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Measure Worksheet

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.
To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 3633e
Corresponding Measures:
Measure Title: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)
Measure Steward: Alara Imaging
sp.02. Brief Description of Measure: This electronic clinical quality measure (eCQM) provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of eligible CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible.
1b.01. Developer Rationale:
Diagnostic CT imaging occurs in more than a third of acute care hospitalizations (Vance 2013) and upwards of 90 million scans are performed annually in the U.S. (IMV 2020). The radiation doses used for these exams are frequently far higher than needed for diagnosis and vary up to 200-fold across facilities for patients imaged for the same clinical reason. (Smith-Bindman 2009, Smith-Bindman 2015, Smith-Bindman 2019, Miglioretti 2013, Demb 2017). Most of this variation reflects clinician preferences rather than appropriate differences based on patient and clinical indications (Smith-Bindman 2019). As described in section 1a.14, the inconsistency in how CT exams are performed represents a significant, unnecessary, and modifiable iatrogenic health risk, as there is extensive epidemiological and biological evidence that suggests exposure to radiation in the same range as that routinely delivered by CT increases a person's risk of developing cancer (Board of Radiation Effects 2006, Pearce 2012, Pierce 2000, Preston 2007, Brenner 2003, Hong 2019). It is estimated that 2% (36,000) of the 1.8 million cancers diagnosed annually in the U.S. are caused by CT exams (Berrington de Gonzalez 2009, NCI Cancer Statistics).
The measure focuses on reducing radiation dose in CT, an intermediate outcome important to cancer prevention. As radiation dose is known to be directly related and proportional to future cancer risk (Board of Radiation Effects 2006, Pearce 2012, Pierce 2000, Preston 2007, Brenner 2003, Hong 2019, Berrington de Gonzalez 2009), any reduction in radiation exposure would be expected to lead to a proportional reduction in cancers. Research suggests that when healthcare organizations and clinicians are provided with a summary of their CT radiation doses, their subsequent doses can be reduced without diminishing the diagnostic usefulness of these tests. Smith-Bindman et al. led a randomized controlled trial of two interventions to optimize CT radiation doses across 100 hospitals and imaging facilities and found that providing feedback to institutions along with education and opportunities for sharing best practices results in meaningful dose reductions. (Smith-Bindman 2020). Though results varied by anatomic region, following the intervention there was up to a 40% reduction in doses with a greater impact on the rate of high dose exams, meaning facilities with high

doses at the beginning of the trial were particularly likely to improve.

On the basis of the current estimated number of CT exams performed annually in the U.S. (IMV 2020), distribution in scan types and observed doses (Demb 2017, Smith-Bindman 2019), modelling of the cancer risk associated with CT at different ages of exposure (Berrington de Gonzalez 2009), and costs of cancer care (Dieguez 2017, Mariotto 2011), an estimated 18,643 cancers could be prevented annually in the U.S., 75% (13,982) of these among Medicare beneficiaries, resulting in $1.86 billion to $5.21 billion in annual cost savings to the Centers for Medicare & Medicaid Services.

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sp.12. Numerator Statement: Diagnostic CT exams that have a size-adjusted radiation dose value greater than the threshold specific to the CT category (reflecting the body region imaged and the radiation dose and image quality required for that exam given the reason for the exam), or a global noise value greater than a threshold specific to the CT Category.
sp.14. Denominator Statement: All diagnostic CT exams performed on adults (aged 18 years and older) during the measurement period of one year that have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.
sp.16. Denominator Exclusions: Denominator exclusions are CT exams that simultaneously include multiple body regions outside of four commonly encountered multiple region groupings (specified as LOINC code 96914-7, CT Dose and Image Quality Category, Full Body). Denominator exclusions are also CT exams with missing patient age, missing size-adjusted radiation dose, or missing global noise. These are technical exclusions ("missing data") from the initial population. Technical exclusions will be flagged, corrected whenever possible, and tracked at the level of the accountable entity.

Measure Type: Outcome: Intermediate Clinical Outcome
sp.28. Data Source: Electronic Health Records
sp.07. Level of Analysis: Clinician: Individual
IF Endorsement Maintenance – Original Endorsement Date:
Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:
IF this measure is paired/grouped, NQF#/title:
sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?:

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☒ **Yes** ☐ **No**

Evidence Summary

- This is an intermediate-outcome measure electronic clinical quality measure (eCQM) utilizing electronic health data at the individual clinician level that provides a standardized method for monitoring the performance of diagnostic Computed Tomography (CT) Scan radiation doses, a risk factor for cancer, while preserving image quality.

- The developer provided a logic model for this intermediate outcome measure which links physician choice of protocol, CT scan, with the intermediate outcome of patient exposure to radiation and the ultimate outcome of cancer.
- The developer cited two systematic reviews:
    - *Early life ionizing radiation exposure and cancer risks: systematic review and meta-analysis* published in Pediatric Radiology in January 2021:
        - The systemic review found that "CT exposure in childhood appears to be associated with increased risk of cancer (leukemia and brain tumors) while no significant association was observed with diagnostic radiographs."
        - The systematic review examined 21 observational studies, including 11 case-control studies and 10 cohort studies each with Newcastle-Ottawa Scale (NOS) scores ranging from seven to nine (with nine being the highest score possible).
        - This systematic review pertained to pediatric patients and not adult patients, which are the focus of this measure.
    - *Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Summary Bias Assessment and Meta-Analysis* published in JNCI Monographs in July 2020 that included a combination of medical and non-medical exposures to radiation and the risk of cancer.
        - The review tested whether the median excess relative risk (ERR) per unit dose equals zero and assessed the impact of excluding positive studies with potential bias away from the null. In addition, there was a meta-analysis to quantify the ERR and assess consistency across studies for all solid cancers and leukemia.
        - The review of 26 studies concluded that these new epidemiological studies directly support excess cancer risks from low-dose ionizing radiation. Furthermore, the magnitude of the cancer risks from these low-dose radiation exposures was statistically compatible with the radiation dose-related cancer risks of the atomic bomb survivors.
- The developer also described the *Epidemiological study to quantify risks for paediatric computerized tomography and to optimise doses* (EPI-CT) study: a European pooled epidemiological study to quantify the risk of radiation-induced cancer from pediatric CT (Bernier, 2019). 4 contributing country-specific portions of the cohort are and show positive associations between CT and cancer incidence:
    - The British study reported a positive dose-response relationship between radiation dose and leukemia and CNS tumors in children and young adults.
    - The German study reported a significantly increased incidence of all cancer and lymphoma in exposed children compared with the general population.
    - The French and the German cohorts reported a dose-related increase for CNS tumors.
    - The Dutch study reported a dose-response relationship for CNS tumors.
- The developer also cited the ongoing Life Span Study (LSS) of atomic bomb survivors in Hiroshima and Nagasaki, Japan, which provides quantitative estimates of cancer risks associated with exposure to radiation and is a major source of human data used for risk assessment in establishing radiation safety standards.
    - The eligible cohort included 105,444 subjects who were alive and had no known history of cancer at the start of follow-up (1958-2009)
    - The developer states that these analyses demonstrate that solid cancer risks remain elevated more than 60 years after exposure and that approximately 10% of cancers in the cohort are due to the radiation.

Questions for the Committee:

Does the Committee agree there is sufficient evidence presented by the developer that links this intermediate process outcome (i.e., radiation exposure) to an outcome (i.e. cancer)?

Guidance from the Evidence Algorithm

Not a health outcome (Box 1)→ Systematic review and grading of the body of empirical evidence for the immediate-outcome measure is provided (Box 3) → → Quality, quantity and consistency of the body of evidence from a systematic review provided (Box 4) → Quality (High), Quantity(Mod) and Consistency (Mod) → MODERATE

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- This eCQM was tested in 7 health systems and 1 vertically integrated organization, including 42,493 CT exams interpreted by 606 physicians between 2020 and 2021.
    - The mean performance score was 30% with a standard deviation of 21% and a range of 0-100%

Disparities

- The developer examined differences based on age (-0.004 correlation) and sex and found minimal variation between male and female patients in the University of California, San Francisco (UCSF) Radiation Dose Registry.
- The developer states that studies have found that social factors including sex, race/ethnicity, and socioeconomic status are not predictive of radiation dose for CT exams., however patients living in poverty are at higher risk for comorbid conditions associated with exposure to multiple scans over time and increased cumulative exposure to ionizing radiation from diagnostic imaging.

Questions for the Committee:

- Is there a gap in care that warrants a national performance measure for clinicians?
- Is there additional concerns about the presence of disparities in this measure?

Preliminary rating for opportunity for improvement: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

- I have questions about evidence. The evidence is just that radiation can be bad for you. There is variability in the evidence but the reasons for the variability and the unintended consequences are unclear to me. Is this like ordering a CT with contrast to spare the kidneys than needing another test because the resolution was not clear enough? Are there reasons a higher radiation dose may be perfectly appropriate?
- Excess risk for cancer associated with excess radiation--dose related response
- Evidence between radiation exposure and cancer is strong, but less clear the relationships with CT scans. Still, face validity for the measure based on the evidence is moderate.
- Review Panel - Moderate
- adequate
- Heavy reliance on literature from childhood exposures.
- This is a new intermediate clinical outcome measure. It intends to improve the performance of diagnostic CT at clinician level, by monitoring excessive radiation dose or inadequate imaging for adult patients. Data would be collected from inpatient, outpatient, and ambulatory care settings. The developer provides research literature from 2000 to 2021. Evidence shows that excess or unnecessary CT imaging is frequent in healthcare. Yet, radiation exposure from X-ray radiation increases the risk of cancer over people's lifetime. So to protect patient safety, it is best to avoid unnecessary radiation or to use the minimum dose of radiation as possible. This measure relates directly to patient outcome. The evidence is rated as moderate.
- Developer provided adequate evidence to support measure focus.
- yes
- Solid, large scale evidence that links to eventual outcome/harm
- I have the same comment for all three related measures - I don't think it passes the evidence threshold - I vote "Low" because 2 systematic reviews cited, one is pediatric and not really applicable, the second one included mostly non medical exposure of radiation and only 4/26 studies were medical and of these 4 2 were pediatric again so I'm not sure there is sufficient evidence linking CT radiation exposure to cancers in adults. Who have potentially less early stage cells than kids and have less remaining lifetime to develop the cancers.
- Evidence obviously high for radiation and cancer. Would appreciate a discussion of evidence or guidelines endorsing reference ranges utilized.
- It does not appear to me that there is an evidence base in the population of interest (adults) to support the relationship that the developer presents.
- Yes, there is variability in the amount of radiation by type of test
- Variability in performance and provider and facility level. Provider: 10th percentile 6% (lowest excess exposure), Median 27%, 90th percentile 53%. No variability noted by the 2 "social risk" factors: sex and age.
- Substantial variation exists across facilities, suggesting a lot of opportunities for improvement.
- Rated High
- tested in 7 health systems with ~42K subjects
- No concerns

- The measure was tested in 7 health systems including 42,493 CT exams interpreted by 606 physicians between 2020 and 2021. The mean performance score was 30% with a standard deviation of 21% and a range of 0-100%. So the performance gap is rated as high. The only disparity that was identified is the patient population at economic disadvantage. These patients have a potential of higher risk of increased accumulative exposure to radiation scans due to comorbidity.
- yes, significant performance gap noted
- There is a gap in performance, but disparities seem minimal.
- Much clear opportunity across locations
- no concerns
- Mean 30% with a SD of 21%.
- There does appear to be a performance gap, and while disparities are suggested, the primary data is not presented in the measure worksheet.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing
2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data
2c. For composite measures: empirical analysis support composite approach

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

- Submitted measure specification follows established technical specifications for eCQMs (QDM, HQMF, and CQL) as indicated Sub-criterion 2a1.
- Submitted measure specification is fully represented and is not hindered by any limitations in the established technical specifications for eCQMs.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Complex measure evaluated by Scientific Methods Panel? ☒ **Yes** ☐ **No**

Evaluators: Alex Sox-Harris, Samuel Simon, Zhenqiu Lin, Laurent Glance, Matt Austin, Terri Warholak, Jeffrey Geppert, Christie Teigland, Eugene Nuccio, Lacy Fabian, Marybeth Farquhar, Joseph Kunisch

Methods Panel Review (Combined)

Methods Panel Evaluation Summary:

This measure was reviewed by the Scientific Methods Panel. A summary of the measure and the Panel discussion is provided below.

Reliability

- Reliability testing at the Accountable Entity Level
    - The developer conducted a signal-to-noise analysis using ICC on electronic health records from 606 clinicians within 7 health systems and one vertically integrated organization from February 2020 to April 2021.
- The number of exams per clinician in the one month of data used for testing ranged from 1 to 604 (mean=77); predicted reliability for 12 months exceeded 0.90 for 89% of participating clinicians.
    - The estimated mean split-half ICC using 47,635 CT exams collected from 606 individual clinicians was 0.99 (after exclusion of clinicians who read only 1 scan in the test month, and Spearman-Brown adjustment to a 12-month data collection period).

Validity

- Validity testing at Patient/Encounter Level
    - ***CT category*** – An ICD-10 based algorithm to assign the CT category was compared to chart review as the gold standard. The results, weighted by the distribution of CT categories in the UCSF International CT Dose Registry, were a sensitivity = 0.86 and specificity = 0.96 (n=978 CT exams). When tested across the 606 individual clinicians, the correct classification rate of the assignment of CT exams to CT category in field-testing was 95% on average.
    - ***Patient size*** – A previously validated algorithm that used cross-sectional imaging to generate patient size estimates was compared to how often this method generated clinically plausible and non-missing data. Size-adjusted radiation dose could be calculated and was within plausible range for 99% of CT exams and was missing for 0.4% of exams.
    - ***Radiation dose*** – Dose-length product is an element is generated by the CT machine for each examination and relies on published work. The developer tested how often this method generated clinically plausible and non-missing values for radiation dose in testing data.
    - ***Size-adjusted radiated dose*** - Using field testing data, the developer assessed whether it could calculate size-adjusted radiation dose within a plausible range and quantified missing data. Size-adjusted radiation dose could be calculated and was within plausible range for 99% of CT exams and was missing for 0.4% of exams.
    - ***Global noise*** – The developer tested whether global noise could be calculated within a plausible range and quantified missing data. Global noise was also correlated with physician dissatisfaction with image quality. Global noise could be calculated and was within a plausible range for 100% of CT exams in field-testing. Global noise was missing for 0.01% of examinations. The correlation between noise and physician dissatisfaction with image quality is 0.37 overall based on the image quality study (n=727 CT exams).
    - Thresholds for “out-of-range” values to define numerator – The developer used physician satisfaction with CT images as a basis for establishing the maximum radiation dose and minimum image quality thresholds for each CT category.
- Validity testing at the Accountable Entity Level:
    - Gold standard comparison: The developer compared the eCQM against medical record review using field testing data collected from 8 health systems/vertically integrated organizations.
        - The "medical record review" was a human-reviewed indicator of whether the size-adjusted radiation dose or global noise of each sampled exam exceeds predetermined thresholds, thus constituting a “gold standard.”
        - In a sample of 8000 exams (1000 per site), the out-of-range results (measure score) from the medical record review and the eCQM computation were identical with no discrepancies between the two approaches

        - The developer stated the results indicate a correct and robust implementation of the measure logic.
    - Face validity: A 6-question poll was posed to a TEP which represented a diverse group of clinicians (N=10), patient advocates (N=2).
        - 100% (voted “very likely,” or “somewhat likely on a Likert scale) of the TEP agreed that radiation dose and imagine noise are relevant metrics of quality for CT imaging, size is an appropriate method for adjusting for radiation dose for a given indication, and performance on this measure of radiation dose and image quality, adjusted for size, stratified by indication, would be a representation of quality.
        - 94%-100% agreed that implementation of the measure in federal programs would lead to a reduction in average CT radiation dose while maintaining adequate CT image quality
- Missing data:
    - One SMP member expressed concerns about missing data only focusing on the "radiation dose" aspect of the measure. The missing data information provided in Table 2b-3 also made the SMP question where there could be issues with wider implementation of the measure.

Questions for the Committee regarding reliability:

- *Does the committee have concerns with the reliability of this measure?*
- *The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?*

Questions for the Committee regarding validity:

- *Does the committee have concerns about the results or approach to the validity testing for this measure?*
- *The Scientific Methods Panel is satisfied with the validity testing for the measure. Does the Committee think there is a need to discuss and/or vote on validity?*

Preliminary rating for reliability: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

- reliability looks fine
- This is an ecqm. All data elements are available in EMR; PACS data may have to be calculated and sent to EMR for use as an eCQM (calculated CT-adjusted dose, DICOM). Measure tested in Epic, Cerner, Allscripts and Meditech.
- No concerns; agree with SMP panel rating of high as it appears the the metrics can be accurately and consistently pulled from machines
- Review panel rated high
- yes
- No concerns
- It seems that the measure follows technical specifications for eCQMs and is not hindered by any limitations. I have no concerns.
- THe scientific panel found that there is high reliability.
- Reliability seems fine.
- No concerns about data draws, well described
- no concerns
- No concerns with reliability
- No concerns related to reliability re specifications which seem clear
- no
- No. Intraclass correlation coefficient (ICC(1)) =0.99 at the individual physician level.
- no concerns
- no
- no concerns based on the information supplied
- No concerns
- Reviewed by SMP. Reliability testing was conducted at clinician level using electronic health records from 606 clinicians from February 2020 to April 2021. The predicted reliability for 12 months exceeded 0.90 for 89% of participating clinicians. The preliminary rating on reliability is high.
- no
- no
- Strong, no concerns
- no concerns
- No
- No concerns related to reliability testing
- Depends. Valid to measure inappropriate radiation use - yes I do have concerns. Validity that the proposed metric measures radiation dose adequately, no, that seems reasonable
- eCQM validated against medical record review (considered a gold standard); results were identical, 100% agreement.
- No, agree with a moderate ranking for validity based on evidence and frameworks.
- Review panel rated moderate
- no concerns
- No concerns

- Reviewed by SMP. Validity was tested at both patient/encounter level and clinician level. In a sample of 8000 exams (1000 per site), measure score from the medical record review and the eCQM computation were identical with no discrepancies between the two approaches. The developer believes the results indicate a correct and robust implementation of the measure logic. The preliminary rating on validity is moderate.
- no
- In linking ionizing radiation overdoses to cancer incidence, one must consider the age of the patient. The risk in a 20-year-old person is much higher than in an 80-year-old person. It also seems that the magnitude of the overdose of radiation should be considered.
- Very strong, no concerns
- no concerns
- No
- No
- If appropriateness for higher doses was better understood (e,g. higher dos for abscess or cancer) risk adjustment would be helpful
- Risk adjustment done with patient size seems appropriate; no social risk adj. was warranted.
- Exclusions of multi-site CT scans described by developer seem appropriate. All adult patients are included. Risk adjustment for body size seem very well justified.
- No
- appropriate
- No concerns
- There does not appear to be any risk adjustment.
- no concerns
- as noted above
- Well handled
- no concerns
- Exclusions and risks seem appropriate.
- No concerns related to threats to validity
- appropriate
- yes

Criterion 3. Feasibility

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- Data for this measure generated or collected by and used by healthcare personnel during the provision of care
- ALL data elements are in defined fields in a combination of electronic sources
- The submission includes two measure specifications, a HQMF/QDM measure specification and a FHIR measure specification. Both measure specifications follow established technical specifications for eCQMs as indicated Sub-criterion 2a1.
- Submitted measure specifications are fully represented and are not hindered by any limitations in the established technical specifications for eCQMs.

- Using a simulated data set, the submission demonstrates that the evaluation of 100% of the measure logic can be automated.
- The Feasibility Scorecard indicated that the no data elements have issues with accuracy and 100% coverage in simulated data unit tests.
- There was concern from an SMP member that specification was heavily dependent on proprietary software developed by UCSF and Alara Imaging, Inc. to access and process primary data elements from the electronic systems to calculate the three variables required by the measure – CT category, size-adjusted radiation dose, and global noise. This software in turn requires access to raw imaging data. Although the developer states that this process has been tested in multiple settings, the SMP member was concerned that there was no evidence that a garden variety clinician could reliably replicate.

Questions for the Committee:

- Does this measure appear to be feasible as an eCQM?

Preliminary rating for feasibility: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

Criteria 3: Feasibility

- seems feasible
- Appears feasible. Data is input by clinicians and available in EHR and PACS. No burden on clinicians. IT workflows may be affected.
- Very feasible, no concerns
- High
- EHR based- no concerns
- No concerns
- The preliminary rating is high, although a SMP member raised concern that specification was heavily dependent on proprietary software developed by UCSF and Alara Imaging, Inc.
- data obtained electronically
- no concerns
- Strong and seem extractable without hassles
- no concerns
- Committee should discuss the feasibility of this measure which is generated by a commercial company. What impact does endorsement of this measure have on clinicians and providers not doing business with the company?
- No concerns related to feasibility

Criterion 4: Usability and Use

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial

endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☐ **Yes** ☒ **No**

Current use in an accountability program? ☐ **Yes** ☒ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☒ **Yes** ☐ **No**

Accountability program details

- The measure is not currently in use in any accountability programs.
- The developer states that this measure will be submitted for Centers for Medicare & Medicaid Services (CMS) Merit-based Incentive Payment System (MIPS). MIPS measures are publicly reported on Care Compare by 2026 because measures are not publicly reported for two years.
- The developer also states that this measure will be submitted to CMS' Measures Under Consideration list for 2022.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- The developer states that verbal feedback was provided by site participants on the video calls. Feedback from sites often reflected a recognition and understanding for why radiation doses were particularly high.
- Feedback received influenced the developer to the feedback for the measure to be more nuanced than the aggregate level to make the measure actionable.

Additional Feedback: N/A

Questions for the Committee:

- Can the performance results be used to further the goal of improving patient safety through reducing excessive radiation dosing?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- This eCQM is not currently used in any quality improvement program.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- One unexpected finding was the lack of consistency among facilities saving Radiation Dose Structured Reports (RDSR). The developer worked with sites to modify their systems to save the RDSR to capture 94% of dose reports.
  As the goal of this measure is the reduction of patient exposure to radiation, the developer noted a concern that radiation dose reduction might result in deteriorated image quality but did not find any evidence of poor image quality in the results. The developer stated that this potential issue will be monitored annually.

Potential harms

- There are no harms identified by the developer.

Additional Feedback: N/A

***Questions for the Committee**:*

- How can the performance results be used to further the goal of safer care?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

RATIONALE:

Committee Pre-evaluation Comments:

Criteria 4: Usability and Use

- The unintended consequence of repea scans because of inadequate visualization should be measured
- Not currently in an accountability programs. Would like to include in MIPS and OQR.
- Planned inclusion in an accountability program, not currently publicly reported. Plans for use in MIPS reporting and CMS
- Not currently publicly reported or used in accountability, plans for however
- initial 7 systems data incorporated
- No concerns
- The measure is currently not publicly reported in any accountability program. However, the developer indicates that this measure will be submitted to the Centers for Medicare & Medicaid Services (CMS) Merit-based Incentive Payment System (MIPS). MIPS measures are publicly reported on Care Compare by 2026 because measures are not publicly reported for two years. The developer also states that this measure will be submitted to CMS' Measures Under Consideration list for 2022. Site participants provided feedbacks via video calls, which showed recognition and understanding of high radiation doses. I think the performance results can be used to further the goal of improving patient safety through reducing excessive radiation dosing or unnecessary imaging. The preliminary rating for use is pass.
- The measure is not currently in use in any accountability programs and is not publicly reported, however the developer states this measure will be submitted to CMS' MUC list for 2022.
- not in use
- Solid feedback on these issues
- plan to include in public reporting
- Not in use.
- The feedback that was provided seems to have been quite qualitative, and informal, although developer states it influenced design.
- This should be only used in an accountability program is the increase radiation dose is truly inappropriate, not just variable
- Planned use: quality improvement with benchmarking or internal PI.

- Does not appear to be high risk of unintended consequences. Image quality concerns will be monitored per developer.
- Moderate - not used in any QI program
- depends on availability of data
- No concerns
- The developer noted a concern that radiation dose reduction might result in deteriorated image quality but did not find any evidence of poor image quality in the results. The developer will monitor this potential issue annually. No potential harm was identified, though. The usability is preliminarily rated as moderate.
- lack of consistency among facilities; this measure will reduce patient exposure to radiation unnecessarily and reduce cancer risk.
- The prevention of cancer depends on the magnitude of the overdose and the age of the patient. None the less, it seems that limiting overdoses matters.
- No concerns, little threat to image quality created by measure
- no concerns
- No harms identified by the developer.
- A lack of consistency among facilities related to where the measure data was being saved (RDSR) and the need for the developer to work with sites to modify systems to save this data is concerning at scale.

Criterion 5: Related and Competing Measures

Related or competing measures

- Two measures were identified as related:
    - 2820: Pediatric Computed Tomography (CT) Radiation Dose (UCSF)
    - 3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single (American College of Radiology)

Harmonization

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

- Population: All diagnostic CT exams performed on adults (aged 18 years and older) during the measurement period of one year that have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.
- Outcome: Assesses radiation dose according to thresholds determined by the underlying clinical indication for imaging

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single (Facility; Clinician-Group Level)

- Population: Includes all patients regardless of age. Includes CT Abdomen-pelvis exams with contrast (single phase scans), CT Chest exams without contrast (single phase scans), and CT Head/Brain (single phase scans)
- Outcome: Weighted average of 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase

2820: Pediatric Computed Tomography (CT) Radiation Dose

- Population: Diagnostic CT scans performed on children of the head, chest, abdomen/pelvis and chest/abdomen/pelvis in children.
- Outcome: Whether CT doses exceed published benchmarks

Committee Pre-evaluation Comments: Criterion 5:
Related and Competing Measures

- nothing relevant
- Several process measures looking at different populations (pediatrics, specific CT scan sites). This measure calculates excess dose while others look only at dose received.
- related measures do not appear to be major competing.
- 2 measures - one for pediatrics and one as a composite
- No concerns
- Two measures were identified as related: (1) #2820: Pediatric Computed Tomography (CT) Radiation Dose (UCSF); (2) #3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single (American College of Radiology). But I do not think they are competing or overlapping.
- There are two competing measures - one for pediatric and one for 3 CT exam types.
- #3621 seems to cover much of the same ground as this measure.
- 3621 overlaps much but is distinct; not sure 3621 needed
- 2820 and 3621
- No concerns

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 2/1/2022

- **Of the 3 NQF members who have submitted a support/non-support choice:**
  - **2 support the measure**
  - **1 do not support the measure**

Comments and Member Support/Non-Support Submitted as of: 2/1/2022

Comment 1 by: J. Leonard Lichtenfeld

I am pleased to provide this comment in support of NQF quality measures 3633e, 3662e and 3663e. These comments reflect my personal opinion and not any other organization with which I may be affiliated. CT scans have assumed a primary role in the evaluation and diagnosis of many medical conditions, and are very commonly performed procedures. Less appreciated by the public and many professionals (including non-radiology physicians) is the variation in image quality and dose that has been recognized for many years by researchers who have evaluated these factors. As such, there can be substantial variation in CT scan dose and quality, even within the same institution. As a patient, this consideration has figured prominently in my own decisions as to whether or not to proceed with serial CT scans for follow-up of medical conditions. These measures have been carefully crafted to create an effective and validated method to monitor CT image and quality based on indications for the studies and in consideration of individual patient-related variables. As such, they provide a useful and meaningful way to offer our patients and the public the assurance that the scans they are receiving meet reasonable

safety and professional standards--which is not routinely available otherwise. These quality measures will meaningfully improve the ability of physicians and health systems alike to monitor the equipment utilized for these studies in a manner that minimizes interference with the typical workflow of a radiology center (or other center) where such studies are performed and will provide a significant and substantial increase in the quality of scans while reducing dose variability that can occur because of machine settings/performance or patient characteristics. Cumulative radiation dose should decline as a result of implementing these measures. At the very least, there will be assurance that the right dose is used for the right scan in the right patient. As a physician and patient advocate for many years, I offer my support for these measures for the reasons stated. And as someone who served as an advisor for this measure, I will add that I was impressed by the exceptional commitment of the developers and their colleagues to provide a meaningful, validated and effective quality measure as they created new processes to measure CT dose and quality, always with an eye towards making this measure acceptable to the professional and consumer communities. (Disclosures: As noted, I was an advisor during the development of this measure and received compensation for those services. I have also served on the NQF Cancer Committee without compensation. I have no other relevant conflicts.)

Comment 2 by: Karen Orozco

The American College of Radiology, representing more than 40,000 radiologists, radiation oncologists, medical physicists, and nuclear medicine physicians, appreciates the opportunity to submit comment on NQF #3633e, #3662e and #3663e: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level, Clinician Group Level and Facility level, respectively). ***The ACR does not support the endorsement of NQF #3633e, #3662e, and #3663e.***
General Comments Protocol selection appropriate for a clinical indication is an important component of radiation dose management along with radiation dose optimization. Each component needs to be addressed as a separate quality action. The specific aspect(s) of performance to be improved is not intuitive due to the multiple components to the measures (size-adjusted dose, image quality, clinical indication). It is premature to measure performance on excessive radiation dose based on thresholds by clinical indication for an exam until the level of standardization and availability of national benchmarks is further along as discussed below. It is true that the most accurate way to address appropriate and safe use of multi-phase studies is to measure both the clinical indication of an exam and the radiation dose output (dose indices per exam) and look at the two separately or distinctly together. ***However, these measures conflate the appropriateness of protocol for the clinical indication and radiation dose optimization, disregarding applicability, from which a facility may not be able to determine if its performance could be improved by adjusting protocols or by focusing on appropriateness of the ordered exam. Therefore, improvement may be limited.[1]*** Dose optimization results in a quality action for facilities to adjust their protocols and is a responsibility of the team as a whole – physicists, technologists, and physicians who oversee the team at the facility. Protocol selection addresses the appropriateness of the exam for the clinical indication and other factors such as patient time on the scanner and optimal radiation dose. There are challenges with the implementation of an indications-based measure. Indications for exams do not have standardized language that could be used to track them. Most health and IT systems capture ICD-10 coding for reimbursement, but typically not enough standardized information to characterize the patient's condition. As a result, the clinical reason for performing an imaging exam is often extremely limited in the exam order. Electronic Health Records (EHRs) are notoriously incomplete with this type of information and interoperability issues exist with other software systems that might contain such information. ***A *validated* method for determining classification of studies using high-dose versus routine protocols appropriate to the indication must be incorporated into such a measure; these three measures include specifications which have not been validated.*** Please refer to the validity section below for more details. ***NQF #3633e, #3662e, and #3663e deviate from international standards, like diagnostic reference levels, and lack peer-reviewed, broadly**

accepted consensus on global noise. For these measures, global noise is defined solely by the measure developer. Endorsing this method may encourage facilities to accept a narrow view of image quality.* *The ACR requests the developer further clarify the global noise table used in calculating the numerator.* The benchmark source is not transparent, and its applicability is unclear. For example, Table sp-1, Size-adjusted radiation dose and global noise thresholds by CT category, has the same global noise threshold for several CT categories, such as head low dose, head routine dose, and head high dose. Is it intentional that the same global noise threshold should be applied to both low and high dose head CTs? If the image noise thresholds are the same, the size-adjusted radiation dose thresholds should be the same, unless the scan length is remarkably different between the 3 CT categories. Additionally, current CT scanners display dose values based on either a 16 cm or 32 cm phantom for a neck scan, which must be carefully accounted for in measure performance calculations. ***There is little to no acknowledgement of limitations.*** These measures have multiple limitations, including the lack of widespread acceptance and implementation, and the issues with the method of measuring global noise. The developer states their company can provide the service of quantifying the measure at a cost; this should also be included as a potential limitation. The measure developer does provide specifications for other entities to implement the measure, but the burden of implementation may be significant. Finally, the author cites publications from their group to justify the benchmarks, but they have not been vetted through a broader consensus process. ***The ACR strongly encourages the Patient Safety Standing Committee to re-vote on the scientific acceptability of these measures based on the following concerns.* *Validity/Feasibility*** These eCQMs require multiple variables that may be captured in software systems external to electronic health records (EHRs), such as dictation systems housing radiology reports or DICOM standard-based systems, such as CT device software. Data element validity testing should demonstrate that the testing sites were able to integrate and validate the variables used to construct the data elements used by the eCQM in addition to the usual validation of the eCQM's electronic output against the medical record review. ***We are uncertain that this validation has been completed. Therefore, this submission does not demonstrate the measure can be reproduced in a reliable and valid manner by practices or facilities across multiple settings.*** For example, for CT category (or other elements deriving/collecting data using custom natural language processing (NLP) tools), the developer used NLP for obtaining data such as reason for study or protocol name used in the calculation of this variable. The submission does not provide information on the NLP results' reliability and validity. Because ***this comparison of the NLP-derived data against a medical record review was only completed in a sample from one site (UCSF Health System), there is uncertainty whether the results are generalizable across EHRs or other databases***.* These measures rely on custom made NLP trained and validated on a small group of pilot sites; it is not clear whether this type of NLP would work outside these sites nor how sites would get access to use this custom NLP tool. Testing information does not demonstrate adequate validation of this critical data element. Additionally, ***sufficient evidence should demonstrate that the definitions/variables used are valid and do not rely on one study or use in a single system, such as what is provided to support the thresholds of "out of range" performance values.*** While the process to determine these thresholds is detailed, we do not believe that a Technical Expert Panel (TEP) conclusion in the absence of independent data validation is sufficient. *M**ultiple unstructured variables are required to construct the data elements for the numerator, denominator, and exclusions. Assessments of the feasibility of the integration of these unstructured data into the measure calculations would be useful to ensure that the underlying data can, in fact, be integrated if practices and facilities that choose not to use the edge device.*** For example, the level of effort required to integrate the Binning algorithm for the CT categories and ensure that the results are reproducible and valid remains unclear. The ACR is concerned with the selection bias for the accountable entity-level (measure score) validity. ***Assessing measure score face validity through the TEP that created these measures lessens the extent of credibility for these results***.* Although the TEP is knowledgeable and represents a variety of stakeholders, there is a vested interest in ensuring these measures are available for use. ***Most importantly, as one of the TEP members noted in the survey, the performance score from these measures does not clearly indicate what corrective action needs to be taken by the clinician, clinician**

group, and/or the facility to improve performance.* ***Usability*** While implementing these measures as specified may not impose a substantial burden on clinicians, ***it may necessitate substantial organizational effort to access and process the data elements required to calculate the measure score**.* The measure steward states that their software is available on a non-commercial basis to calculate this measure, and that other vendors may also develop their own software to implement the measure specifications using the information included in this submission. Will the measure steward review other vendors' software to ensure comparable calculation methods? Measure stewards frequently make specifications available "as is" without warranty, leaving it to the implementer to appropriately update any software or tools as measure specifications are changed. But the complexity of these measure specifications may warrant greater oversight. External vendor software will need to be maintained and updated to ensure the software's accuracy and reflect any changes in specifications and coding. ***For all the reasons stated above, the ACR does not support the endorsement of these three measures.*** We thank the NQF staff for their transparent endorsement process. **Reference: 1. '**Mahesh M. Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough?Radiology. 2021 Nov 9:212624. doi: 10.1148/radiol.2021212624. Online ahead of print. PMID: 34751622

Comment 3 by: Angela Keyser

What is AAPM: The American Association of Physicists in Medicine (AAPM) is the primary scientific and professional organization of physics in radiology and radiation oncology in the United States. The mission of AAPM is advancing medicine through excellence in the science, education and professional practice of medical physics; a broad-based scientific and professional discipline which encompasses physical principles with applications in biology and medicine. 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 radiation oncology and medical imaging procedures through research, education and the maintenance of professional standards. AAPM has a staff of 33 and an annual budget of $10.7M, and is located at 1631 Prince Street, Alexandria, VA 22314. **AAPM comments on the proposed measures:** AAPM does not support the endorsement of NQF #3633e, #3662e, and #3663e. This application proposes electronic clinical quality measures (eCQM) that 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. While efforts to enhance consistency of CT practice are noble and include initiatives by AAPM and others worldwide, the proposal has significant limitations that impact its 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. The authors indicate that their company (Alara Imaging, Inc.) can provide the service of quantifying the measures at a cost. A steward of measures requires an extensive track record for scientific and technical expertise and policy making that represents a broad consensus of the community. These important elements should be carefully reviewed within this application. One cited reference supports the proposed measure, however, this cited article has an accompanied editorial that highlights the limitations of the proposed approach [Mahesh M.Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough? Radiology. 2021 Nov 9:212624. doi: 10.1148/radiol.2021212624. Online ahead of print. PMID: 34751622]. The editorial and stated limitations are not addressed in the proposal. The AAPM agrees that effort needs to be continually placed on ensuring diagnostic quality CT imaging, optimizing CT dose, and achieving consistency across facilities, considering differing technologies and practices. The non-profit entities of

the AAPM, the American College of Radiology (ACR), and Image Wisely and Image Gently Alliances have spent decades towards this goal and continue to do so through many initiatives. Among them, the non-profit ACR CT Dose Index Registry (DIR; https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry, established in 2011) has the significant stature of implementing a dose registry that enables facilities to compare dose indices nationally, to ensure the highest quality imaging with lowest possible dose. The ACR CT DIR implementation incorporates the expert, consensus opinions of the medical imaging community. ACR dose optimization measure recently endorsed by NQF provides a further valuable measure to manage imaging radiation dose (https://www.qualityforum.org/QPS/3621). The imaging community's valuable clinical benchmarks greatly benefit from consensus decisions based on sound scientific and technical review and discourse. The proposal herein should be carefully reviewed for any additional contributions or advantages it would provide to our existing robust consensus measures and resources, such as available with the ACR. After a detailed review of the measures by multiple expert members of the AAPM, we have concluded that the **AAPM does not support the endorsement of NQF #3633e, #3662e, and #3663e.** This position stems from eight major concerns about the proposed measures: 1) Unscientific characterization of CT scan risk: The proposal is based on estimation approaches that are not reflective of the consensus of the scientific community and do not acknowledge the uncertainties of the estimates. A NQF measure focused on radiation risk should uphold scientific objectivity, integrity, and responsibility not evident in the presentation and assessment of radiation risk in this proposal. 2) Inactionability of the measures to enable targeted change to improve practice: It is not evident how the proposed measures can be practically used to improve imaging practice and exactly how a facility can do to achieve compliance, given the wide varieties of factors and technologies involved. 3) Inadequate addressing of the complexity of CT categorization: The proposal does not address the magnitude of this challenge nor has suggested means to overcome it given that current standards are even lacking in uniform characterization of protocols. Inaccurate classification of data can lead to significant and misleading errors. 4) Inadequate assessment of noise: Noise in a CT image can be influenced by a variety of factors including justified differences in CT technologies including new reconstruction methods that dramatically alter noise. Further, noise does not have a singular value in a CT exam. A "global noise" ignores this diversity and can misrepresent the quality of an exam. 5) Inadequate assessment of image quality: Image quality is affected by a myriad of factors including resolution and contrast, as well as the intended purpose of the exam. A singular representation of image quality via global noise overly simplifies this space and can lead to gross misrepresentation of image quality and thus mis-service to patient care. 6) Flawed assumption on dose reduction vs dose optimization: The application focuses primarily on radiation dose reduction as oppose to right-sizing the dose for the best care of the patient. Individualization and optimization of care and safety should be the goal not minimization. This approach can lead to some patients getting under exposed, leading to missed diagnosis, while others may be over-dosed for their exact need and condition. 7) Inadequate accuracy in patient size estimation: Assessing a patient size is not a trivial task, stemming from 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. Algorithms are continuously evolving and no evidence is provided that the company can do this task with sufficient accuracy. 8) Limited expertise and track record of the company: The company is a new (2020) company with no experience of having previously performed a project of such wide scope, scientifically or technically. There is no scientific track record on CT technology, size estimation, or image quality assessment for the company to be considered a steward of measures on which there is a lack of expertise, publication, and scientific history. These concerns are detailed specially in our complete review submitted via email to patientsafety@qualityforum.org, along with selected specific observations on the proposal on January 19, 2022. The AAPM recognizes that this topic is complex, including scientific, technical and clinical components. We welcome the opportunity for greater in-depth discussion on meaningful measures of quality imaging practice.

Respectfully submitted,

American Association of Physicists in Medicine (AAPM) January 19, 2022

Comment 4 by: Angela Keyser

What is AAPM:

The American Association of Physicists in Medicine (AAPM) is the primary scientific and professional organization of physics in radiology and radiation oncology in the United States. The mission of AAPM is advancing medicine through excellence in the science, education and professional practice of medical physics; a broad-based scientific and professional discipline which encompasses physical principles with applications in biology and medicine. 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 radiation oncology and medical imaging procedures through research, education and the maintenance of professional standards. AAPM has a staff of 33 and an annual budget of $10.7M, and is located at 1631 Prince Street, Alexandria, VA 22314.

AAPM comments on the proposed measures:

AAPM does not support the endorsement of NQF #3633e, #3662e, and #3663e.

This application proposes electronic clinical quality measures (eCQM) that 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.

While efforts to enhance consistency of CT practice are noble and include initiatives by AAPM and others worldwide, the proposal has significant limitations that impact its 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. The authors indicate that their company (Alara Imaging, Inc.) can provide the service of quantifying the measures at a cost. A steward of measures requires an extensive track record for scientific and technical expertise and policy making that represents a broad consensus of the community. These important elements should be carefully reviewed within this application. One cited reference supports the proposed measure, however, this cited article has an accompanied editorial that highlights the limitations of the proposed approach [Mahesh M. Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough? Radiology. 2021 Nov 9:212624. doi: 10.1148/radiol.2021212624. Online ahead of print. PMID: 34751622]. The editorial and stated limitations are not addressed in the proposal.

The AAPM agrees that effort needs to be continually placed on ensuring diagnostic quality CT imaging, optimizing CT dose, and achieving consistency across facilities, considering differing technologies and practices. The non-profit entities of the AAPM, the American College of Radiology (ACR), and Image Wisely and Image Gently Alliances have spent decades towards this goal and continue to do so through many initiatives. Among them, the non-profit ACR CT Dose Index Registry (DIR; https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry, established in 2011) has the significant stature of implementing a dose registry that enables facilities to

compare dose indices nationally, to ensure the highest quality imaging with lowest possible dose. The ACR CT DIR implementation incorporates the expert, consensus opinions of the medical imaging community. ACR dose optimization measure recently endorsed by NQF provides a further valuable measure to manage imaging radiation dose (https://www.qualityforum.org/QPS/3621). The imaging community's valuable clinical benchmarks greatly benefit from consensus decisions based on sound scientific and technical review and discourse. The proposal herein should be carefully reviewed for any additional contributions or advantages it would provide to our existing robust consensus measures and resources, such as available with the ACR.

After a detailed review of the measures by multiple expert members of the AAPM, we have concluded that the **AAPM does not support the endorsement of NQF #3633e, #3662e, and #3663e.** This position stems from eight major concerns about the proposed measures:

1) Unscientific characterization of CT scan risk: The proposal is based on estimation approaches that are not reflective of the consensus of the scientific community and do not acknowledge the uncertainties of the estimates. A NQF measure focused on radiation risk should uphold scientific objectivity, integrity, and responsibility not evident in the presentation and assessment of radiation risk in this proposal.

2) Inactionability of the measures to enable targeted change to improve practice: It is not evident how the proposed measures can be practically used to improve imaging practice and exactly how a facility can do to achieve compliance, given the wide varieties of factors and technologies involved.

3) Inadequate addressing of the complexity of CT categorization: The proposal does not address the magnitude of this challenge nor has suggested means to overcome it given that current standards are even lacking in uniform characterization of protocols. Inaccurate classification of data can lead to significant and misleading errors.

4) Inadequate assessment of noise: Noise in a CT image can be influenced by a variety of factors including justified differences in CT technologies including new reconstruction methods that dramatically alter noise. Further, noise does not have a singular value in a CT exam. A "global noise" ignores this diversity and can misrepresent the quality of an exam.

5) Inadequate assessment of image quality: Image quality is affected by a myriad of factors including resolution and contrast, as well as the intended purpose of the exam. A singular representation of image quality via global noise overly simplifies this space and can lead to gross misrepresentation of image quality and thus mis-service to patient care.

6) Flawed assumption on dose reduction vs dose optimization: The application focuses primarily on radiation dose reduction as oppose to right-sizing the dose for the best care of the patient. Individualization and optimization of care and safety should be the goal not minimization. This approach can lead to some patients getting under exposed, leading to missed diagnosis, while others may be over-dosed for their exact need and condition.

7) Inadequate accuracy in patient size estimation: Assessing a patient size is not a trivial task, stemming from 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. Algorithms are continuously evolving and no evidence is provided that the company can do this task with sufficient accuracy.

8) Limited expertise and track record of the company: The company is a new (2020) company with no experience of having previously performed a project of such wide scope, scientifically or technically. There is no scientific track record on CT technology, size estimation, or image quality assessment for the company to be considered a steward of measures on which there is a lack of expertise, publication, and scientific history.

These concerns are detailed specially in our complete review submitted via email to patientsafety@qualityforum.org, along with selected specific observations on the proposal on January 19, 2022.

The AAPM recognizes that this topic is complex, including scientific, technical and clinical components. We welcome the opportunity for greater in-depth discussion on meaningful measures of quality imaging practice.

Respectfully submitted,
American Association of Physicists in Medicine (AAPM)
January 19, 2022

Comment 5 by: Bradley Delman

I am writing to lend my support for the endorsement of CT quality measures 3633e, 3662e, and 3663e developed by the University of California, San Francisco. As an implementation testing partner, I coordinated Mount Sinai Health System's inclusion in the test. To summarize, after installing the data collection software, we routed CT imaging data from PACS and sent order and billing data from various electronic systems to the software. We also worked with UCSF and our CT vendors to ensure the Radiation Dose Structured Report (RDSR) was being saved for each exam sent to PACS. As we discussed in our interview with UCSF, this work fell on the PACS team and IT colleagues, without requiring effort from clinicians above my initial planning and coordination. Besides some technical challenges, which were all resolved, we faced few barriers to successful implementation and had very little missing data. In total we submitted 11,588 scans, representing just over 3 weeks of CT data from our health system. Based on our experience, the participation in the proposed quality measure is feasible. However, I suspect that spirited engagement from PACS, RIS and/or EHR vendors would greatly enhance participation and timely provision of data. We have also been satisfied with the feedback we've received from Alara Imaging on our measure performance, which brought to our attention areas of high radiation dose. This feedback has identified individual exams as well as imaging protocols that contribute high radiation dose. Although we have been a dose-conscious department, the feedback highlighted areas of variability in both routine and size-adjusted datasets. Furthermore, we learned which protocols and classes of studies fell within and beyond expected range for dose, and how dose can vary between scanners for protocols with the same name. We also learned that some types of studies may need to be renamed or reclassified for appropriate grouping of results. A quality measure the quantifies dose while ensuring preservation of imaging quality can help mitigate the use of excessive radiation doses used in CT. I support the work of the measure developers to improve patient safety and CT quality.

Comment 6 by: Daniel Hirsch

I write in support of CT quality measures 3633e, 3662e, and 3663e developed by the University of California, San Francisco. They are important proposals that would markedly reduce unnecessary radiation exposures in medicine, and the cancers induced therefrom, while providing the same yield of diagnostic information. Many, many lives could thus be saved were the proposals adopted. I have spent much of my professional career attempting to reduce the risks to public health from ionizing radiation associated with nuclear waste, reactor accidents, nuclear weapons tests, uranium mining and milling, and radioactively contaminated sites involved in the production of nuclear weapons and other nuclear activities. It is with some alarm that I have viewed in recent years the extraordinary increase in public exposures to ionizing radiation associated with the remarkable escalation of exposures in medicine, largely due to ever-more frequent CT scans, resulting in doses from medical procedures now dwarfing

exposures from the nuclear activities that have so long concerned me. The proposals made by UCSF would help reign in unnecessarily high radiation doses from these medical procedures while still producing the diagnostic information needed by physicians for their patients. The important revelation in the studies cited in the proposals is that the doses currently received by patients in these procedures are frequently very much higher—often ten times higher—than necessary. One can get the same medical benefit from the procedure at one tenth the cancer risk. The proposals indicate that many thousands of unnecessary radiation-induced cancers could be avoided were CT scans kept to the minimum level necessary to produce the required image. This seems quite correct. The National Academies of Sciences, Engineering and Medicine has produced over the years the primary studies on the matter of ionizing radiation and cancer induction. The most recent Biological Effects of Ionizing Radiation study (BEIR VII) estimates a risk of 1.17 cancers per 1000 person-rems of exposure, and concludes, as have all the BEIR studies, that there is no threshold below which there is no risk. All radiation protection agencies (e.g., US EPA) have adopted the BEIR conclusions. Currently, exposures to medical radiation are estimated as averaging about 350 millirem/year per person. Given that degree of exposure, and the current U.S. population, medical radiation would be estimated to produce many millions of cancers over the population's lifetime. Reducing unnecessarily high exposures while still producing the necessary diagnostic image could thus prevent a very large number of cancers and deaths, while, not incidentally, also reducing Medicare expenditures for their treatment. I strongly urge adoption of quality measures that assure CT exposures use the lowest reasonable doses necessary for the procedures. Daniel Hirsch retired Director of the Program on Environmental and Nuclear Policy at University of California at Santa Cruz

Comment 7 by: Dawn Ritzwoller

I am a college student and Environmental Biology (E-bio) major, and I am pediatric cancer survivor. I am writing today in support of this radiation dose quality measure. Beginning ten years ago, and both during and after I finished treatment, I recieved multiple CTs (to multiple parts of my body) as part of my diagnostic and follow-up care. Not once during this period, did any of my doctors or other, discuss with me the downstream risk of all of the radiation exposure I experienced. It was only years after my treatment ended, and now via classes I have take for my E-bio major, that I am beginning to understand the risk associated with radiation exposure. What is also now clear to me is the importance that providers use the most appropriate (low) dose for the specific diagnostic or follow-up exam. I know that image quality is important for diagnosis, but patients (like me) need the confidence that their doctors and hospitals are using the best and lowest dose possible for the exam that they order. Thank you!

Comment 8 by: Debra Ritzwoller

I am writing in support of this important measure. I am a cancer health services researcher *and* a mother of a pediatric cancer survivor. It is well documented in the literature that there has been a significant secular increase in CT use within and across most patient populations. While CT use, and therefore radiation exposure has increased over time, I know that personally and professionally that excessive radiation dose remains a significant quality issue, and it is one that is often not adequately addressed by researchers and healthcare providers/delivery systems. This quality metric is necessary now, in order to provide the incentives and the resources needed to generate the metrics and the benchmarks that may actually influence practice that may in turn translate into a meaningful reductions in the radiation dose that patients are exposed to. This metric is designed to address the clinical indication associated with the respective exam, rather than just the type of advanced imaging that is performed. The measure is also constructed to ensure that the dose benchmarking does not adversely impact the quality of the

metric. Given the noted harms of CT based radiation exposure (e.g USPSTF Lung Cancer Screening "B" recommendation), this measure is addresses a timely and needed quality metric.

Comment 9 by: Ehsan Samei

Duke University, Ravin Advanced Imaging Laboratories (Ravin Labs) and Clinical Imaging Physics Group (CIPG), Durham, NC 27710 The Ravin Labs is a 50-member leading translation imaging research laboratory in the country with over 30 years of history. The lab conducts rigorous NIH-funded research with an additional mandate to practice its science through CIPG, an imaging physics group of 15 experts dedicated to quality and safety in the practice of radiology. The group, highly integrated into the clinical domain, has devised and put to practice imaging dose and image quality monitoring systems at the level of individual patients within the Duke University Health System with additional pilot installations at MD Anderson Cancer Center and Stanford University. The group has published extensively on its technology and findings (upward of 500 papers), with over 30 referred publications on dose and quality monitoring alone. The effort has led to significant reduction of patient radiation dose at our facilities and right-sizing it per individual needs of patients. **We do not support the proposed measures.** The rationale is detailed below. **Overall:** While we applaud the effort to introduce new quality measures in the practice of medical imaging, the proposed electronic clinical quality measures (eCQM) are misleading and overly simplistic leading to significant unintended consequences. The limitations stem from the fact that the proposed risk measures are based on CT scanner output and not the actual dose burden to individual patients at the organ level, the quality measure is based on noise alone ignoring the multi-faceted reality of diagnostic quality, and lack of methods that standardize protocols across vast diversity of examinations. There is significant ambiguity in the exact method used for noise and size estimation with no track record or peer review of otherwise black-box methods. This approach will likely produce measures that can be orders of magnitude off from their actual values, and therefore lack clinical relevance and fidelity. Measures can lead to misleading and erroneous conclusions while also potentially jeopardizing the use and development of better approaches, as inaccurate low-bar measures can prevent accurate ones in the future. But most importantly, the measure can lead to unintended consequences and even harm the patient. For example, an imaging team can take an action that is not in the best interest of a patient, like applying too little dose for some patients such that disease would be missed, a "wasted dose" with no medical benefit and health and cost consequence of a miss. Conversely others might get more radiation than needed as the measures do not account for individual patient needs and tasks. Improving consistency in imaging practice is a laudable goal that needs a proper solution anchored to scientific understanding of radiation risk, image quality need of patients, diversity of practices, and the CT technology. The proposal is lacking on all these four fronts. A solution to inconsistency in images can only be brought forth through a broad consensus of the scientific and practicing communities (including ACR, AAPM, Image Gently, and Image Wisely), CT manufacturers (represented by MITA), standard methods of data categorizations and measures (supported by the medical community), and evidence-based radiation risk and image quality measures at the level of indication and organ where they are actually relevant to the individual patient. A for-profit company with no track record or transparency of its methods cannot be considered a steward of such a space. Below we further detail 12 concerns regarding the proposed measures:

1. **Inadequate attention to image quality:** The measures are heavily dose related, emphasizing this over measures of quality. Dose and minimizing it is important but equally important is image quality as an inadequate image quality would be a dis-service to the patient regardless of the dose. This is explicitly stated in the International Commission of Radiological Protection (ICRP) in Publication n. 135.

2. **Inaccurate assessment of radiation risk:** The measure of size-adjusted radiation risk, adjusting the CT scanner outputs with 'patient size' to perform risk estimation is not a standard

method nor endorsed by any scientific or professional body. The method is in fact explicitly discouraged by the AAPM Task Group 204. Patient risk can only be assessed with the knowledge of organ doses that is not even mentioned in the application let alone pursued. The proposed method CANNOT be used as surrogate for future cancer risk.

3. **Incomplete/Inaccurate representation of image quality:** The measures include image noise. Yet, noise is just one component of image quality. For example, the noise of an image can be fine but image quality totally inadequate. And conversely noise can be too high but image quality totally adequate. To assess image quality properly, one should include the actual task at hand (eg, detecting a pancreatic cancer vs bowel obstruction vs kidney stone) as well as other equally important facets of quality, like noise texture, resolution, and contrast. These factors have not been even mentioned let alone tackled in this application. Focusing on noise as a singular metric of quality can lead to major mis-representation of the needs of a quality and safe imaging practice.

4. **Neglecting the impact of image rendition:** Critical and relevant to clinical practice, the measure of noise proposed does not take into consideration how differing reconstruction algorithms and parameters affect noise (up to 200%). Without considering this influence, a measure of noise as proposed is irrelevant and misleading.

5. **Subjectivity:** The measures are anchored to subjective perception by radiologists as how they "like" the images. There is in fact no evidence provided that the measures can lead to an improvement in diagnostic accuracy. In fact, it might lead to a degradation.

6. **Lack of integrating dose and quality:** There is no indication as to how image quality is linked to radiation dose and at what level; or instance, how they propose to manage multiple reconstructions of the same exposure event.

7. **Not addressing the multiplicity of exam components**: A CT exam often includes multiple phases (series) each of which has a noise and radiation dose of its own. Averaging noise across series is meaningless. The measures do not recognize or account for this multiplicity and diversity.

8. **Under-recognizing the diversity of exams:** The measures do not address the notable diversity of exam nomenclature across institutions and practices. This is a significant component of any dose or quality monitoring system. Without a standard for CT protocols, which cannot be devised by a for-profit company without consensus of manufacturers and users, the data can be mislabeled and mishandled leading to major errors in the results and subsequent negative effect on mis-dosing and mis-diagnosing patients.

9. **Inaccurate assessment of patient size:** The measure of size proposed is calibrated to earlier work and publication from our group at Duke University for academic purposes. That early method they have embraced has had major errors (upward of 300% is certain applications) that have been corrected in subsequent versions that have not been shared. Without essential newer refinements to assure fidelity, the company cannot be a responsive steward of the measure that it has had no expertise to advance or maintain.

10. **Inaccurate assessment of noise:** The measure of noise proposed references earlier work and publication from our group at Duke University. That early method exhibited errors, corrected in subsequent versions that have not been shared. Without essential newer refinements, the company cannot be a responsive steward of the measure that it has had no expertise to advance or maintain.

11. **Lack of guidance toward compliance:** To us it is difficult to defend (1) measuring imaging practices based on ambiguous and questionably-relevant metrics promoted to represent the actual safety or quality of CT practice, and (2) not offering any guidance as to how a practitioner

responsible for “outlier” examinations can bring their practice to the proposed definition of compliance. Together, these can easily create signification confusion and potential disruption in the imaging practice

12. **Lack of support from manufacturers:** Having worked in dose and image quality monitoring for over a decade, academic centers of excellence, including ourselves, have a close connection with major CT manufacturers including MITA, Medical Imaging Technology Alliance, which comprises all CT manufactures. Our discussions regarding this measure lead us to believe that there will be little support from scanner manufacturers for a non-transparent and unpredictable product that lacks maturity from a private for-profit entity. There are substantial differences in image processing, detector efficiency, and such across scanners that will have significant bearing on the CT image. The proposed measure does not account for such important nuances, leading to erroneous results.

Comment 10 by: James Seibert

January 27, 2022 To: National Quality Forum Dear NQF Standing Committee, I am writing to lend support for the endorsement of CT quality measures 3633e, 3662e, and 3663e developed by the University of California, San Francisco, where I have served on the Technical Expert Panel and have been a long-time collaborator for similar projects between UCSF and UC Davis. I led the implementation of measure testing at my institution, University of California Davis Health, which required local installation of the software, configuring connections to the PACS, extracting CPT and ICD-10 data from the EHR, and supervising the aggregation and transfer of all this data to the UCSF software. Most of this work was completed by our PACS administrator and did not impact the work of our clinicians at any time. One challenge we encountered was that transfer of data from PACS to the software was slow; we believe this was due to capacity limitations of our PACS relative to the query-retrieve process. Nevertheless, we set up auto-transfers of the data over nights and weekends so as not to impact the operation of our PACS during our busiest clinical hours. Besides this issue, the testing was completed successfully with minimal missing data. Based on our experience, the proposed quality measure is highly feasible, and will, in my opinion, be able to appropriately identify CT exams that are significantly above diagnostic reference level (DRL) doses(*), as well as inadequate CT exams with insufficient dose, for specific diagnosis indications versus radiation dose versus image quality. There are certainly many parameters and issues that can potentially confound such CT quality measures, particularly with the assessment of corresponding image quality, but significant advances in developing robust algorithms to recognize such confounding factors have largely mitigated such concerns. I believe this quality measure can significantly reduce the use of excessive high radiation dose as well as inadequate, sub-optimal low dose used for clinical CT studies, by identifying outliers and thereby increasing the awareness and importance of CT protocol optimization. I support the work to improve patient safety and CT quality as described in these measures. Sincerely, J. Anthony Seibert, PhD, FAAPM, FACR, FSIIM, FIOMP Professor Emeritus, Department of Radiology UC Davis Health (*) Kanal KM, Butler PF, Sengupta D, Bhargavan-Chatfield M, Coombs LP, Morin RL. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology 284(1), 120-133, 2017. Disclosure: I have served on the Technical Expert Panel for this effort and have received some minor compensation for participation (honoraria) but have no other relevant conflicts. The opinions expressed here are my own.

Comment 11 by: Kenneth Wang

I am pleased to provide my support for the proposed CT quality measures 3633e, 3662e and 3663e developed by the University of California, San Francisco. I have been a practicing radiologist in the Veterans Affairs (VA) system for more than ten years, during which time I have led efforts in CT dose

optimization across the VA Maryland Health Care System. I also serve in a number of volunteer roles within the Radiological Society of North America (RSNA) and the American College of Radiology (ACR), leading efforts in informatics, standards, interoperability and registries. However, this letter reflects my personal opinion, and not necessarily those of any organization with which I am affiliated. I have also served as a member of the Technical Expert Panel (TEP) advising on the formulation of these proposed quality measures, since the inception of this project.

The impetus for this work rests on fundamental principles which are widely accepted. Namely, that CT constitutes an important source of radiation dose to patients, and that CT imaging presents an opportunity for dose reduction, but that it is of paramount importance to maintain the diagnostic quality of the imaging obtained. The proposed measures have been developed using a scientific approach incorporating extensive testing and validation, as well as expert consensus, while maintaining a focus on practicality. This has been all the more impressive given the complex nature of the technical factors involved, such as CT exam types, size-adjusted dose, and diagnostic image quality. By leveraging extensive data, including but not limited to data in the UCSF International CT Dose Registry, data obtained from practicing radiologists on image quality, and feedback from testing facilities, the measures strike a practical balance intended to identify opportunities for CT dose reduction while maintaining a floor for diagnostic quality (which was rarely violated in measure testing).

As such, these measures represent an important step beyond simple dose reduction. I also believe that these measures will provide actionable feedback, especially given the many different techniques now available on modern CT scanners for dose adjustment.

As a radiologist, I know there will never be universal agreement on subjective assessments such as image quality. However, the proposed measures take a balanced approach, informed by extensive testing and validation, which serves a very practical and important quality objective. For these reasons, I support the adoption of these measures.

Comment 12 by: Krishna Nallamshetty

I would like to submit a comment regarding this measure. As a practicing radiologist for greater than 15 years, we have seen tremendous growth in medical imaging that requires radiation, specifically computed tomography (CT). The public awareness of the potential long-term effects of ionizing radiation has become mainstream and as a result, a primary objective of the American College of Radiology and other governing bodies. The objective focuses on reducing radiation exposure as much as possible without compromising the diagnostic information that is obtained

This measure evaluates radiation dose for every patient who undergoes CT *based on the clinical indication for imaging* rather than solely on the type of examination that is performed. It ensures patients receive the most appropriate CT acquisition protocol and level of radiation for their individual condition. The measure also assesses image noise, safeguarding image quality against potential effects of dose reduction, and is the first quality measure to do so.

The measure would have a large, positive impact on patients and protect them from unnecessary over-exposure of radiation without compromising the diagnostic value of medical imaging. It would be the first time a measure addresses both radiation and image quality.

Comment 13 by: Krishna Nallamshetty

I would like to submit a comment in support of this measure. I am a practicing radiologist for the past 15 years and serve as the Associate Chief Medical Officer of Radiology Partners, the largest medical imaging practice in the United States. I am the chair of our national Patient Safety

Committee. We have seen tremendous growth in medical imaging that requires radiation, specifically computed tomography (CT). The public awareness of the potential long-term effects of ionizing radiation has become mainstream and as a result, a primary objective of the American College of Radiology and other governing bodies. The objective focuses on reducing radiation exposure as much as possible without compromising the diagnostic information that is obtained

We have recognized that there is large variability in how CT scans are acquired all over the country. Techniques and radiation exposure is extremely varied but yet appropriate clinical diagnosis are made. This measure evaluates radiation dose for every patient who undergoes CT *based on the clinical indication for imaging* rather than solely on the type of examination that is performed. It ensures patients receive the most appropriate CT acquisition protocol and level of radiation for their individual condition. The measure also assesses image noise, safeguarding image quality against potential effects of dose reduction, and is the first quality measure to do so.

The measure would have a large, positive impact on patients and protect them from unnecessary over-exposure of radiation without compromising the diagnostic value of medical imaging. It would be the first time a measure addresses both radiation and image quality.

Comment 14 by: Maribel Escobar

Submitting on behalf of ARA's CMO, Dr. John Kish: January 25, 2022 Dear NQF Standing Committee, I am writing to lend my support for the endorsement of CT quality measures 3633e, 3662e, and 3663e developed by the University of California, San Francisco. As an implementation testing partner, my institution, ARA Diagnostic Imaging, was required to install the data collection software, route CT data from PACS and order and billing data from various electronic systems to the software, and oversee the migration of data. We also worked with UCSF and our CT vendors to ensure the Radiation Dose Structured Report (RDSR) was being saved from each exam in the PACS. As we discussed in an interview with UCSF, this work fell on the PACS team and IT colleagues and did not require effort from clinicians. Besides some technical hiccups, which were all resolved, we faced few barriers to successful implementation and had very little missing data. Based on our experience, the proposed quality measure is highly feasible. We have also been satisfied with the feedback we have received from Alara Imaging on our measure performance, which brought to our attention some areas of opportunity to decrease radiation dose. The feedback provided by Alara Imaging has taken the burden of researching problem areas away from my institution, by identifying specific exams, imaging protocols and even specific CT units that contribute to high radiation dose and need improvement. We have plans to address each accordingly. Given our positive experience, my organization is moving towards a commercial relationship with Alara to continue to submit data, receive feedback, and strive to optimize our CT doses. I earnestly believe this quality measure can help mitigate the use of excessive radiation doses used in CT. I support these measure developments in order to improve patient safety and CT quality. Sincerely, John Kish, MD Chief Medical Officer

Comment 15 by: Mary White

I am writing in support of this CT radiation dose safety measure. As a cancer epidemiologist, I recognize that excessive exposure to medical radiation increases cancer risk. And I understand that this measure will be valuable for protecting patients from unnecessarily high levels of radiation from CT imaging. The measure is designed to evaluate radiation dose for every patient based on the clinical indication for imaging. The measure also assesses image noise, ensuring adequate image quality despite the reduction

in radiation dose. This measure fills an important quality void and has the potential to substantially reduce the contribution of CT scans to the incidence of cancer in the population.

Comment 16 by: Matthew Nielsen

I am writing in support of this important measure. The utilization of CT imaging int he United States has dramatically increased over recent decades, providing numerous benefits to patients and clinicians in the management of countless medical conditions. There has also been increasing recognition of the potential for unintended harms due to potentially avoidable variation in radiation in radiation dose for many patients. Evidence from research and quality improvement efforts demonstrates the potential to mitigate these harms with a feedback loop and benchmarking to radiologists and staff. This measure provides needed resources to disseminate these early successes, preserving the benefit of advanced imaging with CT while providing a means for healthcare facilities and clinicians to improve the safety of the studies they provide patients. The design of this measure importantly takes into account the indication for the study as the framework for dose benchmarking, with balancing measures of image quality to assure that efforts to reduce dose do not come at the expense of diagnostic quality. Given the increased recognition from patients and providers of the potential harms of imaging-associated radiation, this measure fills a timely and important gap in the current measurement portfolio.

Comment 17 by: Pavlina Pike

I am writing to lend my support for the endorsement of CT quality measures 3633e, 3662e, and 3663e developed by the University of California, San Francisco. I am a Medical Physicist and Radiation Safety Officer at Huntsville Hospital and led the testing of UCSF's quality measure at my health system, which involved installing the data collection software, routing CT data from PACS and order and billing data from various electronic systems to the software, and overseeing the migration of data. We came onboard late in the testing period, leaving a tight window of time to collect the data prior to UCSF's submission deadlines. I am proud of my PACS and IT colleagues for pulling together so efficiently and completing the work rapidly with very little missing data. The work in no way impacted our physicians or clinical workflows. We faced few barriers to implementation, and based on our experience, the proposed quality measure is highly feasible.

We have also been satisfied with the feedback we've received from Alara Imaging on our measure performance, which brought to our attention areas of high radiation dose. Our exams were compared to thresholds established based on input from 125 radiologists and 50,000 CT examinations from other facilities. The analysis includes comparisons of the performance of different model CT scanners, exams, protocols, patient size, facility, etc. The feedback from the Alara software is helpful and actionable as we are able to identify what changes will have the greatest impact on patient dose and make the appropriate changes. In addition it provides suggestions for billing inconsistencies which was very helpful to our administration.

I earnestly believe this quality measure can help mitigate the use of excessive radiation doses used in CT. I support the work of the measure developers to improve patient safety and CT quality.

Comment 18 by: Pavlina Pike

I am writing to lend my support for the endorsement of CT quality measures 3633e, 3662e, and 3663e developed by the University of California, San Francisco. As an implementation testing partner, my institution, Huntsville Hospital, was required to install the data collection software, route CT data from PACS and order and billing data from various electronic systems to the software, and oversee the migration of data. As we discussed in the interview with UCSF, this work fell on the PACS team and IT colleagues and did not require effort from clinicians. Besides some technical hiccups, which were all resolved, we faced few barriers to successful implementation and had very little missing data. Based on our experience, the proposed quality measure is highly feasible. We have also been satisfied with the feedback we've received from Alara Imaging on our measure performance, which brought to our attention areas of high radiation dose. Our exams were compared to thresholds established based on input from 125 radiologists and 50,000 CT examinations from other facilities. The analysis includes comparisons of the performance of different model CT scanners, exams, protocols, patient size, facility etc. The feedback from the Alara software is helpful and actionable as we are able to identify what changes will have the greatest impact on patient dose and make the appropriate changes. In addition it provides suggestions for billing inconsistencies which was very helpful to our administration. I earnestly believe this quality measure can help mitigate the use of excessive radiation doses used in CT. I support the work of the measure developers to improve patient safety and CT quality.

Comment 19 by: Robert Gould

I am writing as a physician who has worked for decades as a leader in Physicians for Social Responsibility, as well as the International Physicians for the Prevention of Nuclear War toward eliminating nuclear weapons, cognizant of the public health dangers of radiation initially derived from studies of victims of the twin atomic bombings in Japan. Informed by the central tenet of physician practice to "at first do no harm," I strongly support CT quality measures 3633e, 3662e, and 3663e developed by the University of California, San Francisco. While my long experience as a practicing pathologist has made me understand at a profound level how diagnostic radiation is a critical tool in medical practice, it has also underscored to me the often-overlooked risks of carcinogenesis that must always be balanced against the benefits of various radiological procedures. Over time, research has documented that many radiological procedures are medically unnecessary when information that is desired can be obtained by other means than exposing a patient to ionizing radiation; it is also unwarranted when employed as a "hedge" against possibility of malpractice litigation. In addition, when radiological imaging is indeed required and justifiable, it is not uncommon, where standards are not uniformly applied in practice, for radiation exposures to exceed what would be required for achieving images satisfactory for diagnostic purposes. As such, the lack of attention to standardizing, and minimizing exposures inevitably results in the induction of significant numbers of unnecessary cancers that would not occur if lower doses were employed to achieve adequate imaging. I believe that CT quality measures 3633e, 3662e, and 3663e would be important steps to assuring that physicians can obtain the information necessary from diagnostic imaging while minimizing the number of unnecessary cancers induced by the procedures.

Comment 20 by: Suz Schrandt

As a patient advocate with significant experience navigating the healthcare system--including repeated exposures to a variety of diagnostic imaging studies--I submit these comments in endorsement of this measure. The measure takes into account different contexts and parameters for a given patient and his or her unique benefit/risk profile. At a more foundational level, the measure calls into focus the significant variation in practices in CT imaging that can expose patients to unnecessary and/or unsafe levels of radiation, a risk many patients are not even aware of. The wide-spread use of this measure could

standardize imaging practices and should the measure be adopted, I strongly encourage a robust dissemination plan to inform patients and families of its existence. Our ability to access safe and effective care should not be left to change; measures such as this help to close key gaps in our system.

Comment 21 by: Melissa Danforth

Founded in 2000 by large employers and other purchasers, The Leapfrog Group is a national nonprofit organization driving a movement for giant leaps forward in the quality and safety of American health care. The flagship Leapfrog Hospital Survey collects and transparently reports hospital performance, empowering purchasers to find the highest-value care and giving consumers the lifesaving information they need to make informed decisions. For the past several year's Leapfrog has been collecting and publicly reporting hospital performance on an NQF-endorsed Pediatric CT Radiation Dose (NQF 2820) measure. The new Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Group Level) fills a critical gap in evaluating radiation dose for adult patients who undergo CT. Additionally, because the measure is based on the clinical indication for imaging – rather than on the type of examination the radiologist chose to perform – it can help ensure patients receive the right type of CT and amount of radiation for their individual condition, which is a primary concern of Leapfrog and our purchaser and employer membership. The measure also assesses image noise, safeguarding image quality against potential effects of dose reduction, and is the first quality measure to do so. Leapfrog strongly supports this measure.

Comment 22 by: Carly Stewart

We thank the American College of Radiology for their comments from 1/19/22 but wish to address several factual inaccuracies in the comments. (Response PART 1) **Comment:** *Indications for exams do not have standardized language that could be used to track them. Most health and IT systems capture…coding for reimbursement, but typically not enough... As a result, the clinical reason for performing an imaging exam is often extremely limited in the exam order... A validated method for determining classification of studies .. must be incorporated into such a measure.* **Response:** This statement indicates that the commenter does not understand how clinical indication is determined in the proposed measure. It does not rely on the clinical reason for performing an imaging exam in the exam order. As described in Specifications, sp-11, clinical indication for imaging is determined using an algorithm that combines procedure (CPT®) and diagnosis (ICD-10-CM) codes associated with the clinical visit when the test was ordered, information provided as part of the order, and information on the final bill. The codes are available in the radiology electronic systems and/or the EHR or billing systems. The goal in creating the CT categorization decision rules was to identify exams that are exceptions to the routine dose category (i.e. either high or low dose). The approach of assigning CT exams to the various CT categories in an automated fashion using an algorithm was developed using over 4.5 million CT exams in the UCSF International CT Dose Registry. We confirmed that the CT categories were representative of groupings that require different radiation dose and image quality (Smith-Bindman 2021). The algorithm was validated using over 10,000 patient records from UCSF Health. The CT category assignment determined by the algorithm was compared with a "gold standard" chart review, as described in Validity sections 2b.02 and 2b.03. Since we did not have access to complete medical records at testing sites, we developed a second referent standard that determined CT category based on natural language processing of DICOM data and the full radiology report. This second referent standard was found to be accurate compared to the gold standard chart review of the same sample of UCSF Health exams (sensitivity = 0.92, specificity = 0.97; see 2b.02). When the algorithm was deployed at testing sites, the correct classification rate of CT category assignment was on average 92% across clinician groups and hospitals and 95% in individual clinicians (see 2b.03). Knowing that the algorithm was developed using data from a single

health system, we performed detailed investigation of the categorization results at testing sites – comparing the assigned CT category against full radiology reports – for the purpose of improving the algorithm, which we did. **Reference:** Smith-Bindman R, Yu S, Wang Y, et al. An Image Quality-informed Framework for CT Characterization. Radiology. 2021 Nov 9:210591. **Comment:** *The developer states their company can provide the service of quantifying the measure at a cost; this should also be included as a potential limitation. The measure developer does provide specifications for other entities to implement the measure, but the burden of implementation may be significant.* **Response:** This is inaccurate. As stated in Feasibility, 3.07, there are no fees for users submitting their eCQM data to CMS programs. The eCQM can be run and the measure score calculated by any EHR vendor or hospital and reporting entities can partner with any commercial partner capable of developing reporting software using the eCQM specifications. The measure steward's software to ingest this data and calculate the measure is freely available. Alara Imaging has created an edge device that can assemble data from different electronic sources (e.g. EHR, RIS [Radiology Information Systems], PACS [Picture Archiving and Communication Systems], and billing) to calculate the CT category, size-adjusted dose, and image noise that can then be consumed by the eCQM. If practices want to calculate these variables without using the Alara edge device, they may access a free online portal to calculate these variables and provide them to any entity implementing the measure. A prototype of this software was deployed at 8 testing sites (7 hospital systems and 1 ambulatory imaging network). Sites were asked to install the software, configure local connections to PACS, EHR, and other electronic systems as needed, and oversee the transfer of data to it from these sources. Burden was found to be no more or less onerous than the effort required by participation in other eCQMs or national registries, such as the ACR Dose Index Registry (Feasibility, 3.06). **Comment:** *For CT category … the developer used NLP for obtaining data such as reason for study or protocol name used in the calculation of this variable. The submission does not provide information on the NLP results' reliability and validity… or how sites would get access to use this custom NLP tool.* **Response:** This is incorrect; the measure does not use NLP. As described in the submission and above, it uses an algorithm that combines CPT® and ICD-10-CM codes to categorize CT exams. NLP was deployed as a method to validate the CT categorization determined by the algorithm at testing sites, where we did not have access to medical records. The sensitivity and specificity of this NLP referent standard are given above. **Comment:** *Multiple unstructured variables are required to construct the data elements for the numerator, denominator, and exclusions…* **Response:** This is incorrect; the measure does not use unstructured data. All data elements used to calculate the measure come from structured variables listed in the feasibility scorecards and in Specifications, Table sp-2: CPT® and ICD-10-CM codes; dose length product stored in the DICOM data; and patient diameter and image noise calculated on imaging data. The measure would not have met the requirements of an eCQM had it relied on unstructured data. **Comment***: Protocol selection appropriate for a clinical indication is an important component of radiation dose management along with radiation dose optimization. Each component needs to be addressed as a separate quality action. The specific aspect(s) of performance to be improved is not intuitive due to the multiple components to the measures… It is true that the most accurate way to address appropriate and safe use of multi-phase studies is to measure both the clinical indication of an exam and the radiation dose output… However, these measures conflate the appropriateness of protocol for the clinical indication and radiation dose optimization… a facility may not be able to determine if its performance could be improved by adjusting protocols or by focusing on appropriateness of the ordered exam.* **Response:** We agree that selecting an appropriate CT protocol and limiting radiation dose given the selected protocol are separate quality actions, but the commenter misses the crucial point that intermediate outcome measures typically reflect multiple opportunities for improvement. By analogy, we recognize systolic blood pressure control and glycosylated hemoglobin control as intermediate outcome measures for patients with hypertension and diabetes, respectively, even though there are many potential ways to manage these conditions. The fact that these intermediate outcomes can be improved by diet, exercise, medications, or combined approaches does not invalidate glycosylated hemoglobin or blood pressure control as quality measures. Similarly the fact that our measure would be responsive to multiple, interrelated process steps is a key strength that will improve its value for reducing radiation

exposure at the population level. Further, reporting entities will be provided with feedback for each CT exam, including its assigned CT category, radiation dose, size-adjusted radiation dose, and image noise, allowing recipients to identify the causes of performance gaps. Reporting entities will be able to assess if they are systematically assigning patients to the wrong protocol, or if they are choosing protocol settings that are inappropriate with respect to radiation dose or image noise. The actionability of the feedback is noted in the other letters written in support of the measure. To further demonstrate the potential of this measure, we conducted a randomized controlled trial in 100 hospitals and outpatient radiology practices to study the impact of providing detailed audit feedback, similar to what will be provided as part of the feedback on this measure. We found that this intervention resulted in significant reductions in radiation dose and dose variation with no impact to image quality, described in Usability, 4b.01. (Smith-Bindman, 2020) **Reference:** Smith-Bindman R, Chu P, Wang Y, et al. Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. JAMA Intern Med. 2020 May 1;180(5):666-675.

Comment 23 by: Carly Stewart

We thank the American College of Radiology for their comments from 1/19/22 but wish to address several factual inaccuracies in the comments. (Response PART 2) **Comment:** *NQF #3633e, #3662e, and #3663e deviate from international standards, like diagnostic reference levels, and lack peer reviewed, broadly accepted consensus on global noise. For these measures, global noise is defined solely by the measure developer. Endorsing this method may encourage facilities to accept a narrow view of image quality.* **Response:** The ACR correctly notes that we have defined an approach to measuring noise. We did so only after testing and comparing multiple approaches described in peer-reviewed literature and validating noise measurements against radiologists' assessment of image adequacy for diagnosis. Image quality is a much less common problem than excessive use of radiation in CT imaging. While there may be other reasons to study CT image quality, our interest was simply to ensure that CT image quality did not erode as an unintended consequence of lowering radiation doses. There is no reason to believe that endorsing this measure will encourage facilities to "accept a narrow view of image quality" because radiologists have a requirement for adequate images to perform their work. They have no desire or motivation to alter their standards of what constitutes an adequate image. Radiologists do not want to read inadequate images and routinely request that such images be repeated or complemented by other imaging modalities. **Comment:** *The ACR requests the developer further clarify the global noise table used in calculating the numerator... For example, Table sp-1 has the same global noise threshold for several CT categories, such as head low dose, head routine dose, and head high dose... If the image noise thresholds are the same, the size-adjusted radiation dose thresholds should be the same.* **Response:** We tested various published methods for measuring image noise and opted for a modified version of the method proposed by Malkus in 2017. The approach for setting the thresholds for image quality and radiation dose were based on the referent standard of radiologists' satisfaction with image quality. This did not always result in the relationship the ACR has suggested. For example, radiologists might want a minimum level of image quality for all head CT categories whereas the upper dose threshold might vary across the three head categories reflecting the different clinical indications comprising each group. Radiologists in our image quality study graded the majority of head exams as having acceptable image quality, even those at the lower dose range, meaning the minimum noise threshold is similar for all three categories. **Reference:** Malkus A, Szczykutowicz TP. A method to extract image noise level from patient images in CT. Med Phys. 2017 Jun;44(6):2173-2184. **Comment:** *Additionally, current CT scanners display dose values based on either a 16 cm or 32 cm phantom for a neck scan, which must be carefully accounted for in measure performance calculations.* **Response:** As the ACR correctly notes, CT scanners display dose values based on a 16 cm or 32 cm phantom. If comparisons are made across reporting entities it is important that they use the same phantom, as this impacts the scanner reported DLP. The manufacturers are highly consistent in their use of phantoms for different body regions. In a study of 106,837 pediatric

patients (a population where potential variation in phantom choice would most likely occur), 100% of CT exams in the neck are referenced to the 32 cm phantom, and it is thus unnecessary to account for phantom selection (Chu 2021). **Reference:** Chu PW, Yu S, Wang Y, et al. Reference phantom selection in pediatric computed tomography using data from a large, multicenter registry. Pediatr Radiol. 2021 Dec 6. **Comment:** *These eCQMs require multiple variables that may be captured in software systems external to electronic health records (EHRs), such as dictation systems housing radiology reports or DICOM standard-based systems, such as CT device software. Data element validity testing should demonstrate that the testing sites were able to integrate and validate the variables used to construct the data elements used by the eCQM in addition to the usual validation of the eCQM's electronic output against the medical record review. We are uncertain that this validation has been completed. Therefore, this submission does not demonstrate the measure can be reproduced in a reliable and valid manner by practices or facilities across multiple settings.* **Response:** This comment is entirely erroneous. No data are pulled from dictation systems or CT device software. The measure derives and uses codified and specified data from DICOM standard based systems, such as PACS, and EHR and billing claims. Our data element validity testing did demonstrate that 8 testing sites, reflecting 16 hospitals and 13 outpatient imaging facilities, were able to integrate, collect, and report the variables used to construct the data elements ingested by the eCQM. The letters of support from these testing sites independently confirm their ability to assemble the required data across diverse practice types and settings. **Comment:** *The ACR is concerned with the selection bias for the accountable entity-level… validity. Assessing measure score face validity through the TEP that created these measures lessens the extent of credibility for these results. Although the TEP is knowledgeable and represents a variety of stakeholders, there is a vested interest in ensuring these measures are available for use.* **Response:** All of the TEP members and their affiliations are identified in our submission materials (2b.02). Conflicts of interest were reviewed at each meeting and included with meeting minutes in a publicly available website (https://ctqualitymeasure.ucsf.edu/). The TEP members all voluntarily provided public service by joining the TEP. None of our TEP members has any "vested interest" in the outcome of the NQF endorsement process other than the ACR which served as a single member of the TEP. None of our TEP members is employed by the developer organization (UCSF) or its funder (CMS), nor has any financial interest in the company that is offering technical support for software implementation (Alara Imaging). To be clear, these measures were developed by an academic radiology, quality improvement, and analytics team based at UCSF and supported by CMS, NIH and PCORI. The TEP was organized and tasked to provide broad multidisciplinary input to this team. Their endorsement of the validity of the measures is highly credible, as it reflects the fact that their advice was heeded at every stage of the development and testing process. Our TEP process followed the CMS Blueprint as well as NQF guidance, and 16/17 members agreed that that implementation of the measure will lead to a reduction in average CT radiation dose while maintaining adequate CT image quality if adopted (reported in 2b.03).

Comment 24 by: Carly Stewart

We thank the American Association of Physicists in Medicine for their perspectives but wish to address several factual inaccuracies: **Comment 1:** *Unscientific characterization of CT scan risk: The proposal is based on estimation approaches that are not reflective of the consensus of the scientific community* **Response:** The measure is not focused on radiation risk and does not calculate nor report radiation risk. The measure evaluates dose length product (DLP), and specifically whether size-adjusted DLP exceeds thresholds specific to CT category. DLP is the radiation dose measure most directly under the control of providers, determined by selected parameters. Further, DLP is universally reported by CT manufacturers. It is thus the ideal measurement to use when assessing the quality of CT exams. The TEP, which included the ACR, radiologists and a medical physicist, unanimously supported the radiation dose measure used and agreed is a relevant metric of quality for CT imaging (2b.03).There is also considerable precedent for using DLP to evaluate radiation dose in CT. The American College of Radiology has used DLP to set

benchmarks [Kanal 2017] and to measure dose in its own NQF-endorsed quality measure #3621. **Reference:** Kanal KM et al. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology. 2017;284(1):120-133. **Comment 2:** *Inactionability of the measures to enable targeted change to improve practice: It is not evident how the proposed measures can be practically used* **Response:** Reporting entities will be provided with specific feedback for each CT scan on its assigned CT category, radiation dose, size-adjusted radiation dose, and image noise, allowing recipients to identify causes of performance gaps and make targeted changes to improve quality. Comments in support of the measure from the testing sites describe how useful the information provided was to allow them to understand and improve their practice. As described in our submission, we found in a randomized controlled trial in 100 imaging facilities that providing detailed audit feedback on radiation doses, similar to what will be provided as part of the feedback on this measure, resulted in significant reductions in radiation dose with no impact on satisfaction with image quality (see Usability, 4b.01). (Smith-Bindman, 2020) **Reference:** Smith-Bindman R et al. Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. JAMA Intern Med. 2020 May 1;180(5):666-675. **Comment 3:** *Inadequate addressing of the complexity of CT categorization* **Response:** A detailed response to this question was provided in our response to the ACR. In short, the approach of assigning CT examinations to the different CT categories as specified in the measure was first developed using records from over 4.5 million CT exams in the UCSF International CT Dose Registry (Smith-Bindman, 2021). We then developed an approach for determining the clinical indication for imaging using an algorithm that combines procedure (CPT®) and diagnosis codes (ICD-10-CM) provided in Specifications, sp-11. This algorithm was developed using detailed review of over 10,000 patient records from UCSF Health. We validated the CT category assignment using the algorithm against "gold standard" chart review, as described in Validity sections 2b.02 and 2b.03. When the algorithm was deployed at our testing sites the correct classification rate of the assignment of CT exams to CT category was on average 92% across clinician groups and hospitals and 95% in individual clinicians. **Comment 4:** *Inadequate assessment of noise: Noise in a CT image can be influenced by a variety of factors* **Comment 5:** *Inadequate assessment of image quality: Image quality is affected by a myriad of factors* **Response:** The primary focus of our measure is to assess radiation dose adjusted for body size. The image quality component was included to protect against the unlikely possibility of substantial degradation of image quality as an unintended consequence of dose reduction. Our measure of image quality reflects what radiologists in practice regard as adequate. Others might have an interest in other ratings of image quality for other purposes, but that was not our intent. We tested and found that noise as a measure of image quality was associated with radiologists' satisfaction with the adequacy of CT images. These results were included in the submission (2b.03). **Comment 6:** *Flawed assumption on dose reduction vs dose optimization: The application focuses primarily on radiation dose reduction as opposed to right-sizing the dose.* **Response:** This is incorrect. We created the CT categories based on radiation dose and image quality requirements specific to clinical indications for imaging. Using radiologists' satisfaction with image quality, we established an image quality floor for each category, below which an exam is considered to have inadequate quality, and a radiation dose ceiling, beyond which doses are considered unnecessarily high. The purpose is to allow detailed assessment of each CT exam to ensure the dose is optimal based on the clinical indication for imaging. In current practice, there are no such benchmarks created by clinical indication, making it impossible for providers to know the right dose range for each patient. In our testing data, far more CT exams exceeded the radiation dose ceiling (average = 30%) than failed to meet the image quality requirement (average < 1%) (see section 1b.02). The measure encourages entities to reduce the proportion of exams that may "be overdosed for their exact need and condition" while preserving the minimum image quality. **Comment 7:** *Inadequate accuracy in patient size estimation: Assessing a patient size is not a trivial task, stemming from significant variability in the differences in the habitus of different patients, coupled with the existential challenge that there is no single metric* **Response:** We agree that measuring patient size is important. Our approach for using mid-scan diameter is highly correlated with patient weight: in separate, NIH-funded research on CT use in children up to age 21 (Kwan 2022), we

have shown that diameter in 4,239 children as measured on mid-scan axial images is highly predictive of patient weight, correlation = 0.904, Figure 1.

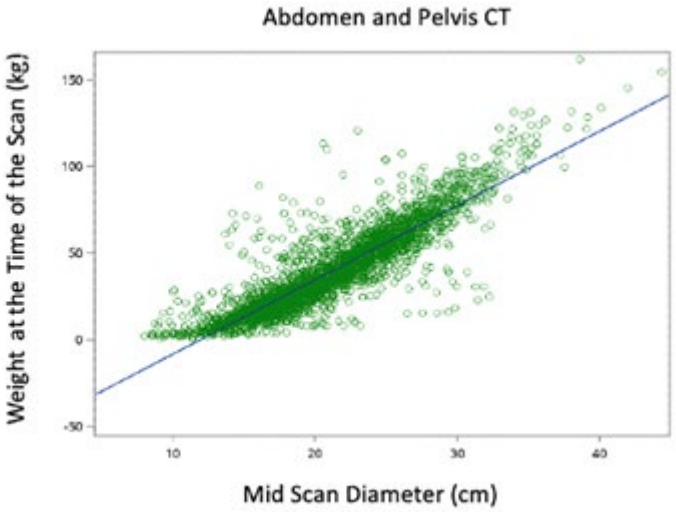


Figure 1. Mid scan patient diameter versus patient weight at the time of the CT, Kwan 2022

For this measure, patient size was measured using CT image pixel data, either on the mid-scan axial image or the coronal scout image when the mid-scan axial image was not available. This approach has been validated using data from UCSF Health, the UCSF Registry, as well as the data assembled for measure testing. While there may be different ways to measure patient size, and different reasons for measuring patient size, it is a crucial piece of information that must be practically defined to ensure that the types of patients (case mix) at different practices do not bias the number of scans graded as out-of-range. We are adjusting for patient size primarily to ensure that entities that see larger patients are not penalized for doing so. Figure 2a shows the relationship between radiation dose (in DLP) and patient diameter using data from the UCSF Registry for abdomen CT. We chose abdomen CT as this is the category most influenced by patient size, and where patient mix could impact an entity's out-of-range rate. The raw correlation between patient diameter and unadjusted DLP is 0.50, and the marginal R-squared of the log-linear model used for adjustment is 0.15. After size-adjustment, the relationship is nearly removed: Figure 2b shows size-adjusted DLP by patient diameter using the same data; the raw correlation is far lower (-0.09), and the modeled marginal R-squared post-adjustment is 0. This demonstrates adequacy of the approach for adjustment of patient size.

Figure 2a: Unadjusted Dose Length Product vs Patient Diameter

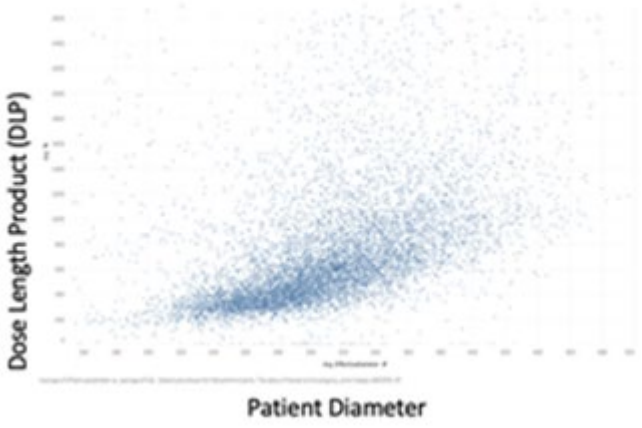


Figure 2b: Size-Adjusted Dose Length Product vs Patient Diameter

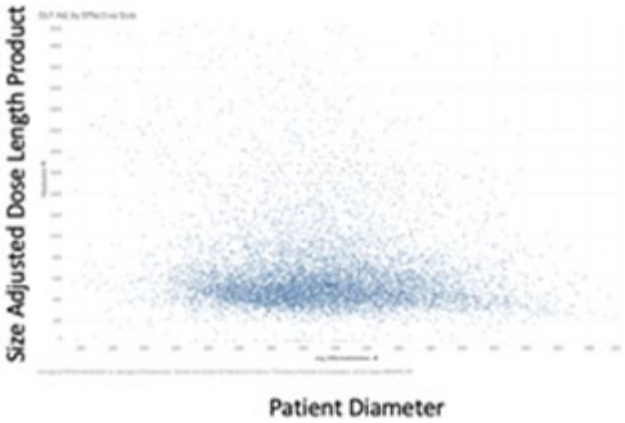


Table 1a) Proportion of exams out-of-range on routine dose abdomen exams based on **unadjusted** DLP across the 16 hospitals, shown by decile in patient size. The proportion of out-of-range exams increased with patient size, seen in the table as an increase in dark shading in the lower rows of the table. Among patients in the highest size decile – those in last row– the out-of-range proportions across the 16 hospitals ranged from 93-100%.

Size Decile	Hospitals															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	0.27	0.22	0.11	0.00	0.27	0.29	0.30	0.14	0.34	0.20	0.24	0.40	0.06	0.17	0.11	0.17
2	0.30	0.00	0.00	0.00	0.08	0.11	0.13	0.29	0.24	0.30	0.04	0.19	0.00	0.07	0.16	0.09
3	0.15	0.06	0.15	0.00	0.17	0.18	0.22	0.75	0.21	0.30	0.17	0.18	0.08	0.18	0.17	0.12
4	0.07	0.17	0.29	0.15	0.25	0.32	0.09	0.82	0.43	0.25	0.07	0.42	0.10	0.17	0.19	0.21
5	0.45	0.15	0.13	0.14	0.28	0.43	0.00	0.93	0.40	0.42	0.19	0.38	0.00	0.14	0.48	0.55
6	0.42	0.20	0.25	0.36	0.55	0.61	0.27	0.96	0.55	0.19	0.31	0.51	0.08	0.46	0.47	0.78
7	0.79	0.47	0.45	0.58	0.70	0.75	0.17	1.00	0.69	0.37	0.26	0.73	0.06	0.71	0.66	0.90
8	0.81	0.37	0.75	0.69	0.67	0.86	0.24	1.00	0.89	0.35	0.58	0.77	0.22	0.80	0.91	0.95
9	0.96	0.85	1.00	0.75	0.88	0.93	0.26	0.93	0.94	0.64	0.78	0.93	0.63	0.90	1.00	1.00
10	1.00	0.96	0.98	0.93	0.97	0.97	0.93	0.94	1.00	0.95	0.98	0.96	0.85	0.95	0.94	1.00

Table 1b) Proportion of exams out-of-range on routine dose abdomen exams, based on **size-adjusted** DLP across the 16 hospitals shown by decile in patient size. High proportion of out-of-range exams are no longer concentrated among the larger patients. Among patients in the highest size decile, out-of-range rates ranged from 11-53%.

Size Decile	Hospitals															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	0.55	0.61	0.22	0.20	0.42	0.48	0.48	0.61	0.49	0.70	0.37	0.62	0.10	0.37	0.22	0.51
2	0.50	0.25	0.00	0.18	0.19	0.31	0.22	0.71	0.36	0.61	0.15	0.38	0.00	0.08	0.33	0.21
3	0.15	0.18	0.15	0.11	0.37	0.39	0.33	0.96	0.30	0.50	0.26	0.36	0.10	0.23	0.43	0.22
4	0.27	0.17	0.29	0.15	0.35	0.54	0.09	0.97	0.43	0.38	0.11	0.53	0.10	0.18	0.31	0.30
5	0.45	0.15	0.13	0.14	0.26	0.46	0.00	0.93	0.40	0.42	0.19	0.38	0.00	0.19	0.52	0.59
6	0.33	0.10	0.25	0.36	0.39	0.45	0.27	0.96	0.47	0.13	0.31	0.40	0.05	0.34	0.45	0.72
7	0.29	0.18	0.20	0.46	0.50	0.42	0.17	0.90	0.57	0.16	0.17	0.60	0.04	0.50	0.36	0.70
8	0.43	0.05	0.19	0.25	0.54	0.39	0.12	0.70	0.58	0.09	0.35	0.62	0.09	0.59	0.53	0.83
9	0.48	0.26	0.48	0.30	0.45	0.27	0.11	0.19	0.72	0.07	0.18	0.56	0.06	0.62	0.60	0.66
10	0.35	0.27	0.40	0.39	0.38	0.11	0.27	0.11	0.61	0.37	0.29	0.44	0.11	0.27	0.53	0.36

assessing radiation dose. He noted the observed, significant differences *between* CT categories versus *within* categories was "an encouraging result for anyone trying to optimize CT studies based on clinical indications." He noted the study was "a good start" on the road to optimizing CT protocols based on image quality. He opined that the CT classification would be more useable and easier to implement if based on current procedural terminology codes. This is precisely what we have done in this measure.

Comment 25 by: Rebecca Smith-Bindman

We thank Dr. Ehsan Samei for sharing his perspectives on the measure and for collaborating with us early in the measure development process. We wish to address a few inaccuracies and misunderstandings in Dr. Samei's comments. The majority of Dr. Samei's comments focus on image quality and his concern that the measure does not offer a comprehensive assessment of image quality. Our measure is not intended to be a comprehensive assessment of image quality. Criticizing the proposed measure for what it is not is beyond the scope of what should be considered in assessing the usefulness of what has been submitted. The primary focus of our measure is to assess radiation dose adjusted for body size, and the image quality component provides a means to protect against the unlikely possibility of substantial degradation of image quality as an unintended consequence of dose reduction. The approach for creating thresholds is described in Validity, 2b.02. **Comment:** ***Inaccurate assessment of patient size:*** *The measure of size proposed is calibrated to earlier work and publication from our group at Duke University for academic purposes. That early method they have embraced has had major errors.* **Response**: We are adjusting for patient size primarily to ensure that entities that see larger patients are not penalized for doing so. Although we explored code that Dr. Samei provided early in our initial efforts to measure patient body habitus we found that it was inadequate, particularly for some CT categories, and we have not relied upon it. We developed our own approach for measuring size using CT image pixel data from the mid-scan axial image or the coronal scout image when the mid-scan axial image was not available. Our approach of measuring size was shown to be highly correlated with patient weight (correlation = 0.904) in a large study in children described in our response to the AAPM. For this measure, the measurement of size was validated using data from UCSF Health, the UCSF Registry, as well as the data assembled for measure testing. The adequacy of the approach we have adopted for size adjustment is described in the initial application and the response to the comments by the AAPM. **Comment:** ***Inaccurate assessment of noise:*** *The measure of noise proposed references earlier work and publication from our group at Duke University. That early method exhibited errors, corrected in subsequent versions that have not been shared…* **Response:** Dr. Samei's approach and code for measuring image quality were explored in the process of developing our measure but were not included in the final measure specifications. Any errors in his approach are not relevant to the measure. **Comment:** ***Inaccurate assessment of radiation risk:*** *The measure of size-adjusted radiation risk, adjusting the CT scanner outputs with 'patient size' to perform risk estimation is not a standard method nor endorsed by any scientific or professional body… Patient risk can only be assessed with the knowledge of organ doses that is not even mentioned in the application let alone pursued. The proposed method CANNOT be used as surrogate for future cancer risk.* **Response:** The measure does not calculate or report radiation risk. The measure evaluates radiation *dose* (measured in dose length product, DLP), and whether size-adjusted DLP exceeds thresholds specific to CT category. The empirical validity of the risk-adjustment approach based on patient size is described in the application (section 2b.26 – 2b.31) and in our response to the comments by the AAPM. The approach of evaluating CT safety by comparing machine output (whether DLP or CTDIvol) against benchmarks is widely accepted in the radiology field. (Kanal 2017) In contrast, organ dose has no standard definition, is not reported by the manufacturers, is not available in a structured format, would be time intensive to calculate in clinical settings and most importantly has limited actionability as this is not under the direct control of technologists or physicians. Organ doses may be useful for counseling patients or in the context of epidemiological studies, but we do not believe it has a role as a metric for CT quality measurement. **Reference:** Kanal KM, Butler PF, Sengupta D, et al. U.S. Diagnostic Reference Levels and

Achievable Doses for 10 Adult CT Examinations. Radiology. 2017;284(1):120-1 ***Comment: Subjectivity:*** *The measures are anchored to subjective perception by radiologists as how they "like" the images. There is in fact no evidence provided that the measures can lead to an improvement in diagnostic accuracy. In fact, it might lead to a degradation.* **Response:** The measure is not intended to improve diagnostic accuracy. The purpose of the measure is to establish a radiation dose ceiling to avoid excessive radiation exposure, and an image quality floor to safeguard against unintended deterioration of image quality. There is precedent for using radiologist satisfaction with image quality to set or validate noise targets, including work by Dr. Samei. (Cheng 2019, IAEA 2009) This also reflects clinical practice: radiologists subjectively assess images and regularly ask for scans to be repeated when they are not adequate. As described in the response to ACR comments, Radiologists do not want to read inadequate images and routinely request that such images be repeated or complemented by other imaging modalities. Radiologist's subjective assessment provides a practical way to ensure the image quality is not degraded through efforts to optimize the radiation doses. **References:** Cheng Y, Abadi E, Smith TB, Ria F, Meyer M, Marin D, Samei E. Validation of algorithmic CT image quality metrics with preferences of radiologists. Med Phys. 2019 Nov;46(11):4837-4846. doi: 10.1002/mp.13795. Epub 2019 Sep 20. International Atomic Energy Agency (IAEA), Dose Reduction in CT while Maintaining Diagnostic Confidence: A Feasibility/Demonstration Study, TECDOC Series, 2009.

Scientific Acceptability: Preliminary Analysis Form

Measure Number: *3633e*
Measure Title: *Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)*

Measure is:

☒ **New** ☐ **Previously endorsed** ***(****NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)*

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☒ **No**

   Submission document: Items sp.01-sp.30

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**
   For example: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

   Reviewer 1: none
   Reviewer 3: This is a well specified measure. My main concern is with using missing data as technical exclusion (for example, missing radiation dose). This may not be an issue if missing rate is rare or low, but if it is high, it may lead to bias.
   Reviewer 4: The determination of numerator ("failed value based on table of specifications by body part and size-adjusted radiation dose and global noise") is very complex. Hopefully, the developer evaluated the reliability of the "failed" determination, especially if there are higher incidents of "failed" for some body parts. In a later section the developer reports that five body regions (head, chest, cardiac, abdomen, and combined head & neck) have "low, routine, and high" radiation dose categories that were not included in the data table included in the materials. This introduces additional complications to

determining failure. Time period for data collection seems inconsistent "One calendar year, although shorter periods can be used for high-volume entities." Operational definition of "high-volume" was not presented. Denominator exclusions (typically multiple areas scanned) may be problematic if these types of scans are the most common an the source of problems with too low or high dosages.
Reviewer 5: no concerns
Reviewer 6: No concerns
Reviewer 7: The specification is heavily dependent on proprietary software developed by UCSF and Alara Imaging, Inc. to access and process primary data elements from the electronic systems to calculate the three variables required by the measure – CT category, size-adjusted radiation dose, and global noise. This software in turn requires access to raw imaging data. Although the developer states that this process has been tested in multiple settings, that is not evidence that a garden variety clinician could reliability replicate.
Reviewer 8: Would like to know more about the software and integrated edge device that seems to be required and/or the approach to "export from HER and radiology electronic clinical data systems via "custom reports"--what the cost or no cost alternatives might be to use this proprietary measure.
Reviewer 11: Clear definitions and description of the eCQM.
Reviewer 12: no concerns

RELIABILITY: TESTING

TYPE OF MEASURE:

☒ Process ☐ Process: Appropriate Use ☐ Structure ☐ Efficiency ☐ Cost/Resource Use

☒ Outcome ☐ Outcome: PRO-PM ☐ Outcome: Intermediate Clinical Outcome ☐ Composite

DATA SOURCE:

☐ Claims ☒ eCQM (HQMF) implemented in EHRs ☒ Abstracted from Electronic Health Records
☐ Abstracted from Paper Medical Records ☐ Instrument-Based Data ☒ Registry
☐ Enrollment Data ☒ Other (please specify)
Reviewer 7: Raw images

LEVEL OF ANALYSIS:

☐ Group/Practice ☒ Individual Clinician ☐ Hospital/facility/agency ☐ Health Plan
☐ Population: Regional, State, Community, County or City ☐ Accountable Care Organization
☐ Integrated Delivery System ☐ Other (please specify)
Submission document: Questions 2a.01-09

3. **Reliability testing level**
   For example: for some types of measures, if patient/encounter level validity is demonstrated, additional reliability testing is not required. Please review table above.

   ☒ Accountable-Entity Level ☒ Patient/Encounter Level ☐ Neither
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure**

NOTE: "level of analysis" reflects which entity is being assessed or held accountable by the measure.
For example: If a measure is specified for a clinician level of analysis, but facility-level testing is provided, then testing does NOT match level of analysis. Or, if two levels of analysis are specified (e.g., clinician and facility) but testing is conducted for only one, then testing does NOT match level of analysis. Or, if claims data are selected as a data source, but testing data doesn't include claims data, then testing does NOT match data source.

Also, check "NO" if only descriptive statistics are provided or submitter only describes process for data management/cleaning/computer programming.

☒ **Yes** ☐ **No**

5. If accountable-entity level and/or patient/encounter level reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical *VALIDITY* testing** of **patient-level data** conducted?
   According to current guidance patient/encounter level validity testing can be used for patient/encounter level reliability testing. Answer ONLY if you responded "Neither" on question #3 and/or "No" to question #4. Note that for some types of measures, additional reliability testing is not required IF patient/encounter level validity is demonstrated.

   ☐ **Yes** ☒ **No**

6. **Assess the method(s) used for reliability testing**

   Submission document: Question 2a.10

   For example: Is the method(s) appropriate? If not, please explain (and offer potential alternatives if possible). Does the testing conform to NQF criteria and guidance? Was testing was conducted with the data source and level of analysis indicated for this measure? Address each level of testing provided, and each analysis under each method.

   Reviewer 1: Methods were appropriate
   Reviewer 3: Split-half method was used to test measure score reliability and seemed appropriate.
   Reviewer 4: Split-sample reliability testing: ICC 0.99
   Reviewr 6: Data element - CT category, adjusted dose, global noise Measure score – ICC
   Reviewer 8: Measure score reliability was estimated at the clinician level using the intraclass correlation coefficient (ICC), using randomly split samples for each accountable entity with 1,000 repetitions, applying a one-way random effects model, assuming that both entity effects and residual effects are random, independent, and normally distributed with mean 0. The Spearman-Brown prophecy formula was applied, in the usual manner, to adjust reliability from one-month test samples to the anticipated 12-month sample (i.e., (12*r)/(1 + (11*r)). These ICC(1) estimates (bounded between 0 and 1) were then logit-transformed and used to model the linear relationship between entity volume and logit reliability. By ranking predicted reliabilities across the complete range of potential volumes, the volume threshold that would correspond to ICC(1)=0.9 for an accountable entity was estimated.
   Reviewer 9: Intraclass correlations coefficient (ICC) was used. Description of the actual calculation methodology was vague ("we estimated the measure score reliability…"). The logit-transformed process was cryptic.
   Reviewer 10: ICC
   Reviewer 11: Appropriate methods used for testing.
   Reviewer 12: Testing appropriate, similar to same measure tested at hospital level

7. **Assess the results of reliability testing**

   Submission document: Question 2a.11

   For example: Is the test sample adequate to generalize for widespread implementation? Is there high or moderate confidence that the measure results and/or the data used in the measure are reliable? Address each level of testing provided, and each analysis under each method.

   Reviewer 1: Excellent Split sample and SNR reliabilities.
   Reviewer 3: Testing results indicated high reliability for this measure.
   Reviewer 4: Reliability is acceptable
   Reviewer 5: predicted reliability for 12 months exceeded 0.90 for 89% of participating clinicians. An ICC estimate greater than 0.90 may be interpreted as excellent reliability.
   Reviewer 6: Mean split half ICC = 0.99
   Reviewer 8: The estimated mean split-half ICC using 47,635 CT exams collected from 606 individual clinicians was 0.99 (after Spearman-Brown adjustment to a 12-month data collection period). The number of exams per clinician in the one month of data used for testing ranged from 1 (which were excluded) to

604 (mean=77); predicted reliability for 12 months exceeded 0.90 for 89% of participating clinicians; 8% of individual clinicians in field-testing would not meet the minimum denominator to achieve ICC > 0.90.
Reviewer 9: If the calculation methodology is correct, then the reported reliability values are impressive (>0.9).
Reviewer 10: 0.99.
Reviewer 11: Adequate sample size showing high confidence that the data used are reliable.
Reviewer 12: yes

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? **NOTE:** If multiple methods used, at least one must be appropriate.
   Submission document: Question 2a.10-12
   For example: Appropriate signal-to-noise analysis; random split-half correlation; other accepted method with description of how it assesses reliability of the performance score.

   ☒ **Yes**
   ☐ **No**
   ☐ **Not applicable**

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?
   Submission document: Question 2a.10-12

For example: inter-abstractor agreement (ICC, Kappa); other accepted method with description of how it assesses reliability of the data elements

Answer NO if: only assessed percent agreement; did not assess separately for all critical data elements (or at minimum, for numerator, denominator, exclusions)

☒ **Yes**
☐ **No**
☒ **Not applicable** (patient/encounter level testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and **all** testing results):

    ☒ **High** (NOTE: Can be HIGH **only if** accountable-entity level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has **not** been conducted)

    ☐ **Low** (NOTE: Should rate **LOW** if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate **INSUFFICIENT** if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of *OVERALL RATING OF RELIABILITY* and any concerns you may have with the approach to demonstrating reliability.**
    Reviewer 1: good methods and results.
    Reviewer 3: High ICC as expected for a measure with binary outcome and large volume.
    Reviewer 4: Reliability is acceptable
    Reviewer 5: Used appropriate method for testing. predicted reliability for 12 months exceeded 0.90 for 89% of participating clinicians. An ICC estimate greater than 0.90 may be interpreted as excellent reliability.
    Reviewer 6: No concerns
    Reviewer 9: Given the lack of specificity in the description, the reported results may or may not be correct. The rating is a "benefit of the doubt" value.
    Reviewer 10: ICC, reasonable score
    Reviewer 11: No concerns.
    Reviewer 12: No concerns

12. **Validity testing level (check all that apply):**
    ☒ **Accountable-Entity Level** ☒ **Patient or Encounter-Level** ☐ **Both**
13. **Was the method described and appropriate for assessing the accuracy of ALL *critical data elements*? NOTE** that data element validation from the literature is acceptable.

    Submission document*:* Questions 2b.01-02.

For example: Data validity/accuracy as compared to authoritative source- sensitivity, specificity, PPV, NPV; other accepted method with description of how it assesses validity of the data elements.

Answer NO if: only assessed percent agreement; did not assess separately for all critical data elements (or at minimum, for numerator, denominator, exclusions)

☒ **Yes**

☒ **No**

☐ **Not applicable** (patient/encounter level testing was not performed)

14. **Method of establishing validity at the *accountable-entity level*:**
    NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.
    Submission document: Questions 2b.01-02
    ☒ **Face validity**
    ☒ **Empirical validity testing at the accountable-entity level**
    ☐ **N/A (accountable-entity level testing not conducted)**
15. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**
    Submission document: Question 2b.02
    For example: Correlation of the accountable-entity level on this measure and other performance measures; differences in performance scores between groups known to differ on quality; other accepted method with description of how it assesses validity of the performance score

    ☒ **Yes**

    ☐ **No**
    ☒ **Not applicable** (accountable-entity level testing was not performed)
16. **Assess the method(s) for establishing validity**

    Submission document: Question 2b.02

    For example:

- *If face validity the only testing conducted: Was it accomplished through a systematic and transparent process, by identified experts, explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality, and the degree of consensus and any areas of disagreement provided/discussed?*
- *If a maintenance measure, but no empirical testing conducted, was justification provided?*
- *If construct validation conducted, was the hypothesized relationship (including strength and direction) described and does it seem reasonable?*

Reviewer 3: The developer conducted face validity testing at measure level and compared eCQM calculations with reviews based on sampled CT exams for data element validity testing.
Reviewer 4: see comment below
Reviewer 5: Data-element: measure developer took reasonable steps to validate individual data elements, either by comparing to a gold standard or relying on studies Measure-score: relied on systematic evaluation of face validity
Reviewer 6: no concerns
Reviewer 8: CT category: The measure uses an algorithm to assign each CT exam to one of 18 CT categories based on the diagnosis associated with the exam order (codified in ICD-10-CM codes) and

procedure performed (codified in CPT® codes). Developers used criterion validity to compare agreement between the CT category assigned using this method versus a gold standard method based on expert review of the complete medical record.
Patient size: Methods for measuring patient diameter on CT images have been previously validated including measuring patient size on axial and coronal images. Developer relied on published work and tested how often this method generated clinically plausible and non-missing values for size in testing data.
Radiation Dose: The measure uses a standardized data element, generated by virtually (>99%) all CT machines, that is well validated and used broadly to reflect the radiation dose delivered to the patient. The proposed measure adjusted DLP for patient size to ensure that differences in patient mix would not result in differences in measure scores across reporting entities. Developers relied on this published work and tested how often this method generated clinically plausible and non-missing values for radiation dose in testing data.
Size-Adjusted Radiation Dose: When out-of-range rates are unadjusted for patient size, observed failure rates are strongly associated with size, with almost all failures occurring in larger patients. When failure rates are adjusted for size, there is no association. Using field testing data, developers assessed whether we could calculate size-adjusted radiation dose within a plausible range and quantified missing data.
Global noise: Adapted previously validated approaches. Developer assessed whether they could calculate global noise within a plausible range and quantified missing data using field-testing data.
They also calculated the correlation between global noise and physician dissatisfaction with image quality using data from the Image Quality Study and explored the rate of physician dissatisfaction in CT exams that exceeded global noise thresholds.
Thresholds for "out-of-range" values to define numerator: Radiologists' satisfaction with CT images was used as a basis for establishing the maximum radiation dose and minimum image quality thresholds for each CT category.
Empirical validity testing: validated the eCQM output (encounter-level validity) against medical record review using field testing data collected from electronic clinical data systems from 8 health systems/vertically integrated organizations.
Accountable entity-level (measure score) validity was tested using systematic assessment of face validity of measure score as an indicator of quality through a 6-question poll to the Technical Expert Panel (TEP) assembled for the creation of this measure. The TEP represents a diverse group of clinicians (N=10), patient advocates (N=2), and leaders of medical specialty societies, payers, and healthcare safety and accrediting organizations. TEP members were identified by reaching out to key stakeholder organizations and advocates and identifying researchers who had contributed to the relevant literature.
Reviewer 9: Face validity method produced a very high level of agreement that the measure and its components were valid.
Reviewer 10: TEP, compared medical abstraction
Reviewer 11: Used face validity for determining the validity via a systematic and transparent process.
Reviewer 12: Yes, similar to hospital based version

17. **Assess the results(s) for establishing validity**

Submission document: Questions 2b.03-04

For example: Is the test sample adequate to generalize for widespread implementation? Do the results demonstrate sufficient validity so that conclusions about quality can be made? Do you agree that the score from this measure as specified is an indicator of quality?

Reviewer 3: Data element testing indicated excellent results, particularly, 100% agreement in out-of-range identification between eCQM calculation and review based on 8,000 CT exams. The TEP survey results indicated strong support for the face validity of this measure.
Reviewer 4: Established face validity using TEP – very high level of agreement with questions on face validity. Data element validity – accuracy of measure algorithm to assign CT category had 95% accuracy.

Should have used Kappa analysis or sensitivity/specificity instead. The eCQM computed identical results for a sample of 8,000 CT exams, compared to medical record review.
Reviewer 5: Data-element: correct classification rate of the assignment of CT exams to CT category in field-testing was 95% on average. Measure-score: 100% of members agreed that the measure is a valid measure of quality
Reviewer 6: CT category - sensitivity = 0.86, specificity = 0.96 Tested on individual clinicians - correct classification rate = 95% average Size adjusted radiation dose - in plausible range for 99% of exams Global noise - correlation between noise and physician dissatisfaction = 0.37 Gold standard comparison - no discrepancies with chart review Face validity acceptable
Reviewer 8: CT category: Results, weighted by the distribution of CT categories in the UCSF International CT Dose Registry, were: sensitivity = 0.86 and specificity = 0.96 (n=978 CT exams). When tested across the 606 individual clinicians, the correct classification rate of the assignment of CT exams to CT category in field-testing was 95% on average. About 90% of tested individual clinicians had a correct classification rate of 80% or above. Most of the individual clinicians with correct classification rates below 80% had very low sample sizes from the 1 month testing period (i.e., 5.1% read only 1 CT scan).
Size-Adjusted Radiation Dose: In field testing data, size-adjusted radiation dose could be calculated and was within plausible range for 99% of CT exams and was missing for 0.4% of exams.
Global Noise: Global noise could be calculated and was within a plausible range for 100% of CT exams in field-testing. Global noise was missing for 0.01% of examinations. The correlation between noise and physician dissatisfaction with image quality is 0.37 overall based on the image quality study (n=727 CT exams).
Based on the field-testing data, there were few exams which exceeded the global noise thresholds. There were 4 CT categories with exams in which global noise exceeded the allowable threshold. For other CT categories, exams were not observed above the threshold.
Empirical Validity Testing: The results of the medical record review were compared with the results of the eCQM computation by selecting a sample of exams (N=8,000) representative of exams generated by the 606 individual clinicians across the 8 health systems/vertically integrated organizations. The out-of-range results (measure score) from the medical record review and the eCQM computation were identical with no discrepancies between the two approaches, indicating a correct and robust implementation of the measure logic.
Face validity results were very strong with items having 100% agreement.
In spite of above reported results, at the individual clinician level, only 52% of participating clinicians would meet the threshold to detect an “out-of-range” prevalence 5 percentage points above the mean (i.e., 38%). Only 54% of participating clinicians would meet the threshold to detect an “out-of-range” prevalence 5 percentage points below the mean (i.e., 28%). To resolve this problem the developers propose: (1) we measure users accept the ability to detect only larger deviations in performance; and (2) to set a minimum volume threshold for reporting purposes. For example, **a minimum annual volume of 145 CT scans (for reporting purposes) would provide 80% power to detect an “out-of-range” threshold either 10 percentage points above or below the mean (i.e., 23% or 43%)** while excluding only 22% of participating clinicians, based on our test data. THESE LIMITATIONS WOULD NEED TO BE CLEARLY STATED IN IMPLEMENTATION SPECS.
Reviewer 9: Face validity method produced a very high level of agreement that the measure and its components were valid.
Reviewer 10: Reasonable approaches
Reviewer 11: Sample size is adequate. Face validity demonstrates sufficient validity for this new measure. No PPV, NPV or other source. Used "gold standard" of abstractor going back to review the medical record including notes. No inter-rater reliability scores of abstractors shared.
Reviewer 12: Yes, similar to hospital based version

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

18. **Please describe any concerns you have with measure exclusions.**

Submission document: Questions 2b.15-18.

For example: Are there exclusions? If so, are the exclusions/exceptions of sufficient frequency and variation across providers to be needed (and outweigh the data collection burden)? Are any patients or patient groups inappropriately excluded from the measure? If patient preference (e.g., informed decision-making) is a basis for exclusion, does it impact performance and if yes, is the measure specified so that the information about patient preference and the effect on the measure is transparent? If you have concerns based on a clinical rationale, please note here as well as in question #29.

Reviewer 3: Same concern with missing data technical exclusion. It would be helpful if the developer could provide the missing data information across clinicians by key data elements as they did for 3662e measure.
Reviewer 5: none.
Reviewer 6: No concerns
Reviewer 10: None
Reviewer 11: No concerns.
Reviewer 12: No

19. **Risk Adjustment**

Submission Document: Questions 2b.19-32
Applies to all outcome, cost, and resource use measures. Please answer all checkbox questions (19a -19d), then elaborate on your answers in your response to 19e.

19a. **Risk-adjustment method**

☒ None ☒ Statistical model ☒ Stratification

☐ Other method assessing risk factors (please specify)

19b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☒ Yes ☐ No ☒ Not applicable

19c. **Social risk adjustment:**

19c.1 Are social risk factors included in risk model? ☒ Yes ☒ No ☒ Not applicable

19c.2 Conceptual rationale for social risk factors included? ☒ Yes ☒ No

19c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☒ Yes ☒ No

19d.**Risk adjustment summary:**

19d.1 All of the risk-adjustment variables present at the start of care? ☒ Yes ☒ No

19d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☒ Yes ☒ No

19d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☒ No

19d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☒ Yes ☒ No

19d.5.Appropriate risk-adjustment strategy included in the measure? ☒ Yes ☒ No

19e**. Assess the risk-adjustment approach**

For example: If measure is risk adjusted*:*

- *If the developer asserts there is no conceptual basis for adjusting this measure for social risk factors, do you agree with the rationale?*
- *How well do social risk factor variables that were available and analyzed align with the conceptual description provided?*
- *Are the candidate and final variables included in the risk adjustment model adequately described for the measure to be implemented?*
- *Are all of the risk adjustment variables present at the start of care (if not, do you agree with the rationale)?*
- *If social risk factors are not included in the risk-adjustment approach, do you agree with the developer's decision?*

- *Is an appropriate risk-adjustment strategy included in the measure (e.g., adequate model discrimination and calibration)?*
- *Are all statistical model specifications included, including a "clinical model only" if social risk factors are included in the final model?*

***If measure is NOT risk-adjusted**:*

- *Is a justification for not risk adjusting provided (conceptual and/or empirical)?*
- *Is there any evidence that contradicts the developer's rationale and analysis for not risk-adjusting?*

Reviewer 1: I'm not sure this measure is risk adjusted in the usual sense. The calculation of the outcome involves consideration of patients size.
Reviewer 3: I would defer to the TEP on size correction adjustment.
Reviewer 4: Risk adjustment model is not intended as a predictive model, but only to adjust for need to use higher radiation does to adequately image larger structures and patients. Unclear to me why the Rsquared value for the model should not be used to assess model performance. Nor is it clear to me why they did not assess model performance using entire data set which included all CT body regions and patient weights.
Reviewer 5: Only adjust for patient size. R-squared for most CT categories is close to zero.
Reviewer 6: No concerns
Reviewer 7: Although the approach is described as "risk adjustment" it is really the definition of the outcome variable that happens to vary based on a patient characteristics. The results would be un interpretable without it.
Reviewer 9: Meaningful differences description was confusing. Simplify the presentation and emphasize the # of clinicians who meet the minimum # of produced CTs, then the % who fail low, high by grouped # of CTs, etc.
Reviewer 11: Appropriate model.
Reviewer 12: Justification for not including social risk factors appropriate. Only risk adjusted by size of radiation area

20. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    Submission document: Questions 2b.05-07

    For cost/resource use measures, does this measure identify meaningful differences about cost and resource use between the measured entities?

    Reviewer 3: No concern. The measure seems to be able to differentiate clinicians from each other. The range of performance score is reasonably wide.
    Reviewer 5: Only adjust for patient size. R-squared for most CT categories is close to zero.
    Reviewer 6: The authors note that variation in measure scores for individual clinicians is larger than group or hospital level (SD=21% vs 9% vs 9%).
    Reviewer 7: Although there is variability in performance whether these results are clinically meaningful to the patient is not directly addressed
    Reviewer 9: Meaningful differences description was confusing. Simplify the presentation and emphasize the # of clinicians who meet the minimum # of produced CTs, then the % who fail low, high by grouped # of CTs, etc.
    Reviewer 10: None
    Reviewer 11: No concerns.
21. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
    Submission document: Questions 2b.11-14.

***Note**: This item is directed to measures that are risk-adjusted (with or without social risk factors) **OR** to measures **with more than one set of specifications/instructions**. It does **not apply** to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing*

performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

Note if not applicable. Note if applicable but not addressed. If multiple sets of specification (e.g., due to different data sources or methods of data collection): Do analyses indicate they produce comparable results?

Reviewer 3: No concern.
Reviewer 5: Not applicable.
Reviewer 10: None
Reviewer 11: No concerns.
Reviewer 12: no concerns

22. **Please describe any concerns you have regarding missing data.**

Submission document: Questions 2b.08-10.

For example: Are there any sources of missing data not considered? Is it clear how missing data are handled? Is missing data more of a problem for some providers or patients than others? Does the extent of missing data impact the validity of the measure?

Reviewer 3: Missing radiation dose related exclusion is a concern.
Reviewer 5: 92% had no missing data. Missing data seems to be within the control of the accountable entity.
Reviewer 6: None
Reviewer 7: There was significant missing data even among study hospital that had all the advantages of mentoring by the study team. The "real world" level of missing data is likely to be much higher.
Reviewer 9: The data seem dependent upon installing software package. If we endorse the measure, are we imposing the cost of this software package on all entities that produce CT scans?
Reviewer 10: None
Reviewer 11: No concerns.
Reviewer 12: no concerns

For cost/resource use measures ONLY:

If not cost/resource use measure, please skip to question 25.

23. **Are the specifications in alignment with the stated measure intent?**
Consider these specific aspects of the measure specifications: attribution, cost categories, target population.
☐ **Yes** ☐ **Somewhat** ☐ **No (If "Somewhat" or "No", please explain)**
24. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**

Attribution: Does the accountable entity have reasonable control over the costs/resources measured? Is this approach aspirational (intending to drive change) or was it developed based on current state?
Costing Approach: Do the cost categories selected align with the measure intent, target population and care settings? Is the approach for assigning dollars to resources
Carve Outs: Has the developer addressed how carve outs in the data source are handled (or should be handled for other users)? For example, if pharmacy data is carved out (missing) from the data set, can a measure that focuses on cost of care for asthmatics still be valid?
Truncation (approach to outliers): What is the threshold for outliers (i.e., extremely high cost or low cost cases) and how are they handled?

25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

☒ **High** (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)

☒ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has NOT been conducted)

☐ **Low** (NOTE: Should rate LOW if you believe that there **are** threats to validity and/or relevant threats to validity were **not assessed OR** if testing methods/results are not adequate)

☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the accountable-entity level and the patient/encounter level **is required**; if not conducted, should rate as INSUFFICIENT.)

26. **Briefly explain rationale for rating of *OVERALL RATING OF VALIDITY* and any concerns you may have with the developers' approach to demonstrating validity.**

Reviewer 3: Empirical testing at data element level and face validity testing at performance score level.
Reviewer 5: Tested both data element and measure score validity. Results for both were strong.
Reviewer 7: There are several statements in the submission which seem to contradict clinician level validity: technical decisions on how to perform CT are made at the facility level rather than at the individual patient level. Because decisions are made at the level of patient groups, rather than individual patients, the logic model does not include varying technical parameters for individual patients Given that this measure is an eCQM, no patient-reported data were collected. Therefore, social risk factors were not available and not analyzed (this sentence just doesn't make sense)
Reviewer 9: The rating is based on the strong Face Validity results and the fact that this is a new measure.
Reviewer 10: ICC Score
Reviewer 11: Results of testing.
Reviewer 12: Demonstrated validity

For composite measures ONLY

If not composite, please skip this section.
Submission documents: Questions 2c.01-08
Examples of analyses:
1) If components are correlated - analyses based on shared variance (e.g., factor analysis, Cronbach's alpha, item-total correlation, mean inter-item correlation).
2) If components are not correlated - analyses demonstrating the contribution of each component to the composite score (e.g., change in a reliability statistic such as ICC, with and without the component measure; change in validity analyses with and without the component measure; magnitude of regression coefficient in multiple regression with composite score as dependent variable, or clinical justification (e.g., correlation of the individual component measures to a common outcome measure).
3) Ideally, sensitivity analyses of the effect of various considered aggregation and weighting rules and the rationale for the selected rules; at a minimum, a discussion of the pros and cons of the considered approaches and rationale for the selected rules.
4) Overall frequency of missing data and distribution across providers. Ideally, sensitivity analysis of the effect of various rules for handling missing data and the rationale for the selected rules; at a minimum, a discussion of the pros and cons of the considered approaches and rationale for the selected rules.

27. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**

For example: Do the component measures fit the quality construct and add value? Are the objectives of parsimony and simplicity achieved while supporting the quality construct? Do analyses demonstrate the aggregation and weighting rules fit the quality construct and rationale?

☐ **High**

☐ **Moderate**

☐ **Low**

☐ **Insufficient**

28. **Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION**

ADDITIONAL RECOMMENDATIONS

29. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

1. Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria

---

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

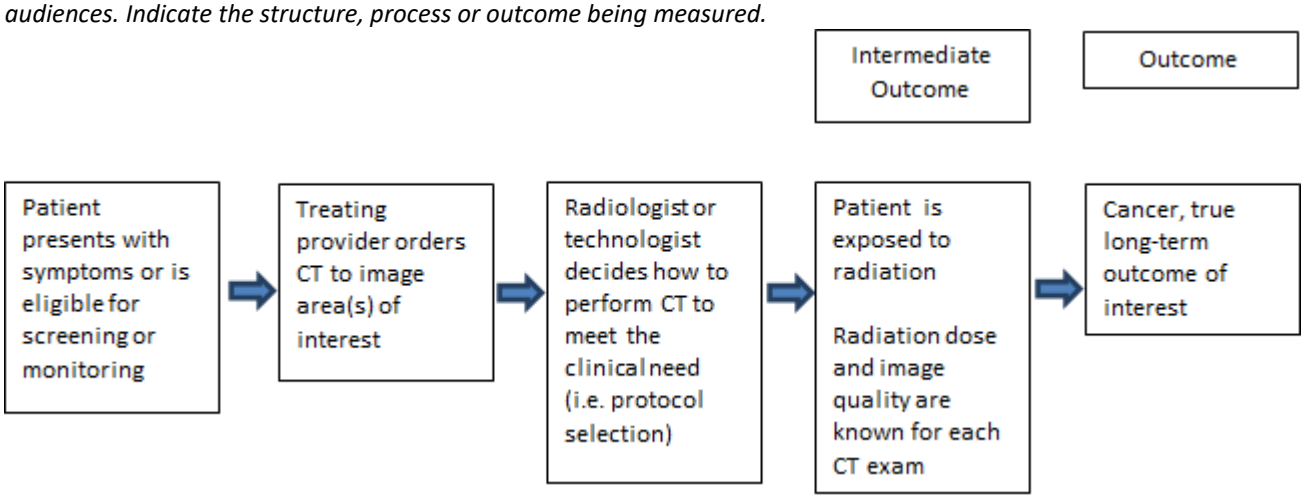
2021 Submission:
Updated evidence information here.

2018 Submission:
Evidence from the previous submission here.

1a. Evidence (subcriterion 1a)

1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.



[Response Begins]

Figure 1a-1. Logic model demonstrating the steps and relationships between imaging based on clinical indication, the intermediate outcome (radiation dose), and the ultimate outcome of interest (cancer).

There is substantial variation in the radiation doses used for CT exams (Kanal 2017, Smith-Bindman 2009) which is primarily due to differences in how radiologists choose to perform them – in other words, their choice of a specific imaging protocol (for example, a single or multiple phase CT) and the specific technical parameters used such as scan length, milliampere-seconds, and kilovoltage peak. (Smith-Bindman 2019) More than patient or CT machine characteristics, this subjective protocol selection is the single greatest predictor of radiation dose. (Smith-Bindman 2019) However, there are no benchmarks currently available to guide practice from this point of evaluating patients with

particular symptoms. In practice, patients are often assigned to a protocol that uses a higher radiation dose than the underlying indication warrants. The proposed measure directly assesses size-adjusted radiation dose and image quality used in CT exams *based on the clinical indication for imaging, shown as the first step in the process*. In this framework, the measure assesses both the earlier step of protocol selection and the later step of radiation dose (and image quality) given the protocol selected.

There is also substantial evidence (discussed later in this section) that radiation doses used for CT are carcinogenic, and that the risk of cancer is directly proportional to the doses used. Therefore, risks would be directly reduced by reducing doses. However, it is not feasible to identify the incidence of cancer associated with the physician's imaging decisions and resultant patient doses because of the potentially long lag between exposure and cancer onset. As highlighted in this application, cancer risks continue to be elevated for over 50 years after exposure. However, the cancer risk will be directly related to the radiation dose used, which is known at the time of the exam. Thus, the radiation dose for each CT exam is an intermediate outcome that can be used as a surrogate for (future) cancer risk.

[Response Ends]

1a.02. Select the type of source for the systematic review of the body of evidence that supports the performance measure.

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.
[Response Begins]
Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center)
[Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking "Add" after the final question in the group.
Evidence - Systematic Reviews Table (Repeatable)
Group 1 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins]
Early life ionizing radiation exposure and cancer risks: systematic review and meta-analysis.

Abalo KD, Rage E, Leuraud K, Richardson DB, Le Pointe HD, Laurier D, Bernier MO.

Pediatr Radiol. 2021 Jan;51(1):45-56. doi: 10.1007/s00247-020-04803-0.

https://link.springer.com/article/10.1007/s00247-020-04803-0
[Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins]
"CT exposure in childhood appears to be associated with increased risk of cancer (leukemia and brain tumors) while no significant association was observed with diagnostic radiographs." Although the benefits of diagnostic radiation examinations may outweigh the risks associated with the doses delivered by these procedures (benefits were not evaluated in the studied patients), the results of this analysis justify continued efforts to optimize doses to patients.
[Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins]
Newcastle-Ottawa Scale (NOS) for studies of radiation exposure in children = 7 to 9

The NOS assesses the quality of non-randomized studies, using 8 items grouped into 3 domains (I.e., selection, comparability/confounding, and outcome/exposure assessment), with 9 being the best possible score. NOS scores of 6 to 9 equate with "good quality" in the Agency for Healthcare Research and Quality (AHRQ) standards for observational studies. Good quality is the highest possible rating on the AHRQ scale.
[Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins]
The DerSimonian and Laird random-effect model was used to estimate the overall effect size to account for within- and between-study heterogeneities. The authors reported moderate heterogeneity (I^2 = 60%, p=0.03) among 6 studies of the risk of leukemia following childhood CT exposures, but no substantial alteration of the aggregate excess relative risk (ERR) with exclusion of individual studies from the meta-analysis (with one exception, where exclusion of a Dutch study led to a higher pooled ERR). There was small heterogeneity (I^2 = 32%) among 5 studies reporting on the risk of brain tumors following childhood CT exposures.

Publication and selection bias were assessed and tested using the Egger test. Some evidence of publication bias was reported (p=0.03) in the leukemia analysis, suggesting that studies of small size with negative results were less often published, but this seemed "not to be a major limitation of our analysis as demonstrated by statistical tests." There was no evidence of publication or selection bias in the brain cancer analysis (p=0.16).
[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins]
N/A – there is no direct recommendation
[Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins]
N/A
[Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins]
21 observational studies, including 11 case-control studies and 10 cohort studies, were included in the systematic review. All studies were assessed to be of good quality, with NOS scores ranging from 7 to 9. (Additional included studies looked at prenatal exposure, but the findings discussed below relate only to childhood exposure).
[Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

[Response Begins]

The study assesses the risk associated with radiation exposure from medical imaging, not the benefit.
[Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

[Response Begins]
The authors report pooled excessive relative risk (ERR) per unit (Gray, Gy) of exposure for leukemia and brain tumors. ERR is the most commonly reported measure in this domain. Overall, the pooled analysis included over 11 million subjects including 437 cases of leukemia and 478 brain tumor cases. The authors observed a significant increased risk for leukemia (ERR_{pooled}=26.9 Gy^{-1}, 95% CI: 2.7–57.1), which represents an increase of 2.69% per mGy of dose over the background risk of leukemia. The pooled ERR for brain tumors was also significantly increased (ERR_{pooled}=9.1 Gy^{-1}, 95% CI: 5.2–13.1), which represents an increase of 0.91% per mGy of dose over the background risk of brain tumors. In other words, for a CT exam delivering 10 mGy to the red bone marrow, the risk of leukemia increases by about 27% over the background risk, holding all other factors constant. In 2017, this was the average bone marrow exposure from one CT in a child, and just slightly above the average bone marrow dose for an abdomen CT in an adult. For a CT exam delivering 10 mGy to the brain, the risk of brain tumor increases by about 9% over the background risk, holding all other factors constant.
[Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins]
N/A – the systematic review is from 2021.
[Response Ends]

Group 2 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins]
Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Summary Bias Assessment and Meta-Analysis.

Michael Hauptmann, Robert D. Daniels, Elisabeth Cardis, Harry M. Cullings, Gerald Kendall, Dominique Laurier, Martha S. Linet, Mark P. Little, Jay H. Lubin, Dale L. Preston, David B. Richardson, Daniel O. Stram, Isabelle Thierry-Chef, Mary K. Schubauer-Berigan, Ethel S. Gilbert, Amy Berrington de Gonzalez

J Natl Cancer Inst Monogr (2020) 2020(56): lgaa010

https://academic.oup.com/jncimono/article/2020/56/188/5869934vv
[Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins]
This systematic review and meta-analysis concludes that “new epidemiological studies directly support excess cancer risks from low-dose ionizing radiation,” in the radiation dose range used in CT imaging. “Furthermore, the magnitude of the cancer risks from these low-dose radiation exposures was statistically compatible with the radiation dose-related cancer risks of the atomic bomb survivors.”
[Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins]
No specific grading system was used, but included studies were assessed for bias in the following ways:

1. To identify bias in dose estimates, the authors "assessed the strengths and weaknesses of dosimetry systems with respect to the directness, complexity, and completeness of the dosimetry, the dosimetric uncertainty, and the validity of dose estimates."

2. In assessing the evidence for confounding and selection bias, they "summarized methods to control confounding and assessed the likelihood of uncontrolled confounding as well as its direction."

3. They "reviewed the possible impact of differential outcome ascertainment across radiation dose levels, and considered loss to follow-up, under- or over ascertainment of cancer outcomes, misclassification of outcomes, and changing classifications over time."

4. They then "performed a summary of the assessments of different biases for each study and considered both the direction of the observed effect and the direction of the bias."

Of 26 eligible studies, 3 had known or suspected bias in dose estimates that could bias the risk estimate away from the null, and 1 study was likely biased toward the null. Various sources of confounding and selection bias were identified, but the authors could not "draw a definitive conclusion on the impact of bias adjustment with the available data." Four studies "may have had cancer ascertainment possibly differential by radiation exposure"; three of these were likely biased away from the null, and one was likely biased toward the null.
[Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins]
In performing the meta-analysis of excess relative risk (ERR), they tested for homogeneity and variance due to heterogeneity (by computing Cochran's Q and the I^2 statistic, respectively.) Heterogeneity was very low for all analyses after excluding one study that contributed significant heterogeneity.
[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins]
N/A – there is no direct recommendation
[Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins]
N/A
[Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins]
There were 26 eligible human studies on low-dose radiation exposure and cancer risk. Of 22 studies on solid cancer risk, 4 positive studies with potential positive bias were excluded. Of 25 studies on leukemia risk, 5 positive studies with potential positive bias were excluded. Following these exclusions, the authors were able to exclude bias as the cause of the positive associations between low-dose ionizing radiation and elevated cancer risk.
[Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

[Response Begins]
The study assesses the risk associated with radiation exposure from medical imaging, not the benefit.
[Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

[Response Begins]
For solid cancers, after excluding 4 positive studies with potential positive bias, 12 of 18 studies reported positive excess relative risks (ERR) per unit of dose. For leukemia, 17 of 20 studies were positive. For both meta-analyses, the authors rejected the null hypothesis that the median ERR per unit of radiation dose equals zero. For adulthood exposure, the meta-ERR at 100 mGy was 0.029 (95% CI = 0.011 to 0.047) for solid cancers and 0.16 (95% CI = 0.07 to 0.25) for leukemia. For childhood exposure, the meta-ERR at 100 mGy for leukemia was 2.84 (95% CI = 0.37 to 5.32). The authors concluded that the majority of studies reported positive risk estimates and that these data directly support excess cancer risks from low-dose ionizing radiation.
[Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins]
This systematic review was published in 2020; the developers are not aware of any newer studies that have changed the conclusion from this systematic review.
[Response Ends]

1a.13. If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.

[Response Begins]
In addition to the systematic reviews described in 1a.03-1a.12 above, further epidemiological evidence derived from literature review is provided in 1a.14 below.
[Response Ends]

1a.14. Briefly synthesize the evidence that supports the measure.

[Response Begins]
There is extensive epidemiological and biological evidence that suggests exposure to radiation in the same range as that routinely delivered by CT (10-100 milli-Sieverts, mSv) increases a person's risk of developing cancer (Board of Radiation Effects 2006, Pearce 2012, Pierce 2000, Preston 2007, Brenner 2003, Hong 2019). **It was estimated in 2009 that 2% of cancers diagnosed annually are the result of CT**; in 2019 that would amount to 36,000 cancers diagnosed each year due to the use of CT. (Berrington de Gonzalez 2009, NCI Cancer Statistics).

The relationship between exposure to radiation and cancer has been shown across a large epidemiological literature, including numerous case control studies, cohort studies including the follow up of individuals exposed to radiation from the atomic bombs, and in recent years, cohort studies showing a direct association between CT imaging and cancer risk. For example, Pearce showed that **among 178,604 children exposed to CT radiation between 1985-2002 and followed through 2008, bone marrow and brain organ doses in the range of 30-50 mGy tripled the risk of leukemia and brain cancer within 10 years.** (Pearce 2012) Far from uncommon, these absorbed radiation doses are frequently delivered by CT imaging. (Miglioretti 2013, Stewart 2021) In the longest follow-up study of survivors of the Hiroshima and Nagasaki atomic bombings (where the median dose to survivors was 40 mSv, in the same range as a single CT exam), the survivors remain at significantly elevated risk for every cancer type through all years of follow up. (Sadakane 2019, Brenner 2020, Sakata 2019, Sugiyama 2020) Overall, more than 10% of cancers in this population are attributed to the radiation exposure.

There have been several systematic reviews, summarized above, assessing the relationship between diagnostic medical radiation exposure and cancer. Abalo et al. (2021) performed a literature search of five electronic databases covering publications from 2000 to 2019 on the relationship between medical radiation exposure in children up to age 21 and cancer. Pooled excess relative risk (ERR) was reported, representing the excess of leukemia and brain tumor risk per unit (Gray, Gy) of organ dose – this metric reflects the proportional increase in risk over the background rate of cancer (in the absence of exposure), per unit of dose. The authors observed a significantly increased risk for leukemia (ERR_{pooled}=26.9 Gy−1, 95% CI: 2.7–57.1), which represents an increase of 2.69% per mGy of dose over the background risk of leukemia. The pooled ERR for brain tumors was also significantly increased (ERR_{pooled}=9.1 Gy−1, 95% CI: 5.2–13.1), which represents an increase of 0.91% per mGy of dose over the background risk of brain tumors.

Dr. Amy Berrington De Gonzalez, Chief of Radiation Epidemiology at the National Cancer Institute, was the senior author of a second systematic review and meta-analysis of studies evaluating the association between radiation exposure and cancer. (Hauptmann 2020) The authors identified 26 studies which: 1) reported a mean dose of less than 100 mGy (corresponding to exposures used in medical imaging); 2) individualized dose estimates, risk estimates, and confidence intervals (CI) for the dose-response relationship; and 3) were published between 2006-2017. They systematically assessed the potential for bias from each primary study and performed a meta-analysis to quantify the ERR and to assess consistency across studies for all solid cancers and leukemia. For adulthood exposure, the meta-ERR at 100 mGy was 0.029 (95% CI: 0.011 to 0.047) for solid cancers and 0.16 (95% CI: 0.07 to 0.25) for leukemia. For childhood exposure, the meta-ERR at 100 mGy for leukemia was 2.84 (95% CI: 0.37 to 5.32). The authors concluded that **the majority of studies reported positive risk estimates and that these data directly support excess cancer risks from low-dose ionizing radiation.** Furthermore, the magnitude of the cancer risks from these low-dose radiation exposures was statistically compatible with the radiation dose-related cancer risks of atomic bomb survivors.

A number of cohort studies are being conducted as part of the EPI-CT study: a European pooled epidemiological study to quantify the risk of radiation-induced cancer from pediatric CT (Bernier, 2019). The full results are forthcoming, but 4 contributing country-specific portions of the cohort have been published and show positive associations between CT and cancer incidence (Table 1a-1):

(1) **The British study reported a positive dose-response relationship between radiation dose and leukemia and CNS tumors in children and young adults.** (Pearce 2012, Berrington 2016)

(2) **The German study reported a significantly increased incidence of all cancer and lymphoma in exposed children** compared with the general population. (Krille 2015)

(3) **The French and the German cohorts reported a dose-related increase for CNS tumors**. (Journy 2015, Journy 2016, Krille 2015)

(4) **The Dutch study reported a dose-response relationship for CNS tumors.** (Meulepas 2016, Meulepas 2019)

Table 1a-1. Results from EPI CT National Cohort (Bernier 2019).

Results from EPI-CT national cohorts

Outcome by country	Cases	Risk estimates		(IC 95%)
CNS tumour risk according to the brain dose				
UK[a] (Pearce *et al.*, 2012)	135[b]	ERR per mGy	0.023	(0.010, 0.049)
UK[a] (Berrington *et al.*, 2016)	122[b] without PF	ERR per mGy	0.019	(0.008, 0.043)
France (Journy *et al.*, 2015)	22	ERR per mGy	0.022	(−0.016, 0.061)
The Netherlands (Meulepas *et al.*, 2018)	84	ERR per mGy	0.0086	(0.0020, 0.022)
Germany (Krille *et al.*, 2015)	7	HR per mGy	1.008	(1.00, 1.01)
France (Journy *et al.*, 2016)	15 without PF	HR per 10 mGy	1.07	(0.99, 1.10)
	7 with PF	HR per 10 mGy	0.8	(0.45, 1.06)
UK[a] (Pearce *et al.*, 2012)	135[b]	RR [50-74 mGy] vs <5 mGy	2.82	(1.34, 6.03)
Leukaemia risk according to RBM dose				
UK[a] (Pearce *et al.*, 2012)	74	ERR per mGy (RBM dose)	0.036	(0.005, 0.120)
France (Journy *et al.*, 2015)	17	ERR per mGy	0.057	(−0.079, 0.193)
The Netherlands (Meulepas *et al.*, 2018)	44	ERR per mGy	0.0004	(−0.0012, 0.016)
UK[a] (Berrington *et al.*, 2016)	70 without PF	ERR per mGy	0.037	(0.005, 0.126)
France (Journy *et al.*, 2016)	12 without PF	HR per 10 mGy	1.16	(0.77, 1.27)
France (Journy *et al.*, 2016)	5 with PF	HR per 10 mGy	0.57	(0.06, 1.32)
Germany (Krille *et al.*, 2015)	17	HR per mGy	1.009	(0.98, 1.04)
UK (Pearce *et al.*, 2012)	74	RR [>30 mGy] vs <5 mGy	3.18	(1.46, 6.94)
Lymphoma risk according to RBM dose				
France (Journy *et al.*, 2015)	19	ERR per mGy	0.018	(−0.068, 0.104)
UK[a] (Berrington *et al.*, 2017)	65[c]	RR [>20] vs <5 mGy	0.92	(0.22, 2.94)

CNS, central nervous system; PF, predisposing factor; RBM, red bone marrow; ERR, excess relative risk; RR, relative risk; HR, hazard ratio; mGy, milligray.

[a]Follow-up period until 2005 only.
[b]Exclusion period 5 years instead of 2 years.
[c]Hodgkin lymphoma only.

Lastly, the ongoing Life Span Study (LSS) of atomic bomb survivors in Hiroshima and Nagasaki, Japan, provides quantitative estimates of cancer risks associated with exposure to radiation and is a major source of human data used for risk assessment in establishing radiation safety standards. Although this is not a systematic review, it is the gold standard, epidemiological study of radiation in the same dose range as encountered with CT. The most recent publications describe solid cancer incidence in the LSS cohort through 2009. (Brenner 2020, Grant 2017, Sadakane 2019, Sakata 2019, Sugiyama 2020) The eligible cohort included 105,444 subjects who were alive and had no known history of cancer at the start of follow-up. The follow-up period was 1958-2009, providing 3,079,484 person-years of follow-up. Cases were identified by linkage with population-based Hiroshima and Nagasaki Cancer Registries. Poisson regression methods were used to elucidate the nature of the radiation-associated risks per Gy of weighted absorbed organ doses using both excess relative risk (ERR) and excess absolute risk (EAR) models adjusted for smoking and other covariates**. These analyses demonstrate that solid cancer risks remain elevated more than 60 years after exposure and that approximately 10% of cancers in the cohort are due to the radiation.** Studies by type of tumor confirm the strong association between radiation exposure and particular cancer types such as CNS tumors (Braganza, 2012 and Brenner, 2020), upper gastrointestinal tract tumors (Sakata, 2019) and liver and pancreas tumors (Sadakane, 2019) and colon tumors (Sugiyama, 2020)

There is also increasing understanding of the mechanisms involved in carcinogenesis. In a prospective evaluation of 67 adults undergoing cardiac CT, patients underwent extensive blood work just prior to and following the exam to look for cellular processes implicated in carcinogenesis. (Nguyen, 2015) Immunohistochemistry and full gene sequencing were performed, and diverse markers of DNA damage, repair, and cell death were evaluated. The average exposure from a single CT exam was 30 mSv (similar to the Hiroshima and Nagasaki exposures), and there was a three-fold increase in markers of DNA damage and cell death. These changes were seen at doses of 7 mSv and greater, and these changes persisted for at least a month.

Despite the known risks of CT, its use has grown substantially over the last few decades (Harvey L Neiman 2017), with 91.4 million CT exams performed in the United States in 2019 (IMV 2020), including 428 exams per 1000 patients aged 65 years and older (Smith-Bindman 2019). The radiation doses used for CT exams are frequently far higher than needed for diagnosis and have been shown to vary up to 200-fold across facilities for patients imaged for the same clinical reason. (Smith-Bindman 2009, Smith-Bindman 2015, Smith-Bindman 2019, Miglioretti 2013, Demb 2017). For example, the American College of Radiology reported that CT exams to assess kidney stones had an average dose of 10 mSv, while the optimum dose is 2-4 mSv. (Lukasiewicz, 2014) In a prospective randomized trial of different imaging strategies for patients with suspected kidney stones, 5% of patients received an appropriate dose of 4 mSv or less. (Smith-Bindman, 2014)

Evidence of the association between medical imaging and cancer risk has been reviewed by many professional societies and government, quality, and oversight organizations, which have all identified CT radiation dose reduction as a safety imperative and issued guidelines asking radiologists to track, optimize, and lower CT radiation doses. These organizations include: the American College of Radiology (Kanal 2017); the Radiology Society of North America (Hricak 2010); The Society of Interventional Radiology (Stecker 2009); The Society of Cardiovascular CT (Halliburton 2011); Cardiovascular Imaging Societies (Writing Committee 2018); Image Wisely (a joint initiative of the American College of Radiology, Radiological Society of North America, American Society of Radiological Technologists, and American Association of Physicists in Medicine); and the FDA (US Food and Drug Administration 2019).

[Response Ends]

1a.15. Detail the process used to identify the evidence.

[Response Begins]
The evidence was obtained through comprehensive searches or PubMed, Embase, and Web of Science from inception to August 2021. Each search consisted of Medical Imaging, Cancer and Epidemiology concept blocks with additional search terms including Computed Tomography and CT. References of all publications were searched to identify additional publications. Additionally, there are a small number of investigators who lead studies in this area (such as Dr. Amy Berrington De Gonzales, Chief of Radiation Epidemiology at the NCI and Dr. Alina Brenner at the Radiation Effects Research Foundation) whose names were added to searches.
[Response Ends]

1a.16. Provide the citation(s) for the evidence.

[Response Begins]

1. Abalo KD, Rage E, Leuraud K, Richardson DB, Le Pointe HD, Laurier D, Bernier MO. Early life ionizing radiation exposure and cancer risks: systematic review and meta-analysis. Pediatr Radiol 2021;51(1):45-56. doi: 10.1007/s00247-020-04803-0
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[Response Ends]

1b. Performance Gap

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]
Diagnostic CT imaging occurs in more than a third of acute care hospitalizations (Vance 2013) and upwards of 90 million scans are performed annually in the U.S. (IMV 2020). The radiation doses used for these exams are frequently far higher than needed for diagnosis and vary up to 200-fold across facilities for patients imaged for the same clinical reason. (Smith-Bindman 2009, Smith-Bindman 2015, Smith-Bindman 2019, Miglioretti 2013, Demb 2017). Most of this variation reflects clinician preferences rather than appropriate differences based on patient and clinical indications (Smith-Bindman 2019). As described in section 1a.14, the inconsistency in how CT exams are performed represents a significant, unnecessary, and modifiable iatrogenic health risk, as there is extensive epidemiological and biological evidence that suggests exposure to radiation in the same range as that routinely delivered by CT increases a person's risk of developing cancer (Board of Radiation Effects 2006, Pearce 2012, Pierce 2000, Preston 2007, Brenner 2003, Hong 2019). It is estimated that 2% (36,000) of the 1.8 million cancers diagnosed annually in the U.S. are caused by CT exams (Berrington de Gonzalez 2009, NCI Cancer Statistics).

The measure focuses on reducing radiation dose in CT, an intermediate outcome important to cancer prevention. As radiation dose is known to be directly related and proportional to future cancer risk (Board of Radiation Effects 2006, Pearce 2012, Pierce 2000, Preston 2007, Brenner 2003, Hong 2019, Berrington de Gonzalez 2009), any reduction in radiation exposure would be expected to lead to a proportional reduction in cancers. Research suggests that when healthcare organizations and clinicians are provided with a summary of their CT radiation doses, their subsequent doses can be reduced without diminishing the diagnostic usefulness of these tests. Smith-Bindman et al. led a randomized controlled trial of two interventions to optimize CT radiation doses across 100 hospitals and imaging facilities and found that providing feedback to institutions along with education and opportunities for sharing best practices results in meaningful dose reductions. (Smith-Bindman 2020). Though results varied by anatomic region, following the intervention there was up to a 40% reduction in doses with a greater impact on the rate of high dose exams, meaning facilities with high doses at the beginning of the trial were particularly likely to improve.

On the basis of the current estimated number of CT exams performed annually in the U.S. (IMV 2020), distribution in scan types and observed doses (Demb 2017, Smith-Bindman 2019), modelling of the cancer risk associated with CT at different ages of exposure (Berrington de Gonzalez 2009), and costs of cancer care (Dieguez 2017, Mariotto 2011), an estimated 18,643 cancers could be prevented annually in the U.S., 75% (13,982) of these among Medicare beneficiaries, resulting in $1.86 billion to $5.21 billion in annual cost savings to the Centers for Medicare & Medicaid Services.

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[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]
The measure has been field-tested across 7 health systems and 1 vertically integrated organization, including 42,493 CT exams interpreted by 606 physicians. The measure is reported at the level of the individual physician (identified by the national provider identification number, NPI). The physicians represent diverse practices with regard to community vs. academic, urban vs. nonurban care settings, and geographic location (Alabama, California, Michigan, Texas, New York). Data were collected from an approximately four-week period at each testing site, spanning the years 2020-2021.

Performance scores at the individual clinician level are as follows:
Mean measure (out-of-range) score: 30%, standard deviation: 21%
Range: minimum = 0%, maximum = 100%
Interquartile range: 22% (17%-39%)
Proportion out-of-range by percentile:
The physicians with the lowest (best) out-of-range scores are in the top percentile

- 10^{th} = 6%
- 20^{th} = 15%
- 30^{th} = 20%
- 40^{th} = 23%
- 50^{th} = 27%
- 60^{th} = 32%
- 70^{th} = 36%
- 80^{th} = 43%
- 90^{th} = 53%

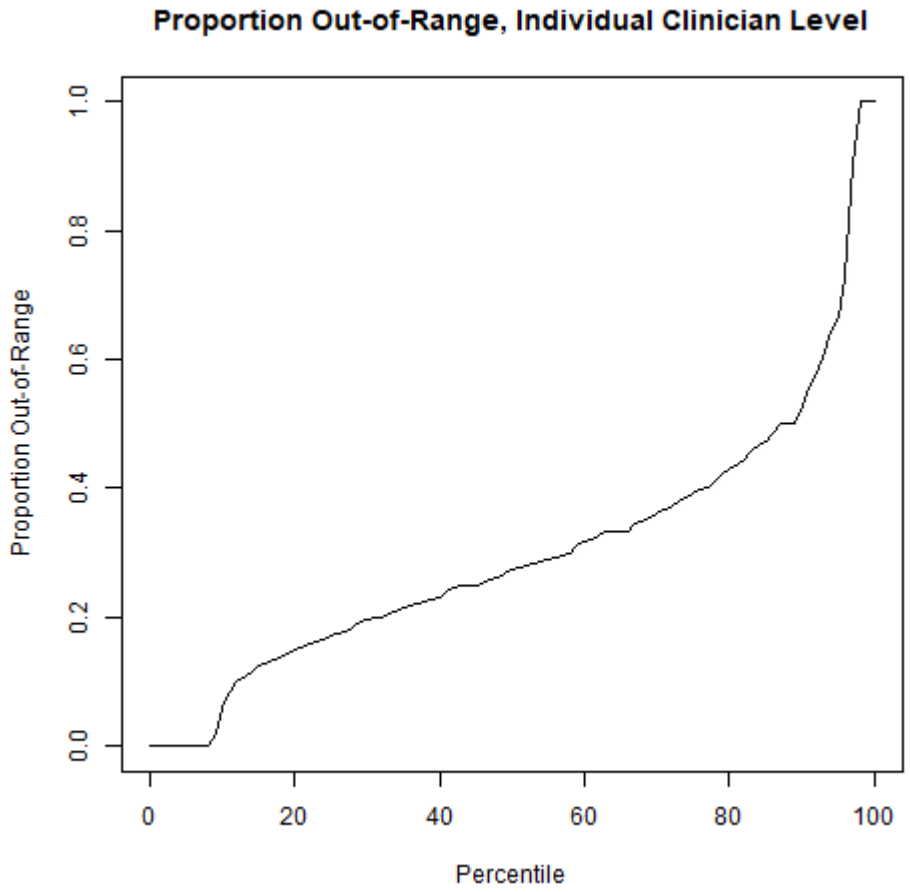

Figure 1b-1. Out-of-range scores by percentile. Clinicians with the lowest (best) out-of-range scores are on the bottom left.

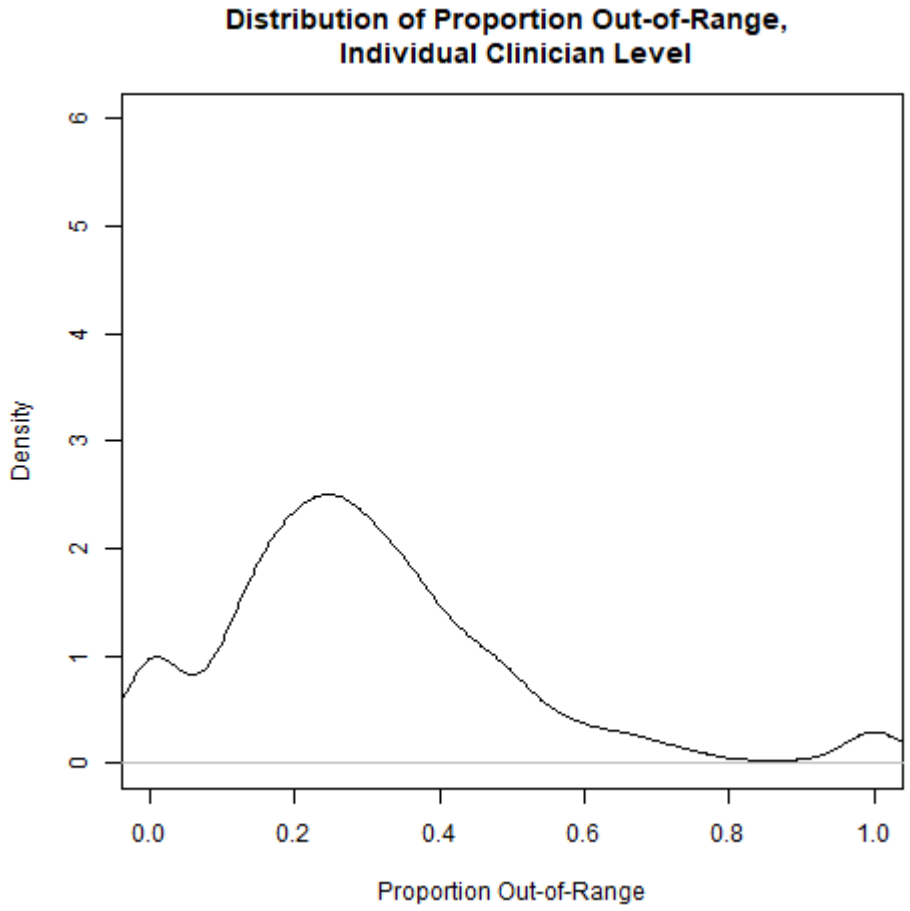

Figure 1b-2. Distribution in proportion out-of-range scores by individual clinician. This probability distribution is presented as an estimated density function, which is defined as a smooth function such that the probability of an outcome lying between any two given points on the x-axis is equal to the area under the curve of those two points (i.e. the area under the entire curve equals 1).

GLOBAL NOISE

Virtually all out-of-range scores are driven by excessive radiation doses, rather than global noise. The few clinicians with non-trivial quantities of out-of-range values by noise had very low sample size. The 90th percentile of out-of-range by global noise is 0.06%, and the 95th percentile is 1.4%, meaning fewer than 5% of clinicians had an out-of-range score based on noise of 1.4% or greater. This finding suggests image quality as reflected by global noise is not currently a large problem, and that there is considerable opportunity to optimize radiation doses without impacting quality. However, it is important to include the global noise in the measure as a balancing component to ensure that incentivizing the reduction of size-adjusted radiation doses does not compromise image quality.

PERFORMANCE IN THE UCSF INTERNATIONAL CT DOSE REGISTRY

When we applied the proposed measure to data assembled in the UCSF International CT Dose Registry – a repository of CT data containing over 6.5 million exams from 161 hospitals and imaging facilities – overall 33% of CT exams were out-of-range based on radiation dose exceeding thresholds. Overall, 135 facilities (84%) had out-of-range scores over 10%. Global noise cannot be assessed in the registry, but given the out-of-range values for global noise were <1% in field-testing data, we would expect it to also be low in the Registry. It is not possible to identify clinician groups in the UCSF registry, only facility-level performance.

Performance data at the facility level is as follows:

Mean measure (out-of-range) score: 30%, standard deviation: 18%

Range: minimum = 2%, maximum = 100%

Interquartile range: 27% (16%-43%)

Scores by percentile:

- 10^{th} = 7%
- 20^{th} = 11%
- 30^{th} = 17%
- 40^{th} = 22%
- 50^{th} = 27%
- 60^{th} = 31%
- 70^{th} = 39%
- 80^{th} = 46%
- 90^{th} = 53%

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]
Previous studies support the same performance gaps observed in our field-testing. The radiation doses used for CT exams are frequently far higher than needed for diagnosis and have been shown to vary up to 200-fold across facilities for patients imaged for the same clinical reason. (Demb 2017, Hricak 2010, Miglioretti 2013, Raff 2009, Smith-Bindman 2009, Smith-Bindman 2015, Smith-Bindman 2019,Tack 2014). For example, in a study of 151 organizations across seven countries, even after adjusting for patient characteristics, abdominal CT exams had a four-fold range in mean effective radiation dose and a 17-fold range in the proportion of high dose exams. (Smith-Bindman 2019)

There is also evidence that radiation doses can be reduced meaningfully without compromising the diagnostic usefulness of CT. In general, a direct relationship exists between radiation dose and image quality. As the dose increases, the image quality increases until a threshold is reached at which point no further benefit in image quality occurs. There is a concern that reducing radiation dose will compromise image quality, undermining the clinical value of CT exams. However, several studies suggest that radiation doses may be lowered 50-90% without impacting image quality or diagnostic accuracy because there is such a wide range in quality that is acceptable and that does not impact accuracy. (Catalano 2007, Smith-Bindman 2020, Konda 2016, Huppertz 2015, den Harder 2018, Rob 2017). A randomized trial of audit feedback combined with an educational intervention across 100 imaging facilities achieved 23-58% reductions in the proportion of high-dose exams (Smith-Bindman 2020), without any reduction in physician satisfaction with image quality.

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[Response Ends]

1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]
Age and sex were explored in the general population, represented by all data in the UCSF International CT Dose Registry. No meaningful differences in radiation dose were identified either based on patient age or sex, after adjustment for patient size. The correlation between size-adjusted radiation dose and patient age is -0.004, with minimal variation between CT categories. The prevalence of out-of-range size-adjusted dose averaged 34% for female patients and 35% for male patients, with minimal variation between CT categories. A similarly comprehensive dataset was not available to assess the relationship between image noise and patient age or sex in the general population, though testing data shows that noise contributes minimally to the body of exams determined as "out-of-range" in our measure.

Despite this lack of disparity in the overall population, and despite no clinical justification for dosing differences by age or sex, individual clinicians, clinician groups, or hospitals may still express disparities between age and sex groups due to localized practice, and the proposed measure may have a role in reducing disparities.

Age and sex were explored in the testing data. Notable differences in radiation dose and noise out-of-range prevalence based on patient age and sex were identified in some individual clinicians. Overall, variability between clinicians was greater than between clinician groups or hospitals.

Table 1b-1. Distribution of proportion out-of-range by age and sex by clinician percentile.

Percentile of Clinician	Sex: Female	Sex: Male	Age: 18-20	Age: 21-30	Age: 31-40	Age: 41-50	Age: 51-60	Age: 61-70	Age: 71-80	Age: 80-89
5th	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
25th	0.14	0.16	0.00	0.00	0.00	0.00	0.07	0.11	0.11	0.00
50th	0.25	0.26	0.00	0.17	0.25	0.25	0.25	0.25	0.25	0.17
75th	0.40	0.42	0.25	0.40	0.50	0.50	0.43	0.40	0.43	0.34
95th	0.68	1.00	1.00	1.00	1.00	1.00	1.00	0.76	0.80	1.00

Other social factors were not analyzed in field testing, because this information was not available to the developers and there was no *a priori* reason to believe that social factors such as insurance status, socioeconomic status, and/or functional status/disability would affect CT radiation dose. Therefore, disparities data by other population groups are not available.

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]
To the extent they have been studied, social factors including sex, race/ethnicity, and socioeconomic status are not predictive of radiation dose for CT exams. (Strauchler 2012, Freeman 2012, Hou 2014, Messenger 2015). However, as described in the studies led by Strauchler and Freeman, patients living in poverty are at higher risk for comorbid conditions associated with exposure to multiple scans over time and increased cumulative exposure to ionizing radiation from diagnostic imaging. Thus, it is particularly important to ensure that the doses used for CT in these individuals are not excessive, because vulnerable patients are at greatest risk of chronic disease and more likely to be exposed to many irradiating exams.

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[Response Ends]

2. Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

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sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

[Response Begins]
Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)
[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]
This electronic clinical quality measure (eCQM) provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of eligible CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible.
[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]
Other (specify)
Diagnostic Radiology
[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]
Safety
[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]
Adults (Age >= 18)
[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]
Clinician: Individual
[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.
[Response Begins]
Ambulatory Care
Inpatient/Hospital
Outpatient Services
[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]
https://www.alaracare.com/qualitymeasures

Please note, we have developed and tested the eCQM in both a Quality Data Model (QDM) format, to allow immediate implementation, and a FHIR format to align with CMS's strategy for increasing interoperability. The human readable outputs for both QDM and FHIR formats are attached to this application and available at the website above.
[Response Ends]

sp.10. Indicate whether Health Quality Measure Format (HQMF) specifications are attached.

Attach the zipped output from the eCQM authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications).
[Response Begins]
HQMF specifications are attached.

[Response Ends]

Attachment: CMS1056-v0-0-022-QDM-5-6.zip
Attachment: CMS1076FHIR-v0-0-026-FHIR-4-0-1.zip
Attachment: Human_readable_1056_QDM_Clinician.pdf
Attachment: Human_readable_1076_FHIR_Clinician.pdf

sp.11. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.
[Response Begins]
Available in attached Excel or csv file
[Response Ends]

Attachment: Binning algorithm CPT ICD List_2021.08.02 v18.xlsx
Attachment: LOINC_code_table.xlsx

sp.12. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]
Diagnostic CT exams that have a size-adjusted radiation dose value greater than the threshold specific to the CT category (reflecting the body region imaged and the radiation dose and image quality required for that exam given the reason for the exam), or a global noise value greater than a threshold specific to the CT Category.
[Response Ends]

sp.13. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]
The numerator represents the total number of out-of-range (i.e. failed) exams.

Through this application, these LOINC variable names will be shortened for brevity, as follows:

Calculated CT Size-Adjusted Dose = size-adjusted radiation dose

Calculated CT Global Noise = global noise

CT Dose and Image Quality Category = CT category

Definitions

Size-adjusted radiation dose reflects the total radiation dose delivered during a CT, risk-adjusted for patient size. The total radiation dose is recorded for each CT exam using the standardized metric of dose length product (ACR–AAPM–SPR: Practice parameter, European Commission, Radiation Protection No. 185, ICRP Publication 135, Kanal 2017, Smith-Bindman 2019). The patient size is defined as the effective diameter of the anatomic area scanned in millimeters, computed on the mid-slice of the scan. Where axial images are available showing the entire anatomic area, the patient size is computed as the average effective patient diameter on the axial image (Cheng 2013). If axial images showing the entire anatomic area are unavailable, the effective diameter is computed on the coronal localizer image (Christianson 2012). The dose length product is adjusted for patient size using log-transformed linear regression models. The size-adjusted radiation dose value is compared with thresholds that vary by the CT category.

Global noise reflects the image quality of the CT exam. Noise is the most widely used measure of CT image quality. (Catalano 2007, Christianson 2012, Malkus 2017, Schindera 2009, Smith 2008, Szczykutowicz 2017, Szczykutowicz 2021, Willemink 2014) Noise represents differences in the appearance of homogenous areas of tissue that is not a result of inherent tissue composition, but rather of the quality due to imaging technique. In general, image noise in CT reflects the number of x-ray photons hitting the detector, and this will be influenced by the x-ray tube voltage and tube current, as well as patient factors such as the patient's body habitus, the body region being evaluated, and other scanning parameters such as the slice thickness. Different clinical questions require different values of noise, yet in general, the greater the noise, the worse the image quality and the poorer the diagnostic accuracy, although this is not a simple linear relationship. Diagnostic accuracy may be acceptable for a large range of noise values, but unacceptable only at a high value. Noise can be quantified in CT images by positioning standard elliptical regions of interest in a known density structure (e.g. water, air, soft tissue) and measuring the standard deviation of the measured values in Hounsfield units. (Catalano 2007). Noise as defined in this measure is calculated on every CT image within a scan (a single irradiating event), and the global noise value for each scan is the mean value across all images. For CT exams that have multiple scans (for example a scan without contrast, followed by a scan with contrast, followed by a delayed scan), the exam is assigned the "best" global noise value across all scans, i.e. the highest quality scan. The global noise value for each scan is also standardized to a 3 mm slice thickness. (Alshipli 2017) The global noise value is compared with thresholds that vary by the CT category.

Details needed to calculate the numerator

To calculate the numerator, the size-adjusted radiation dose and global noise for each CT exam are compared against the following evidence-based thresholds specific to the CT Category (Table sp-1). If a CT exam has a size-adjusted radiation dose and/or global noise value exceeding these thresholds, the exam is considered out-of-range (i.e. "failed") and is counted in the numerator.

Table sp-1. Size-adjusted radiation dose and global noise thresholds by CT category.

CT Category	Size-Adjusted Radiation Dose THRESHOLD (Dose length product, mGy-cm)	Global Noise THRESHOLD (Hounsfield units)
Abdomen and Pelvis Low Dose	598	64
Abdomen and Pelvis Routine Dose	644	29
Abdomen and Pelvis High Dose	1260	29
Cardiac Low Dose	93	55
Cardiac Routine Dose	576	32
Chest Low Dose	377	55
Chest Routine Dose	377	49
Cardiac High Dose or Chest High Dose	1282	49
Head Low Dose	582	115
Head Routine Dose	1025	115
Head High Dose	1832	115
Extremity	320	73

CT Category	Size-Adjusted Radiation Dose THRESHOLD (Dose length product, mGy-cm)	Global Noise THRESHOLD (Hounsfield units)
Neck or Cervical Spine	1260	25
Thoracic or Lumbar Spine	1260	25
Simultaneous Chest and Abdomen and Pelvis	1637	29
Simultaneous Thoracic and Lumbar Spine	2520	25
Simultaneous Head and Neck Routine Dose	2285	25
Simultaneous Head and Neck High Dose	3092	25

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[Response Ends]

sp.14. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]
All diagnostic CT exams performed on adults (aged 18 years and older) during the measurement period of one year that have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.
[Response Ends]

sp.15. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]
Target population

The target population includes all diagnostic CT exams of specified anatomic sites performed on adults during the measurement period.

On a practical level, to be included, the exam must have an assigned CT category and must have a size-adjusted radiation dose value and a global noise value (meaning the relevant CT data must be available to allow calculation of patient size and image quality.)

CT exams performed in conjunction with nuclear medicine (such as SPECT and PET-CT), biopsies, procedures related to an intervention, assessments of bone mineral density, where the body region is not specified, or where no primary images were obtained, are not included as they are not diagnostic CT.

Definitions

CT Dose and Image Quality Category (short term: "CT category"): reflects the type of exam performed based on the body region and the clinical indication for the exam. Each CT category has a specific set of radiation dose and global noise thresholds. The categories are:

1. Abdomen and Pelvis Low Dose
2. Abdomen and Pelvis Routine Dose
3. Abdomen and Pelvis High Dose
4. Cardiac Low Dose
5. Cardiac Routine Dose
6. Chest Low Dose
7. Chest Routine Dose
8. Cardiac High Dose or Chest High Dose
9. Head Low Dose
10. Head Routine Dose
11. Head High Dose
12. Extremity
13. Neck or Cervical Spine

14. Thoracic or Lumbar Spine
15. Simultaneous Chest and Abdomen and Pelvis
16. Simultaneous Thoracic and Lumbar Spine
17. Simultaneous Head and Neck Routine Dose
18. Simultaneous Head and Neck High Dose

Time period for data collection

One calendar year, although shorter periods can be used for high-volume entities

Codes

LOINC codes representing the data elements required for this measure are published in the Value Set Authority Center (VSAC). They are attached in section sp.11. The data elements themselves and data sources are described in section sp.29.

[Response Ends]

sp.16. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]
Denominator exclusions are CT exams that simultaneously include multiple body regions outside of four commonly encountered multiple region groupings (specified as LOINC code 96914-7, CT Dose and Image Quality Category, Full Body). Denominator exclusions are also CT exams with missing patient age, missing size-adjusted radiation dose, or missing global noise. These are technical exclusions ("missing data") from the initial population. Technical exclusions will be flagged, corrected whenever possible, and tracked at the level of the accountable entity.
[Response Ends]

sp.17. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]
Exclusions

CT exams that cannot be placed into a CT category because they are simultaneous include exams of multiple body regions outside of four commonly encountered multiple region groupings are excluded. The four commonly encountered multiple region groupings are: (1) Simultaneous Chest and Abdomen and Pelvis; (2) Simultaneous Thoracic and Lumbar Spine; (3) Simultaneous Head and Neck Routine Dose; and (4) Simultaneous Head and Neck High Dose. Simultaneous exams of the abdomen and lower extremity are already included as a subset of exams included as part of the "Abdomen and Pelvis High Dose" category. Chest and cardiac are not considered separate body regions for purposes of determining whether the exam contains multiple body regions.

Technical exclusions

CT exams missing any of the four data elements required to calculate measure score are considered technical exclusions: CT category; size-adjusted radiation dose; global noise; birth date.
[Response Ends]

sp.18. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins]
The only stratification variable is the CT category, which is constructed using International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes and CPT® (Current Procedural Terminology) procedure codes from the billing entity's claim (or other mapped fields in the electronic health record).

CT categories were constructed to reflect various body regions and different clinical indications for imaging, since different amounts of radiation and image quality are needed to create images sufficient for diagnosis depending on these factors. The framework for creating these categories took an image-quality informed approach, which first relied on categorizing CT exams into 10 body regions. In five of these regions (extremities, neck [including cervical spine], thoraco-lumbar spine [reflecting either thoracic spine or lumbar spine], combined chest-abdomen, and combined thoraco-lumbar spine [reflecting both thoracic and lumber spine]), clinical indications for scanning do not play a substantial role in altering the amount of radiation needed to produce required images; thus, there is a single CPT®-determined category for each of these body regions. In five other body regions (head, chest, cardiac, abdomen, and combined head and neck), clinical indications do affect the optimal radiation dose, thus these regions were sub-divided based on ICD-10-CM/CPT® defined clinical indications into low, routine, or high radiation dose categories. The "combined head and neck" category was divided into routine and high dose. The approach to determining low, routine, or high radiation doses within these categories was informed by: 1) a review of the published literature; 2) consultation with radiologists with specialty expertise; 3) input from a Technical Expert Panel; and 4) empirical evaluation of about 4.5 million consecutive CT exams from 161 imaging facilities that contribute to the UCSF International CT Dose Registry (January 1, 2016 to December 31, 2019). The categories had face validity as assessed by the Technical Expert Panel, and a manuscript describing this work is under resubmission review in *Radiology.* The strategy in creating the logic to assign exams to CT categories was to identify indications that were *exceptions* to the routine radiation dose category, rather than to identify every indication for scanning within the routine category. For example, lung cancer screening is the only defined indication for low-dose chest CT, and evaluation for suspected aortic rupture or dissection (or, more generally, a patient in acute shock) is the only defined indication for high-dose chest CT, leaving all other chest CTs in the routine-dose category. As in this example, all strata were constructed to mimic clinical decision-making regarding the most appropriate imaging protocol and its associated radiation dose range. The logic and code table for assigning body regions and indications to CT categories is provided in sp.11.

Size-adjusted radiation dose and global noise are assessed against thresholds specific to the CT category, as described further below. However, the measure score is binary (in-range or out-of-range), and the total number/proportion of out-of-range exams is summed for a reportable entity without need for separate stratified calculation or reporting. The measure is not weighted by the stratum, but rather every CT exam contributes equally to overall score. An entity that performs CT exams within only a few strata has its exams judged against the thresholds for the exams that it performs.
[Response Ends]

sp.19. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.
[Response Begins]
Statistical risk model
[Response Ends]

sp.20. Select the most relevant type of score.

Attachment: If available, please provide a sample report.
[Response Begins]
Rate/proportion
[Response Ends]

sp.21. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score
[Response Begins]
Better quality = Lower score
[Response Ends]

sp.22. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]
At a high level, the following steps occur for each CT exam assessed during the reporting period for the reporting entity:

1. The CT exam is assigned to a CT category using diagnosis (ICD-10-CM) and procedure (CPT®) codes.
2. The patient's size is calculated from DICOM (pixel) data included with the CT exam.
3. The size-adjusted radiation dose is calculated from DICOM data, including the Radiation Dose Structured Report (RDSR) and image pixel data, stored with the CT exam.
4. The global noise is calculated from DICOM (pixel) data stored with the CT exam.
5. The size-adjusted radiation dose and global noise are compared with allowable thresholds, and if either (or both) exceed the allowable thresholds, the CT exam is considered out-of-range (failed).
6. The measure score for the reporting entity is calculated as the proportion of out-of-range CT exams for the reporting entity.

As described in section sp.29, the measure derives standardized data elements from structured fields within the EHR and the radiology electronic clinical data systems including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS).

In its existing framework, the eCQM cannot consume primary imaging data in its original format and thus cannot access the requisite data for measure calculation. UCSF and Alara Imaging, Inc. have developed software to access and process primary data elements from the electronic systems to calculate the three variables required by the measure – CT category, size-adjusted radiation dose, and global noise – which can then be ingested by the eCQM for calculating the measure score. The calculation of these variables is broadly described as "pre-processing."

This approach was tested across diverse EHR and PACS platforms. The software is installed at imaging facilities or hospitals within the firewall and functions as an edge device, drawing in data from the specified sources and calculating the variables that can be ingested by the eCQM in a manner that minimizes burden. The software can be fully integrated locally into existing data flows using QDM or FHIR or can be available as a web interface for organizations that do not desire a fully integrated solution.

Consecutive, diagnostic CT exams over one calendar year will be evaluated by the eCQM. These exams may be submitted prospectively in real-time or batch-submitted retrospectively (daily, weekly, monthly). The following steps take place to ingest and calculate the measure score on consecutive CT exams:

Ingestion – Edge Device

1. Radiology electronic clinical data systems record and store information related to medical imaging studies. EHRs record and store information related to the patient and medical imaging encounters.

2. Radiology electronic clinical data systems are configured to automatically forward relevant CT studies with included RDSR reports via DICOM protocols to the edge device. Once the CT study is forwarded to the edge device, the edge device queries the EHR via FHIR or direct API calls for additional information that is then linked to the related exam.

Ingestion – Web Interface

3. For sites not using the integrated edge device, information can be exported from the EHR and radiology electronic clinical data systems via custom reports such as FHIR resources, CCDA documents, and DICOM studies. Relevant information can then be uploaded by sites through a web application for measure calculation. This service will be provided at cost, or free, to minimize burden on providers.

Calculation

4. Software assesses the information for each CT exam for eligibility based on initial population assessment criteria and missing data. Missing data are flagged for the reporting entity and recovered when possible.

5. Remaining CT exams undergo *pre-processing* on the edge device software or web application, in which the three data elements needed for measure calculation are generated from primary data elements.

1. CT category: The software categorizes the CT exam based on anatomic area (determined by the procedure (CPT®) codes on the exam claims data) and clinical indication (based on the diagnosis (ICD-10-CM) codes associated with the exam order).
2. Size-adjusted radiation dose: The software calculates patient size from image pixel data and receives radiation dose from the Radiation Dose Structured Report (RDSR). The software uses these variables to perform risk adjustment of radiation dose based on patient size. The output of this process is size-adjusted radiation dose.
3. Global noise: The software measures noise in pixel data on CT images. Noise varies by slice thickness, with thinner image slices having higher noise; thus, global noise is adjusted by slice thickness.

6. The eCQM receives all data elements.

7. The eCQM removes denominator exclusions (simultaneous CT exams of multiple body regions outside of four commonly encountered multiple region groupings).

8. For each individual CT exam, the eCQM compares size-adjusted radiation dose and global noise against allowable thresholds specific to the CT category. Exams exceeding dose or noise thresholds are considered failures (out-of-range).

9. The eCQM scores each CT exam in range (pass) or out-of-range (fail). The sum of all out-of-range exams constitutes the numerator for the measure at the patient or population level.

10. An overall measure score (i.e. proportion of CT exams that are out-of-range relative to all evaluated exams) is calculated and can be queried/aggregated at the level of the individual clinician.

For sites that wish to use existing EHR vendors for eCQM computation and submission, primary data elements are sent via the edge device or downloaded via the web interface for ingestion and storage by site EHRs either as a FHIR observation resource, or if FHIR is unavailable, through an integration with an EHR via API.

The measure score can be reported to CMS by the existing EHR vendor, or if preferred, the measure steward is also able to compute and submit measure results to CMS on behalf of sites. Either way, reporting will follow established CMS implementation guidelines.

Feedback will be provided to the individual clinician on the proportion of scans that are out-of-range and the reason these scans are out-of-range to encourage performance improvement.

[Response Ends]

sp.25. If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

[Response Begins]
The measure is not based on a sample.
[Response Ends]

sp.28. Select only the data sources for which the measure is specified.

[Response Begins]
Electronic Health Data
Electronic Health Records
[Response Ends]

sp.29. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]
The measure derives standardized data elements from structured fields within the EHR and the radiology electronic clinical data systems including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). Primary imaging data stored in structured fields in the radiology electronic clinical data systems have been historically inaccessible using the existing eCQM framework. Thus, the eCQM cannot consume CT images and Radiation Dose Structured Reports (RDSR, which contain the radiation dose) in their original DICOM formats. These primary data, listed below, must be processed to create "calculated" data elements that can then be ingested by the eCQM. The measure developers have created software (available to all users to install locally by agreement, or made accessible through a web interface) to access and process primary data elements from these electronic systems to calculate variables that the eCQM uses to calculate the measure score.

The following primary data elements, their sources, and how they are used in the measure, are illustrated in Table sp-2 below. The steps for how these data elements are accessed, ingested, and processed by the eCQM are described in sp.22.

1. Diagnostic Study, Performed: Categorized CT Exams. All diagnostic CT exams performed during the measurement period, including the type of exam performed (derived from procedure (CPT®) codes associated with the exam bill) and the reason for study (derived from diagnosis (ICD-10-CM) codes associated with the exam order and with the exam bill). A validated algorithm uses combinations of diagnosis and procedure codes to generate the ***CT Dose and Image Quality Category*** ("CT category") that specifies the radiation dose and image quality thresholds for each CT exam. (CPT Copyright 2017 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.)

2. Diagnostic Study, performed: CT Studies with Radiation Dose Result. Radiation dose is derived from the Radiation Dose Structured Report (RDSR), a DICOM structured element generated by the CT machine for every exam, giving the total radiation dose delivered by the exam (measured as dose length product, mGy-cm). This is used to generate ***Calculated CT***

Size-Adjusted Dose (“size-adjusted radiation dose”).

3. Diagnostic Study, performed: CT Studies with Image Quality Result. CT image pixel data are generated by the CT machine for every CT exam and stored as DICOM structured data. They are used to measure patient size (measured as diameter on mid-scan axial or coronal images, in mm), which is used in generating the final data element ***Calculated CT Size-Adjusted Dose***. They are also used to generate the final data element ***Calculated CT Global Noise*** (“global noise,” measured in Hounsfield units).

4. Birth date, to confirm the patient is 18 years of age or older.

5. Supplemental data elements: payer, race, ethnicity, and sex.

Table sp-2. Primary data elements are accessed and combined to generate final data elements. “Radiology Electronic Clinical Data Systems” are the core information systems for data storage and practice management that are nearly universal in radiology practices, including the Picture Archiving and Communication System (PACS) and Radiology Information System (RIS).

Data source	Primary Accessed Data Element	Primary Accessed Data Element Code System	Calculated Data Element	Calculated Data Element Code System	Calculated Data Element Description
Electronic Health Record (EHR), or Radiology Electronic Clinical Data Systems (non-EHR)	Diagnostic Study, performed: CT Studies	ICD-10-CM CPT®	CT Dose and Image Quality Category	LOINC	Reflects the type of exam performed based on body region and clinical indication. Each CT category has a specific set of dose and image quality thresholds.
Radiology Electronic Clinical Data Systems (non-EHR)	Diagnostic Study Performed: CT Studies *Result attribute: Radiation Dose Structured Report (RDSR)* Diagnostic Study Performed: CT Studies *Result attribute: Image Pixel Data*	DICOM	Calculated CT Size-Adjusted Dose	LOINC	Reflects the total radiation dose received during CT, risk-adjusted by patient size. The size-adjusted radiation dose thresholds vary by the CT category.
Radiology Electronic Clinical Data Systems (non-EHR)	Diagnostic Study Performed: CT Studies *Result attribute: Image Pixel Data*	DICOM	Calculated CT Global Noise	LOINC	Reflects the image quality (represented by global noise) of the CT. The global noise thresholds vary by the CT category. The measure adjusts global noise measurement by slice thickness.
Electronic Health Record (EHR)	Birth Date	LOINC	Birth Date	LOINC	MM-DD-YYYY, to confirm the patient is eligible

[Response Ends]

sp.30. Provide the data collection instrument.

[Response Begins]
No data collection instrument provided
[Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact NQF staff with any questions. Check for resources at the Submitting Standards webpage.
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the 2021 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.
2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.
2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.
2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;
AND
If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).
2b3. For outcome measures and other measures when indicated (e.g., resource use):
- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration
OR
rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;
OR
there is evidence of overall less-than-optimal performance.
2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.
2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.
2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:
2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and
2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.
(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions
Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).
Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.
Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.
Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.
Risk factors that influence outcomes should not be specified as exclusions.
With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v.$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Scientific Acceptability sections. For example:

2021 Submission:
Updated testing information here.

2018 Submission:
Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]
Electronic Health Data
Electronic Health Records
[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins]
N/A - an existing dataset was not used
[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]
02-01-2020 - 04-15-2021
[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]
Clinician: Individual
[Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]
Data were collected from each of the organizations and testing sites for approximately 4 weeks. Table 2a-1 provides data for the 606 individual clinicians. The clinicians practice within 7 health systems and 1 vertically integrated organization, and within a total of 16 hospitals. Four of the included health systems (8 included hospitals) are members of America's Essential Hospitals, an association representing 300 hospitals that care for the nation's vulnerable and provide vital

services to communities, including caring for many patients with Medicaid. These organizations are noted as “safety net” in Table 2a-1.

Table 2a-1. Organizations and individual clinicians that contributed field-testing data. Annual inpatient, outpatient, and annual emergency department visit volumes are reported for the organization from the most recent year of available data (2018-2020), and annual average number of CT exams are estimated based on 4 week testing.

EHR	Location	Source of Data	Number of Physicians Providing Testing Data	Average Annual CT Scans Interpreted Per Physician (Standard Deviation)	Urban/suburban/rural/safety net
Cerner	Huntsville, AL	Health system, reflecting multiple inpatient and outpatient imaging locations	60	1212 (1236)	Urban, suburban, rural
Epic	Sacramento, CA	Health system, reflecting multiple inpatient and outpatient imaging locations	49	768 (828)	Urban, suburban, rural, safety net
Epic	Irvine, CA	Health system, reflecting multiple inpatient and outpatient imaging locations	37	864 (768)	Urban, suburban, rural, safety net
Epic	San Diego, CA	Health system, reflecting multiple inpatient and outpatient imaging locations	53	540 (480)	Urban, suburban, rural, safety net
Epic	Detroit, MI	Health system, reflecting multiple inpatient and outpatient imaging locations	114	588 (576)	Urban, suburban, rural, safety net
Allscripts	Greater NYC, NY	Health system, reflecting multiple inpatient and outpatient imaging locations	107	744 (744)	Urban, suburban

EHR	Location	Source of Data	Number of Physicians Providing Testing Data	Average Annual CT Scans Interpreted Per Physician (Standard Deviation)	Urban/suburban/rural/safety net
Epic	New York, NY	Health system, reflecting multiple inpatient and outpatient imaging locations	77	2196 (1992)	Urban, suburban
Meditech	Austin, TX	Ambulatory diagnostic imaging centers, part of a vertically integrated organization	109	828 (600)	Urban, suburban, rural

References

American's Safety Net Hospitals, https://essentialhospitals.org/americas-essential-hospitals/, accessed August 1, 2021.

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Consecutive CT scans were assembled from contributing testing sites for approximately 4 weeks without sampling. The distribution of CT scan by age and sex are shown in Table 2a-2 below. Each cell shows the proportion of CTs by sex and within each age strata, for the 25th, 50th, and 75th percentiles of individual clinicians. Data were not collected in adults ages 90 and older related to Institutional Review Board requirements. Race was not collected. All diagnoses that are associated with CT imaging are included and this includes most medical diagnostic groups.

Table 2a-2. Distribution of age and sex per percentile of individual clinicians, in field-testing data.

Percentile	CT Exams	Sex: Female	Sex: Male	Age: 18-20	Age: 21-30	Age: 31-40	Age: 41-50	Age: 51-60	Age: 61-70	Age: 71-80	Age: 80-89
25th Percentile	16	0.48	0.41	0.00	0.00	0.04	0.07	0.13	0.17	0.12	0.03
Median	51	0.53	0.47	0.00	0.05	0.08	0.11	0.18	0.22	0.17	0.10
75th Percentile	104.75	0.59	0.52	0.02	0.08	0.12	0.15	0.23	0.28	0.22	0.14

[Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins]
Data element validity

- CT category, size-adjusted radiation dose, and global noise were each validated on 47,635 CT exams from field-testing data.
- Global noise was validated using 740 exams from the Image Quality Study

Measure score reliability was tested at the individual clinician level and included 606 individual clinicians.

Measure score validity was tested on a random sample of 8,000 CT exams (1,000 CT exams sampled per testing site).

Risk adjustment testing (including correlation between patient size and dose) was conducted using data on 6.5 million adult CT exams from the UCSF International CT Dose Registry.

Exclusions testing was completed on 53,044 exams from field-testing data, including 47,635 included in study, 3,585 technical exclusions ("missing data"), and 1,824 excluded as "uncommon multiple anatomic regions."

[Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins]
Social factors do not fit into the logic model described above, and are not known to affect radiation dose, because technical decisions on how to perform CT are made at the facility level rather than at the individual patient level. Given that this measure is an eCQM, no patient-reported data were collected. Therefore, social risk factors were not available and not analyzed.

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.07 check patient or encounter-level data; in 2a.08 enter "see validity testing section of data elements"; and enter "N/A" for 2a.09 and 2a.10.
[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.07 check patient or encounter-level data; in 2a.08 enter "see validity testing section of data elements"; and enter "N/A" for 2a.09 and 2a.10.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.
[Response Begins]
Accountable Entity Level (e.g., signal-to-noise analysis)
[Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins]
We estimated measure score reliability at the accountable entity 0.99 level using the intraclass correlation coefficient (ICC), a reliability coefficient that conceptually represents the true (between-entity) variance in a measure divided by the sum of true variance and error (within-entity) variance. We used randomly split samples for each accountable entity with 1,000 repetitions, applying a one-way random effects model, assuming that both entity effects and residual effects are random, independent, and normally distributed with mean 0. This approach corresponds to Case 1 or the ICC(1) in McGraw and Wong's seminal description of ICC reliability methods (McGraw 1996). The Spearman-Brown prophecy formula was applied, in the usual manner, to adjust reliability from one-month test samples to the anticipated 12-month sample (i.e., (12*r)/(1 + (11*r)). (Frey 2018)

These ICC(1) estimates (bounded between 0 and 1) were then logit-transformed and used to model the linear relationship between entity volume and logit reliability. By ranking predicted reliabilities across the complete range of potential volumes, we estimated the volume threshold that would correspond to ICC(1)=0.9 for an accountable entity.

ICC(1) is abbreviated by ICC in the results below.

At the individual clinician level, clinicians who read only 1 CT exam during the testing month (equivalent to 12 in a year) were excluded from reliability analysis because split half sampling was impossible.

References

McGraw KO, Wong S. (1996). Forming inferences about some intraclass correlation coefficients. Psychological Methods, 1(1), 30–46.

Spearman-Brown Prophecy Formula. In: Frey B, eds. The SAGE Encyclopedia of Educational Research, Measurement, and Evaluation. Vol. 4. Thousand Oaks, CA: SAGE Publications, Inc.; 2018. Available at: https://methods.sagepub.com/reference/the-sage-encyclopedia-of-educational-research-measurement-and-evaluation/i19400.xml
[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, NQF Measure Evaluation Criteria).

[Response Begins]
The estimated mean split-half ICC using 47,635 CT exams collected from 606 individual clinicians was 0.99 (after exclusion of clinicians who read only 1 scan in the test month, and Spearman-Brown adjustment to a 12-month data collection period). The number of exams per clinician in the one month of data used for testing ranged from 1 to 604 (mean=77); predicted reliability for 12 months exceeded 0.90 for 89% of participating clinicians.

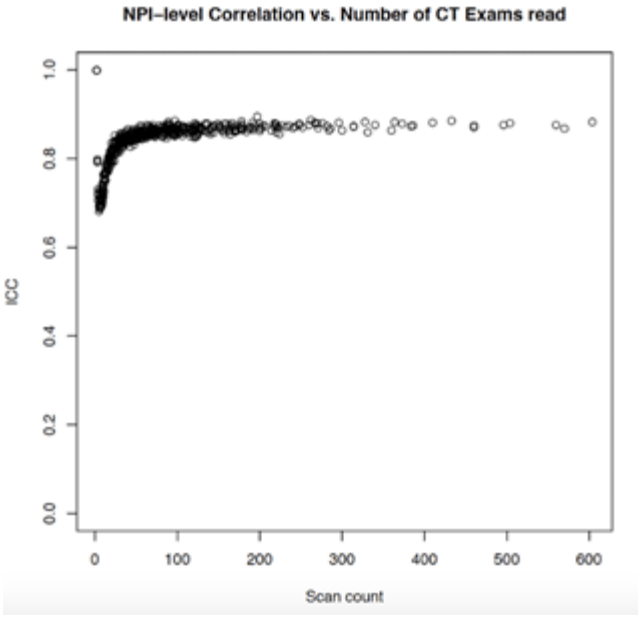

Figure 2a-1. Split sample correlation for each participating clinician as a function of their sample size (i.e., the number of CT scans reported during the 1-month testing period). These correlations are not adjusted to a full 12-month reporting period, so they are lower than the reliabilities reported above.

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]
According to the scale developed by Koo and Li, an ICC estimate between 0.75-0.90 may be interpreted as good reliability, and an ICC estimate greater than 0.90 may be interpreted as excellent reliability (Koo 2016). Based on the mean ICC of 0.99, after Spearman-Brown adjustment to a 12-month reporting period (after excluding the 5% of clinicians who only read 1 CT scan during the testing period) the measure is reliable at the individual clinician level. Only 8% of individual clinicians in our field-testing would not meet the minimum denominator to achieve ICC > 0.90.

Reference

Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med. 2016 Jun;15(2):155-63. Epub 2016 Mar 31. Erratum in: J Chiropr Med. 2017 Dec;16(4):346.
[Response Ends]

Validity Testing

2b.01. Select the level of validity testing that was conducted.

[Response Begins]
Patient or Encounter-Level (data element validity must address ALL critical data elements)
Accountable Entity Level (e.g. hospitals, clinicians)
Empirical validity testing
Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)
[Response Ends]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]
Patient/encounter-level (data element) validity

CT category: The measure uses an algorithm to assign each CT exam to one of 18 CT categories based on the diagnosis associated with the exam order (codified in ICD-10-CM codes) and procedure performed (codified in CPT® codes). We used criterion validity to compare agreement between the CT category assigned using this method versus a gold standard method based on expert review of the complete medical record (including notes from the visit when the exam was ordered, information provided as free text with the test order, and information included in the final, dictated radiology report) for a sample of CT exams from UCSF Health System (alpha testing).

For field-testing (beta testing), we did not have access to complete medical records, so we developed a second referent standard that determines CT category based on natural language processing of DICOM elements in the CT imaging data, including the reason for study, protocol name, study description, and the full radiology report including history, imaging findings, and diagnosis. This second referent standard was compared to the gold standard medical record review in the same sample of UCSF Health System CT exams and found to be accurate (sensitivity = 0.92, specificity = 0.97).

Patient size: Methods for measuring patient diameter on CT images have been previously validated including measuring patient size on axial images (Cheng 2013) and on coronal images (Christianson 2012). We relied on this published work and tested how often this method generated clinically plausible and non-missing values for size in testing data.

Radiation Dose: The measure uses dose length product (DLP), which gives the total radiation imparted to the patient by the CT machine. This is a standardized data element, generated by virtually (>99%) all CT machines, is well validated and used broadly to reflect the radiation dose delivered to the patient. (Kanal 2017, Smith-Bindman 2019.) Further, DLP is currently used in benchmarking in the U.S. and internationally (ACR–AAPM–SPR: Practice parameter, European Commission, Radiation Protection No. 185, ICRP Publication135). The proposed measure adjusted DLP for patient size to ensure that differences in patient mix would not result in differences in measure scores across reporting entities. While there are other dose metrics used in some settings to measure radiation dose (such as size-specific dose estimate (SSDE) or effective dose), these are not suitable for a reliable quality measurement because they are not universally or automatically generated by the CT machine, do not reflect the total dose absorbed by the patient (the most clinically relevant measure), and would not adequately remove differences in measure score that are the result of patient case mix. We relied on this published work and tested how often this method generated clinically plausible and non-missing values for radiation dose in testing data.

Size-Adjusted Radiation Dose: We describe the validation of our method to risk-adjust radiation dose based on patient size in section 2b.26. In summary, when out-of-range rates are unadjusted for patient size, we observe failure rates that are strongly associated with size, with almost all failures occurring in larger patients. When failure rates are adjusted for size, there is no association. Using field testing data, we assessed whether we could calculate size-adjusted radiation dose within a plausible range and quantified missing data.

Global noise: The approach we used for measuring global noise in CT images was an adaptation of previously validated approaches. (Christianson 2017, Malkus 2017) These adaptations were motivated by the need to generate a summary value for global noise for the CT exam in exams with multiple scans, and to adjust for slice thickness, each validated in the Image Quality Study (described below). We also reviewed the literature for association between noise calculations in DICOM data and phantom measurements of noise and human readers' assessment of image quality. Next, using field-testing data, we assessed whether we could calculate global noise within a plausible range and quantified missing data.

We also calculated the correlation between global noise and physician dissatisfaction with image quality, a valid metric of quality as described and explained below, using data from the Image Quality Study (described below). Lastly, we explored the rate of physician dissatisfaction in CT exams that exceeded global noise thresholds. Dissatisfaction is defined as a physician rating CT image quality as "poor" or "marginally acceptable."

Thresholds for "out-of-range" values to define numerator: We used radiologists' satisfaction with CT images as a basis for establishing the maximum radiation dose and minimum image quality thresholds for each CT category. In clinical practice, radiologists are responsible for ensuring the images they interpret are of acceptable quality to allow them to make accurate diagnoses. If they are not satisfied with the image quality, they must ask that the exam be repeated.

Early in development of the proposed measure, we conducted an Image Quality Study to understand the relationship between radiation dose, global noise, and physician satisfaction. We first compiled a test set of 740 CT exams covering a wide range of anatomic areas and clinical indications. The test cases were sampled from the UCSF International CT Dose Registry and were selected from across the CT categories, and within each CT category, images were obtained across the entire observed dose distribution with over sampling of images at the low dose range where we suspected any issues with image quality would occur. CTs were selected from diverse organizations. 125 radiologists from diverse practice settings each graded 200 exams, resulting in 25,000 interpretations used to determine the thresholds for radiation dose and global noise. For each exam, the radiologist reader was asked to characterize the image quality on a four-point scale:

- **Excellent**: the images provide the needed information
- **Adequate**: the images are acceptable but not excellent; you would re-scan and change the parameters for a higher quality if it were easy to repeat, but if not, this is good enough
- **Marginally acceptable**: image quality is less than ideal and may compromise diagnostic quality; if the patient cannot easily be re-scanned you will interpret this, but would change parameters for future scans of this type
- **Poor**: image quality is not adequate for diagnosis and the scan should be repeated

Overall, 49% of exams were rated excellent, 40% adequate, 8% marginally acceptable, and 3% poor for clinical interpretation. Exams rated as excellent or adequate were considered of acceptable quality, and exams rated as either marginally acceptable or poor were considered unacceptable (to set generous thresholds favoring better image quality).

We used the radiologists' interpretations to set the thresholds for size-adjusted radiation dose and global noise. The maximum size-adjusted radiation dose threshold was set at the dose level within each CT category where 90% or more of radiologists graded the exam as acceptable quality (excellent or adequate). Doses above this level expose patients to harm without increasing image quality, as 90% of radiologists are already satisfied with the image quality. If a CT category had no observed threshold because radiologists were satisfied at every dose level, we used the median dose from the UCSF International CT Dose Registry as the threshold. This decision to use the median was based on extensive discussion with the Technical Expert Panel.

The minimum floor for image quality was set at the level where 25% or more of radiologists graded the exam as unacceptable (marginally acceptable or poor). Image quality at or below this level is considered inadequate. This threshold was discussed and agreed upon by the Technical Expert Panel, with the general view that, as images may be sent to many different radiologists to interpret within large practices, at least 75% should feel comfortable interpreting images with the quality level that is within range in this measure. If 25% or more of radiologists are uncomfortable with the quality of images, than the exam should be graded as unacceptable. Image quality is measured using global noise (Makkus 2017, Christiansen 2015) adjusted by slice thickness (Alshipli 2017), where higher global noise generally reflects

worse quality. If a CT category had no observed noise threshold, we set the threshold based on the literature or based on closely related categories. (For example, the CT category cardiac low dose had no observed threshold; thus we used the observed threshold from the chest low dose category, which was observed). The approach to setting thresholds was influenced and strongly supported by our Technical Expert Panel.

Empirical validity testing: Gold standard comparison

Lastly, we validated the eCQM output (encounter-level validity) against medical record review using field testing data collected from electronic clinical data systems from 8 health systems/vertically integrated organizations. The "medical record review" is a human-reviewed indicator of whether the size-adjusted radiation dose or global noise of each sampled exam exceeds predetermined thresholds, thus constituting a “gold standard.”

Accountable entity-level (measure score) validity

Systematic assessment of face validity of measure score as an indicator of quality

We assessed measure score face validity through a 6-question poll to the Technical Expert Panel (TEP) assembled for the creation of this measure, administered by Co-Investigator Dr. Patrick Romano. The TEP represents a diverse group of clinicians (N=10), patient advocates (N=2), and leaders of medical specialty societies, payers, and healthcare safety and accrediting organizations. TEP members were identified by reaching out to key stakeholder organizations and advocates and identifying researchers who had contributed to the relevant literature.

The 6-question poll included the following face validity questions:

1. Do you agree that radiation dose is a relevant metric of quality for CT imaging? (to assess face validity of that data element)

2. Do you agree that image noise is a relevant metric of quality for CT imaging? (to assess face validity of that data element)

- We clarified during polling that this question was not assessing noise as a standalone metric, but as part of a balancing measure of radiation dose and noise.

3. Do you agree that size is an appropriate method for adjusting for radiation dose for a given indication? (to assess face validity of the risk-adjustment approach)

4. Do you agree that performance on this measure of radiation dose and image quality, adjusted for size, stratified by indication, is a representation of quality? (to assess face validity of the measure score)

5. How likely is it that implementation of this size-adjusted and stratified measure, as specified by the UC development team, in the Merit-based Incentive Payment System (MIPS), will lead to a reduction in average CT radiation dose while maintaining adequate CT image quality? (to assess anticipated usability and feasibility)

6. How likely is it that implementation of this size-adjusted and stratified measure, as specified by the UC development team, in the MIPS and hospital quality reporting programs (inpatient/outpatient), will lead to a reduction in average CT radiation dose while maintaining adequate CT image quality? (to assess anticipated usability and feasibility)

Technical Expert Panel members include:

- Mythreyi Bhargavan Chatfield, PhD, Executive Vice President, American College of Radiology
- Niall Brennan, MPP, CEO, Health Care Cost Institute

- Helen Burstin, MD, MPH, FACP, Executive Vice President, Council of Medical Specialty Societies
- Melissa Danforth, Vice President of Health Care Ratings, The Leapfrog Group
- Tricia Elliot, MBA, CPHQ, Director, Quality Measurement, Joint Commission
- Jeph Herrin, PhD, Adjunct Assistant Professor, Yale University
- Hedvig Hricak, MD, PhD, Radiology Chair, Memorial Sloan Kettering Cancer Center
- Jay Leonard Lichtenfeld, MD, MACP, Independent Consultant, Formerly Deputy Chief Medical Officer American Cancer Society, Inc.
- Leelakrishna Nallamshetty, MD, Associate Chief Medical Officer, Radiology Partners
- Matthew Nielsen, MD, MS, Professor and Chair of Urology, UNC Gillings School of Global Public Health
- Debra Ritzwoller, PhD, Patient Advocate and Health Economist (Patient Representative)
- Lewis Sandy, MD, Executive Vice President, Clinical Advancement, UnitedHealth Group
- Mary Suzanne Schrandt, JD, Patient Advocate (Patient Representative)
- James Anthony Seibert, PhD, Professor, University of California, Davis
- Arjun Venkatesh, MD, MBA, MHS, Associate Professor, Emergency Medicine, Yale School of Medicine
- Todd Villines, MD, FSCCT, Professor and Director of Cardiovascular Research and Cardiac CT Programs, University of Virginia
- Kenneth Wang, MD, PhD, Adjunct Assistant Professor, Radiology, University of Maryland, Baltimore

References

ACR–AAPM–SPR: Practice parameter for diagnostic reference levels and achievable doses in medical x-ray imaging. Revised 2018.

Cheng PM. Automated estimation of abdominal effective diameter for body size normalization of CT dose. J Digit Imaging. 2013 Jun;26(3):406-11.

Christianson O, Li X, Frush D, Samei E. Automated size-specific CT dose monitoring program: assessing variability in CT dose. Med Phys. 2012 Nov;39(11):7131-9.

Christianson O, Winslow J, Frush DP, Samei E. Automated Technique to Measure Noise in Clinical CT Examinations. AJR Am J Roentgenol. 2015 Jul;205(1):W93-9.

European Commission, Radiation Protection No. 185, European guidelines on diagnostic reference levels for paediatric imaging. 2018.

ICRP, 2017. Diagnostic reference levels in medical imaging. ICRP Publication 135. Ann. ICRP 46(1).

Kanal KM, Butler PF, Sengupta D, Bhargavan-Chatfield M, Coombs LP, Morin RL. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology. 2017;284(1):120-133.

Malkus A, Szczykutowicz TP. A method to extract image noise level from patient images in CT. Med Phys. 2017 Jun;44(6):2173-2184. doi: 10.1002/mp.12240. Epub 2017 Apr 25.

Alshipli M and Kabir NA 2017 J. Phys.: Conf. Ser. 851 012005.

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]
Patient/encounter-level (data element) validity

CT category: In alpha testing, we validated our method of assigning CT category based on diagnosis and procedure codes against a gold standard. The results, weighted by the distribution of CT categories in the UCSF International CT Dose Registry, were: sensitivity = 0.86 and specificity = 0.96 (n=978 CT exams).

When tested across the 606 individual clinicians, the correct classification rate of the assignment of CT exams to CT category in field-testing was 95% on average. About 90% of tested individual clinicians had a correct classification rate of 80% or above. Most of the individual clinicians with correct classification rates below 80% had very low sample sizes from the 1 month testing period (i.e., 5.1% read only 1 CT scan).

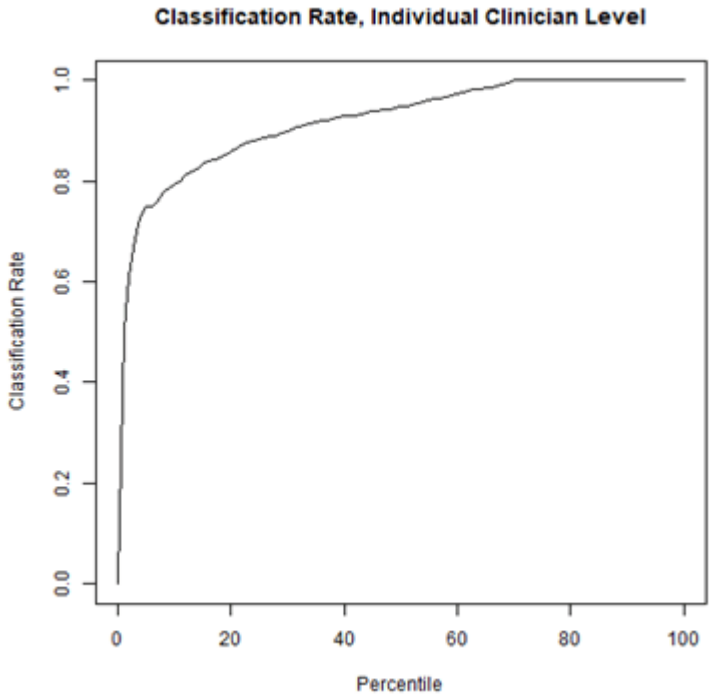

Figure 2b-1. Deciles of correct classification rate, individual clinician level.

Size-Adjusted Radiation Dose: In field testing data, size-adjusted radiation dose could be calculated and was within plausible range for 99% of CT exams and was missing for 0.4% of exams.

Global Noise: Global noise measurements based on DICOM data are highly predictive of phantom measurements of noise and human readers' assessment of image quality (Christianson 2015.) Global noise could be calculated and was within a plausible range for 100% of CT exams in field-testing. Global noise was missing for 0.01% of examinations.

The correlation between noise and physician dissatisfaction with image quality is 0.37 overall based on the image quality study (n=727 CT exams).

Based on the field-testing data, there were few exams which exceeded the global noise thresholds. There were 4 CT categories with exams in which global noise exceeded the allowable threshold; average physician dissatisfaction rates for exams below and above thresholds for those CT categories are shown in the table below. For other CT categories, exams were not observed above the threshold.

Table 2b-1. Dissatisfaction rates for CT exams below and above the global noise threshold, and the proportion of exams above threshold, for CT categories with exams in which global noise exceeded allowable thresholds.

CT Category	Dissatisfaction rate for exams below noise threshold	Dissatisfaction rate for exams above noise threshold	Proportion of exams above noise threshold
Chest Low Dose	0.20	0.47	0.05
Chest Routine Dose	0.11	0.28	0.03
Cardiac High Dose or Chest High Dose	0.11	0.35	0.03
Thoracic or Lumbar Spine	0.13	0.40	0.07

Empirical Validity Testing: Gold standard comparison

The results of the medical record review were compared with the results of the eCQM computation by selecting a sample of exams (N=8,000) representative of exams generated by the 606 individual clinicians across the 8 health systems/vertically integrated organizations. The out-of-range results (measure score) from the medical record review and the eCQM computation were identical with no discrepancies between the two approaches, indicating a correct and robust implementation of the measure logic.

Accountable entity-level (measure score) validity

Systematic assessment of face validity of measure score as an indicator of quality

No TEP members abstained from voting. The results were as follows:

1. Do you agree that radiation dose is a relevant metric of quality for CT imaging?
    - 100% agreement

2. Do you agree that image noise is a relevant metric of quality for CT imaging?
    - 100% agreement

3. Do you agree that size is an appropriate method for adjusting for radiation dose for a given indication?
    - 100% agreement

4. Do you agree that performance on this measure of radiation dose and image quality, adjusted for size, stratified by indication, is a representation of quality?
    - **100% agreement**

5. How likely is it that implementation of this size-adjusted and stratified measure, as specified by the UC development team, in the Merit-based Incentive Payment System (MIPS), will lead to a reduction in average CT radiation dose while maintaining adequate CT image quality?
    - 16/17 members (94%) voted in favor: 5 voted “very likely,” and 11 voted “somewhat likely.” Some comments included:
        - “This measure has sufficient rationale and methodology behind it to very likely achieve the goals stated.”
        - “The quality gap is significant, and if included in the MIPS program it will give a number of interested parties the mechanism to not only publicize the issue, but to monitor progress and share progress publicly.”
        - “Physicians and practices will likely want to respond to feedback from the measure, and it will likely be relatively straightforward to do so.”

    - "The measure as described addresses a performance gap, and [as an eCQM] remove the undue burden on individual physicians."
    - "My expectation would be that this measure linked to the MIPS would drive changes in practice, so dose reduction seems likely. However, there are too many unknowns to expect this with certainty."
- 1 member (6%) voted "somewhat unlikely." This member was concerned that the measure output (an aggregated out-of-range score) on its own does not indicate what corrective action needs to be taken by the clinician group to improve performance. She acknowledged the feedback delivered by the edge device software may address this perceived gap.

6. How likely is it that implementation of this size-adjusted and stratified measure, as specified by the UC development team, in the MIPS and hospital quality reporting programs (inpatient/outpatient), will lead to a reduction in average CT radiation dose while maintaining adequate CT image quality?

- 16/17 members (94%) voted in favor: 10 voted "very likely," and 6 voted "somewhat likely."
- 1 member (6%) voted "somewhat unlikely." This member expressed the same concerns as noted above in question 5.

[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]
Patient/encounter-level (data element) validity

The measure algorithm assigns CT category with 95% accuracy when compared to a validated referent standard.

Size-adjusted radiation dose and global noise have face validity as metrics of quality, as assessed by our Technical Expert Panel, and could be calculated with plausible ranges for virtually all exams in field-testing. Moderate correlation between global noise and physician dissatisfaction with the quality of CT images, another valid quality indicator, supports global noise as a proxy measurement of image quality. And for CT categories where there were exams exceeding global noise thresholds, physician dissatisfaction for those out-of-range exams was considerable (28-47%).

The eCQM computed identical results for a sample of 8,000 CT exams, compared to medical record review.

Accountable entity-level (measure score) validity

100% of our Technical Expert Panel supported the face validity of the measure score, agreeing unanimously that *"performance on this measure of radiation dose and image quality, adjusted for size, stratified by indication, is a representation of quality."*

These results provide evidence that the measure as specified is a valid representation of quality, and the measure score accurately differentiates good performance from poor performance.
[Response Ends]

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

We consider it clinically meaningful to be able to detect entities whose prevalence of "out-of-range" exams (either by size-adjusted dose or by noise) is at least 5 percentage points above or below the average national performance. For testing purposes, this threshold refers to out-of-range prevalence values above 38% or below 28%.

To compute the minimal sample size necessary to be able to detect such out-of-range prevalence with 0.8 power, 0.05 level of significance, we use the equations

$$0.8 = Pr[Z < z_{0.025}\text{-}H(0.33,0.38) * sqrt(N_{high})]$$
$$0.8 = Pr[Z > z_{0.025}\text{-}H(0.33,0.28) * sqrt(N_{low})]$$

Where Z is a normally distributed random variable, $z_{0.025}$ is the 2.5^{th} percentile of a normally-distributed random variable, N_{high} is the minimal required sample size to detect an out-of-range rate of 38%, N_{low} is the minimal required sample size to detect an out-of-range rate of 28%, and

$$H(x,y)=2 * \arcsin(\sqrt{x}) - 2 * \arcsin(\sqrt{y})$$

We then compared these estimated values of N_{high} and N_{low} against the observed distribution of entity-specific volumes in our test data, adjusted to a 12-month reporting period.

Finally, we empirically estimated the distribution of measure scores across the entities that participated in pilot testing, and assessed the statistical significance of their observed values, relative to the national average prevalence of "out-of-range" exams (33%).

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]
At the individual clinician level, only 52% of participating clinicians would meet the threshold to detect an "out-of-range" prevalence 5 percentage points above the mean (i.e., 38%). Only 54% of participating clinicians would meet the threshold to detect an "out-of-range" prevalence 5 percentage points below the mean (i.e., 28%).

To resolve this problem: (1) we encourage measure users to accept the ability to detect only larger deviations in performance; and (2) to set a minimum volume threshold for reporting purposes. For example, a minimum annual volume of 145 CT scans (for reporting purposes) would provide 80% power to detect an "out-of-range" threshold either 10 percentage points above or below the mean (i.e., 23% or 43%) while excluding only 22% of participating clinicians, based on our test data. This proposed threshold would exclude only 1.4% of CT exams from measure reporting, because the excluded clinicians have lower volumes than the national average (e.g., they may be specialized in other areas of radiology such as ultrasound or MRI.

The empirically observed distribution of measure scores from our test data (reflecting only one month of data) is shown in Table 2b-2 below. At the individual clinician level (n=606), we were able to identify 107 clinicians with significantly better than average performance, based on the 95% confidence intervals surrounding the estimated values. These clinicians had a mean "out-of-range" prevalence of 17%, with an interquartile range of 13-21% and a 95^{th} percentile prevalence of 24%. We were able to identify 85 clinicians with significantly worse than average performance; these clinicians had a mean "out-of-range" prevalence of 56%, with an interquartile range of 46-63% and a 5^{th} percentile of 41%. The average width of individual clinician confidence intervals is 33%.

Table 2b-2: Comparative summary of measure score values between clinicians whose confidence interval lies entirely above 33% (positive deviation detected), contains 33% (undetected deviation), and lies entirely below 33% (negative deviation detected). The average width of these confidence intervals is 33 percentage points.

*	Number of Clinicians	Mean Proportion Out-of-Range	5% Percentile	25% Percentile	50% Percentile	75% Percentile	95% Percentile
Worst Performance = Positive Deviation Detected	85	0.56	0.41	0.46	0.53	0.63	0.75
Undetected Deviation	414	0.31	0.00	0.23	0.30	0.38	0.67
Improved Performance = Negative Deviation Detected	107	0.17	0.05	0.13	0.17	0.21	0.24

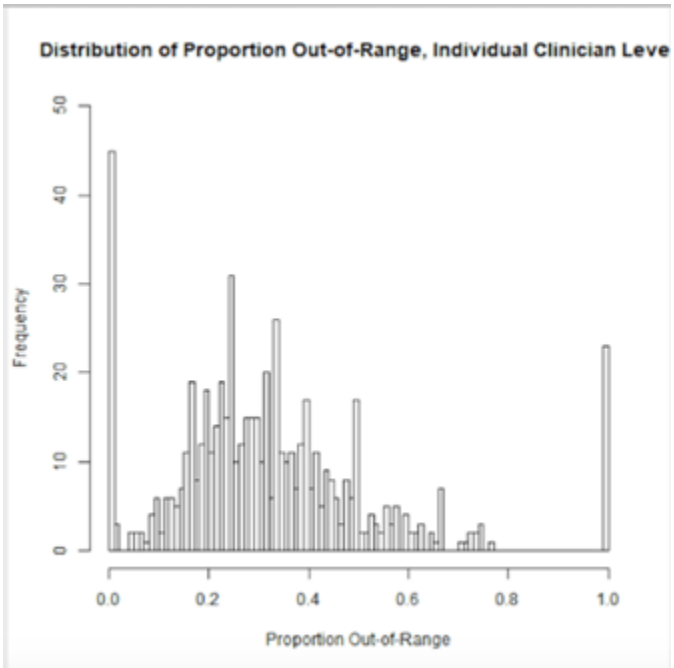

Figure 2b-2. Measure score distribution for clinicians overall.

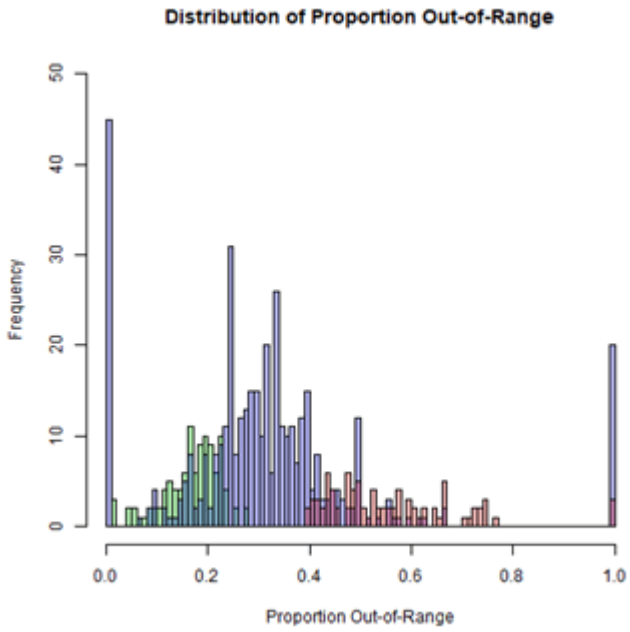

Figure 2b-3. Measure score distributions for clinicians overall, color-coded as follows: confidence interval lies above 33% (red); contains 33% (blue); and lies below 33% (green).

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]
As only one month of data were collected for testing purposes, 31 clinicians had a sample size of 1. Excepting those clinicians, the clinician-level summary table and figures in 2b.06 visually show some separation of distributions between those with detected deviation from the national average and those without detected deviation.

Variation in measure scores is much greater at the individual clinician level than at the clinician group or hospital level (SD=21% versus 9% and 9%, respectively). As a result, a minimum annual volume of 145 CT scans (for reporting purposes) is recommended to improve the ability to detect performance values either 10 percentage points above or below the mean (i.e., 23% or 43%) while excluding only 22% of participating clinicians, based on our test data.

Of the individual clinicians assessed, during one month of testing, 168 had an observed deviation from 33% out-of-range prevalence of less than 10 percentage points. Of the remaining 438 clinicians with detectable difference (meaning observed out-of-range prevalence below 23% or above 43%), only 141 (32%) had confidence intervals not containing 33%, meaning the majority of individual clinicians with deviant out-of-range prevalence values could not be reliably identified.
[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

Of exams submitted for testing, 3,585 were removed from analysis due to missing data (compared with 47,635 which had full data). Missing data can come in one of the following forms:

1. Missing radiation dose (due to missing Radiation Dose Structured Report, RDSR)
2. Missing patient diameter (failure of diameter calculation algorithm)
3. Missing global noise (failure of noise calculation algorithm)

Exams can also be excluded if the patient's age is missing, though patient age was available for all exams in testing data.

To assess the potential impact of missing data on measure scores, we first estimated the percentage of CT scans with missing data at the accountable entity level and identified the extent to which missing data were concentrated at a small number of accountable entities.

Next, we compared the distributions of CT category and patient diameter between CT scans that would be excluded due to missing data (defined as any scan with missing radiation dose, missing patient diameter, or missing global noise) and CT scans that would be retained in the analysis ("non-missing data"). Due to the large sample size of our testing data, we expect even modest, clinically insignificant differences in these distributions to be statistically significant. Thus, rather than perform statistical testing, we focus on the clinical significance of: (1) differences in probability distribution of CT categories between missing and non-missing data; and (2) differences in patient diameter deciles between missing and non-missing data. If data are "missing at random," then the distributions of both CT category and patient diameter should be similar between the CT scans with missing data and those with non-missing dose data.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]
Of the 3,585 CT scans removed due to missing data, 93% were removed due to missing radiation dose and 7% were removed for other reasons. The tables below show missing data rates at the accountable entity level and compare the distributions of CT categories and patient diameters (size) between scans with missing data and scans with non-missing data.

Table 2b-3. Probability distributions of CT category among missing data group and among non-missing data group.

CT Category	Non-Missing Data	Missing Data
Abdomen and Pelvis Low Dose	2%	2%
Abdomen and Pelvis Routine Dose	22%	23%
Abdomen and Pelvis High Dose	5%	4%
Chest Low Dose	1%	1%
Chest Routine Dose	13%	12%
Cardiac Low Dose	3%	1%
Cardiac Routine Dose	9%	12%
Cardiac High Dose or Chest High Dose	0%	0%
Thoracic or Lumbar Spine	1%	1%
Simultaneous Thoracic and Lumbar Spine	0%	0%

CT Category	Non-Missing Data	Missing Data
Simultaneous Chest and Abdomen	10%	11%
Head Low Dose	3%	2%
Head Routine Dose	16%	15%
Head High Dose	0%	0%
Neck or Cervical Spine	3%	3%
Simultaneous Head and Neck Routine Dose	7%	8%
Simultaneous Head and Neck High Dose	0%	0%
Extremity	3%	3%

Table 2b-4. Deciles of patient diameter (in millimeters) of head exams (including CT categories Head Low Dose, Head Routine Dose, Head High Dose, Simultaneous Head and Neck Routine Dose, and Simultaneous Head and Neck High Dose) among missing data group and among non-missing data group. Values shown on patient effective diameter in millimeters.

Percentile	Non-Missing Data	Missing Data*
10%	131	128
20%	145	147
30%	154	155
40%	160	163
50%	166	169
60%	171	174
70%	176	177
80%	182	183
90%	195	193

*Exams with missing patient diameter were excluded from this specific analysis.

Table 2b-5. Deciles of patient diameter (in millimeters) of trunk exams (all exams not represented in the "head exams" table above) among missing data group and among non-missing data group. Values shown on patient effective diameter in millimeters.

Percentile	Non-Missing Data	Missing Data*
10%	190	203
20%	230	234
30%	250	255
40%	266	271
50%	281	285
60%	294	299
70%	309	314
80%	327	331
90%	353	356

*Exams with missing patient diameter were excluded from this specific analysis.

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]
Our results show that only 8% of CT scans from our test sites reported missing data, meaning that the impact of missing data on the measure overall is low. The majority of CT scans with missing data do not have radiation dose available, but do have CT category, global noise, and patient diameter available.

Most accountable entities had very little missing data, indicating that the problem of "missing data" is within the capacity of accountable entities to resolve. Therefore, the developer recommends that "missing data" rates should be tracked, and entities should be expected to reduce their "missing data" rates to zero over time. For example, the hospital with the highest missing radiation dose data (H6) came on board rather late in our testing period. Thus, unlike other sites, they did not have sufficient time to modify their CT machines to save the radiation dose structured report (RDSR), the digitized, structured summary providing the total radiation output during the CT exam. Many CT machines require such modification to save RDSRs; this is discussed elsewhere in this application. This site reported that if it had started earlier, they probably could have adjusted their systems and thus would have had less missing radiation dose data. Because our testing period was only one month in duration, there was insufficient time for all sites to modify their systems to save all RDSR (radiation dose) data.

Finally, assessment of the distributions of CT category and patient diameter among missing data shows that they are very similar to those in non-missing data, and thus missing data are very unlikely to bias results at the accountable entity level.
[Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]
No, there is only one set of specifications for this measure
[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins]
[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]
[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]
[Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]
Yes, the measure uses exclusions.
[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]
The only exams submitted subject to exclusion are exams scanning an "uncommon" combination of multiple body parts. "Common" combinations of body parts are sorted into one of the CT Dose and Image Quality Categories – for example, Simultaneous Chest and Abdomen, Simultaneous Thoracic and Lumbar Spine, Simultaneous Head and Neck Routine Dose, and Simultaneous Head and Neck High Dose. These uncommon combinations of multiple body parts are not part of the population of interest, and thus our measure has no mechanism for computing whether their radiation dose or global noise are out-of-range. The impact of these exclusions thus cannot be precisely calculated. We will, however, assess a range of possible impacts, comparing the performance score of each individual clinician in our testing data under three circumstances:

1. Performance score calculated as intended by our proposed measure.
2. Performance score if uncommon combinations of multiple body parts were hypothetically included, and they were all out-of-range.
3. Performance score if uncommon combinations of multiple body parts were hypothetically included, and none were out-of-range.

[Response Ends]

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]
Across the testing data, there are a total of 1,824 exams scanning uncommon combinations of multiple body parts, compared to 47,635 exams that were included for analysis.

Results at the individual clinician level are comparable to results at the clinician group and hospital levels. A median individual clinician will have a number of excluded exams equal to 4% of included exams (IQR 0-5%, 95th percentile 12%).

If all excluded exams were considered out-of-range, a median individual clinician will see an increase in out-of-range rate

of 0.9 percentage points (IQR 0-3.4, 95th percentile 8.0). If all excluded exams were considered not out-of-range, a median individual clinician will see a decrease in out-of-range rate of 0.3 percentage points (IQR 0-1.0, 95th percentile 3.5).
[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]
The choice to exclude uncommon combinations of multiple body parts is due to a lack of sufficient data that would allow us to construct a reasonable out-of-range threshold for such exams, resulting in their removal from the population of interest. The results of 2b.17 indicate that the prevalence of exclusions is small enough that their impact on performance scores is clinically insignificant.
[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins]
Statistical risk model with risk factors (specify number of risk factors)
Stratification by risk category (specify number of categories)
Stratification by risk category (18 risk categories)
Statistical risk model with risk factors (1 risk factor = patient size)
[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]
The means by which a CT examination is determined to be “out-of-range" with respect to radiation dose is measured by observing whether its patient size-adjusted radiation dose exceeds a pre-determined evidence-based threshold. The value of this size-adjusted radiation dose is calculated with the following equation for any given exam:

$$D_A = D_R * \exp(-(d-d_k) * \beta_k)$$

Where...

D_A is the size-adjusted radiation dose of the exam

D_R is the radiation dose of the exam, without adjustment

d is the diameter of the anatomic area being examined

d_k is the “expected diameter” of the CT category associated with the exam. This “expected diameter” is equal to the median diameter of all exams associated with the CT category in the UCSF International CT Dose Registry containing 6.5 million exams from 161 institutions.

β_k is the “size-adjustment coefficient” of the CT category associated with the exam. This “size-adjustment coefficient” is the slope parameter of a collection of log-transformed linear regression models fit using the UCSF Registry. A total of 18 models were fit, each using data from one of the CT Dose and Image Quality Categories. The models are parametrized such that, in the kth model and associated dataset, for the jth observation, from the ith hospital, we define:

$$\log(\{D_R\}_{ij}) = \{\beta_0\}_k + \beta_k * d_{ij} + \{z_i\}_k + \varepsilon_{ij}$$

Where D_R and d are respectively the radiation dose without adjustment and diameter of the anatomic area being examined, β_0 is an intercept term, z is a random effect indicating variation due to the hospital at which the exam was performed, and ε is the residual variation. We restrict the value of β_k to be greater than 0; when it is less than 0, it is set to 0 and no adjustment is performed. For the estimated values of β_k across CT categories (strata), please see 2b.30 below.

The intended interpretation of D_A is the "expected radiation dose of the exam if the diameter of the anatomic area being examined were equal to the population-level median."

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]
N/A - the outcome is risk adjusted
[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]
Published literature
[Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]
A comprehensive review of the published literature was performed to inform the design of this measure, including the identification of patient-level or exam-level risk factors. This review included all of the literature cited by the American College of Radiology (ACR) in its #3621 submission to NQF, as well as additional literature not cited by the ACR. The UCSF measure development team has actively contributed to this literature. Only patient and machine factors present at the start of care were considered in this review. Because the current measure was designed as an eCQM, we do not have the ability to test risk factors that were not supported by our conceptual model and literature review.

Because decisions are made at the level of patient groups, rather than individual patients, the logic model does not include varying technical parameters for individual patients. To the extent they have been studied, social factors including race/ethnicity and socioeconomic status are not predictive of radiation dose for CT exams. Messenger et al. (2016) used a cohort of 3442 CTs for calcium scoring to assess the relationship between effective dose (dose length product multiplied by a fixed conversion factor) and a variety of patient characteristics including age, sex, ethnic group, and body mass index. Each continuous independent variable was converted into categories, and the means of each category was reported. They reported no substantial differences between effective dose and any categorical/categorized patient characteristic, except age among those >75 years old.

There is a potential concern that the age of CT machines may be associated with increased radiation dose, as newer machines sometimes offer dose reduction software. Theoretically, this could lead to higher doses and poorer performance on the measure in safety-net settings that may have older machines. However, there is no evidence to support a strong association between CT machine factors, including the age of the machine, and increased radiation dose.

(Catalano 2007) In a study of over 2 million CT exams from 151 institutions, including 290 machines from the four largest machine manufacturers and 49 machine models, Smith-Bindman et al. evaluated the contribution of machine characteristics to radiation dose variation. (Smith-Bindman 2019). They observed statistical significance for nearly all variables assessed due to large sample size, but the effect sizes for patient sex and radiation dose, and patient age and radiation dose, were both negligible. The effect size of patient size, measured using effective diameter, was large and substantial in all anatomic areas studied. For chest exams, for example, one standard deviation increase in effective diameter was associated with an increase of 36% in effective dose. For abdomen exams, this effect size was 47%. No patient or machine characteristics explained the variability of effective dose to any notable extent. The authors concluded that differences in observed dose were almost entirely associated with how institutions used the machines, reflecting different choices of technical scanning parameters and not the machines themselves.

Another study showed, among institutions performing low-dose CT exams for lung cancer screening, a significant proportion of institutions and patients had doses that exceeded guideline-recommended dose levels. However, the type of institution, including whether the hospital was a public hospital, was not associated with the radiation dose used. (Demb 2019.) Lastly, several analyses are underway using data from the UCSF International CT Dose Registry demonstrating that optimized doses have been observed across all machine makes and models in the Registry, regardless of machine characteristics.

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[Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins]
Based on the logic model and literature review described above, only one risk factor (patient size) was selected for inclusion in the risk model. The logic model and literature review do not support inclusion of any other risk factors. This decision was endorsed by our Technical Expert Panel, as described above.

[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]
Our decision to not include social risk factors was based on review of the literature and finding no empirical evidence supporting the influence of social risk factors (including provider-level proxies for social risk factors, such as machine characteristics) on radiation dose. Providers who see a disproportionate number of patients from disadvantaged backgrounds, or in safety-net settings which may have older CT machines, are not expected to fail the measure more frequently because of these factors.
[Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]
The purpose of this model is to account for the need for higher radiation doses to adequately image larger structures and patients. Size-adjustment is intended to eliminate bias that would otherwise result from exogenous variation in the size distribution of patients across accountable entities. Literature review and several rounds of expert panel discussions identified no other relevant confounders at the patient level. This is not a predictive model intended to adjust for patient characteristics in predicting patient outcomes, so traditional metrics of classifier performance (i.e., c statistic, receiver operating characteristic curve, precision-recall curve) are not appropriate.

Accordingly, we validate the adequacy of the risk-adjustment method detailed in 2b.20 by fitting a comparable model:

$$\log(\{D_A\}_{ij}) = \{\beta_0\}_k + \beta_k * d_{ij} + \{z_i\}_k + \varepsilon_{ij}$$

Where all variables above are defined as they were in 2b.20. If the size-adjustment were adequate, we would expect the R-squared of the above model to be close to zero. That is, we expect there to be no relationship between patient size and size-adjusted radiation dose. This R-squared should be close to zero whether the above model is fit using the same data set as the one used to acquire D_A, or using a synthetic data set generated by randomly sampling (with replacement) from the data set used to fit the model. We randomly generated 100 synthetic data sets (of the same size as the Registry) to test the adequacy of our method for acquiring D_A.

Note that, a priori, we do *not* expect the above model to have an R-squared value close to zero (or to remove all differences between observed and expected dose values) when it is fit on a randomly-selected clinician or on any other population whose practices may not be representative of the general population. This is because some clinicians, clinician groups, or hospitals may systematically overdose some patient size groups (relative to national norms) while dosing other patient size groups in a manner consistent with national norms.

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]
Prior to size-adjustment, the (marginal) R-squared of the models described in 2b.20 differ by CT category, though the magnitude of the association is notable only in Abdomen, Extremities, and Simultaneous Chest and Abdomen and Pelvis exams.

Table 2b-6. Marginal R-Squared by CT category before size-adjustment.

CT category	Marginal R-Squared
Abdomen and Pelvis Low Dose	0.29
Abdomen and Pelvis Routine Dose	0.15
Abdomen and Pelvis High Dose	0.07
Chest Low Dose	0.08
Chest Routine Dose	0.10
Cardiac Low Dose	0.06
Cardiac Routine Dose	0.07
Cardiac High Dose or Chest High Dose	0.00
Thoracic or Lumbar Spine	0.05
Simultaneous Thoracic and Lumbar Spine	0.03
Simultaneous Chest and Abdomen and Pelvis	0.18
Head Low Dose	0.03
Head Routine Dose	0.01
Head High Dose	0.00
Neck or Cervical Spine	0.04
Simultaneous Head and Neck Routine Dose	0.01
Simultaneous Head and Neck High Dose	0.00
Extremity	0.22

After size-adjustment, the (marginal) R-squared of the models described in 2b.26 are uniformly close to zero (<0.01). There is negligible variation across the 100 synthetic data sets used to obtain these results, confirming that the risk-adjustment models remove bias due to patient size. The discrimination performance (i.e., c statistic) of these models is not relevant, because their purpose is to remove bias due to a single known confounder, not to maximize prediction of the outcome.

[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]
The outcome of our size-adjustment is the size-adjusted dose-length product, a continuous variable. The purpose of this model is to account for the need for higher radiation doses to adequately image larger structures and patients. Size-adjustment is intended to eliminate bias that would otherwise result from exogenous variation in the size distribution of patients across accountable entities. Literature review and several rounds of expert panel discussions identified no other relevant confounders at the patient level. Accordingly, following traditional Hosmer-Lemeshow methods, we sorted all CT exams by patient size (as this is the only risk factor in our risk-adjustment models), and estimated observed and size-adjusted doses, as well as the probability of an exam being classified as “out-of-range," across these size deciles. These differences can be interpreted in the same manner as the differences between observed and expected risk levels from a decile plot analysis, but without a global goodness-of-fit statistic.
[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]
We present the expected dose length product by patient diameter, before and after adjustment. We present results separately for the three largest CT categories, head routine (Table 2b-7), chest routine (Table 2b-8), and abdomen and pelvis routine (table 2b-9.)

Table 2b-7. Dose Length Product by Patient Diameter – Head Routine Dose Exams.

Size Category (Deciles)	Mean Dose Length Product (Unadjusted)	Mean Dose Length Product (Size-Adjusted)	Proportion Out-of-Range (Unadjusted)	Proportion Out-of-Range (Size-Adjusted)
1st	800	879	0.22	0.29
2nd	856	892	0.23	0.27
3rd	873	897	0.25	0.28
4th	887	902	0.26	0.28
5th	905	912	0.28	0.29
6th	923	920	0.30	0.30
7th	943	930	0.33	0.31
8th	966	941	0.36	0.32
9th	1001	960	0.40	0.35
10th	1083	976	0.50	0.39

Table 2b-8. Dose Length Product by Patient Diameter – Chest Routine Dose Exams.

Size Category (Deciles)	Mean Dose Length Product (Unadjusted)	Mean Dose Length Product (Size-Adjusted)	Proportion Out-of-Range (Unadjusted)	Proportion Out-of-Range (Size-Adjusted)
1st	340	638	0.26	0.47
2nd	311	424	0.23	0.38
3rd	338	413	0.28	0.38
4th	369	414	0.33	0.40
5th	402	417	0.39	0.41
6th	444	427	0.46	0.43
7th	491	438	0.54	0.45
8th	550	451	0.64	0.48
9th	640	468	0.74	0.52
10th	863	492	0.85	0.54

Table 2b-9. Dose Length Product by Patient Diameter – Abdomen and Pelvis Routine Dose Exams.

Size Category (Deciles)	Mean Dose Length Product (Unadjusted)	Mean Dose Length Product (Size-Adjusted)	Proportion Out-of-Range (Unadjusted)	Proportion Out-of-Range (Size-Adjusted)
1st	507	993	0.22	0.52
2nd	524	778	0.23	0.45
3rd	580	760	0.28	0.45
4th	646	764	0.35	0.46
5th	721	775	0.43	0.48
6th	811	793	0.53	0.51

Size Category (Deciles)	Mean Dose Length Product (Unadjusted)	Mean Dose Length Product (Size-Adjusted)	Proportion Out-of-Range (Unadjusted)	Proportion Out-of-Range (Size-Adjusted)
7th	917	810	0.65	0.54
8th	1046	822	0.77	0.58
9th	1218	817	0.88	0.60
10th	1551	742	0.95	0.52

[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]
As described in 2b.27. The observed relationship between patient size and radiation dose differs by CT category, meaning a different risk-adjustment coefficient (different β_k) was required for each CT category. The table provided in 2b.27 show the specific results by CT category. These β_k values are as follows:

Table 2b-10. Risk-adjustment coefficients by CT category.

CT Category	β_k
Abdomen and Pelvis Low Dose	0.009
Abdomen and Pelvis Routine Dose	0.008
Abdomen and Pelvis High Dose	0.006
Chest Low Dose	0.005
Chest Routine Dose	0.009
Cardiac Low Dose	0.006
Cardiac Routine Dose	0.007
Cardiac High Dose or Chest High Dose	0.000
Thoracic or Lumbar Spine	0.003
Simultaneous Thoracic and Lumbar Spine	0.003
Simultaneous Chest and Abdomen	0.007
Head Low Dose	0.011
Head Routine Dose	0.006
Head High Dose	0.000
Neck or Cervical Spine	0.004
Simultaneous Head and Neck Routine Dose	0.000
Simultaneous Head and Neck High Dose	0.000
Extremity	0.008

There are four CT categories (Cardiac High Dose or Chest High Dose, Head High Dose, Simultaneous Head and Neck Routine Dose, Simultaneous Head and Neck High Dose) where the value of β_k was less than 0 at initial fitting of the model in 2b.20. In all four of these categories, no adjustment was performed, but the relationship between patient diameter and non-adjusted dose length product was nonetheless minimal, as shown by the R-squared values in section 2b.27.

As sample sizes in the UCSF Registry are very large, non-zero values of β_k are highly statistically significant, with confidence intervals imperceptibly narrow.

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]
The table provided in 2b.27 shows that in some CT Categories, the radiation dose is associated with patient diameter, reflecting the clinical practice of using higher radiation doses to penetrate higher-diameter body structures. The fact that the R-squared values in 2b.27 are consistently close to zero after adjustment, and the much weaker relationship between patient diameter and dose length product after adjustment in 2b.29, shows that the adjustment was adequately conducted. Size adjustment does not completely remove the apparent relationship between size and dose in our beta testing data, because the estimated coefficients shown in 2b.30 were derived from a separate registry database that is over 100 times larger than the test data. When these coefficient estimates are applied to any selected set of clinicians, some residual association may be found if some entities overdose certain size groups (relative to national norms) while dosing other patient size groups in a manner consistent with national norms.
[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]
N/A
[Response Ends]

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]
Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)
Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)
[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.
[Response Begins]
ALL data elements are in defined fields in a combination of electronic sources
[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]
N/A
[Response Ends]

3.05. Complete and attach the NQF Feasibility Score Card.

[Response Begins]
Attached
[Response Ends]

Attachment: Feasibility_scorecards_Clinician.xlsx

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]
Availability of data

There were minimal difficulties surrounding data availability, although issues of missing data are discussed below.

Feasibility scorecards were completed for each EHR system tested: Epic (N=5), Cerner (N=1), Allscripts (N=1), MedInformatix (N=1). At our testing sites, Epic, Cerner, and Allscripts are used in both inpatient and outpatient settings; MedInformatix is used only in outpatient settings. We tested feasibility at the health system or vertically integrated organization level rather than at the individual clinician level because EHR and other electronic clinical data systems did not differ between clinicians within health systems/vertically integrated organizations, and data were collected at the level of the health system/vertically integrated organization, rather than separately for each clinician.

The feasibility scorecard assesses our ability to access the Data Elements in structured fields in electronic clinical data sources (*including both EHR and non-EHR sources*). The results were the same across all EHR systems:

***Availability**:* All primary-access data elements were available and accessible in structured fields in either the EHR or the radiology electronic clinical data systems, including the Radiological Information System (RIS) and the Picture Archiving and Communication System (PACS). The three final data elements – CT category, size-adjusted radiation dose, and global noise – were generated through pre-processing and available for measure score calculation in each system tested.

***Accuracy**:* All data elements have a high likelihood of being correct since they are either entered by a provider into the EHR (typically through text mapping to a code lookup table, or with assistance from a professional coder) for purposes of billing (e.g., ICD-10-CM and CPT® codes, date of birth) or generated by the CT machine itself (RDSR and image pixel data).

***Standards**:* all data elements are structured using nationally accepted vocabularies. Primary-access data elements use code systems ICD-10-CM, CPT®, DICOM, and LOINC. Final data elements are mapped to LOINC codes:

- CT Dose and Image Quality Category: LOINC, 96914-7
- Calculated CT Size-Adjusted Dose: LOINC, 96913-9
- Calculated CT Global Noise: LOINC, 96912-1

Workflow: Once the measure software is implemented, there is no impact on clinician workflow. All data elements are generated during the ordinary course of care or through pre-processing, and no manual abstraction is required.

Missing data

During testing there was some missing data for 8% of exams, and over 90% of the missing data were related to radiation dose. We believe that the issue of missing radiation data is for the most part entirely solvable and within the control of accountable entities. The missing radiation data is not related to an entity's hardware except in very rare situations in which very old machines are used to perform the exam; rather, it is almost entirely a software and data storage issue. The radiation dose data is stored within the Radiation Dose Structured Report (RDSR), a digitized, structured summary of the total radiation output associated with the performance of the CT exam. The RDSR is produced with every CT scan and CMS incentivizes the creation of the RDSR by paying a lower reimbursement for CT scans that do not produce an RDSR. The issue that can arise is that some entities may not *save and store* the RDSR. There is a widespread campaign organized by the American College of Radiology to encourage entities to save and store RDSR information, and the practice is growing. Sites that do not currently save the RDSR in their radiology information systems will need to invest time and resources in modifying their systems to be able to do so. We calculated the amount of time this requires as part of the testing and it was quite modest, as described below and in Table 3-1. Although sites may require vendor support, this work is not excessively burdensome. One of our testing sites went from saving 0% to 96% of their machines' RDSRs in a week's time with remote support from Siemens. Another site with mostly General Electric CT machines increased saving from 10% to 65% within a month, adjusting one machine at a time.

The measure steward will closely monitor missingness at the accountable entity level and report these numbers to the entities, which will be expected to fix the issue within a reasonable period of time. If missingness doesn't resolve to near-zero by the time of NQF Maintenance, we will consider revising the measure to establish a missing data threshold beyond which exams with missing data will be treated as out-of-range (i.e. failed).

Burden and workflow changes (time and cost of data collection)

Interviews were conducted by the UCSF measure development team with representatives from all 8 health systems and vertically oriented organizations that served as measure field-testing sites (including site PIs, PACS administrators, and IT and radiology-IT staff). In these interviews, we explored the burden to physicians and staff in terms of hours, cost, complexity, and changes in workflow.

While the implementation imposed no burden on clinicians, it affected staff (mostly IT) workflow. The structured

interviews centered around four main topics, and we provide the average and range in time reported for each task across all testing sites in Table 3-1. The reported burden decreased over time as the UCSF team became more adept at troubleshooting and advising the testing sites. All testing sites reported that if the testing were repeated, the hours required would be lower in subsequent rounds. The average cost per hour of the personnel working on the project was estimated by testing sites as $50. Thus, testing was completed at an average cost of $2600 per health system or vertically oriented organization. This level of implementation effort is similar to the burden for other eCQMs, and generally less than the effort involved in participating in national registries.

Table 3-1. Range and average number of hours required, per task group, across all testing sites.

Step	Range (hours)	Average (hours)
Server/software set up • Building the server (virtual machine) to house the software edge device • Installing the software and troubleshooting	3-40	11.3
Migration of imaging exams to server • Directing the PACS to send CT exam data to the software • Monitoring the data transfer	1-20	6.1
Extracting diagnostic (ICD-10-CM) and procedure (CPT®) codes and sending to software • Identifying data sources and building queries • Running queries and performing quality control	1-25	9.3
Saving the Radiation Dose Structured Report (RDSR) in PACS • The RDSRs are universally created by the CT machines • This data element is not universally saved nor stored • The process of saving the RDSR varies by manufacturer and needed to be implemented across all scanners within each network	1-50	25.3
Total (based on observed range reported by each testing site)	**8-65**	**52.0**

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

[Response Begins]
There are no fees for users submitting their eCQM data to CMS programs.

As described in sp.22, the measure requires access to and processing of primary data elements from the EHR and radiology electronic clinical data systems into variables that can be ingested by the eCQM for measure score calculation. The steward's software to ingest this data and calculate the measure is freely available, with a license agreement described below that prevents reselling by other companies. The specifications of the measure (e.g., code lists, risk model coefficients, radiation dose and noise thresholds, and required algorithms) are in the public domain. Should they choose, other vendors may also develop their own software to implement the measure specifications using the information included in this submission.

Consistent with other eCQMs, this measure can be reproduced and distributed, without modification, for noncommercial purposes (e.g., use by healthcare providers in connection with their practices). Commercial use is defined as the sale, licensing, or distribution of the measure for commercial gain, or incorporation of the measure into a product or service

that is sold, licensed, or distributed for commercial gain. All commercial uses or requests for modification must be approved by Alara Imaging, Inc. and are subject to a license at the discretion of Alara Imaging, Inc.

Limited proprietary coding is contained in the measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. Alara Imaging, Inc. disclaims all liability for use or accuracy of any third-party code contained in the specifications. CPT(R) contained in the measure specifications is copyright 2004-2021 American Medical Association. LOINC(R) is copyright 2004-2021 Regenstrief Institute, Inc. Due to technical limitations, registered trademarks are indicated by (R) or [R].
[Response Ends]

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a.01.

Check all current uses. For each current use checked, please provide:

Name of program and sponsor

URL

Purpose

Geographic area and number and percentage of accountable entities and patients included

Level of measurement and setting

[Response Begins]
Not in use
This is a new measure submitted for initial endorsement. It is not currently in use in any program.
[Response Ends]

4a.02. Check all planned uses.

[Response Begins]
Payment Program
Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
Quality Improvement (internal to the specific organization)
[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]
N/A – this is a new measure
[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]
This measure is intended for use in the Centers for Medicare & Medicaid Services (CMS) Merit-based Incentive Payment System (MIPS), which seeks to improve the quality and value of healthcare in the US. MIPS adjusts payments on Medicare Part B claims for eligible clinicians based on their performance across four areas: quality, improvement activities, promoting interoperability, and cost. This measure would apply to all MIPS-eligible clinicians who perform diagnostic CT regardless of their medical specialty, in inpatient, hospital outpatient, and ambulatory care settings. Measurement is at the individual clinician level. The measure is also intended for use in the CMS Inpatient and Outpatient Hospital programs.

We will submit this measure to the CMS MUC List in 2022 for consideration in the MIPS and Hospital programs.

CMS publicly reports a subset of MIPS quality measures on its Physician Compare website. The specific measures included are selected "based on statistical and user testing." Quality measures in their first two years of use are not publicly reported; thus, the earliest public reporting of this measure would occur in 2026, reflecting performance in calendar year 2025. As media coverage of radiation overuse has proven this to be an important safety issue to patients and the public, the UCSF measure development team believes there is strong interest and benefit in public reporting of this measure.
[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]
This measure is designed to not only monitor performance but also provide feedback to achieve a meaningful reduction in radiation doses. Though the measure score itself only reflects an aggregated out-of-range rate across all CT categories, the edge device software (described in sp.22) generates stratified feedback to users allowing them to make decisions to improve their performance. The feedback highlights CT categories of poor performance so that sites can see exactly where they need to take corrective action to improve their radiation doses or image quality. While the measure is reported at the accountable entity level, the feedback can be provided at multiple levels, such as the individual clinician, clinician group, facility, imaging center, or hospital level, making the feedback exceedingly actionable.

Also, the feedback will evolve over time in response to user demand. For example, some of our testing sites have asked for optimized protocols to help them achieve in-range radiation dose targets; thus, this is under development.

Alara Imaging, Inc. – our partner in software development – is working with our testing sites to pilot this educational feedback that will be provided during implementation. The testing sites are receiving this information free of charge.
[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]
Sites that provided data for measure testing were convened by video conference call to review their performance on the measure. Sites were able to view their CT exams by CT category and compare (1) their allocations of exams across CT categories relative to the UCSF Registry, (2) a pass ("in-range") rate for exams across each CT category, and (3) a weighted score that combines the frequency and pass rate to assess the CT categories that need the most attention for overall

measure score improvement. Sites are also receiving detailed feedback *by CT protocol* in terms of the technical parameters they used in comparison with sites that have the lowest doses/lowest measure score. This provides highly actionable information to modify practice.
[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]
Verbal feedback was provided by site participants on the video calls. More detail on this feedback is provided in 4a.08 below.
[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]
Feedback from sites often reflected a recognition and understanding for why radiation doses were particularly high. For example, one site that failed a number of exams in the Head Routine Dose category routinely uses three phase scans for this type of scan, an approach that deviates from industry norms and leads to unnecessarily high doses.

Some sites had generally high radiation doses across a number of categories, while others struggled with only one or two high-volume categories. For the sites that had targeted issues, there was an interest in not only ascertaining which imaging protocols were leading to failure in the measure, but also a desire for guidance on alternative protocols to administer in order to optimize dose while maintaining adequate image quality.
[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]
There has been general interest from sites that were not included as testing partners to obtain the type of feedback provided to testing sites. It is often the case that sites are unsure how their doses and image quality compare to peers and there is demand for solutions that can help provide this guidance and tailored feedback in a structured way.
[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]
UCSF, as the measure developer, has been working with 26 health care organizations and 161 imaging facilities for 10 years on ways to assess radiation dose and provide feedback to help organizations improve quality and safety of CT imaging. This work has included a randomized controlled trial of different approaches to audit feedback and education (described at length in 4b.01). The feedback we've received from both Registry and field-testing sites in the form of surveys, interviews, webinars, forums for sharing best-practices, and informal conversations have influenced the development and the specification of the measure. For example, the CT categories were revised several times based on feedback from imaging facilities. The measure was defined to include a 100% sample of CT exams so as not to have selected exams submitted. The approach of providing feedback on the measure score – e.g. to provide feedback at the level of specific machine and on individual patients whose doses exceed thresholds – all came from input from our testing partners. While measure will be scored and reported at an aggregated level, the feedback was requested to be far more nuanced to make it actionable.
[Response Ends]

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people

receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]
This is a new measure not previously in use. Thus, while empirical performance improvement data are not yet available, previous research suggests educational feedback of the kind delivered through measure implementation, described at length in 4a.05, can help reduce excessive radiation doses in CT while preserving diagnostic utility. In a randomized controlled trial involving roughly 1 million CT exams from 100 imaging facilities across 6 countries, Smith-Bindman et al. studied the impact of multicomponent educational feedback on radiation doses used in CT imaging. (Smith-Bindman 2020) This included audit feedback with targeted suggestions, participation in a quality improvement collaborative, and best-practice sharing. Together, these interventions achieved 23-58% reductions in the proportion of high-dose exams, based on organ dose, with no observed change in image quality. Audit feedback alone, comparing radiation doses with those of other facilities, also reduced the proportion of high-dose exams and mean doses, but with a smaller magnitude.

Prior to this randomized trial, smaller, single-center, and/or observational studies reached the same conclusion that educational feedback such as audits reduces radiation doses. The Luxemburg Ministry of Health implemented an audit of radiation doses in its CT imaging departments and observed reductions in the 75th percentile of dose of 18-75%, for all body regions, which were sustainable over time. (Tack 2014). A small, controlled pilot examining the effect of personalized dose audit reports and education directed at radiology technologists within a US health system similarly lowered patients' radiation exposure in CT imaging. (Miglioretti 2014). Another interventional study across the University of California system deployed radiation dose audits and best practice sharing, resulting in considerable dose reductions: a 19% and 25% decrease in mean effective dose for chest and abdomen exams, respectively, and a reduction in the number of exams exceeding allowable benchmarks by 48% and 54% for chest and abdomen, respectively. (Demb 2017).

References

1. Demb J, Chu P, Nelson T, et al. Optimizing Radiation Doses for Computed Tomography Across Institutions: Dose Auditing and Best Practices. JAMA Intern Med. 2017;177(6):810-817.
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3. Smith-Bindman R, Chu P, Wang Y, et al. Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. JAMA Intern Med. 2020 May 1;180(5):666-675.
4. Tack D, Jahnen A, Kohler S, et al. Multidetector CT radiation dose optimisation in adults: short- and long-term effects of a clinical audit. Eur Radiol. 2014;24(1):169-175.

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]
Field testing involved retrospective data collection to capture baseline performance at testing facilities. Since no intervention took place, there were no unintended impacts on patients.

We learned early on in field-testing that the Radiation Dose Structured Report (RDSR) was initially unavailable for many CT exams at all testing sites. This issue is described at length in section 3.06. The RDSR is a digitized, structured summary, automatically generated by the CT machine, providing the total radiation output for each CT exam. Though federal law requires CT machines *generate* the RDSR, there is no mandate that facilities *save* the report, and most of our testing sites were unaware the report was not saved. We worked with our sites to modify their systems to save the RDSR, ultimately capturing 94% of dose reports. Nationwide, awareness of this issue is growing, and more facilities are saving the RDSR. Regulatory solutions should be considered upon measure implementation to ensure this trend continues.

Given the relationship of radiation dose and image noise, there is concern that dose reduction will result in deteriorated

image quality. Theoretically, this reduces the diagnostic utility of CT images and could harm patients by requiring repeated scanning (thus doubling the dose). However, we did not see this play out in our testing data. Out-of-range measure scores due to inadequate image quality (i.e. excessive global noise) were exceedingly rare, with less than 1% of exams, on average, across all reporting entities. This was to some degree expected, given the earlier Image Quality Study, in which radiologists graded 3% and 8% of exams as "poor" or "marginally acceptable" image quality, respectively (this is described at length in the Validity Testing section 2b.02). This finding supports a considerable opportunity to reduce radiation doses without impacting quality. Since field-testing captured only about four weeks' worth of CT data, we did not observe trends in image quality. The measure steward will monitor out-of-range rates annually to determine if image quality is worsening due to declining radiation doses and determine if thresholds should be adjusted or if a subsequent Image Quality Study of radiologist satisfaction should be repeated.
[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]
Testing this measure prompted many sites to learn of the problem of Radiation Dose Structured Reports not being saved in their PACS systems and to implement corrective changes. Beyond that, it is too early to identify other unexpected benefits.
[Response Ends]

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)
[Response Begins]
2820: Pediatric Computed Tomography (CT) Radiation Dose
3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single
[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)
[Response Begins]
[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]
Two existing process measures in the CMS Merit-based Incentive Payment System (MIPS) program are related (not competing) in that they address patient safety related to radiation exposure in CT imaging:

1. Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies (CMIT # 2286, steward: American College of Radiology)
2. Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques (CMIT # 2570, stewards: American College of Radiology, American Medical Association-Physician Consortium for Performance Improvement, National Committee for Quality Assurance)

There are three process measures related to CT in the CMS Hospital Outpatient Quality Reporting Program, but none directly addresses radiation dose:

1. Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 Minutes of ED Arrival (CMIT # 918, steward: Centers for Medicare & Medicaid Services)
2. Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery (CMIT # 1367, steward: Centers for Medicare & Medicaid Services)
3. Abdomen Computed Tomography (CT) Use of Contrast Material (CMIT # 2599, steward: Centers for Medicare & Medicaid Services)

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]
Yes
[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]
Measure 2820 was developed by the same UCSF measure development group as the current proposed measure. It calls for imaging facilities to assess their radiation doses in children against published benchmarks, and it provides a framework to improve doses exceeding benchmarks. In contrast, the proposed new measure is specified in adults. Measure 2820 was a first-generation pediatric measure, and the new measure is a second-generation adult measure that incorporates stratification by clinical indication, adjustment by patient size, and image quality. The UCSF team plans to update measure 2820 in a subsequent review cycle to include stratification for clinical indication and an assessment of image quality and will reflect harmonization with the newly proposed measure.

Measure 3621, developed by the American College of Radiology, is also focused on reducing radiation doses for CT, but the outcomes and target populations are different. The denominator of measure 3621 includes CT exams in all patients who have undergone three specific types of CT scans: single phase CT abdomen-pelvis exams with contrast, single phase CT chest exams without contrast, and single phase CT head/brain exams. This means patients who may have undergone *multi-phase* abdomen, chest and head scans are not included. In contrast, the proposed new measure's denominator is nearly all diagnostic CT exams in adults. Thus, the proposed measure inherently considers the clinician's subjective choice of imaging protocol (e.g. whether to assign a patient to a single or multi-phase abdomen exam), which is the single most important predictor of radiation dose. Measure 3621 does not account for this high impact decision, assessing dose only after the selection of a single phase exam is made. This difference impacts the meaningfulness of the measures. Measure 3621 stratifies by protocol, in essence comparing single phase CT abdomen-pelvis exams with contrast to other single phase CT abdomen-pelvis exams with contrast, regardless of the reason for scanning. Assessing doses in this way, without considering the underlying indication, ignores the variation stemming from protocol selection and fails to identify patients who require a particular protocol, such as single phase abdomen, but who instead received much higher doses through unnecessary multi-phase exams. Most high radiation doses are a result of using multi-phase protocols, and yet these exams are not included in Measure 3621.

In effect, the denominator of measure 3621 is not stable; in some practices this might represent a large portion of patients who underwent CT, whereas in others it might be very few. In the UCSF International CT Dose Registry, which includes over 6.5 million CT scans from 161 hospitals and imaging facilities, these three CT exam types together make up 39% of exams overall across the registry. However, they account for 1% to 83% of exams across the different hospitals and imaging facilities, suggesting the denominator for measure 3621 does not reflect a patient population who *require* these exams, but rather reflects the variable decisions of radiologists to assign patients to different imaging protocols. This is not a hypothetical problem but one that would be expected to occur frequently and miss the most egregious radiation overdosing. A physician group that uses multiphase scanning for most of their CT exams will deliver inappropriately high doses to many patients, but this will not be assessed, flagged, or failed by measure 3621.

An important difference between the measures is that the proposed measure assesses radiation dose *according to thresholds determined by the underlying clinical indication for imaging*, while Measure 3621 uses the average observed dose in the ACR registry for these protocols, without consideration if the doses are appropriate for the underlying indication. Radiation doses should be assessed based on the intent and clinical question of the provider ordering the scan, not on the radiologist's choice of protocol. Nonetheless, Measure 3621 can contribute to dose optimization and potentially encourage physicians to lower radiation doses for single-phase exams.

A final advantage of the proposed measure is that it includes assessment of image quality as a means of protecting the diagnostic value of CT imaging from unintended consequences of excessive dose reduction.

We believe the data collection burden would be nominal if sites choose to report on both measures. In terms of harmonization, both measures utilize data generated during the standard course of clinical care, either by clinicians or CT machines; no human abstraction is required. Both measures use the same radiation dose metric (dose length product)

and use effective diameter as a metric of patient size. In the future, the ACR may require the RDSR, and when they do, the measures will be harmonized on this data source. However, complete harmonization is not possible due to the fundamentally different approaches; for example, the proposed measure uses diagnosis (ICD-10-CM) and procedure (CPT®) codes associated with the exam to assign the CT category, while measure 3621 determines exam type using DICOM data from the CT exam including study description and body region. As an eCQM, our measure is designed to minimize the burden of data collection. As described in section 3.06, the bulk of the cost and effort is in set-up, but minimal effort for staff (no effort for clinicians) is required on an ongoing basis.
[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]
N/A – there are no competing measures

Measure 3621 is related. As described in 5.05, the proposed measure is different than, and improved upon Measure 3621 in the following ways:

(1) It assesses radiation doses by clinical indication, thereby allowing consideration for the *reason* for imaging.

(2) Similarly, it assesses radiation dose *according to thresholds determined by the underlying clinical indication for imaging,* rather than to observed doses without consideration if the doses are appropriate for the underlying indication.

(3) The proposed measure's denominator includes nearly all diagnostic CT exams in adults. Thus, the proposed measure inherently considers the clinician's subjective choice of imaging protocol (e.g. whether to assign a patient to a single or multi-phase abdomen exam), which is the single most important predictor of radiation dose.

(4) Includes assessment of image quality as a means of protecting the diagnostic value of CT imaging from unintended consequences of excessive radiation dose reduction.
[Response Ends]

Appendix

Supplemental materials may be provided in an appendix.: No appendix
Attachment: 1056QDM_Bonnie_screenshot.jpg
Attachment: 1056QDM_Bonnie_test_cases.xlsx
Attachment: FHIR_testing_synthetic_patients.png
Attachment: FHIR_testing_eCQM_code_output.png

Contact Information

Measure Steward (Intellectual Property Owner) : Alara Imaging
Measure Steward Point of Contact: Mazonson, Nathan, nate@alaracare.com
Measure Developer if different from Measure Steward: University of California, San Francisco
Measure Developer Point(s) of Contact: Smith-Bindman, Rebecca, rebecca.smith-bindman@radiology.ucsf.edu
Smith-Bindman, Rebecca, Rebecca.smith-bindman@ucsf.edu
Stewart, Carly, carly.stewart@ucsf.edu

Additional Information

1. Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.

[Response Begins]
No appendix
[Response Ends]

Attachment: 1056QDM_Bonnie_screenshot.jpg
Attachment: 1056QDM_Bonnie_test_cases.xlsx
Attachment: FHIR_testing_synthetic_patients.png
Attachment: FHIR_testing_eCQM_code_output.png

2. List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.

[Response Begins]
Project leadership:

Rebecca Smith-Bindman, MD, Principal Investigator (University of California San Francisco). Dr. Smith-Bindman has had overall responsibility for leading the project, from measure conceptualization through development, implementation, and testing. She supervised all project staff and led the development of the reporting software, the risk adjustment strategy, the measurement of image quality, and alpha and beta testing. Lastly, she directed the Technical Expert Panel and ensured integration of their feedback into the measure.

Marc Kohli, MD, Co-Investigator (University of California San Francisco). Dr. Kohli contributed his expertise in medical informatics, clinical workflow within Radiology and EHR, standards in imaging, and knowledge of data extraction from electronic radiology data to measure development, specifications, testing, and implementation.

Patrick Romano, MD, MPH, Co-Investigator (University of California Davis). Dr. Romano oversaw UC Davis' participation in the project, with a specific focus on supporting the development, testing, refinement, and validation of detailed technical specifications for the proposed measures. He also advised and supported the UCSF team through submissions to the CMS Measure Under Consideration List and National Quality Forum.

Andrew Bindman, MD, Advisor (Kaiser Foundation Health Plan). Dr. Bindman was formerly a Co-Principal Investigator with the University of California San Francisco. He initially shared overall responsibility for the project with Dr. Smith-Bindman, specifically contributing to developing measure concepts, specifications, and the risk adjustment strategy. Following his move to Kaiser in the fall of 2020, he stayed on the project in an advisory capacity.

Technical Expert Panel members include:

- Mythreyi Bhargavan Chatfield, PhD, Executive Vice President, American College of Radiology
- Niall Brennan, MPP, CEO, Health Care Cost Institute
- Helen Burstin, MD, MPH, FACP, Executive Vice President, Council of Medical Specialty Societies
- Melissa Danforth, Vice President of Health Care Ratings, The Leapfrog Group
- Tricia Elliot, MBA, CPHQ, Director, Quality Measurement, Joint Commission
- Jeph Herrin, PhD, Adjunct Assistant Professor, Yale University
- Hedvig Hricak, MD, PhD, Radiology Chair, Memorial Sloan Kettering Cancer Center
- Jay Leonard Lichtenfeld, MD, MACP, Independent Consultant, Formerly Deputy Chief Medical Officer American Cancer Society, Inc.
- Leelakrishna Nallamshetty, MD, Associate Chief Medical Officer, Radiology Partners

- Matthew Nielsen, MD, MS, Professor and Chair of Urology, UNC Gillings School of Global Public Health
- Debra Ritzwoller, PhD, Patient Advocate and Health Economist (Patient Representative)
- Lewis Sandy, MD, Executive Vice President, Clinical Advancement, UnitedHealth Group
- Mary Suzanne Schrandt, JD, Patient Advocate (Patient Representative)
- James Anthony Seibert, PhD, Professor, University of California, Davis
- Arjun Venkatesh, MD, MBA, MHS, Associate Professor, Emergency Medicine, Yale School of Medicine
- Todd Villines, MD, FSCCT, Professor and Director of Cardiovascular Research and Cardiac CT Programs, University of Virginia
- Kenneth Wang, MD, PhD, Adjunct Assistant Professor, Radiology, University of Maryland, Baltimore

[Response Ends]

3. Indicate the year the measure was first released.

[Response Begins]
N/A – this is a new measure
[Response Ends]

4. Indicate the month and year of the most recent revision.

[Response Begins]
N/A – this is a new measure
[Response Ends]

5. Indicate the frequency of review, or an update schedule, for this measure.

[Response Begins]
The measure steward will review measure specifications annually to ensure they remain appropriate to the measure's concept or logic. In particular, the steward will monitor measure annually to determine if the specified radiation dose and image quality thresholds remain appropriate. For example, if radiation doses overall are reduced, the steward will assess if the radiation dose thresholds should change accordingly. Or if dose reduction leads to a concern about image quality, the steward will determine if another Image Quality Study assessing physician satisfaction with CT images is needed.

The steward will also continue to update the algorithm for CT category assignment as diagnosis and procedure codes are created or retired.
[Response Ends]

6. Indicate the next scheduled update or review of this measure.

[Response Begins]
N/A – this is a new measure
[Response Ends]

7. Provide a copyright statement, if applicable. Otherwise, indicate "N/A".

[Response Begins]

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[Response Ends]

8. State any disclaimers, if applicable. Otherwise, indicate "N/A".

[Response Begins]
The Measure is not a clinical guideline, does not establish a standard of medical care, and has not been tested for all potential applications.

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[Response Ends]

9. Provide any additional information or comments, if applicable. Otherwise, indicate "N/A".

[Response Begins]
N/A
[Response Ends]