TO: Consensus Standards Approval Committee

FR: Andrew Lyzenga, MPP; Elisa Munthali, MPH

RE: Results of Voting for *National Voluntary Consensus Standards for Patient Safety: A Consensus Report*

DA: June 13, 2011

The CSAC will review the draft report *National Voluntary Consensus Standards for Patient Safety* on the June 13 conference call. This memo includes summary information about the project, comments received, and Member voting results. The complete voting draft report and supplemental materials are available on the project page.

CSAC ACTION REQUIRED

Pursuant to the CDP, the CSAC may consider approval of five candidate standards as specified in the "voting draft" of the *National Voluntary Consensus Standards for Patient Safety – Phase II: A Consensus Report*. The project followed NQF's version 1.8 of the CDP.

BACKGROUND

Through various projects, NQF has endorsed over 100 consensus standards related to patient safety. In addition, NQF has endorsed 34 safe practices in the 2010 update of the Safe Practices for Better Healthcare and 29 Serious Reportable Events (SREs). The Patient Safety Measures project solicited measures to address environment-specific issues with the highest potential leverage for improvement. The Patient Safety Measures project was split into two phases; the first focuses on healthcare-associated infections and this phase addresses medication safety, querying and counseling on side-effects, colonoscope processing, and radiation dosing. A total of 26 measures, including one composite comprising 10 individual components, were considered under this phase of the project. Two of these measures, including the composite, were withdrawn during the evaluation process and 19 of the initially-submitted measures were not recommended for endorsement. Please note that none of the medication safety or querying and counseling measures were recommended for endorsement.

COMMENTS RECEIVED AND THEIR DISPOSITION

The comments indicated a lack of consensus among the public and NQF members. Generally, there was concern about endorsing measures that should be considered standard-of-care. Some also questioned whether endorsement of those measures would lead to other similar, unnecessary measures; others questioned how meaningful the measures would be to consumers. The Committee's recommendations are presented by measure topic area – i.e., colonoscope

processing measures and radiation dosing measures. Comments on these topic areas are summarized in more detail below. The only substantive measure-specific comments addressed the proposal of a new component to be added to measure PSM-044-10 - Radiation Dose of Computed Tomography.

General comments received during the comment period:

Colonoscope-processing measures (PSM-014-10, PSM-015-10 and PSM-016-10)
Several comments raised concern about the colonoscope measures, indicating that they should be considered the standard of care and addressed through state or medical licensure as opposed to performance measures.

> *Action taken:* 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 colonoscope processing, which is substantiated by several well-publicized studies.

A few comments cautioned that endorsement of these measures could lead to similar measures on many other medical devices in the future.

> *Action taken:* The Committee reiterated that, as with all measures submitted to NQF, any future device-related measures would be evaluated against NQF's criteria for measure endorsement; therefore, endorsement of these colonoscope measures would not automatically warrant the endorsement of future measures related to medical devices.

Radiation dosing measures (PSM-043-10 and PSM-044-10)
One overarching issue emerged from comments on the radiation dose measures – that there is no direct correlation between dose indices and amount of radiation absorbed by patients. In addition, several commenters questioned how meaningful data reported through PSM-044-10 would be for consumers.

> *Action taken:* This concern was addressed in written statements by both developers, the American College of Radiology (ACR) and Dr. Smith-Bindman. The ACR 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 recommended modifying the report's language on this issue to state that "dose indices allow for comparability and benchmarking of CT dosing levels."

Harmonization of Radiation Dosing Measures

Recognizing an opportunity to reduce burden on providers and simplify reporting processes, the developers of PSM-043-10 and PSM-044-10 met via conference call to discuss harmonization of their measures. The developers agreed in principle to adjust their respective measures in such a way that the information required from providers under PSM-043-10 would be aligned with the information required for PSM-044-10. This would simplify data collection efforts. The developers will continue working together to refine their plan for harmonization, and will provide an update on the June 13th CSAC call.

Measure specific comments

Radiation dose of computed tomography (PSM-044-10)

Most member and public comments on this measure addressed concerns about the inclusion of dose indices in the medical record (part b) and the importance of patient weight in relation to appropriateness of dose for an individual patient. 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. As stated above, the comments also questioned how the measure would provide meaningful information to consumers.

Developer's Response and Suggested Modifications: Citing previous research,[1] the developer responded that "the differences based on patient size are small compared to the differences in CT dosing due to other factors."

Action taken: The Committee acknowledged that CT machine outputs allow for comparability and benchmarking of dosing levels, but, as expressed in earlier meetings, they were concerned that reporting dose indices for specific, individual patients without consideration of variation in body type and size or proper explanation of what these data meant would be problematic and potentially misleading to consumers and providers.

Reconsideration: The Committee revisited comments on the inclusion of dose indices in the medical record (part b) and the importance of patient weight in relation to appropriateness of dose for an individual patient. The developer reiterated the proximal relationship of CT dose indices to radiation exposure, stating that these metrics have been widely used for over a decade in several countries and are included in a recently-passed California state law, to be collected beginning in 2012. Data was cited from the University of California San Francisco, which

[1] Smith-Bindman, R., Lipson J, et al. (2009). "Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. " *Arch Intern Med* 169(22): 2078-2086.

demonstrates ease of implementation and indicates increased demand for more information by consumers and providers.

Action taken: The Steering Committee recommended the measure for endorsement as it was originally specified.

NQF MEMBER VOTING

The 30-day voting period for the second report of the Patient Safety Measures project closed on May 5, 2011. Votes were received from 23 Member organizations; no votes were received from the Supplier/ Industry or Public/ Community Health Agency Councils.

Measure-specific comments were submitted by the Iowa Family Foundation, ACR, American Academy of Otolaryngology- Head and Neck Surgery, HealthCare 21 Business Coalition, America's Health Insurance Plans, American College of Emergency Physicians and the Centers for Medicare and Medicaid Services. These comments are included under the voting results for each measure in this memo.

Voting Results

Voting Results for the five candidate consensus standards were mixed and are provided below. Measures #PSM-043-10 Participation in a systematic national dose index registry and PSM-044-10 Radiation dose of computed tomography were approved by an absolute majority. However, there is a lack of clear consensus on the colonoscope processing measures, PSM-014-10, PSM-015-10, and PSM-016-10. The colonoscope processing measures were recommended by the Steering Committee as grouped or paired measures; thus, if one measure is not approved by the membership, the group of measures cannot move forward for endorsement.

Paired Measures:

MEASURE PSM-014-10: Colonoscope Processing Personnel Instruction

Measure Council	Yes	No	Abstain	Total Votes	% Approval Yes/ (Total-Abstain)	% of Councils Approving (>50%)
Consumer	0	2	0	2	0%	50%
Health Plan	3	0	0	3	100%	
Health Professional	4	0	3	7	100%	
Provider Organizations	1	2	0	3	33%	
Public/Community Health Agency	0	0	0	0		**Average Council Approval Rate**
Purchaser	0	5	0	5	0%	50%

QMRI	1	0	2	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**9**	**9**	**5**	**23**	**50%**
Percentage of councils approving (<50%)					50%
Average council percentage approval					56%

Voting Comments

America's Health Insurance Plans voted in support of this measure since "the measure states a minimum frequency."

The Centers for Medicare & Medicaid Services voted against this measure and also submitted the following comments: "Similar to measure PSM-044-10, PSM-14-10 provides desirable information that is more appropriate as a "safe practice" rather than a measure of healthcare quality. The measure is appropriate for survey and certification standards, but is also an insufficient foundation for quality measurement. Survey data collection and reporting challenges are additional concerns."

HealthCare 21 Business Coalition voted against this measure and also submitted the following comments: "The three colonoscope measures reflect activity that should be standard of practice, and at the very most, may be appropriate for internal quality improvement. While the goal of reducing the rates of viral infection associated with colonoscopy is certainly one that we support, we do not feel that the best method of doing so, within the quality enterprise, is by endorsing structural measures of whether an office or Ambulatory Surgery Center a) receives colonoscope operating instruction updates annually, b) reviews colonoscope device reprocessing guidelines annually; or c) documents that their staff are competent at reprocessing colonoscopies and/or changes made in the equipment or recommendations. Issues of adherence to training and cleaning guidelines are more appropriately addressed through state and medical licensing bodies. When we consider measures for NQF endorsement, we must consider whether we believe the measures should be linked to public reporting or payment programs, and in this case, I believe the answer is no. Finally, and perhaps most importantly, these measures are yet further removed from evidence-based linkage to outcomes; they are not even measuring adherence to cleanliness and equipment sterilization standards, but, rather, whether proper training has taken place."

MEASURE PSM-015-10: Colonoscope Processing Currency

Measure Council	Yes	No	Abstain	Total Votes	% Approval Yes/ (Total-Abstain)	% of Councils Approving (>50%)
Consumer	0	2	0	2	0%	50%
Health Plan	3	0	0	3	100%	
Health Professional	4	0	3	7	100%	
Provider Organizations	1	2	0	3	33%	
Public/Community Health Agency	0	0	0	0		**Average Council Approval Rate**
Purchaser	0	5	0	5	0%	50%
QMRI	1	0	2	3	100%	
Supplier/Industry	0	0	0	0		
All Councils	**9**	**9**	**5**	**23**	**50%**	
Percentage of councils approving (<50%)					50%	
Average council percentage approval					56%	

Voting Comments

America's Health Insurance Plans voted in support of this measure but also stated that they "would encourage the measure developer to focus on outcomes measures, such as the number of Polyps detected".

The Centers for Medicare & Medicaid Services voted against this measure and also submitted the following comments: "Similar to measure PSM-044-10, PSM-15-10 provides desirable information that is more appropriate as a "safe practice" rather than a measure of healthcare quality. The measure is appropriate for survey and certification standards, but is also an insufficient foundation for quality measurement. Survey data collection and reporting challenges are additional concerns."

HealthCare 21 Business Coalition voted against this measure and also submitted the following comments: "The three colonoscope measures reflect activity that should be standard of practice, and at the very most, may be appropriate for internal quality improvement. While the goal of reducing the rates of viral infection associated with colonoscopy is certainly one that we support, we do not feel that the best method of doing so, within the quality enterprise, is by endorsing structural measures of whether an office or Ambulatory Surgery Center a) receives colonoscope operating instruction updates annually, b) reviews colonoscope device reprocessing guidelines annually; or c) documents that their staff are competent at reprocessing colonoscopies and/or changes made in the equipment or recommendations. Issues of adherence to training and cleaning guidelines are more appropriately addressed through state and medical licensing bodies. When we consider measures for NQF endorsement, we must consider whether we believe the measures should be linked to public reporting or payment programs, and in this case, I believe the answer is no. Finally, and perhaps most importantly, these measures are yet further removed from evidence-based linkage to outcomes; they are not even measuring adherence to cleanliness and equipment sterilization standards, but, rather, whether proper training has taken place."

MEASURE PSM-016-10: Colonoscope Processing Competency

Measure Council	Yes	No	Abstain	Total Votes	% Approval Yes/ (Total-Abstain)	% of Councils Approving (>50%)
Consumer	0	2	0	2	0%	50%
Health Plan	2	1	0	3	67%	
Health Professional	4	0	3	7	100%	
Provider Organizations	1	2	0	3	33%	
Public/Community Health Agency	0	0	0	0		Average Council Approval Rate
Purchaser	0	5	0	5	0%	50%
QMRI	1	0	2	3	100%	
Supplier/Industry	0	0	0	0		
All Councils	**8**	**10**	**5**	**23**	**44%**	
Percentage of councils approving (<50%)					50%	
Average council percentage approval					50%	

Voting Comments

HealthCare 21 Business Coalition voted against this measure and also submitted the following comments: "The three colonoscope measures reflect activity that should be standard of practice, and at the very most, may be appropriate for internal quality improvement. While the goal of

reducing the rates of viral infection associated with colonoscopy is certainly one that we support, we do not feel that the best method of doing so, within the quality enterprise, is by endorsing structural measures of whether an office or Ambulatory Surgery Center a) receives colonoscope operating instruction updates annually, b) reviews colonoscope device reprocessing guidelines annually; or c) documents that their staff are competent at reprocessing colonoscopies and/or changes made in the equipment or recommendations. Issues of adherence to training and cleaning guidelines are more appropriately addressed through state and medical licensing bodies. When we consider measures for NQF endorsement, we must consider whether we believe the measures should be linked to public reporting or payment programs, and in this case, I believe the answer is no. Finally, and perhaps most importantly, these measures are yet further removed from evidence-based linkage to outcomes; they are not even measuring adherence to cleanliness and equipment sterilization standards, but, rather, whether proper training has taken place."

MEASURE PSM-043-10: Participation in a Systematic National Dose Index Registry

Measure Council	Yes	No	Abstain	Total Votes	% Approval Yes/ (Total-Abstain)	% of Councils Approving (>50%)
Consumer	0	2	0	2	0%	67%
Health Plan	2	1	0	3	67%	
Health Professional	6	0	1	7	100%	
Provider Organizations	2	1	0	3	67%	
Public/Community Health Agency	0	0	0	0		**Average Council Approval Rate**
Purchaser	1	4	0	5	20%	59%
QMRI	2	0	1	3	100%	
Supplier/Industry	0	0	0	0		
All Councils	**13**	**8**	**2**	**23**	**62%**	
Percentage of councils approving (<50%)					67%	
Average council percentage approval					59%	

Voting Comments

HealthCare 21 Business Coalition voted against this measure and also submitted the following comments: "It is unclear what value this measure would add to the NQF portfolio. I would appreciate NQF explaining in greater detail how being able to compare and benchmark CT dosing levels, which is the argument for why this measure is important -- will lead to patient safety improvements related to radiation absorption. I ask that the pre-voting report from this committee discuss this with more clarity and detail so that consumer and purchaser members can make an informed voting decision."

MEASURE PSM-044-10: Radiation Dose of Computed Tomography (CT)

Measure Council	Yes	No	Abstain	Total Votes	% Approval Yes/ (Total-Abstain)	% of Councils Approving (>50%)
Consumer	2	0	0	2	100%	83%
Health Plan	3	0	0	3	100%	
Health Professional	3	3	1	7	50%	
Provider Organizations	2	1	0	3	67%	
Public/Community Health Agency	0	0	0	0		**Average Council Approval Rate**
Purchaser	4	1	0	5	80%	75%
QMRI	1	1	1	3	50%	
Supplier/Industry	0	0	0	0		
All Councils	**15**	**6**	**2**	**23**	**71%**	
Percentage of councils approving (<50%)					67%	
Average council percentage approval					74%	

Voting Comments

The American Academy of Otolaryngology-Head and Neck Surgery voted against this measure and also submitted the following comments: "The American Academy of Otolaryngology- Head and Neck Surgery is supportive of Part A of this measure, namely documenting and monitoring CTDIvol and DLP for common CT examinations at the facility level. This part of the measure is complementary with the ACR measure on participation in dose index registry. We support the use of benchmarks to audit and monitor facility level dose performance and quality improvement, even in the absence of data on patient habitus/size. However, the Academy is very concerned about Part B of the measure that relates to inclusion of dose in the patient report.

The measure recommends reporting patient dose, without adjustment for patient size or exam name standardization, in the patient record. At the patient-level, reporting the individual dose without patient size or reference to appropriate dose level for the given exam is misleading, difficult to act upon and could raise patient alarm unnecessarily. These are issues identified by multiple parties (i.e. ED representative, consumer advocate representative, American Association of Physicists in Medicine AAPM) through the comment period and steering committee discussion, but not completely addressed by the measure developer. Part A of the measure is collection and analysis of data at a facility level; the aggregated data reduces concern as to the patient size, yet Part B requires reporting of dose information at the patient level. To clarify, the value reported in the patient report is not a facility level value that might be averaged across a patient population, but is the value of the dose delivered to an individual which may be variable

for legitimate reasons, including patient size. The measure does not address how the possible and expected variation in doses given from one individual patient to another might be sufficiently explained or presented in a manner helpful to the patient and the ordering physician."

The American College of Emergency Physicians voted against this measure and also submitted the following comments: "ACEP is concerned that the metric of PSM-044-10 does not account for weight based differences. The measure recommends reporting patient dose, without adjustment in the patient record for patient size or exam name standardization.

The dose indices, such as "volume CT dose index" or "dose length product" are important, but more related to the actual technical performance of the CT scan and less significant for the clinician/patient interaction especially given the arguments that it is not organ/dose specific. This measure, if it were to focus on technology performance modulation alone would be fine, but in part B the inclusion of this information within the radiology report places data in the hands of the emergency physician that would be too complex to address during our acute patient encounter. At the patient-level, reporting the individual dose without patient size or reference to appropriate dose level for the given exam is misleading, difficult to act upon and could raise patient alarm unnecessarily."

The American College of Radiology voted against this measure and also submitted the following comments: "The ACR supports Part A of PSM-044-10. This is complementary with the ACR dose index registry measure. We support the use of benchmarks to audit and monitor facility level dose performance and quality improvement.

The ACR is concerned about Part B, which relates to inclusion of dose in the patient report. Specifically, the measure recommends reporting patient dose without adjustment for patient size or accounting for diagnostic task. At the patient-level, reporting in this way could be misleading, difficult to act upon and could raise patient alarm unnecessarily. These issues were identified (i.e. ED representative, consumer advocate representative, the AAPM) through the comment period and steering committee discussion, but not satisfactorily addressed by the measure developer. Part A is at a facility level; such aggregated dose data reduces, but does not eliminate, concern as to the patient size, yet Part B requires dose reporting at the patient level. To clarify, the value proposed for reporting in the patient report is the value of the scanner radiation output used for an individual -- not a facility level value averaged across a patient population. The scale factor between scanner output and patient dose is highly dependent on the patient size and scanner model. Scanner output can vary considerably from patient to patient for legitimate reasons; good medical practice requires that it be varied by a large amount across a spectrum of patient sizes (a factor of 10 -20 between infants and obese adults). The proposed measure does not address how this expected and appropriate variation in dose indices from one individual patient to another will be sufficiently explained or presented in a manner helpful to the patient

and the ordering physician.

In the UCSF measure developer response, findings from the ACR Dose Index Registry are misquoted by not providing adequate context for the numbers (Table "CT of the Abdomen" on page 12). The main finding was that much of the variability in facility average exam dose was explained by the lack of standardization of exam names. "CT of the Abdomen" refers to a wide variety of exams (i.e. ABDOMEN_With (Adult), ABD_PEL_WO, etc.)- some may require higher doses for legitimate clinical reasons. The reference dose indices specified in the ACR Accreditation documents are those delivered to a phantom (not a human patient) for a single phase scan; the values are not comparable to what was found at the exam level for an actual patient in the registry pilot. Further, the phantom matches the attenuating properties of only one size of patient, while the dose registry included data from the full range of patient sizes. Thus, a large variation in reported doses indices exists in the registry for completely appropriate reasons. If using those reference values, patients and providers will be comparing their reported value to a reference value that will frequently not match their situation, potentially and incorrectly concluding that the dose used for their exam was inappropriate. This type of misinformation will create unnecessary concern in patients and providers, and may result in patients not receiving appropriate, needed medical imaging exams.

The measure lists effective dose as one potential value to be placed in the patient record. It is essential that effective dose be explicitly disallowed as a reportable value, especially at the patient level. Effective dose is not an appropriate quantity for use in patient risk assessment. It is a parameter reflecting an average over both genders and all ages and was defined for use in monitoring occupational radiation exposures and "[T]he use of effective dose for assessing the exposure of patients has severe limitations that must be taken into account by medical professionals."

Source: International Commission on Radiation Protection Report No. 103, "2007 recommendations of the International Commission on Radiological Protection.""

The Centers for Medicare & Medicaid Services voted against this measure and also submitted the following comments: "Although we support the PSM-044-10 measure's intent to encourage documentation of radiation exposure dose, we believe that documentation alone is insufficient for a strong measure that can be used for anything beyond internal quality monitoring. Our disapproval decision was also supported by the lack of information and connection to improved patient outcomes. Ultimately, PSM-044-10 provides desirable information that is more appropriate as a "safe practice" rather than a measure of healthcare quality."

The Iowa Foundation for Medical Care voted against this measure and also submitted the following comments: "Some usefulness for this measure's Part B (Part A we have no problem

with as is); but obviously consensus has not been reached yet. It may be prudent to delay endorsement/implementation until this consensus can be reached."