

April 29, 2022

The American Association of Physicists in Medicine (AAPM), is pleased to submit comments to the National Quality Forum (NQF) regarding its Patient Safety Standing Committee (PSSC) evaluation report of the following measures that the PSSC recommended for endorsement:

NQF #: 3633e - Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)

NQF #: 3662e - Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Group Level)

NQF #: 3663e - Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Facility Level)

Background

These electronic clinical quality measures (eCQM) are intended to monitor CT performance to discourage unnecessarily high radiation dose while maintaining adequate image quality. The proposed metrics require CT Category (i.e., the CT exam type), the size adjusted radiation dose [the patient's dose length product (DLP) adjusted by patient size], and the global noise (associated with the variance of the voxel values in CT images). The two reported measures are the percentage of eligible CT cases in a particular category deemed to be "out-of-range" compared to defined thresholds with respect to the size-adjusted radiation dose or the global noise in a set time period. The measures are intended to advance quality assurance.

In January 2022, prior to the Patient Safety Standing Committee's meeting to evaluate these proposed measures, AAPM provided comments on the measure application to the committee. AAPM attended the committee meeting and now responds to the committee's evaluation report.

The AAPM and our leadership in medical physics

AAPM, as the primary scientific and professional organization of physics in radiology and radiation oncology in the United States, is the foremost organization with expertise to speak to the topic under consideration. With 9717 members in 94 countries, AAPM supports the Medical Physics community with a focus on advancing patient care through education, improving safety and efficacy of medical imaging procedures through research, education and the maintenance of professional standards. Medical physicists contribute to the effectiveness of medical imaging by ensuring the safe and effective use of radiant energy (e.g., optical, ionizing, ultrasonic, or radiofrequency) to obtain detailed information about the form and function of the

human body. Medical physicists continue to play a leading role in the development of novel imaging technologies, as well as in guiding the optimization of existing imaging modalities.

General Comments

AAPM commends NQF's efforts in advancing and evaluating quality assurance measures. The last 15 years of CT technology development has included new reconstruction algorithms and tube current modulation techniques resulting in substantial reductions in dose. AAPM supports efforts to enhance consistency of CT practice as evidenced by AAPM's proactive engagement in efforts to ensure diagnostic quality CT imaging, optimizing CT dose, and achieving consistency across facilities, considering differing technologies and practices. AAPM, together with other non-profit entities, including the American College of Radiology (ACR), and Image Wisely and Image Gently Alliances has spent decades working towards this goal and continues to do so through many initiatives.

AAPM does not support the endorsement of NQF #3633e, #3662e, and #3663e. AAPM cautions that the measures recommended for endorsement by the PSSC have significant limitations that impact their scientific and practical value and overall likelihood of clinical acceptance. These limitations include improper representation of image quality, improper estimation of radiation risk, and substantial oversimplified representation of implementation in practice, including not addressing the challenges of implementation. We will address these concerns in the following paragraphs.

Specific Comments

PSSC failed to adequately review and consider expert opinion

The PSSC failed to adequately review or consider AAPM's expert comments, as required. AAPM review of the proposed measures consisted of a detailed analysis by four prominent senior physicists from four separate institutions. AAPM's comments, however, were not considered as evidenced by the deliberations of the committee at its meeting and in the present report.

AAPM's leadership in medical physics – national and international expertise and recognition

AAPM's expertise in medical physics is widely recognized and valued by the Nuclear Regulatory Commission (NRC), Food and Drug Administration (FDA), National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Council on Radiation Protection and Measurements (NCRP), other federal agencies and state radiation safety agencies. These agencies routinely engage AAPM on clinical practice, emerging technology and radiation safety issues and seek out AAPM members to serve on their advisory committees addressing the most cutting-edge issues in the radiation medicine field. Thus, **AAPM's expert voice on this topic is of high scientific and practical relevance to provide consensus guidance on this important topic.**

Unscientific characterization of CT scan risk

The measure developers include specific numbers estimating the number of cancers and deaths due to these cancers from the dose imparted from the CT scans. The authors describe these risks and the resulting estimates as based on models only. The applied linear non-threshold model is currently HIGHLY disputed at diagnostic CT radiation dose levels. The resultant estimates of risk are known to involve large uncertainties. Moreover, the science of radiation risk estimation from CT examinations is based on calculation of dose to individual organs, age, and sex. The measures of risk proposed here, however, mention none of these factors or offer a strategy to incorporate it. The proposed measures are primarily based on radiation output of the CT system, not the risk to the patient.

The benefit, if any, of minimizing patient dose cannot be scientifically statistically determined. AAPM is concerned that the stated risk of patient radiation dose and financial savings are hypothetical, exaggerated, and may contribute to fear of diagnostic medical exams that may in turn lead some patients to refuse safe and appropriate medical imaging, to the detriment of the patient. Diagnostic imaging doses are typically much lower than 100 mSv, and the anticipated benefits to the patient of medically appropriate imaging are highly likely to outweigh any small potential risks.

Measures lack usability

The usability of data resulting from these measures is not clear. In their pilot study, 30% of the CT cases for individual clinicians being out-of-range was the median value with half of the clinicians having between 16% and 43% of their cases out-of-range, as shown in Figure 1b-2 of the application. The measures do not provide the clinician with an analysis of or methodology for determining what improvements should be made to address a poor showing with these parameters. It may not be clear to practitioners what a poor score means or how to address it.

Complexity of CT categorization

The measures rely on the categorization of CT data into cohesive groups. There is, however, significant variability in the CT protocol lexicon across institutions that results in making assignment of a given protocol to one of these categories very challenging. The proposal does not address the magnitude of this challenge or present the means to overcome it, given that current standards lack uniform characterization of protocols.

Inadequate measure of noise

The proposed noise measure is not an adequate or sufficient parameter of overall image quality. Visually different texture patterns can have similar noise values, and each may be of more, or less, diagnostic value for the radiologist. As mentioned in the proposal, noise can be influenced by many different parameters, such as slice thickness, kV, and mAs. The effect on noise of these parameters is mostly predictable (particularly in a well-defined “subject”, such as a phantom). Noise is commonly determined in a standardized phantom.

Noise measured in clinical images is another matter. There has been limited scientific work in that area and none is cited as having been performed by the authors. There is no information provided in the proposal about how the proposed global noise measure is calculated. In particular, the approach does not take into consideration the CT reconstruction settings that can have a dramatic impact on the appearance of the images, including noise, contrast (or CNR), and sharpness. Further, a “global noise” ignores the diversity within the CT series, especially within the (usually) limited locations that depict the abnormality of interest.

Inadequate assessment of image quality

Image noise alone is an insufficient descriptor of image quality. Noise in an image may also be justifiably varied to meet certain clinical needs (such as high resolution). Many other factors must be considered when attempting to define image quality. Spatial resolution, which includes visualizing small objects and image boundaries, and contrast resolution, of which noise is one component, are also critical aspects of image quality. Widely different noise values may be acceptable under different circumstances for similar protocols. Spatial resolution and contrast are as important as image noise. It is not all clear that improvements in global noise will in turn lead to improved clinical performance.

Flawed assumption regarding clinical CT practice

There is substantial variation in the radiation doses used in CT exams because the radiation delivered is protocol-specific. The implication in the proposed measures is that radiologists vary these parameters indiscriminately. In most cases, however, these protocols are established by the institutions based on available equipment, patient population, expertise, scientific evidence, and the nature of cases presented at that institution.

With the proposed measures, an optimum study is one that delivers the least radiation dose with an acceptable global noise level, but no evidence is provided that clinicians with high values for the proposed measures perform better or even adequately, only that they perform with less radiation dose. AAPM recommends using an alternative approach that would optimize the acquisition for the task at hand to deliver the least radiation dose necessary while still providing the diagnostic image quality necessary for the task. Dose reduction in and of itself is not enough to improve CT practice. There should also be no loss of clinical performance which is not guaranteed by these measurements. Global noise is not an adequate sufficient metric for image quality.

Inadequate accuracy in patient size estimation

Assessing a patient size can be challenging because of significant variability in the differences in the habitus of different patients, coupled with the existential challenge that there is no single metric capturing the size of a patient of varying diameter at different cross-sectional locations. The proposed measures rely on the calibration of the company’s black-box size estimation to prior work of Cheng 2013 and Christianson 2012, both of which have been updated to newer versions to correct erroneous measures. The error in size measurements needs transparency and validated results.

Limited expertise and track record of Alara Imaging

Alara Imaging is a new (2020) company without a significant track record of having previously performed a project of such wide scope, scientifically or technically. While the measure developers have published on the topic of radiation dose, they have limited expertise or history with clinical CT, CT image quality, or CT technology. The company has no scientific track record on CT technology, size estimation, or image quality assessment to be considered steward of measures on which it lacks expertise, publication, or scientific history. Moreover, Alara Imaging has limited experience in IT development, with no demonstrated history of interfacing with complex EHR or Radiology Clinical Data systems. The software interface is problematic because it is a vector to a 3rd party product, which can expose healthcare organizations to ransomware attacks by malicious actors seeking valuable patient medical information.

In summary, AAPM does not support the endorsement of NQF #3633e, #3662e, and #3663e. AAPM urges NQF to:

- Address the concerns identified by AAPM experts; and
- Reconsider its recommendation endorsing these measures as proposed.

AAPM recognizes that this topic is complex, including scientific, technical and clinical components, and we would welcome the opportunity for greater in-depth discussion on meaningful measures of quality imaging practice. Thank you again for the opportunity to comment on the PSSC evaluation report. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Project Manager, at 571-298-1227 or Richard@aapm.org.