotomy (Midline > mediolateral. Although some literature suggests this may actually be protective) and assisted vaginal delivery (forceps > vacuum). Some

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populations are at increased risk (Asian, advanced maternal age, nullipara, large fetal weight, long second stage). Understanding these high risk populations can help alter practice to decrease the laceration rate.

Royal College of Obstetricians and Gynaecologists (RCOG). The management of third- and fourth-degree perineal tears. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2007 Mar. 11 p. (Green-top guideline; no. 29).

B - Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to the angle cut away from the midline.

Risk factors for third-degree tears have been identified in a number of retrospective studies. Taking an overall risk of 1% of vaginal deliveries, the following factors are associated with an increased risk of a third-degree tear:

Risk factors include: (from Guideline Title)

- * Birth weight over 4 kg (up to 2%)
- * Persistent occipitoposterior position (up to 3%)
- * Nulliparity (up to 4%)
- * Induction of labour (up to 2%)
- * Epidural analgesia (up to 2%)
- * Second stage longer than 1 hour (up to 4%)
- * Shoulder dystocia (up to 4%)
- * Midline episiotomy (up to 3%)
- * Forceps delivery (up to 7%)

This measure is part of the AOI composite measure with a weight of 5 points. This measure has been used in three published articles totaling more than 50,000 deliveries (see references). In addition, NPIC/QAS has used the AOI, WAOS and SI with a number of collaborative perinatal patient safety initiatives (a total of 63 hospitals) with a Baseline range from .031 to .130. Please see AOI composite submission for details on variation in performance.

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]

1) http://www.qualitymeasures.ahrq.gov/summary/summary.aspx?doc_id=12735.

2) <http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/Pregnancy+and+Related+Conditions+Core+Measure+Set.htm>

3) Ogunyemi D, Manigat B, Marquis J, Bazargan M. Demographic variations and clinical associations of episiotomy and severe perineal lacerations in vaginal delivery. J Natl Med Assoc. 2006 Nov;98(11):1874-8.

4) Dandolu V, Chatwani A, Harmanli O, et al. Risk factors for obstetrical anal sphincter lacerations. Int Urogynecol J Pelvic Floor Dysfunct. 2005;16:304-7.

5) Mikolajczyk RT, Zhang J, Troendle J, Chan L. Risk factors for birth canal lacerations in primiparous women. Am J Perinatol. 2008 May;25(5):259-64.

6) Kudish B, Blackwell S, Mcneeley SG, et al. Operative vaginal delivery and midline episiotomy: a bad combination for the perineum. Am J Obstet Gynecol. 2006 Sep;195(3):749-54.

1b.4 Summary of Data on Disparities by Population Group: [For Maintenance – Descriptive statistics for performance results for this measure by population group]

Some data suggest that Asian race is an independent risk factor for perineal tear. African American race may be protective. It is unclear what the mechanism is for this.

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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 included]

1: Ogunyemi D, Manigat B, Marquis J, Bazargan M. Demographic variations and clinical associations of episiotomy and severe perineal lacerations in vaginal delivery. J Natl Med Assoc. 2006 Nov;98(11):1874-81. PubMed PMID: 17128701; PubMed Central PMCID: PMC2569796.

2: Groutz A, Hasson J, Wengier A, Gold R, Skornick-Rapaport A, Lessing JB, Gordon D. Third- and fourth-degree perineal tears: prevalence and risk factors in the third millennium. Am J Obstet Gynecol. 2011 Apr;204(4):347.e1-4. Epub 2010 Dec PubMed PMID: 21183150.

3: Stotland NE, Caughey AB, Breed EM, Escobar GJ. Risk factors and obstetric complications associated with macrosomia. Int J Gynaecol Obstet. 2004 Dec;87(3):220-6. Erratum in: Int J Gynaecol Obstet. 2005 Jul;90(1):88. PubMed PMID: 15548393.

4: Goldberg J, Hyslop T, Tolosa JE, Sultana C. Racial differences in severe perineal lacerations after vaginal delivery. Am J Obstet Gynecol. 2003 Apr;188(4):1063-7. PubMed PMID: 12712111.

5: Howard D, Davies PS, DeLancey JO, Small Y. Differences in perineal lacerations in black and white primiparas. Obstet Gynecol. 2000 Oct;96(4):622-4. PubMed PMID: 11004370; PubMed Central PMCID: PMC1226415.

6: Combs CA, Robertson PA, Laros RK Jr. Risk factors for third-degree and fourth-degree perineal lacerations in forceps and vacuum deliveries. Am J Obstet Gynecol. 1990 Jul;163(1 Pt 1):100-4. PubMed PMID: 2375331.

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.**

Quantity: H M L I Quality: H M L I Consistency: H M L I

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

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

Does the measure pass subcriterion1c?
Yes IF rationale supports relationship

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):

The rate of 3rd or 4th degree perineal tear may exceed 40% in some populations. This complication is associated with perineal pain and anal incontinence.

Episiotomy (esp midline) and assisted vaginal delivery are consistent risk factors

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

Clinical Practice Guideline, Other

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):

1) http://www.qualitymeasures.ahrq.gov/summary/summary.aspx?doc_id=12735.

2) <http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/Pregnancy+and+Related+Conditions+Core+Measure+Set.htm>

3) Ogunyemi D, Manigat B, Marquis J, Bazargan M. Demographic variations and clinical associations of episiotomy and severe perineal lacerations in vaginal delivery. J Natl Med Assoc. 2006 Nov;98(11):1874-8.

4) Dandolu V, Chatwani A, Harmanli O, et al. Risk factors for obstetrical anal sphincter lacerations. Int Urogynecol J Pelvic Floor Dysfunct. 2005;16:304-7.

5) Mikolajczyk RT, Zhang J, Troendle J, Chan L. Risk factors for birth canal lacerations in primiparous women. Am J Perinatol. 2008 May;25(5):259-64.

6) Kudish B, Blackwell S, Mcneeley SG, et al. Operative vaginal delivery and midline episiotomy: a bad combination for the perineum. Am J Obstet Gynecol. 2006 Sep;195(3):749-54.

No randomized trial exist regarding the impact of episiotomy or assisted vaginal delivery on the rate or severity of 3rd/4th degree perineal laceration. However, large population-based series' have consistently demonstrated these as independent risk factors.

The references below all used the AOI as a main outcome measure in a research setting:

Nielsen P, Goldman MB, Mann, S, et al. Effects of Teamwork Training on Adverse Outcomes and Process of Care in Labor and Delivery: A Randomized Controlled Trial. Obstetrics & Gynecology: January 2007 - Volume 109 - Issue 1 - pp 48-55.

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 intraclass 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.

Pratt MD, Stephen D., Susan Mann MD, Mary Salisbury RN, Penny Greenberg RN, Ronald Marcus MD, Barbara Stabile RN, Patricia McNamee RN, Peter Nielsen MD, and Benjamin P. Sachs MD. "Impact of CRM-Based Team Training on Obstetric Outcomes and Clinicians' Patient Safety Attitudes." *The Joint Commission Journal on Quality and Patient Safety* 33.12 (2007): 720-25. Dec. 2007.

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.

Pettker MD, Christian M., Stephen F. Thung MD, Errol R. Norwitz MD PhD, Catalin S. Buhmichi MD, Cheryl A. Raab RNC, Joshua A. Copel MD, Edward Kuczynski MA, Charles J. Lockwood MD, and Edmund F. Funai MD. "Impact of a comprehensive patient safety strategy on obstetric adverse events" *American Journal of Obstetrics & Gynecology* 200.5 (2009): 492. *American Journal of Obstetrics & Gynecology*. 02 Mar. 2009.

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:

Gosman GG, Baldisseri MR, Stein KL, et al. Introduction of an obstetric-specific medical emergency team for obstetric crises: implementation and experience. *American Journal of Obstetrics and Gynecology*. Volume 198, Issue 4, April 2008, Pages 367.e1-367.e7

Pettker CM. Standardization of intrapartum management and impact on adverse outcomes. *Clin Obstet Gynecol*. 2011 Mar;54(1):8-15.

Shea-Lewis A. Teamwork: Crew Resource Management in a Community Hospital
Journal for Healthcare Quality Volume 31, Issue 5, pages 14–18, September/October 2009

Riley W, Davis S, Miller, K, et al. Didactic and Simulation Nontechnical Skills Team Training to Improve Perinatal Patient Outcomes in a Community Hospital. *Joint Commission Journal on Quality and Patient Safety*, Volume 37, Number 8, August 2011, pp. 357-364(8)

Wagner B, Meirowitz N, Shah J, et al. Comprehensive Perinatal Safety Initiative to Reduce Adverse Obstetric Events. *Journal for Healthcare Quality*. Article first published online: 1 MAR 2011

Nicholson JM, Parry S, Caughey AB, Rosen S, Keen A, Macones GA. The impact of the active management of risk in pregnancy at term on birth outcomes: a randomized clinical trial. *Am J Obstet Gynecol*. 2008 May;198(5):511.e1-15.

1c.5 Quantity of Studies in the Body of Evidence (*Total number of studies, not articles*): No randomized trial exist regarding the impact of episiotomy or assisted vaginal delivery on the rate or severity of 3rd/4th degree perineal laceration. However, large population-based series have consistently demonstrated these as independent risk factors.

In addition to those cited above 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): Population-based series have consistently demonstrated these as independent risk factors.

Recommendations from the Royal College of Obstetricians and Gynecologists are Grade B with regards to prevention.

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.

Schulz RNC MS, Phyllis E. "Introduction of Adverse Outcomes Index to Assess Quality of Obstetrical Care in a Wyoming Hospital." Association of Women's Health, Obstetric and Neonatal Nurses. June 2008. Web. 7 Nov. 2011.

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%, WOAS- 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<7.00, 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.

Janakiraman, Vanitha, and Jeffrey Ecker. "Quality in Obstetric Care: Measuring What Matters." Obstetrics & Gynecology 116.3 (2010): 728-32. American College of Obstetricians and Gynecologists. Sept. 2010. The adverse Outcome Index is one quality 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.

Pettker 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*):
Episiotomy has consistently inferred a 3-4 fold increased risk of 3rd/4th degree perineal laceration, while assisted vaginal delivery has been associated with a 2-3 fold increased.

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*):

Avoidance of episiotomy and assisted vaginal delivery would likely decrease the rate of 3rd/4th degree lacerations by 50-90%.

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-- an additional net benefit to the hospital under review. If the frequency of adverse events is correct, they 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? **Yes**

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The recommendations were graded according to the level of evidence upon which they were based. The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group of the National Health Service Executive

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

1c.12 If other, identify and describe the grading scale with definitions: Clinical Outcomes Group of the National Health Service Executive

1c.13 Grade Assigned to the Body of Evidence:

1c.14 Summary of Controversy/Contradictory Evidence:

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

1c.16 Quote verbatim, the specific guideline recommendation (*Including guideline # and/or page #*):

Can Obstetric Anal Sphincter Injury Be Predicted and Prevented?

B - Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to the angle cut away from the midline.

Risk factors for third-degree tears have been identified in a number of retrospective studies. Taking an overall risk of 1% of vaginal deliveries, the following factors are associated with an increased risk of a third-degree tear:

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- * Birth weight over 4 kg (up to 2%)
- * Persistent occipitoposterior position (up to 3%)
- * Nulliparity (up to 4%)
- * Induction of labour (up to 2%)
- * Epidural analgesia (up to 2%)
- * Second stage longer than 1 hour (up to 4%)
- * Shoulder dystocia (up to 4%)
- * Midline episiotomy (up to 3%)
- * Forceps delivery (up to 7%)

1c.17 Clinical Practice Guideline Citation: <http://www.guideline.gov/content.aspx?id=11384>

1c.18 National Guideline Clearinghouse or other URL: <http://www.guideline.gov/content.aspx?id=11384>

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: [Clinical Outcomes Group of the National Health Service Executive](#)

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

1c.22 If other, identify and describe the grading scale with definitions:

1c.23 Grade Assigned to the Recommendation: B

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: [Moderate](#) 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.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

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.)

NQF #0748 Third or fourth degree perineal laceration

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 meet above criteria

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

Occurring during delivery hospitalization only. Can be run for any period of time to determine rate

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 or 774-775 with diagnosis codes 664.2 – 3rd degree perineal laceration or 664.3 4th degree perineal laceration

2a1.4 Denominator Statement (Brief, narrative description of the target population being measured):

As part of the AOI/WAOS/SI- all women who deliver.

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):

Same as numerator

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):

DRGs 370-375 or MS DRGs 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):

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):

None

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.):

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 data; risk adjustment; etc.):

1) identify all delivered women for the time period under review 2) scan dx code string for all codes of 664.2 – 3rd degree perineal laceration or 664.3 4th degree perineal laceration 3) establish count of cases for the time period.

This measure is part of the Adverse Outcome Index composite measure; please see AOI composite submission.

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

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):

No sampling required.

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, Patient Reported Data/Survey

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/ UB04

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.

Hospitals tracking this through the Joint Commission as part of the previously Perinatal Care Measure set.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):

Case by case review; reconciliation of the coded data with data from other internal sources.

2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):

Administrative and audited data had a strong match; when there was not a strong match, cases that had a documented "2nd degree with extension" or "3rd degree with extension" and were coded as 3rd and 4th degree laceration (as required by coding conventions) there was an opportunity to correct that data prior to calculation of the AOI/WAOS or SI.

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:

The definition of a 3rd or 4th degree perineal laceration is consistent. Coding errors and mis-diagnoses can impact the detection rate.

Identification of Obstetric Anal Sphincter Injuries

How Can the Identification of Obstetric Anal Sphincter Injuries Be Improved?

C - All women having a vaginal delivery with evidence of genital tract trauma should be examined systematically to assess the severity of damage prior to suturing. (<http://www.guideline.gov/content.aspx?id=11384>)

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):

Tracking and monitoring perineal tears has decreased this adverse event during this period.

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):

None

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.)

2b5.1 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):

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.

1) Nielsen PE, Goldman MB, Mann S, Shapiro DE, Marcus RG, Pratt SD, et al. Effects of teamwork training on adverse outcomes and process of care in labor and delivery: a randomized controlled trial. *Obstet Gynecol* 2007; 109:48-55.

2) Pratt SD, Mann S, Salisbury M, et al. Impact of CRM-based team training on obstetric outcomes and clinicians' patient safety attitude. *Joint Commission Journal on Quality and Patient Safety* 2007; 33:720-5.

3) Nicholson JM, Parry S, Caughey AB, et al. The impact of the active management of risk in pregnancy at term on birth outcomes: a randomized clinical trial. *Am J Obstet Gynecol.* 2008; 198:511.e1-15.

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):

As part of the AOI, a 95% confidence interval is put around a hospital's AOI/WAOS and SI rates and compared to a Baseline comparison rate and target benchmark for the follow-up period. In addition, the rate of change between the two periods and over the life of data points is tested for significance.

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):

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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 increased 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):

All Beth Israel cases between Q 3-2005 and Q2 2006 were reconciled using abstracted data.

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.

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):

Administrative and audited data had a strong match.

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):

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

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

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): [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.]

Used in a public reporting initiative-

The Joint Commission

Measure Set: [Pregnancy and Related Conditions \(PR\)](#)

Set Measure ID: PR-3

Performance Measure Name: [Third or Fourth Degree Laceration](#)

<http://manual.jointcommission.org/releases/Archive/TJC2010B1/MIF0064.html>

AHRQ

Title: [Obstetric trauma \(3rd or 4th degree lacerations\): rate per 1,000 instrument-assisted vaginal deliveries.](#)

Source(s): [AHRQ quality indicators. Guide to patient safety indicators \[version 3.1\]. Rockville \(MD\): Agency for Healthcare Research and Quality \(AHRQ\); 2007 Mar 12. 76 p. \(AHRQ Pub; no. 03-R203\).](#)

<http://www.qualitymeasures.ahrq.gov/content.aspx?id=26532>

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: [3rd or 4th degree perineal tears can lead to perineal pain, fecal or urinary incontinence, and increased risk for tears in subsequent pregnancies. While coding and diagnostic errors can occur, it is clear that clinical decisions making \(especially in high risk groups\), impacts the rate of this complication.](#)

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): [As part of the AOI composite measure it has been used to report to numerous NPIC/QAS members, hospitals involved in the Maryland 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].

[Joint Commission and AHRQ already endorse this measure](#)

[In addition, it has been used as part of the AOI in the following studies and collaboratives.](#)

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Schulz RNC MS, Phyllis E. "Introduction of Adverse Outcomes Index to Assess Quality of Obstetrical Care in a Wyoming Hospital." Association of Women's Health, Obstetric and Neonatal Nurses. June 2008. Web. 7 Nov. 2011.

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%, WOAS- 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.

Nielsen P, Goldman MB, Mann, S, et al. Effects of Teamwork Training on Adverse Outcomes and Process of Care in Labor and Delivery: A Randomized Controlled Trial. Obstetrics & Gynecology: January 2007 - Volume 109 - Issue 1 - pp 48-55.

Pratt MD, Stephen D., Susan Mann MD, Mary Salisbury RN, Penny Greenberg RN, Ronald Marcus MD, Barbara Stabile RN, Patricia McNamee RN, Peter Nielsen MD, and Benjamin P. Sachs MD. "Impact of CRM-Based Team Training on Obstetric Outcomes and Clinicians' Patient Safety Attitudes." The Joint Commission Journal on Quality and Patient Safety 33.12 (2007): 720-25. Dec. 2007.

Pettker MD, Christian M., Stephen F. Thung MD, Errol R. Norwitz MD PhD, Catalin S. Buhmichi MD, Cheryl A. Raab RNC, Joshua A. Copel MD, Edward Kuczynski MA, Charles J. Lockwood MD, and Edmund F. Funai MD. "Impact of a comprehensive patient safety strategy on obstetric adverse events" American Journal of Obstetrics & Gynecology 200.5 (2009): 492. American Journal of Obstetrics & Gynecology. 02 Mar. 2009.

Gosman GG, Baldisseri MR, Stein KL, et al. Introduction of an obstetric-specific medical emergency team for obstetric crises: implementation and experience. American Journal of Obstetrics and Gynecology. Volume 198, Issue 4, April 2008, Pages 367.e1-367.e7

Pettker CM. Standardization of intrapartum management and impact on adverse outcomes. Clin Obstet Gynecol. 2011 Mar;54(1):8-15.

Shea-Lewis A. Teamwork: Crew Resource Management in a Community Hospital
Journal for Healthcare Quality Volume 31, Issue 5, pages 14–18, September/October 2009

Riley W, Davis S, Miller, K, et al. Didactic and Simulation Nontechnical Skills Team Training to Improve Perinatal Patient Outcomes in a Community Hospital. Joint Commission Journal on Quality and Patient Safety, Volume 37, Number 8, August 2011 , pp. 357-364(8)

Wagner B, Meiorowitz N, Shah J, et al. Comprehensive Perinatal Safety Initiative to Reduce Adverse Obstetric Events. Journal for Healthcare Quality. Article first published online: 1 MAR 2011

Nicholson JM, Parry S, Caughey AB, Rosen S, Keen A, Macones GA. The impact of the active management of risk in pregnancy at term on birth outcomes: a randomized clinical trial. Am J Obstet Gynecol. 2008 May;198(5):511.e1-15.

3b.2. 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:

3rd or 4th degree perineal tears can lead to perineal pain, fecal or urinary incontinence, and increased risk for tears in subsequent pregnancies. While coding and diagnostic errors can occur, it is clear that clinical decisions making (especially in high risk groups), impacts the rate of this complication

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): ALL data elements in electronic claims

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:

Correct documentation and coding are key to the accuracy of this measure. Coders will code a second degree tear with an extension as a third degree or third degree with an extension as a fourth degree. If providers are not aware of this, the rate can be overstated.

Potential problems could be audited by: Providing case counts and MRNs for numerator cases can help hospitals audit their data for incomplete documentation or incorrect coding.

These potential problems were audited during testing. Problems at test sites were minimal but provided opportunity for provider and coder education.

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 liable 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

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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:

0345 : Accidental Puncture or Laceration Rate (PSI 15)

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?

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

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):

CONTACT INFORMATION

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

Co.4 Point of Contact: Susan, Mann, MD, smann@bidmc.harvard.edu, 617-504-0728-

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. Bimbach, 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, respresentatives 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.

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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:

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2006

Ad.4 Month and Year of most recent revision: 09, 2011

Ad.5 What is your frequency for review/update of this measure? On-going; latest revision 09/2011

Ad.6 When is the next scheduled review/update for this measure? 09, 2013

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (MM/DD/YY): 05/21/2010