NATIONAL QUALITY FORUM

# Memo

**April 24, 2019**

**To**: Patient Safety Standing Committee

**From**: NQF staff

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

## Purpose of the Call

The Patient Safety Standing Committee will meet via web meeting on May 1, 2019 from 1:00 pm to 3:00 pm 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' expression of support of the measures under consideration; and
- Determine whether reconsideration of any measures or other courses of action are warranted.

## Standing Committee Actions

1. Review this briefing memo and the draft report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments.
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:

**Speaker dial-in #:** 800-768-2983

**Access code:** 5599410

**Web link:** https://core.callinfo.com/callme/?ap=8007682983&ac=5599410&role=p&mode=ad

## Background

Patient safety-related events occur across healthcare settings and include a variety of preventable and potentially preventable incidents such as pressure ulcers, falls, and healthcare-associated infections. Medical errors are a major cause of patient safety events. The 22-person Patient Safety Standing Committee oversees the NQF Patient Safety portfolio and assesses both novel and existing performance measures for endorsement using NQF's measure evaluation

criteria. This portfolio contains 74 measures: 24 process measures, 42 outcome measures, two intermediate outcome measures, two structure measures, and four composite measures.

During this review cycle, the Patient Safety Standing Committee reviewed six measures undergoing maintenance review related to the following key safety topics: medication monitoring, medication review, surgical site and hospital-acquired infections, and nurses' practice environment. The Standing Committee recommended all six measures for continued endorsement:

- 0553 Care for Older Adults (COA) – Medication Review
- 0555 INR Monitoring for Individuals on Warfarin
- 0753 American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure
- 1716 National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure
- 1717 National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure
- 3450 Practice Environment Scale - Nursing Work Index (PES-NWI) (composite and five subscales)

## Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits 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 solicits 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 November 29, 2018 to closed on January 18, 2019. As of January 2019, seven comments were submitted and shared with the Committee prior to the measure evaluation web meetings. Five comments were in support of measure 3450. Two comments questioned if testing was sufficient for measures 1716 and 1717.

### Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on March 11, 2019 for 30 calendar days. During this commenting period, NQF received 13 comments from two member organizations:

| Member Council | # of Member Organizations Who Commented |
|---|---|
| Consumer | 0 |
| Health Plan | 0 |

| Member Council | # of Member Organizations Who Commented |
|---|---|
| Health Professional | 1 |
| Provider Organization | 1 |
| Public/Community Health Agency | 0 |
| Purchaser | 0 |
| QMRI | 0 |
| Supplier/Industry | 0 |

We have included all comments that we received (both pre- and post-evaluation) in the comment table (excel spreadsheet) posted to the Committee SharePoint site. 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 Committee's consideration. Please review this table before the meeting and consider the individual comments received and the proposed responses to each.

In order to facilitate discussion, the majority of the post-evaluation comments have been categorized into major topic areas or themes. Although all comments are subject to discussion, the intent is not to discuss each individual comment on the May 1 post-comment call. Instead, we will spend the majority of the time considering the four themes discussed below, and the set of comments as a whole. Please note that the organization of the comments into major topic areas is not an attempt to limit Committee discussion. Additionally, please note measure stewards/developers were asked to respond where appropriate. Where possible, NQF staff has proposed draft responses for the Committee to consider.

## Comments and their Deposition

### *Themed Comments*

Four major themes were identified in the post-evaluation comments, as follows:

1. Validity testing
2. Measure alignment with guideline recommendations
3. Related and competing measures
4. Supportive comments

#### Theme 1 – Validity Testing

NQF received four comments related to the data element validity testing for measures 1716 *National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure* and 1717 *National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure*. Commenters expressed concerns regarding the lack of data element testing at the hospital level, questioned the sampling method and presentation of validity by state, and suggested that the validity testing provided did not meet NQF's validity

criteria. One commenter also supported the Committee's recommendations to explore additional risk factors in the developer's adjustment approach.

**Measure Steward/Developer Response:**

Critical data elements for LabID events such as the CDI and MRSA measures include two criteria: a laboratory test and date of hospitalization. Each facility makes the determination of a case, based on the two elements stated above. NHSN provides a guidance toolkit that suggests the selection methodology of a sample of facilities and medical charts to determine the accuracy of data elements. The recommended sample sizes are developed with a priori assumptions of expected accuracy and prevalence of LabID events. The state health departments using the NHSN guidance methodology conduct external validations. Data validations are conducted at each facility, and facility specific data accuracy estimates are provided to each facility by the respective state health departments. These data are shared with NHSN on an aggregate level for estimation of state specific accuracy of reporting. Results from individual facility and state validations have been published in peer-reviewed journals, via scientific presentations at national public health meetings, and in annual public reports of healthcare-associated infection data in several states.

NHSN has confidence that the sampling methodology as described is adequate for purposes of rendering estimates of accuracy and meets the NQF criteria for data element validity.

Peer reviewed publication

Gase KA, Haley VB, Xiong K, Van Antwerpen C, Stricof RL. Comparison of 2 Clostridium difficile surveillance methods: National Healthcare Safety Network's laboratory-identified event reporting module versus clinical infection surveillance. *Infect Control Hosp Epidemiol*. 2013 Mar;34(3):284-90.

Health Department annual reports

New York
http://www.health.state.ny.us/statistics/facilities/hospital/hospital_acquired_infections/

South Carolina http://www.scdhec.gov/health/disease/hai/

Pennsylvania
http://www.portal.state.pa.us/portal/server.pt/community/healthcare_associated_infections/14234

New Mexico https://nmhealth.org/data/view/report/2213/

**Proposed NQF Response:**

Data element validity testing aims to demonstrate that data elements are correct by analyzing agreement with another authoritative source of the same information. For measures 1716 and 1717, the critical data elements from a sample of patient charts

from a sample of facilities in various states were reviewed against medical records by trained abstractors. The statistical results were presented across states but were validated at the facility level. The testing presented by the developer meets NQF's requirements for demonstration of data element validity.

**Proposed Committee Response:**

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on May 1, 2019.

**Action Item:**

On the Post-Comment Call, the Committee will discuss the commenter's concern, the developer's response, and NQF's response.

### Theme 2 – Measure Alignment with Guideline Recommendations

Three commenters expressed concern that the 8-week monitoring interval for measure 0555 *INR Monitoring for Individuals on Warfarin* is not entirely consistent with existing conflicting guideline recommendations and, therefore, did not support the Committee's recommendation for re-endorsement.

**Measure Steward/Developer Response:**

Clinical practice guidelines recommend regular INR monitoring for patients taking warfarin with recommendations ranging from 4 weeks to up to 12 weeks for patients with stable INRs.[1,2] The current evidence suggests that monitoring less frequently than 56 days is associated with a decrease in the time in therapeutic range (TTR),[3] which is associated with adverse outcomes of bleeding and thromboembolism.[4-8] Recent literature suggests that there has been clinical hesitancy in adopting the 12-week interval due to limited evaluation in practice[9,10] and after a 24-month study of the 12-week interval, it was concluded that even for patients with long-term INR stability, past stability is not a predictor of future stability.[11] This topic was discussed by the NQF Patient Safety Committee and based on current evidence the majority of members voted to retain the measure as specified with the 56-day interval.[12]

1. Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012;141(2 Suppl):e152S-184S. doi: 10.1378/chest.11-2295.

2. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2014;64(21):e1-76. doi: 10.1016/j.jacc.2014.03.022.

3. Rose AJ, Miller DR, Ozonoff A, et al. Gaps in monitoring during oral anticoagulation: insights into care transitions, monitoring barriers, and medication nonadherence. Chest. 2013;143(3):751-757. doi: 10.1378/chest.12-1119.

4. Liu S, Li X, Shi Q, et al. Outcomes associated with warfarin time in therapeutic range among US veterans with nonvalvular atrial fibrillation. Curr Med Res Opin. 2018;34(3):415-421. doi: 10.1080/03007995.2017.1384370.

5. Vanerio G. International Normalized Ratio Variability: A Measure of Anticoagulation Quality or a Powerful Mortality Predictor. J Stroke Cerebrovasc Dis. 2015;24(10):2223-2228. doi: 10.1016/j.jstrokecerebrovasdis.2015.05.017.

6. Labaf A, Sjalander A, Stagmo M, Svensson PJ. INR variability and outcomes in patients with mechanical heart valve prosthesis. Thromb Res. 2015;136(6):1211-1215. doi: 10.1016/j.thromres.2015.10.044.

7. Deitelzweig S, Evans M, Hillson E, et al. Warfarin time in therapeutic range and its impact on healthcare resource utilization and costs among patients with nonvalvular atrial fibrillation. Curr Med Res Opin. 2016;32(1):87-94. doi: 10.1185/03007995.2015.1103217.

8. Nelson WW, Wang L, Baser O, Damaraju CV, Schein JR. Out-of-range international normalized ratio values and healthcare cost among new warfarin patients with non-valvular atrial fibrillation. J Med Econ. 2015;18(5):333-340. doi: 10.3111/13696998.2014.1001851.

9. Porter AL, Margolis AR, Schoen RR, Staresinic CE, Ray CA, Fletcher CD. Use of an extended INR follow-up interval for Veteran patients in an anticoagulation clinic. J Thromb Thrombolysis. 2017;43(3):318-325. doi: 10.1007/s11239-016-1448-y.

10. Barnes GD, Kong X, Cole D, et al. Extended International Normalized Ratio testing intervals for warfarin-treated patients. J Thromb Haemost. 2018;16(7):1307-1312. doi: 10.1111/jth.14150.

11. Porter AL, Margolis AR, Staresinic CE, et al. Feasibility and safety of a 12-week INR follow-up protocol over 2 years in an anticoagulation clinic: a single-arm prospective cohort study. J Thromb Thrombolysis. 2019;47(2):200-208. doi: 10.1007/s11239-018-1760-9.

12. National Quality Forum. Patient Safety, Fall 2018 Review Cycle: CDP Report. Washington, DC: National Quality Forum; 2019. . Accessed March 26, 2019.

**Proposed Committee Response:**

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on May 1, 2019.

**Action Item:**

On the Post-Comment Call, the Committee will discuss the commenter's concern and the developer's response.

### Theme 3 – Related and Competing Measures

One commenter suggested that the developer consider measure 0553 *Care for Older Adults (COA) – Medication Review* as a competing measure with the Pharmacy Quality Alliance's (PQA's) MTM Program Completion Rate Comprehensive Medication Review measure.

**Measure Steward/Developer Response:**

Thank you for your commentary on this measure. NQF defines a competing measure as a measure that has the same measure focus (e.g., target process, condition, event, or outcome; i.e., numerator) AND the same target population (i.e., denominator). PQA's MTM measure does not share either with NCQA's COA – Medication Review measure.

- PQA's measure seeks completion rate of medication therapy management (which is a broader process than medication review involving a face-to-face or telehealth encounter and producing an individualized written summary for the beneficiary), and the denominator is members in Part-D plans (Part-D plans must offer MTM services, BUT they have some flexibility in which patients they target for MTM programs. A recent analysis by CMS shows that 71% of patients targeted for MTM programs are defined as being eligible by being on 8 or more medications.*) The COA-Medication Review measure, in contrast, includes all patients 65 and older in SNP and Medicare-Medicaid plans.
- Both the numerator and denominator are sufficiently different that they should not be considered competing measures.
- The commenter contends that the measure has been adopted by Part-D plans so it may be more widely utilized. However, the COA-Medication Review measure is used in CMS Medicare Stars Rating program for Part-C plans, requiring all Part-C and Part-C+D plans to report.
- We also believe both measures support quality for their respective populations.

**Proposed Committee Response:**

Thank you for your comment.

**Action Item:**

No Committee action required.

### Theme 4 – Supportive Comments

Five comments expressed support for the Committee's recommendation for re-endorsement of measure 3450 *Practice Environment Scale - Nursing Work Index (PES-NWI)* (composite and five subscales). Commenters noted the measure's contribution to helping advance improvement of the work environment for nurses.

**Proposed Committee Response:**

Thank you for your comments.

**Action Item:**

No Committee action required.

### *Measure-Specific Comments*

**0555 INR Monitoring for Individuals on Warfarin**

One of the comments about this measure (included under theme 2 – measure alignment with guideline recommendations) also supported the Committee's recommendation that the developers consider risk adjustment and analyze the impact of social risk factors in the adjustment model.

**Measure Steward/Developer Response:**

Regarding risk adjustment, the NQF Standing Committee agreed that it was acceptable to not consider risk adjustment during this comprehensive review since the measure is a process measure and the data were not available for conducting the required testing from the participating health plans. However, further evaluation of risk adjustment is planned for next comprehensive review since data from implementation may be available to support the analysis.

**Proposed Committee Response:**

Thank you for your comment.

**Action Item:**

No Committee action required.

## 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 Committee's recommendations. Two NQF members provided their expressions of support: See Appendix A.

## Appendix A: NQF Member Expression of Support Results

Two NQF members provided their expressions of support. Three of the six measures under consideration did not receive support from NQF members. Results for each measure are provided below.

**0555 INR Monitoring for Individuals on Warfarin (CMS/Mathematica Policy Research, Inc.)**

| Member Council | Support | Do Not Support | Total |
|---|---|---|---|
| Consumer | 0 | 0 | 0 |
| Health Plan | 0 | 0 | 0 |
| Health Professional | 0 | 1 | 1 |
| Provider Organization | 0 | 1 | 1 |
| Public/Community Health Agency | 0 | 0 | 0 |
| Purchaser | 0 | 0 | 0 |
| QMRI | 0 | 0 | 0 |
| Supplier/Industry | 0 | 0 | 0 |

**1716: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (Centers for Disease Control and Prevention)**

| Member Council | Support | Do Not Support | Total |
|---|---|---|---|
| Consumer | 0 | 0 | 0 |
| Health Plan | 0 | 0 | 0 |
| Health Professional | 0 | 1 | 1 |
| Provider Organization | 0 | 1 | 1 |
| Public/Community Health Agency | 0 | 0 | 0 |
| Purchaser | 0 | 0 | 0 |
| QMRI | 0 | 0 | 0 |
| Supplier/Industry | 0 | 0 | 0 |

**1717: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (Centers for Disease Control and Prevention)**

| Member Council | Support | Do Not Support | Total |
|---|---|---|---|
| Consumer | 0 | 0 | 0 |

| Member Council | Support | Do Not Support | Total |
|---|---|---|---|
| Health Plan | 0 | 0 | 0 |
| Health Professional | 0 | 1 | 1 |
| Provider Organization | 0 | 1 | 1 |
| Public/Community Health Agency | 0 | 0 | 0 |
| Purchaser | 0 | 0 | 0 |
| QMRI | 0 | 0 | 0 |
| Supplier/Industry | 0 | 0 | 0 |