Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults for use in CMS Hospital Programs

Educational Summary

Quality Issue That Led to the Development of This Measure

Administered computed tomography (CT) radiation doses are highly variable across patients, radiologists, and hospitals throughout the United States.[1] Some patients receive excessive radiation doses without diagnostic benefit, needlessly increasing their personal risk of developing cancer. This inconsistency in how CT exams are performed represents a modifiable health risk, as doses can be reduced through auditing and feedback to hospitals and physicians.[2]

Measure Development and Testing

In 2019, the University of California San Francisco (UCSF) successfully competed for a cooperative agreement from CMS to develop a CT radiation dose-focused measure that could be incorporated into CMS programs, which use financial incentives to motivate clinicians and hospitals to improve clinical outcomes and patient safety. The measure is designed to identify when a CT exam is performed with unnecessarily high radiation doses and includes a balancing component to ensure that financial incentives to lower these radiation doses does not result in increases in image noise to the point that the test loses diagnostic value.

Recognizing that appropriate radiation doses vary widely based on patient size, body part, and indication for imaging, each scan is assigned to one of 18 CT categories. Each CT category has separate thresholds for size-adjusted dose and image noise.[3] Studies for which size-adjusted radiation dose or image noise exceed measure category thresholds are considered out of range, regardless of the underlying reason. In validation testing, most CT exams rated as out of range were due to radiation dose rather than image noise.

The measure underwent field testing, and the results were utilized as part of the National Quality Forum's decision to endorse the measures for use in judging hospital inpatient, hospital outpatient, and physician quality.[4] Data from four of the most prevalent EHR vendors as well as four of the most prevalent CT vendors were represented in the testing data.

Measure Format

CMS required that this measure be designed as an electronic clinical quality measure (eCQM). This eCQM is the first radiology measure to be written in this format. Because the eCQM framework was not designed to calculate performance based on DICOM Radiation Dose Structured Report (RDSR) or image data, hospitals who desire to report on these measures must use software to translate radiology data into an eCQM compatible format.

As measure steward, Alara's translation software was developed for this purpose. Free use of this software provides CMS with secure, reliable, and consistent measurement across populations so that results are accurate and that comparisons are meaningful. As measure steward, Alara is responsible for ensuring the measure is calculated and reported appropriately and consistently by every reporting institution and physician in the United States.

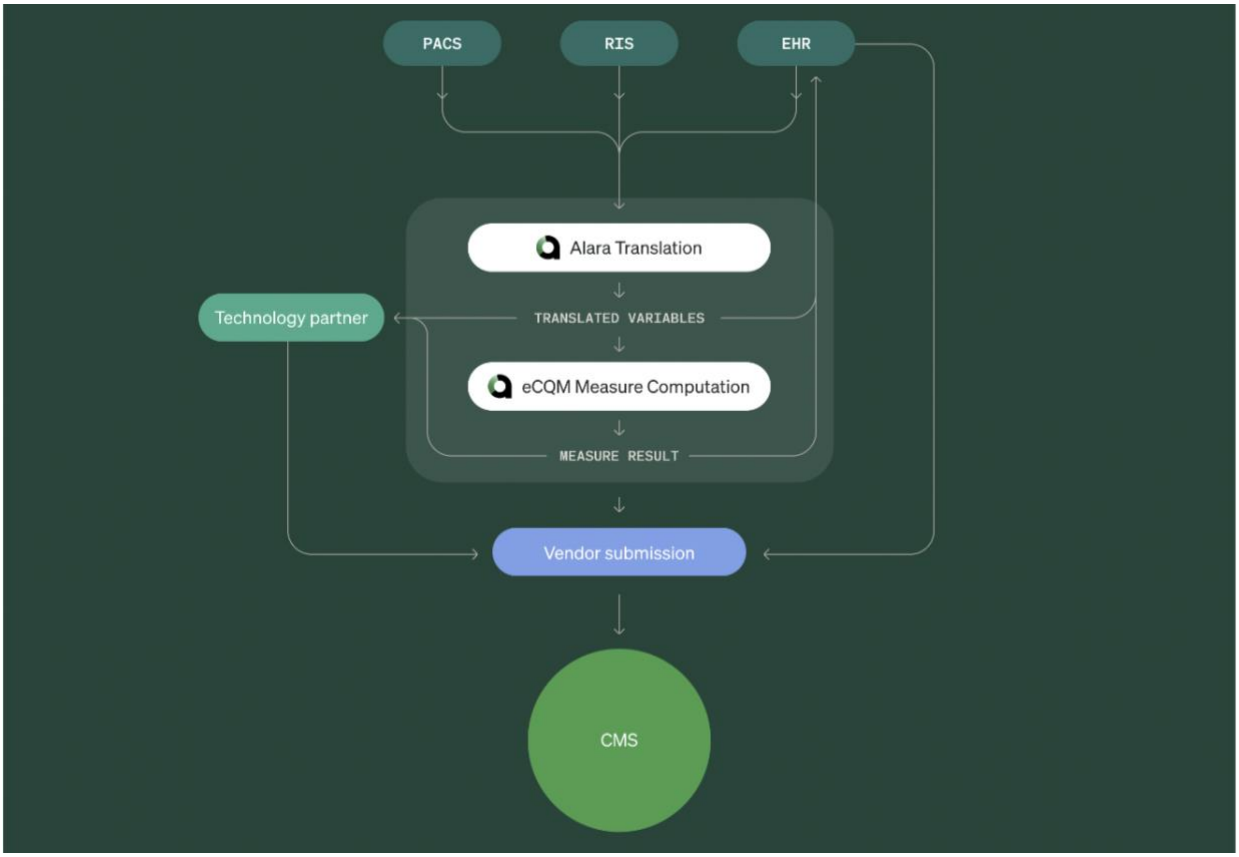
Automation & Software Costs

The Alara Medical Imaging Gateway is provided free of charge to health systems and physicians for CMS measure translation. Measure calculation is performed using DICOM CT pixel data (size normalization and image noise) and DICOM RDSR (radiation dose), with imaging indication and exam performed in the form of CPT and ICD-10 codes respectively (CT Category).

Calculations are automated in the Alara Medical Imaging Gateway. Sites can choose to send CT studies directly from CT machines, with a routing rule in PACS, or with a DICOM router. All calculations are performed on-premises without data leaving the provider's network.

For each study, the Alara Medical Imaging Gateway takes CT image, RDSR, and indication data and calculates three intermediate variables: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise. These intermediate variable results are eCQM compatible and can be shared with a variety of software platforms or entities that calculate and report measures to CMS.

Additional technical details regarding Alara Medical Imaging Gateway technical requirements and installation can be found here: https://www.alaragateway.com/documentation



Integration Costs

Alara does not charge integration fees and is actively developing integration standards with EHR, radiation dose management, and measure calculation vendors. If you are a technology partner and want to work with Alara on software integration into your product, please contact Alara through this web page: https://www.alaragateway.com/contact

Common Questions

Does the measure consider why a CT scan was performed? Yes, a CT done for a suspected kidney stone is not judged against the same radiation dose and image noise thresholds as a CT done for abdominal pain or a suspected aortic dissection. The relationship between different indications for CT and the CT categories has been published in peer-reviewed medical literature.[3] The Alara Medical Imaging Gateway's proprietary algorithm ensures consistency in these categories based on anatomy and clinical indication.

Does the measure consider patient size? Yes, patient size is an important contributor to dose and is accounted for through normalization of total dose based on patient size. The purpose of the size adjustment is to ensure that heterogeneity of patient size between sites does not unfairly impact measure score. In extensive testing, the size adjustment successfully accounted for the impact of differently sized patients in assessing whether the radiation dose and image noise was within range.

Why doesn't the measure include other variables in the calculation such as patient demographics or the type of scanner used to perform the test? In extensive research, the only patient factor that is a strong predictor of dose is patient size.[1] Other patient factors (e.g., adult age, sex) have little association with radiation dose. Further, the addition of more variables would increase complexity of measure calculation, increasing burden without benefit.

How were image noise thresholds established and will radiologists be inundated with low image quality CTs? The measure sets a standard for acceptable image noise and radiation dose within each CT category. These thresholds were established using a rigorous research design in which a broad range of radiologists' assessments were used as a gold standard.[5] During testing, fewer than 1% of studies were judged to have unacceptable image noise (range of 0.0% - 0.6% across hospitals).

How can I be responsible for radiation dose levels given the hospital pays for and manages the machinery and technologists? The measure has been adopted for the Hospital Inpatient Quality Reporting Program, the Hospital Outpatient Quality Reporting Program, and the Physician Payment Program (MIPS) expressly to help align physicians, technologists, and hospitals to work together to reduce radiation doses.

How is image quality calculated? The measure was not intended and does not attempt to quantify all aspects of image quality. The measure assesses image noise and is only intended to ensure that radiation dose is not lowered to such a degree that the diagnostic value of the test is compromised.

Implementation Summary

New Radiology-focused Electronic Clinical Quality Measures

Alara has been selected by the Centers for Medicare and Medicaid Services (CMS) to steward new quality measures that become eligible for reporting January 1, 2025. These measures, titled *Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults*, were developed in partnership with the University of California, San Francisco (UCSF). The measures have been adopted into three CMS programs: The Hospital Inpatient Quality Reporting (IQR) program, the Hospital Outpatient Quality Reporting (OQR) program, and the Merit-Based Incentive Payment System (MIPS) program.

Why the Measure Steward Software is Necessary

Electronic clinical quality measure (eCQM) frameworks were not designed for radiology and cannot currently access and consume elements from ubiquitous DICOM objects, the accepted standard for

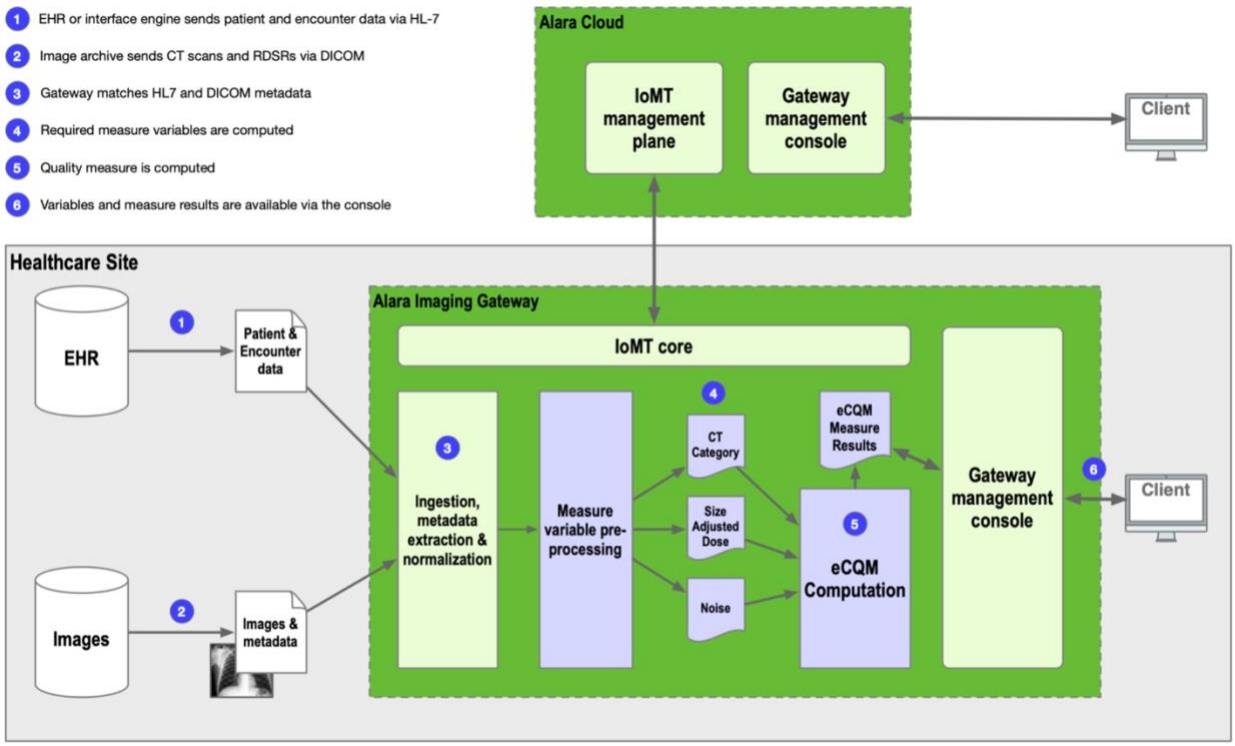
radiology data. The measure steward's translation software was developed to transform primary data into a format that can be integrated into systems performing eCQM calculations.

This translation software is provided freely to hospitals and physician groups. Hospitals and physician groups can then use their preferred vendor for eCQM calculation and CMS reporting.

The measure steward's proprietary software has been designed to ensure accurate and secure calculation across the U.S. population for healthcare sites.

How to Report on the Measures

The Alara Medical Imaging Gateway is a software deployable within a healthcare site's virtual infrastructure and interfaces with EHR and PACS systems to receive and process the data necessary for computation of the new electronic quality measures for radiology. The following is an overview of the system and its connections:



The translation software collects the data necessary to calculate three intermediate variables, which come from a combination of HL7 v2, FHIR, tabular, and DICOM sources depending on what is most easily accessible at each site. The intermediate variables are:

1. Computerized Tomography (CT) Dose and Image Quality Category: Reflects the type of exam performed based on body region and clinical indication. Each CT Dose and Image Quality Category has a specific set of dose and image noise thresholds. Based on the study's ICD-10 and CPT-4 codes, logic classifies the study into one of pre-defined categories based on body part.

2. Calculated CT Size-Adjusted Dose: Reflects the total radiation dose received during a CT after adjusting for patient size. The calculation for this variable normalizes the Dose Length Product (DLP) parsed from the DICOM RDSR and a patient size obtained by analyzing the images.

3. Calculated CT Global Noise: A balancing factor to ensure that dose is not so low that it affects clinical interpretability. The calculated CT Global Noise thresholds vary by the CT Dose and Image Quality Category and are not intended to be a holistic assessment of image quality.

Data Requirements for Measure Computation

The Alara Medical Imaging Gateway has predefined clinical data endpoints for immediate connectivity. Health sites can connect and configure HL7 and DICOM for any available flow directly from the Gateway Management User Interface.

DICOM

The gateway supports both DICOM DIMSE and DICOMWeb protocols. The recommended configuration is for the local site to create a routing rule in their archive or DICOM router to send CT studies to the Alara Medical Imaging Gateway. An alternative configuration is to have the gateway perform query / retrieve from the archive based on the accession numbers received from RIS or EHR data.

HL-7

The gateway supports industry standard HL7v2.x and HL7 FHIR messages to receive CPT and ICD codes.

Tabular Data Exports

While HL7 integration is preferred, alternative options including CSV files on shared network locations will also be supported. We recommend tabular exports as the last option considered, as it requires manual intervention and does not advance the objective of burden reduction.

Software Implementation, Deployment, and Onboarding

As measure steward, Alara's proprietary software allows for ease of implementation, deployment, and scalability. Alara has built software designed for swift implementation and scalability utilizing low burden technology - only requiring a Virtual Machine (VM). The software also has a heavy focus on cybersecurity for IT clearance, including HIPAA, SOC II, and HITRUST Certification by a third-party auditor.

Alara's onboarding portal allows for efficient completion of documents and security reviews, as well as gateway provisioning and technical integration.

Please see the step-by-step instructions below:

1. Contact Alara here or by email at information@alaracare.com.

2. Alara will set up a software demo with your stakeholders.

3. Receive onboarding credentials from Alara.
4. Fill out the appropriate forms, documentation, and accept the Terms of Service in the portal.
5. Provide Alara with any health system specific required documentation (BAA, IT Security, etc.).
6. Determine how many gateways will need to be deployed for the health system and/or health provider.
7. Provision an Alara Medical Imaging Gateway for CMS Measure Computation.

Alara's expert team will provision, integrate, and test the gateway with your IT and/or PACS team.

Additional Information

Please visit the CMS eCQI resource page for measure information from CMS.

Please visit the Alara CMS Measure Compliance webpage for more information on the company.

To receive a direct response, please visit www.alaragateway.com, or contact Alara at information@alaracare.com.

References

1. Smith-Bindman R, Wang Y, Chu P, et al. International variation in radiation dose for computed tomography examinations: prospective cohort study. *BMJ (Clinical research ed)*. Jan 2 2019;364:k4931. doi:10.1136/bmj.k4931
2. 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 internal medicine*. Mar 30 2020;JAMA Intern Med. 2020;180(5):666-675doi:10.1001/jamainternmed.2020.0064
3. Smith-Bindman R, Yu S, Wang Y, et al. An Image Quality-informed Framework for CT Characterization. *Radiology*. Feb 2022;302(2):380-389. doi:10.1148/radiol.2021210591
4. National Quality Forum, Patient Safety, Fall 2021 Cycle: CDP Report, Technical Report, September 26, 2022. https://www.qualityforum.org/Publications/2022/09/Patient_Safety_Final_Report_-_Fall_2021_Cycle.aspx
5. Smith-Bindman R, Wang Y, Stewart C, et al. Improving the Safety of Computed Tomography Through Automated Quality Measurement: A Radiologist Reader Study of Radiation Dose, Image Noise, and Image Quality. *Invest Radiol*. Jan 25 2024;doi:10.1097/RLI.0000000000001062