DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
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OCT 19 2011

National Quality Forum
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Washington, D.C. 20005
Email: patientsafety@qualityforum.org

Re: NQF Measure #0739: Radiation Dose of Computed Tomography (CT) [Proposed as PSM-044-10]

Dear National Quality Forum Board of Directors:

The FDA is supportive of NQF's efforts to develop quality indicators that measure radiation dose and promote quality improvement in medical imaging. We recognize that dose optimization and exam appropriateness are complex issues that are not easily resolved. And we understand the difficulty associated with establishing reasonable measures of dose that can be used to enhance patient safety and improve the practice of medical imaging.

In fact, FDA's Center for Devices and Radiological Health has long-standing programs directed at characterizing radiation dose from medical imaging exams. Under the Federal Food, Drug, and Cosmetic Act, FDA has authority to "plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation" (21 USC 360ii). FDA's *Nationwide Evaluation of X-ray Trends* (NEXT) program (http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/NationwideEvaluationofX-RayTrendsNEXT/default.htm), conducted in partnership with the Conference of Radiation Control Program Directors (CRCPD), conducted CT dose surveys in 2000 and 2005. Most recently, the Agency's *Initiative to Reduce Radiation Exposure from Medical Imaging* (http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199904.htm) promotes the collection of dose data and the development of diagnostic reference levels through national registries.

The purpose of this letter is to express FDA's concern that NQF Measure #0739, *Radiation Dose of Computed Tomography (CT)*, is not well designed, is confusing, and may adversely affect the quality of medical imaging exams. While we believe that monitoring CT dose data as part of clinical facilities' radiation dose management responsibilities is an important public health goal, we request that the NQF Board of Directors reconsider measure #0739 for the following reasons:

1. CT dose indices (such as CTDI or DLP) vary, and should vary, depending on both patient size and the clinical task. It is an accepted principle that radiation dose should be lower for a small child than for a large adult, as NQF has endorsed in its Safe Practice 34 for pediatric imaging in the Safe Practices for Better Healthcare- 2009 Update (http://www.qualityforum.org/Publications/2009/03/Safe_Practices_for_Better_Healthcare%e2%

80%932009_Update.aspx). It is also an accepted principle that the dose should be appropriate for the imaging task (see Image Wisely's Protocol Design site: http://www.imagewisely.org/Imaging-Professionals/Imaging-Physicians/Articles/CT-Protocol-Design.aspx?CSRT=8330411862503156369). The proposed measure stratifies data only by age subgroups (<1, 1-5, >5-10, >10-15, and >15), anatomic areas (head, chest, abdomen/pelvis, and lumbar spine), and by CT system.

Because CT dose and image quality depend on the size of the body region examined, size, not age, data should be collected based on population subgroups defined by both age and size. Nearly every major CT equipment manufacturer provides scanning features that modulate patient dose based on patient size, not age. While it is important to stratify collected dose data according to patient age in recognition of the increased sensitivity to radiation detriment for certain populations (eg. pediatric patients), grouping collected dose data for all exams of the head, chest, abdomen/pelvis, and lumbar spine only according to age subgroups may result in data that are confusing and lead to adverse health outcomes. In addition, the dose data should be further stratified based on clinical indication, which may require different doses for exams on the same body region. For example, a high-resolution chest exam for diffuse lung disease requires greater image quality and therefore more dose than a chest exam performed on a patient with known or suspected lung cancer (see: National Radiological Protection Board: Doses from Computed Tomography (CT) Examinations in the UK - 2003 Review. Shrimpton PC et al. National Radiological Protection Board, Childton, Didcot, Oxon, ISBN 0859515567 (http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947420292).

As an example of the measure adversely affecting quality of care, a facility may find that its dose data for a "medium child (>5-10)" chest protocol are higher than the CTDI and DLP values reported from other facilities; the facility may then lower its technique factors. However, as the NQF #0739 measure is currently proposed, the reason for the variation would not be clear, but may be clinically appropriate. The facility may be examining 5-10 year olds who are on average much larger than those in other facilities or the facility may have a high volume of chest exams requiring higher image quality based on the diagnostic task. In either case its higher dose protocols would be appropriate.

The proposed measure does not take into account the body of national and international knowledge on how to collect CT dose data for use in facility quality assurance programs:

- The International Council on Radiation Protection (ICRP) has provided guidance on how to collect dose data to calculate reference levels; individual facilities can use these reference levels to benchmark the dose for their exams to other facilities. The ICRP has suggested that a reference group of patients be defined based on height and weight in collection of dose data:

> **Additional Advice on Diagnostic Reference Levels from ICRP Committee 3**
> (http://www.icrp.org/docs/DRL_for_web.pdf)
> "Objective of a Diagnostic Reference Level (12) The objective of a diagnostic reference level is to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task. This is accomplished by comparison between the numerical value of the diagnostic reference level (derived from relevant regional, national or local data) and the mean or other appropriate value observed in ***practice for a suitable reference group of patients or a suitable reference phantom. A reference group of patients is usually defined within a certain range of physical parameters (e.g. height, weight)***. If an unselected sample of patients were used as a reference group, it would be

difficult to interpret whether the observed value for the sample is higher or lower than the diagnostic reference level. A diagnostic reference level is not applied to individual patients."

This method has been the standard for more than 20 years (Wall BF, Shrimpton PC. The historical development of reference doses in diagnostic radiology. Radiat Prot Dosimetry. 1998;80(1-3):15-9).

- The importance of carefully stratifying radiation dose by patient size and type of examination in radiation dose surveys is recognized worldwide. For example, the UK National Protocol for Patient Dose Measurements in Diagnostic Radiology recommends that the mean weight of a sample of patients in a specific room should lie in the range 65–75 kg (Hart D, Hillier MC, Wall BF. National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK. Br J Radiol. 2009;82(973):1-12). A mean weight of 70 kg is used throughout the world, even in countries where the mean patient weight can be expected to differ from the European or American norm (Kim YH, Choi JH, Kim CK, et al. Patient dose measurements in diagnostic radiology procedures in Korea. Radiat Prot Dosim. 2007;123(4):540-5.).

- The proposal NQF # PSM-044-10 cites a report from the UK's National Radiological Protection Board: Doses from Computed Tomography (CT) Examinations in the UK - 2003 Review. Shrimpton PC et al. National Radiological Protection Board, Childton, Didcot, Oxon, ISBN 0859515567 (http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947420292). In this report, the exams included are carefully delineated based on patient size and clinical indication. While ages are used to categorize subgroups, data were collected only for patients representing "average" or "typical" sizes (for example the adult data corresponds to patients with weights close to 70 kg). Also, the exams represented in this survey are carefully defined according to indication (e.g., chest, lung cancer vs. high resolution scan for diffuse lung disease).

- In its CT dose index registry, the ACR has recognized the importance of recording patient size data so that this variable can be appropriately accounted for in data analysis. Also the ACR CT registry uses standardized nomenclature (RadLex) to ensure that like examinations are being compared across facilities.

- FDA's NEXT surveys have long used phantoms that are representative of a pre-defined patient size for exposure measurements to ensure that statistical comparisons are scientifically sound.

2. It is essential that any proposed CT dose measure be accompanied by clear instructions for implementation. It is unclear what instructions will accompany Measure #0739. While detailed "Measure Descriptive Information" (PSM-044-10) is posted on the NQF website, this document is difficult to find and is not posted along with the summary of the measure (http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=221#p=4&s=n&so=a&k=radiation&e=1&st=&sd=&mt=&cs=). Regardless of whether this measure or some alternative measure is finally adopted, detailed instructions must be easily accessible.

3. The application for proposing measures to the NQF includes a question to the submitting party (steward) whether the measure has been "fully developed and tested". Although the

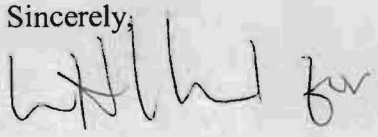
submission appears to indicate that the measure has met this requirement, the FDA is presently not aware of any such supporting data that has collected, analyzed, and promulgated (at least) to participants the results of such an activity. The FDA encourages the NQF to ensure that this component of the measure submission is met.

FDA does support the principle goal of NQF Measure #0740, *Participation in a Systematic National Dose Index Registry*: facilities should be encouraged to manage patient dose in part by participating in a dose registry. Such a registry could be a local, regional, health network-based, or even state level activity. And while we are not appealing NQF Measure #0740, we encourage NQF to make it clear that participation in a regional registry that collects data according to patient age, size and clinical indication would also fulfill the goals of this radiation safety metric. Regardless of the scope of participation, a facility will likely improve patient care by participating in such activity.

The FDA in general supports NQF's efforts to promote use of CT dose as a quality indicator. The details of how this is accomplished are critical to obtaining an understandable and useable measure. For the reasons stated above, we are appealing the Board's endorsement of NQF Measure #0739. FDA supports alternative measures for tracking CT dose that account for patient size and clinical task. We encourage further development of medical radiation safety quality measures, and we offer the assistance of staff in FDA's radiological health program with such future efforts.

Thank you for your consideration. If you have any questions, please contact Dr. Donald Miller at donald.miller@fda.hhs.gov.

Sincerely,



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