Re: PSM-044-10 of the National Voluntary Consensus Standard for Patient Safety Measures, 2nd Report

Dear members of the National Quality Forum Board:

As Professors of Radiologic Physics (at Mayo Clinic and UCLA, respectively), our expertise is in CT technology and dose management. We absolutely support the efforts of the National Quality Forum to develop and implement data-driven processes that will ensure patient safety in CT imaging.

Recently, we participated in NQF telephone calls representing the American Association of Physicists in Medicine (AAPM). Our comments regarding measure PSM-044-10 are attached.

The purpose of this letter is to formally appeal the decision to make PSM-044-10 an NQF Endorsed Safe Practice.

The bases for this request for reevaluation through your appeal process are as follows:

- The concern that we focused too narrowly on specific technical details, perhaps clouding the conversation, and that the best outcome for patient safety for this important measure was not achieved.
- The AAPM fully supports the implementation of dose registries, whether on a national level or within specific practices and institutions, as quality assessment and improvement tools. However, the measure as written is inadequate for these purposes.
- It is essential to have the right data to assess, monitor, and improve the quality and safety of CT imaging. It because these data are essential for patients, physicians, and those who perform CT examination to clearly understand the doses being applied, *and to be able to make correct assessments of what doses are reasonable vs. not reasonable*, the metrics associated with PSM-044-10 measure need to be modified.
- Simply put, CT Dose Index (CTDI) and its derivative Dose Length Product (DLP), which are used in PSM-044-10, are merely a measurement of the radiation output of the scanner, not a measure of the radiation dose delivered to a patient. It can be appropriate for CTDI and DLP to vary widely when care is taken to use the proper dose of radiation.
- For instance, large adult patients require more radiation than children for a given scan. That is why the existing **NQF Safe Practice 34** sets forth the following *"When CT imaging studies are undertaken on children, "child-size" techniques should be used to reduce unnecessary exposure to ionizing radiation"* (page 381 of the 2010 NQF Safe Practices Report).
- While we agree that reviews of protocols and patient cases may reveal systematic overuse of multiphase protocols, larger scanning regions, or higher-

dose settings, we disagree that this can be done by simply reviewing CTDI and DLP values, which do not account for patient size and clinical factors. It is essential to record and account for patient and exam variables in order to determine if observed variations in dose indices are or are not appropriate. CTDI and DLP are essential parts of that process, but of themselves are insufficient metrics.

- Our primary message to you is that to use CT as effectively and safely as possible, the various dose metrics used in CT must be precisely understood and accurately applied. We want to reduce the risk of harm to patients from oversimplifying complex issues and metrics.
- This letter is a request to allow the technical experts within the AAPM and the national community to re-evaluate and optimize the proposed measure to help ensure that the safety measures and processes that we put into place will have the intended outcome of improving patient safety.
- The likelihood of broad acceptance by the national stakeholder community is directly related to properly addressing the issues mentioned above, and we are certain that a re-evaluation of this measure will be worth the effort.

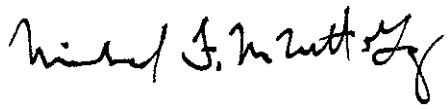
PSM-044-10 contains the right goals and is being brought forward at the right time. Dose tracking, reporting, and analysis are the first-line tools needed to improve patient safety in CT, and we unequivocally support the NQF's endorsement of this activity.

We look forward to hearing from you on how we can support the NQF in this important initiative.

Sincerely,

Cynthia H. McCollough, PhD
Professor, Department of Radiology
Mayo Clinic
200 First Street SW
Rochester, MN 55905

+1-507-284-6875
mccollough.cynthia@mayo.edu



Michael McNitt-Gray, PhD
Professor, Department of Radiological Sciences
David Geffen School of Medicine at UCLA
924 Westwood Blvd., Suite 650
Los Angeles, CA 90095

+1-310-794-8979
mmcnittgray@mednet.ucla.edu

American Association of Physicists in Medicine
One Physics Ellipse
College Park, MD 20740-3846
(301) 209-3350
Fax (301) 209-0862
http://www.aapm.org

February 11, 2011

Comments Regarding: National Voluntary Consensus Standards for Patient Safety Measures, Second Report

The following comments on the proposed NQF report were prepared by Drs. Michael McNitt-Gray and Cynthia McCollough, co-chairs of The American Association of Physicists in Medicine[1] (AAPM) Computed Tomography (CT) Committee.

Summary

First, we fully support the American College of Radiology (ACR) Dose Index Registry and strongly recommend that this measure (which is essentially a Yes/No question as to whether a site is participating in a national dose registry) be supported.

For the second proposal, we have some concerns, especially in the interpretation of the Dose Index information. In the proposal from UCSF, the proposed measure would first require CT scan providers to record the dose index (CTDIvol, DLP, or "effective dose"– an estimate based on DLP and other factors) for a consecutive sample of CTs conducted in the head, chest, abdomen/pelvis, and lumbar spine. Under the second part of the measure, these dose indices would be required to be included in patients' final medical reports.

While this measure is well intended, **we believe there are problems with this approach that will not allow it to be used as intended, primarily because size of the patient is NOT taken into account. That is, as described below, it is entirely appropriate for dose indices to vary with patient size; however if one only looks at the dose index value - without any information about patient size - it is *impossible* to determine whether variations in the dose indices between patients for a given exam type are due to *appropriate* adaptations of system output to differences in patient size or *inappropriate* variation in protocols. This has tremendous implications for making appropriate adjustments for patient size, such as reducing tube output for pediatric patients. If a site is looking to reduce the variation in a**

[1] The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics; a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,500 medical physicists.

dose index value, without any information about patient size, then this could lead to a lack of adjustment for patient size or diagnostic task. This would result in a one size fits all approach to adjusting scanner output - which may lead to the same technical factors being used for both pediatric and adult patients - and which goes against what we know is appropriate clinical practice.

Therefore, we recommend that this proposal either be modified or delayed until it can implemented with appropriate information recorded (i.e., some index of patient size); otherwise, variations in dose indices that are entirely appropriate may be (and already have been) interpreted as being inappropriate variations within a clinical practice.

Background (Based on References [1-3])

The CTDIvol is a standardized measure of the radiation output of a CT system, measured in a cylindrical acrylic phantom, which allows users to gauge the amount of emitted radiation and to compare the dose between different scan protocols or scanners. Very complex calculations are required to map scanner output to patient dose, taking into account the patient's size, irradiated organs, body composition, and the scan range. The actual dose to any given patient directly depends on the size and shape of the patient.

Examples of the inappropriate use of CTDIvol, dose-length product, and effective dose include the widely publicized reports of large variations in "doses" from CT exams. The problem with such reports, however, is the lack of correction for patient size. For example, in Monte Carlo simulations of absorbed patient dose that take into account patient size, it has been shown that the effective dose increases much more slowly than the CTDIvol or dose-length product. To achieve similar image quality, the scanner output (CTDIvol) should be increased by about a factor of two as patient size changes from a typical adult abdomen (lateral dimension of 35-40 cm) to an obese adult abdomen (lateral width of 45-50 cm). Even though the scanner output increases by a factor of two, the dose to many of the radiosensitive internal organs used in the calculation of effective dose does not increase by the same amount due to the attenuation of the additional adipose tissue. **Rather, the factor of two increase in the CTDIvol, combined with the larger patient size, results in a net increase in effective dose of only approximately 20-30%.**

An important implication of the need to take patient size into account, both when estimating patient dose and when prescribing the correct scanner output settings, is that considerable variation in CTDI-based dose metrics can, and should, be expected. **Facilities that adjust their CT technique appropriately for patient size, whether with manual technique charts or automatic exposure control, will prescribe a wide range of scanner output (CTDI) values. This is a good outcome, reflecting the facility's conscientiousness in "right-sizing" the dose settings based on specific patient habitus, especially for pediatric patients**. Further, **variability in the image quality criteria for various diagnostic tasks and clinical applications introduces variability in the scanner output settings that one should prescribe, even for patients of the same size.** For example, scanner output should vary markedly between CT colonography and CT enterography, even for the same patient. Thus, radiation management in CT requires right-sizing the scanner output, not only for patient size, but also for the imaging task.

CTDIvol provides a very useful way of comparing the quantity of radiation delivered by various scan protocols or to achieve a specific level of image quality. Through the use of x-ray technique charts and diagnostic reference levels, CTDIvol can be used to prescribe the right scanner output for a specific patient size and diagnostic task. But, CTDIvol cannot be used as a surrogate for patient dose, either in epidemiological assessments of potential late effects or for potential deterministic effects (e.g. skin injury). **Neither CTDIvol nor its derivative, dose-length product (DLP, which is the product of CTDIvol and the irradiated scan length), should be used to estimate effective dose or potential cancer risk for any individual patient**. The published "k factors" used to convert dose-length-product to effective dose all assume a standard-sized patient. For the adult k factors, this "standard" patient is a relatively thin adult by today's standards (70 kg nominal body mass). Similarly, the k factors for newborns, 1-, 5-, 10- and 15-year-olds refer to a generic child of that age, even though the dimensions assigned to an age do not always correlate well with individual patient sizes. Both for children and adults, the idealized patient model is a hermaphrodite; that is, it has the sexual organs of both genders.

Thus, the patient models used to estimate dose using DLP represent no real patient. ***It is inaccurate and misleading to associate an estimate of effective dose with any specific patient.*** That it, effective dose should not be calculated and placed in a any patient's image data (e.g., DICOM header) or in their medical record. Cancer risk estimates for any one individual require estimation of *that individual's* organ doses and use of the age- and sex-specific risk coefficients for each individual organ and tissue. Effective dose *estimates* represents a generic estimate of risk from a given procedure to a generic model of the human body. It in no way represents a risk to any one individual, and therefore should NOT be reported as part of a patient's medical record. Recording scanner output in terms of CTDIvol and DLP, along with the images of a specific patient, provide all the information that is necessary to retrospectively estimate the mean dose to *that individual patient*, and potentially organ doses to that patient, taking into account that specific patient's body habitus, thereby developing an estimate of risk that is appropriate for that specific patient. The DLP-derived values are overly simplified shortcuts that are not accurate estimates of risks for the majority of patients.

While dose indices are not directly related to the amount of radiation absorbed by patients, they may allow for comparability and benchmarking of CT dosing levels, but only under very specific conditions (e.g., for a "standard sized patient") and not for individual patient exams.

Therefore, due to the reasons outlined above, the recording of dose indices without concurrently recording information about patient size and diagnostic task, may lead to incorrect interpretation of data recorded. Without this information, variations in dose indices that reflect appropriate adaptation to patient size and diagnostic task may be interpreted as inappropriate variations in clinical practice.

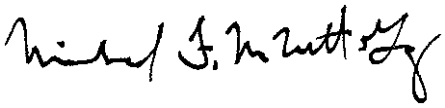
In fact, if sites seek to reduce variation in dose index values, this may lead to a lack of adjustment for patient size or diagnostic task – resulting in a one size fits all approach to adjusting system output, which goes against what we know is appropriate clinical practice.

The AAPM is currently addressing these issues through several mechanisms. First, its Task Group 204 is completing a report that describes how users can convert measures of scanner

output, i.e., CTDIvol, to an estimate of patient dose for patients of any size. Second, we are working with manufacturers and the organization that standardizes data fields in medical imaging (DICOM) to integrate a robust assessment of patient size into scanner software and the DICOM data fields. When this is accomplished, the essential step of adjusting for patient size will be able to be accomplished, and tracking of variation in CT doses can be properly performed on a national scale. We support your efforts to make CT imaging as safe as possible through the tracking and reporting of dose information, and offer our support and partnership in implementing such efforts in a practical and scientifically appropriate manner.

If you have any questions, please contact Lynne Fairobent, Manager of Legislative and Regulatory Affairs at lynne@aapm.org or 301-209-3364.

Respectfully submitted,



Michael McNitt-Gray, PhD, DABR
Co-Chair, AAPM CT Committee
Professor
UCLA Department of Radiology

Cynthia McCollough, PhD, DABR
Co-Chair, AAPM CT Committee
Professor
Mayo Clinic Department of Radiology

References

[1] McCollough CH, Leng S, Yu L, Cody DD, Boone JM, McNitt-Gray MF. CT Dose Index (CTDI) and Patient Dose: They Are Not The Same Thing. In Press, Radiology 2011.

[2] Turner AC, Zhang D, Khatonabadi, Zankl, DeMarco JJ, Cagnon CH, Cody DD, Stevens DM, McCollough CH, McNitt-Gray MF. The feasibility of patient size-corrected, scanner-independent organ dose estimates for abdominal CT exams. Med. Phys. **38**(2), 820–829 (2011).

[3] McCollough CH, Christner JA, Kofler JM. How effective is effective dose as a predictor of radiation risk? AJR Am J Roentgenol. 2010 Apr;194(4):890-6. Erratum in: AJR Am J Roentgenol. 2010 May;194(5):1404. PMID: 20308487.