

NATIONAL QUALITY FORUM

CONFERENCE CALL FOR THE STEERING COMMITTEE OF THE NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PATIENT SAFETY MEASURES

February 22, 2011

Committee Members Present: William A. Conway, MD (Co-chair); Lisa J. Thiemann, CRNA, MNA (Co-chair); Jan Allison, RN; Robert Bunting, Jr., MSA, CPHRM, CPHQ; Steven Clark, MD; Clifton Knight, MD; Kris Kowdley, MD; Stephen T. Lawless, MD, MBA; Alan Levine; Stephen E. Muething, MD; Paul Nagy, PhD; Daniel Solomon, MD; Iona Thraen, MSW; David E. Turner, MD, PhD, MPH

NQF Staff Present: Heidi Bossley, MSN, MBA; Andrew Lyzenga, MPP; Elisa Munthali, MPH; Lindsey Tighe, MS; Jessica Weber, MPH

Others Present: Judy Burleson; Lynne Fairobent, American Association of Physicists in Medicine; Ronald Gabel; Rita Gallagher, American Nurses Association; Naomi Kuznets Accreditation Association for Ambulatory Health Care; Cynthia McCollough, Mayo Clinic; Richard Morin, American College of Radiology; Rebecca Swain-Engel, American Academy of Neurology.

WELCOME AND INTRODUCTION

Ms. Munthali welcomed the Steering Committee and thanked them for their participation. Dr. Conway and Ms. Thiemann explained the procedure for reviewing comments and then asked National Quality Forum (NQF) staff to provide a project update. Mr. Lyzenga informed the Steering Committee of the status of two surgical site infection (SSI) measures initially presented in Report I of the Patient Safety Measures project. Pursuant to the Steering Committee's recommendation, the developers of these two measures continue to work towards harmonizing their submissions. As a result, those measures will be moved to a future NQF measure endorsement project, and the central line-associated bloodstream infection (CLABSI) and urinary tract infection (UTI) measures will be presented along with any measures recommended for endorsement during this call, in a single report.

REVIEW OF COMMENTS

Ms. Thiemann and Dr. Conway led the Steering Committee through the comments received on each colonoscopy and radiation dosing measure. All discussion related to the comments is captured in the attached spreadsheet. A summary of detailed discussion topics is captured below.

Colonoscopy Measures

Measures # PSM-014-10, PSM-015-10, and PSM-016-10 assess colonoscopy processing related to personnel instruction, currency, and competency respectively. In response to feedback received during the comment period, the Steering Committee debated whether these measures would be more appropriate as safe practice guidelines or accreditation standards rather than performance metrics. During their discussion, the Committee noted the potential for serious adverse health outcomes as a result of inadequate colonoscopy processing, which is substantiated by several well-publicized studies.

Some commenters were concerned that endorsement of these measures could lead to similar measures on many other medical devices in the future. The Committee reiterated that, as with all measures submitted

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to NQF, any future device-related measures would be evaluated against NQF's criteria for measure endorsement; therefore, endorsement of these colonoscopy measures would not automatically warrant the endorsement of future measures related to medical devices. Ultimately, the Steering Committee upheld their original decision to recommend these measures for time-limited endorsement, stating that the measures met NQF's criteria for endorsement, including importance to measure and report. These measures were recommended as a group measure.

Radiation Dosing Measures

One overarching issue emerged from comments on measures # PSM-043-10 (Participation in a systemic national dose index registry) and # PSM-044-10 (Radiation dose computed tomography) that specifically addressed a statement in the draft report, which indicated that there is no direct correlation between dose indices and amount of radiation absorbed by patients. That being said, several commenters questioned how meaningful this measurement would be for consumers. In their dissenting remarks, NQF Members and the public suggested that radiation absorption amount would serve as a more meaningful measurement for consumers. This concern was addressed in written statements by both developers, the American College of Radiology (ACR) and Dr. Smith-Bindman. The ACR further explained that if dose indices are at optimal levels, then absorbed dose is also optimized. Dose indices measure radiation output of the scanner, i.e., CTDIvol or DLP. Gathering data on the amount of radiation used on patients during an exam—while also examining the associated image quality—can help standardize lower dose techniques on a majority of patients. Measuring the actual absorbed dose for each individual patient is logistically and technically difficult, thus “effective dose” has been used as a proxy. Effective dose is calculated by converting scanner output factors (CTDIvol, DLP) to an estimated dose for a standard size patient, not specific to each patient. The Committee accepted the developers' responses and agreed that dosing indices are directly proportional to radiation absorbed—when one goes up the other goes up proportionally; therefore, the Committee recommends the above quoted text from the draft report be changed as follows: “Dose indices allow for comparability and benchmarking of CT dosing levels.”

In addition to the concern mentioned above, the Steering Committee discussed a number of issues specific to measure # PSM-044-10. In response to feedback received during the comment period, the developer proposed revisions to the measure by adding a third component, which would require anonymous reporting of measure results to a third-party auditing group. (Unfortunately the measure developer was not available and therefore unable to elaborate further on the proposed revised measure.) The Steering Committee believed that this change would be a significant addition to the measure, which would warrant NQF Member and public comment on the proposed revised measure. The Steering Committee asserted that if the measure developer wished to add this component to the measure, the measure should be withdrawn and resubmitted to a future NQF measure endorsement project.

The second component of measure # PSM-044-10 generated several comments particularly about the inclusion of radiation dose indices in the final medical report. (Although the measure developer responded to some of these inquiries in written statements prior to the meeting, she was not available to address these concerns directly.) Many believed that inclusion of this information in the medical report without context or proper comprehension of dose indices could lead to confusion and misuse of results and could also add to the providers' data collection requirements. A number of commenters suggested that dose indices—especially if they are not adjusted for characteristics like patient size—are not sufficiently correlated with patients' actual exposure to radiation. The Steering Committee reaffirmed their position that radiation dose indices are highly correlated with the actual radiation dose received by the patient, and are at present, the best available indicators of radiation exposure without performing an

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invasive procedure on the patient. Nonetheless, the Committee acknowledged that patients may not easily understand radiation dose indices, and while significant variation in dose indices between patients and procedures is both likely and often justified, patients are unlikely to have the background to understand these variations. Consequently, there would be undue burden placed on the provider to interpret and explain data in the reports to patients. Furthermore, providers who do not have radiology expertise may also lack the depth of understanding to properly educate patients on the meaning and significance of radiation dose indices. Following this lengthy discussion, the Steering Committee reversed their initial decision to recommend measure # PSM-044-10 for endorsement. As a result, this measure will not proceed through this patient safety measures project in order to allow the measure developer time to modify the measure and address the aforementioned concerns.

RECONSIDERATION OF PSM-010-10

The American Academy of Neurology (AAN) submitted a letter to NQF requesting formal reconsideration of their submitted measure, # PSM-010-10 Querying and counseling about anti-epileptic drug (AED) side-effects.

The Steering Committee restated their concerns about the measure, noting that the submission did not provide sufficient evidence that demonstrated the link between querying and counseling about AEDs and improved patient outcomes. (The developer did not submit additional data with their reconsideration request.) Therefore, the Steering Committee upheld their original decision not to recommend PSM-010-10 for endorsement.

NQF MEMBER AND PUBLIC COMMENT

Dr. McCollough and Ms. Burlison raised concerns, addressed above in this summary, about the requirement to report radiation dose indices to patients in PSM-044-10.

NEXT STEPS

Ms. Munthali informed the Steering Committee members that the draft report would be redlined based on these discussions, and that the CLABSI and UTI measures from the first report would be merged into this current report. The redlined draft report will be distributed to the Steering Committee for review prior to Member Voting.

The call was adjourned at 4:00 pm ET.