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# Memo

**June 2, 2021**

**To**: Perinatal and Women's Health Standing Committee

**From**: NQF staff

**Re**: Fall 2020 Post-comment web meeting to discuss received public comments and NQF member expressions of support

## Introduction

NQF closed the public commenting period for the fall 2020 draft technical report and the measure submitted for endorsement consideration to the Perinatal and Women's Health project on April 28, 2021. Four comments were received. One comment was a coding clarification from the measure developer and three comments were in support of the measure. One of the three supportive commenters "reluctantly" favored the endorsement recommendation in lieu of other available measures.

## Purpose of the Call

The Perinatal and Women's Health Standing Committee will meet via web meeting on June 2, 2021 from 12:00pm – 2:00pm ET. The purpose of this call is to:

- Review and discuss comments received during the post-evaluation public and member comment period;
- Provide input on proposed responses to the post-evaluation comments;
- Review and discuss NQF members' expressions of support of the measures under consideration; and
- Determine whether reconsideration of the endorsement evaluation recommendation or other courses of action are warranted.

## Standing Committee Actions

1. Review this briefing memo and draft report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments (see comment table and additional documents included with the call materials).
3. Review the NQF members' expressions of support of the submitted measures.
4. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

## Conference Call Information

Please use the following information to access the conference call line and webinar:

**Meeting link:** https://nqf.webex.com/nqf/j.php?MTID=m07a288e346ec7aa37dfce3ce2b4c8474

**Meeting number (access code):** 173 367 0291

**Meeting password:** Ux33vMJR8PD

**Join by phone:** 1-844-621-3956

## Background

According to the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin 165, 53–79% of women will sustain some type of laceration during a vaginal delivery. Severe perineal lacerations (i.e., third- and fourth-degree injury) involve tearing of the vaginal wall to the anal sphincter complex and are called obstetric anal sphincter injuries (OASIS). Episiotomy is a surgical enlargement of the posterior aspect of the vagina by an incision to the perineum that is performed when there is a clinical need for expedited vaginal delivery of the fetus or a soft tissue dystocia. Evidence shows that episiotomies are linked to increased OASIS rates and maternal morbidity. Hence, ACOG does not encourage its routine use.

The National Quality Forum's (NQF) portfolio of measures for Perinatal and Women's Health includes an array of measures for reproductive health; pregnancy, labor and delivery (i.e., including episiotomy); high-risk pregnancy; newborn, premature, or low birthweight newborns; and postpartum patients. Some measures that represent other aspects women's health are reviewed by other Standing Committees in other projects (e.g., a perinatal vaccination measure is in the Prevention and Population Health Standing Committee portfolio).

During the February 12, 2021 web meeting, the 25-person NQF Perinatal and Women's Health Standing Committee evaluated one maintenance measure for endorsement consideration, NQF #0470 *Incidence of Episiotomy*.

## Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF accepts comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments during a 16-week comment period via an online tool on the project webpage.

### Pre-evaluation Comments

NQF accepts comments prior to the evaluation of the measures via an online tool on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from December 23, 2020 to January 26, 2021, for the measure under review. No comments were received during this period.

### Post-evaluation Comments

The fall 2020 draft report was posted on the project webpage for 30 calendar days to receive public and NQF member comments, beginning on March 30, 2021. During this commenting period, NQF received four comments from four non-member organizations and zero member organizations. Member organizations councils include Consumer, Health Plan, Health Professional, Provider Organization, Public/Community Health Agency, Purchaser, Quality Measurement, Research, and Improvement (QMRI), Supplier/Industry.

We have included all four comments that we received in the comment table (excel spreadsheet) posted to the Standing Committee SharePoint site and the Perinatal and Women's Health webpage. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—draft responses (including measure steward/developer

responses) for the Standing Committee's consideration. Please review this table in advance of the meeting and consider the individual comments received and the proposed responses to each. These comments, along with the Standing Committee's recommendations, will be reviewed by the Consensus Standards Approval Committee (CSAC) on November 30 and December 1, 2021. The CSAC will determine whether to uphold the Standing Committee's recommendation for the measure submitted for endorsement consideration. All Standing Committee members are encouraged to attend the CSAC meeting to listen to the discussion.

Although all comments are subject to discussion, the intent is not to discuss each individual comment on the June 2 post-comment call. Instead, we will spend the majority of the time considering the comment summarized below and the set of comments as a whole. Please note that measure stewards/developers were asked to respond where appropriate. Where possible, NQF staff has proposed draft responses for the Standing Committee to consider.

## Comments and Their Disposition

The developer submitted a comment clarifying that a code was mistakenly left out of the text in the denominator details, MS-DRG 806 (Vaginal Delivery Without Sterilization/D&C with CC). They state the denominator details should state, "Any woman with a vaginal delivery calculated by either MS DRG 774,775,767,768: MS DRGs starting with 10/1/2018 discharges: 768,796,797,798,805,806 and 807". They further clarify that "all data and statistical analyses in the document correctly included MS-DRG 806 and it has been included in the publicly available measure-specific web page (https://www.npic.org/data-partnership/nqf-measure-steward/) since the MS-DRG was added for discharges starting in 10/1/2018".

### *Themed Comments*

Three major themes were identified in the other three post-evaluation comments, as follows:

1. Measure modifications are recommended to identify performance gaps and improve outcomes.
2. Measure stratification is recommended by indication for episiotomy, and vaginal delivery and episiotomy types.
3. Coding updates are needed to differentiate episiotomy type (i.e., midline and mediolateral episiotomies).

The three commenters supported the measure, albeit one reluctantly, and urged for the restricted use of episiotomies unless clinically warranted. Future measure modification recommendations included adding the indication for episiotomy, and adding delivery (i.e., spontaneous vaginal, vacuum-assisted, and forceps-assisted) and episiotomy (i.e., midline/vertical and mediolateral/angled) types. One commenter stated the risk of OASIS is low in a spontaneous vaginal delivery, moderate in operative vacuum delivery, and high with operative forceps delivery. These additional details could assist in identifying performance gaps and when episiotomy may be appropriate (i.e., should not be included in the measure numerator). Two commenters were not supportive of adding OASIS laceration degree to the measure or having a measure that assesses OASIS laceration degree as implementation may inadvertently encourage the unintended consequence of increasing the use of caesarean section births to reduce laceration potential.

To adequately capture the episiotomy type, the American Medical Association's (AMA) Current Procedural Terminology (CPT®) or the World Health Organization's (WHO) International Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) coding are needed to detail both midline and mediolateral episiotomies. These currently are not available in either coding vocabulary. A midline episiotomy is generally easier to repair, but it has a higher risk of extending into the anal area. A

mediolateral episiotomy offers the best protection from an extended tear affecting the anal area, but it is often more painful and is more difficult to repair. One commenter provides an exception to the evidence as the United Kingdom's (UK) Royal College of Obstetricians and Gynaecologists (RCOG) Green-Top Guideline 29 (2015) in the United Kingdom (UK) *The Management of Third- and Fourth-Degree Perineal Tears,* Green-top Guideline No. 29 recommends considering a mediolateral episiotomy for operative (i.e., forceps and vacuum) deliveries, while ACOG discourages all episiotomies except when clinically indicated.

### *Measure-Specific Comment*

**NQF #0470 Incidence of Episiotomy**

The commenter acknowledges the main goal of the measure is to reduce the rate of OASIS by reducing the use of episiotomy in vaginal deliveries. However, the commentor notes the measure introduces the unintended consequence that by avoiding the use of episiotomy, providers could be incentivized to perform more cesarean sections, which is also discouraged unless clinically appropriate.

The commenter also notes that the denominator of the measure combines three different procedures (i.e., spontaneous vaginal delivery, vacuum-assisted delivery, and forceps-assisted delivery) and the numerator combines two different procedures (i.e., midline episiotomy and mediolateral episiotomy), all of which impart different risks of OASIS. Midline and mediolateral episiotomies are not distinguished in ICD-10 or CPT® coding.

The commenter also points out that the United Kingdom's RCOG recommends that routine mediolateral episiotomy be considered for forceps-assisted and vacuum-assisted deliveries.

Finally, the commenter adds they remain "reluctantly" in favor of continued endorsement of #0470, while noting the need for improvements to the measure to allow for the nuances described above.

**Measure Steward/Developer Response:**

We thank Dr. Coombs for his thoughtful comments and support a number of his points. We note that the issue is complex and therefore the measure is not able to account for all clinical scenarios accurately. We note that these limitations eventually lead to Dr. Coombs' endorsement of the measure, albeit reluctantly.

Specific to the points that are made we note the following:

1. As is noted by the reviewer there is no difference in codes for mediolateral vs. midline episiotomy. More specific coding would allow for the measure to be further refined which we would support. We encourage the development of separate codes but note that this lies out of our purview as measure developers. We do note that codes for operative vaginal delivery do exist in ICD-10 and highlight this as a potential future opportunity.
2. Consistent with ACOG 165 the goal of the measure is to encourage restrictive rather than routine episiotomy. The current measure supports this goal; though to the reviewer's point, it fails to capture the subtlety that he rightfully brings forward on the use of mediolateral episiotomy on operative deliveries. We acknowledge this limitation which is an outgrowth of coding deficiencies.
3. We note that the evidence that mediolateral episiotomy preventing OASIS in ACOG TB 165 comes from a retrospective review of the Collaborative Perinatal Project which only found benefit in primiparous women. We note that the only prospective trials of routine mediolateral episiotomy vs. no episiotomy was associated with increased pain as a balancing harm. The Technical Bulletin ultimately states, "although observational data support a

possible reduction in third-degree and fourth-degree lacerations, data are insufficient to support long-term improvement in pelvic floor function with routine mediolateral episiotomy."

4. Though RCOG has chosen a different point of view, we note that it is not uncommon for different professional societies to differ in their interpretation of the evidence. Nonetheless, as this is a US measure we would advocate for following the point of view of ACOG.
5. Finally, we note that the minority of deliveries are operative and that the majority of episiotomies performed in the US are midline not mediolateral. As such the use case the reviewer cites is a small fraction of cases until more accurate coding exists.

In summary, we agree that there is an opportunity to refine the measure but are limited by a lack of coding. We look forward to reevaluating this issue with the next review.

**Proposed Committee Response:**

Thank you for your comments. The Standing Committee will review this comment during its deliberations on the Post-Comment Call scheduled on June 2, 2021.

**Action Item:**

The Standing Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

## NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ("support" or "do not support") for each measure submitted for endorsement consideration to inform the Standing Committee's recommendations. Zero NQF members provided their expressions of support: See Appendix A. Two non-members provided their expressions of support.

## Appendix A: NQF Member Expression of Support Results

Zero NQF members provided their expressions of support/nonsupport. Results for the measure are provided below.

### NQF #0470: Incidence of Episiotomy (Christiana Care Health System)

| Member Council | Support | Do Not Support | Total |
|---|---|---|---|
| Consumer | 0 | 0 | 0 |
| Health Plan | 0 | 0 | 0 |
| Health Professional | 0 | 0 | 0 |
| Provider Organization | 0 | 0 | 0 |
| Public/Community Health Agency | 0 | 0 | 0 |
| Purchaser | 0 | 0 | 0 |
| QMRI | 0 | 0 | 0 |
| Supplier/Industry | 0 | 0 | 0 |