AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Quality Measures #494)

We thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on Quality Measure #494 and the prospect of implementation of this new quality measure published in the 2024 Medicare Physician Fee Schedule Final Rule (CMS-1784-F).

American Association and Physicists in Medicine (AAPM)[1] is fully committed to advancing the optimization of medical imaging. This is demonstrated by decades of expert clinical practice in the domain. Most recently, the AAPM convened a Quality Measures roundtable held in October 2023 at the AAPM headquarters in Alexandria, Virginia. The roundtable brought together a broad spectrum of 20 organizations (including NIH, FDA, MITA, RSNA, AHRQ, NCRP, and the Joint Commission) to form a broad consensus about how the quality, safety, and consistency of medical CT imaging can be assured. The outcome is being encapsulated into a consensus statement expected to be released soon.

Further, in preparation for the implementation of the new CMS rule, AAPM commissioned an intersocietal panel of experienced, practical, and committed experts in dose, image quality, and patient care including industry representatives, academics, clinical practitioners, and leaders from professional societies primarily as an effort to help practitioners and implementers of the new rule. The panel includes individuals from AAPM, ACR, Duke Health, Image Wisely, Imalogix, Jefferson University, MITA, Qaelum, Mayo Clinic, and UCLA.

This expert panel is currently focused on consolidating a list of ambiguities identified in the current CMS rule to provide reasonable suggestions and interpretations of the rule to facilitate implementation. The work is expected to be completed by April 2024. Meanwhile, we believe it would be beneficial for CMS to know what functional ambiguities and fundamental limitations the panel has identified thus far. These, if unaddressed, could cause significant variability in the

[1] The American Association of Physicists in Medicine (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 ensure 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 required by numerous federal and state regulatory agencies. AAPM represents over 9,000 medical physicists.

implementation of measures and delivery of imaging care across the nation, thus undermining its very intent.

AAPM, as well as this expert panel, will be happy to engage CMS to facilitate the assurance of quality imaging practice. We stand ready to aid in any of the needs and suggestions noted below.

Functional Ambiguities

1. The terms “scan” and “exam” are ambiguous and not part of the standard medical imaging nomenclature (such as that provided by DICOM).
2. It is unclear precisely what studies the rule is applicable to. As not all adult cases are included, variation in the inclusion across sites creates arbitrary outputs across clinical practices.
3. The justification for the measure outlined in the Rationale section of the ruling (where imaging dose is noted as a definitive cancer risk) is questionable.
4. It is unclear from the rule what is meant by the phrase “clinical terminology” and if that is synonymous with CT Dose and Image Quality Category.
5. The rule states that there is a pathway for alternative approaches as long as the measure specifications are followed, yet some of the measure specifications are proprietary and opaque to the public. As such, the rule relies on proprietary ALARA software (the exact details of which are not disclosed) leaving many details to guesswork that would lead to diverse implementation.
6. It is unclear what aspects of the Copyright are owned by ALARA Imaging (e.g. the software, the method, the specific dose and noise values, the whole concept, the names of the parameters that will be tested). It is also unclear how other companies (some of which already have software deployed at healthcare facilities) can offer a software alternative with this ownership clause in place.
7. It is unclear what the process would be for contesting or correcting non-sensible results generated by the ALARA-specified methodology.
8. It is unclear whether PHI is ever sent to the cloud by the translation software.
9. It is unclear how inpatient and outpatient designations can be systematically maintained given the diversity of practices, status changes across care episodes of individual patients, and emergency applications.
10. It is unclear how combination studies (e.g., Head and Cervical Spine) which are subsequently split into separate studies in the PACS are to be managed in accordance with the rule.
11. It is unclear whether an HL7 connection to the EMR (and subsequent retrieval of coding and demographic data) is absolutely required for compliance with the rule. It is further unclear if provision of these “Supplemental Data Elements” to CMS is required.
12. It is unclear how API and data transfer should be configured for communication of the measure, computed variables, and Supplemental Data Elements to CMS by entities other than ALARA.
13. It is unclear exactly how “exams” (e.g., CT WO IVCON) are mapped to CT Dose and Image Quality Categories.

14. It is unclear under what circumstances should the variables CT Global Noise, CT Size-Adjusted Dose, and CT Dose and Image Quality Category be considered “incalculable,” “inadequate,” or “inappropriate.”
15. It is unclear why there are different CT Dose and Image Quality Categories with identical CT Size-Adjusted Dose or CT Global Noise thresholds for the same anatomical region.
16. It is unclear how the CT Size-Adjusted Dose (i.e., size-adjusted DLP) is computed. The method is non-standard, unpublished, and therefore not possible to verify or validate. Furthermore, the limited details that are provided seem contrary to the metrologies supported by the AAPM (which has ramifications in the State of California where Section 115111 of the California Health and Safety Code requires alternative dose units to be provided by the AAPM).
17. It is unclear if the ALARA method for patient size assessment (computed en route to CT Size-Adjusted Dose) is consistent with the IEC standard measurement of water equivalent diameter, and if not, why an alternative measure of patient size (diameter) is necessary.
18. It is unclear how CT Size-Adjusted Dose is computed for rejected image series and irradiation events that do not yield diagnostic images (such as monitoring series) since the corresponding reconstructed images are not provided to the translational software.
19. It is unclear how the measurement of CT Global Noise is performed due to limited documentation of the methodology and the lack of an official standard for implementation.
20. It is unclear if the CT Global Noise is exclusively obtained from axial reconstructions, or if it is obtainable from coronal, sagittal, or 3-D reconstructions. Further, it is unclear how the CT Global Noise is aggregated for an imaging study containing multiple series.
21. The performance expectations for percent of “exams” exceeding variable thresholds are unclear.
22. It is unclear how a single CT orderable (e.g., Coronary CTA) can be reasonably compared to a single set of dose and image quality benchmarks when it is justifiably performed two very different ways in normal clinical practice (e.g., with retrospective and prospective gating depending on factors such as patient heart rate).
23. It is unclear exactly how the thresholds for the CT Global Noise and the CT Size-Adjusted Dose were defined. It is important for practitioners to understand the methodologies for threshold derivation to facilitate understanding and validation of the standards to which they are being held.

Fundamental Limitations and Future Prospects

These ambiguities, some of which have conflicts with standards of practice and can cause major roadblocks to acceptance and implementation, primarily stem from some fundamental limitations that should and could inform the implementation of robust quality measures in CT imaging. Towards that prospect, we urge CMS to consider the following suggestions.

1. We strongly advise CMS to move away from a “black box” vendor-specific resource and move toward a community-owned and managed approach that includes an open-source version of the basic components of the process (including data categorization/mapping, dose estimation, and image quality estimation). This avoids ambiguities making it possible for diverse users

and implementers to comply with the CMS requirements. The code base could be maintained by the medical imaging community, and due to its open-source nature, can be readily audited and validated.

2. We strongly advise CMS to provide source data from observer studies that were the basis of the current standard to ensure verifiability in any measure development and claim.
3. We strongly advise CMS to provide a lookup table for CT Dose and Image Quality Category mapping.
4. We strongly advise CMS to consider holistic treatment of image quality. Over reliance on CT Global Noise as a sole arbiter of quality is highly insufficient for the characterization of diagnostic quality, further undermined by machine learning and advanced image processing methods that can even make it irrelevant.

We thank you for this opportunity and are excited to facilitate consensus methods and processes to advance the cause of quality and consistent practice of medical imaging. If we can provide any additional information, please contact AAPM's Senior Government Relations Manager, David Crowley (david@aapm.org).

Sincerely,

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