NATIONAL QUALITY FORUM

## Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

## Brief Measure Information

**NQF #:** 0739
De.2. **Measure Title:** Radiation Dose of Computed Tomography (CT)
Co.1.1. **Measure Steward:** University of California San Francisco
De.3. **Brief Description of Measure:** The measure requires hospitals and output facilities that conduct Computed Tomography (CT) studies to assess the radiation dose associated with the most frequently conducted examination types – CT's of the head, chest, abdomen/pelvis obtained in children and adults. The measure provides a simple framework for how facilities can assess their dose, a framework that currently does not exist. By assessing their doses, facilities can monitor the doses they use over time and compare their doses to benchmarks. The creation of benchmarks is not part of this measure per se. However, if facilities use this measure, I believe professional societies, researchers, and oversight organizations can separately create their benchmarks. Several research groups, including my own, have published benchmarks and published manuscripts that have used the framework of this measure to assess changes in radiation dose over time (Keagan, JACR, 2014) and to assess the impact of an educational intervention on doses, using the specifications of the measure to assess the results of a randomized trial (Miglioretti, JACR, 2014).

This measure was initially developed for diagnostic CT, but can equally be used for CT used in conjunction with radiation therapy for cancer. Professional organizations within various medical specialties can create appropriate benchmarks depending on the application.
1b.1. **Developer Rationale:** Radiologists and other physicians such as cardiologists, orthopedists, urologists and other medical specialists determine how the CT tests are performed. However, there are few national guidelines on how these studies should be conducted and, therefore, there is great potential for practice variation that could introduce unnecessary harm from excessive radiation dosing. Several publications, including our own, have demonstrated 20-50 fold variation in doses when a patient goes to different facilities to obtain a CT (Smith-Bindman, JAMA IM 2009 and JAMA 2012 and Miglioretti JAMA Pediatric 2013). Furthermore, since information on radiation is reported differently across the different types of CT machines, it is difficult for physicians to standardize their practice. Currently, physicians do not know the typical radiation doses received by their patients. This tool provides the framework for measurement – the first step towards quality improvement.

Creation of a simple standard for collection of radiation dose information would help facilities understand their current practice, would allow understanding changes in practice over time (Keegan, JACR 2014) would allow comparisons to local and national standards, and would indicate to facilities whether their is a need to improve. There is currently a high level of interest in this area - facilities are being asked by their patients and governing boards to report whether they are performing CT safely - and this measure is an ideal starting point for facilities to assemble this information to answer these questions. If facilities collect dose information, it is the first step towards trying to compete on a measure of safety and to lower the doses they use.

The measure will lead to the creation of diagnostic reference levels, and UCSF and numerous professional organizations will contribute to their creation. This will lead to dose awareness and inevitable improvements as it will enable physicians to consider dose as an important measure.

There are few diagnostic reference levels In the U.S. that are currently reflective of current practice. The American College of Radiology has published reference levels based on their CT certification program but this includes a very small number of self-selected scans from facilities who participate in the certification program (McCullough, JACR 2011). Because these references are based on so few and self selected examination, they may not reflect actual current practice. Goske has published Diagnostic Reference Ranges in children, also based on a relatively small number of studies (< 1000).

S.4. **Numerator Statement:** Radiation Dose, quantified using the distribution in four dose metrics (DLP, CTDIvol, SSDE, ED); within anatomic area, age, and machine-type strata. SSDE only pertains to abdomen scans.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only generates dose metrics for a single metric, there is a lot of information and performance information to be gleaned.

CTDIvol will reveal the settings used per small scan length. This is directly generated by most modern CT scanners.

DLP reflects both the dose per small scan length, but also the length of scan that is conducted, and is defined as CTDIvol x scan length. This is directly generated by most modern CT scanners.

Effective dose takes into account the total amount of radiation emitted from the machine as well the radio-sensitivity to developing cancer in the area radiated. The measure thus combines both radiation dose and future cancer risk. The metric is the only one that can be combined across types of studies and anatomic areas and is thus useful for dose monitoring dose surveillance and facility performance (see Smith-Bindman, Radiology, 2011).

While there are many different ways to calculate Effective Dose, and many current dose monitoring software products can do this automatically, a simple rule of thumb can be used to convert DLP to Effective dose in adults (see Huda, below). In the brain, given typical machine settings that are used, the DLP can be converted to Effective Dose by multiplying DLP measured in mGy-Cm by 0.002 to yield Effective Dose measured in milli-Sieverts. Effective Dose of CT scans though the chest can be estimated by multiplying the DLP measured in mGy-cm by .017 to yield Effective Dose measurements in mSv; and Effective Dose of abdominal and pelvis CT can be estimated by multiplying DLP by 0.18. It is not clear that using greater precision in the quantification of effective dose is necessary for the quality improvement purposes outlined in this measure.

Additional relevant citations for effective dose

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

S.7. **Denominator Statement:** Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis

S.10. **Denominator Exclusions:** CT examinations conducted in anatomic areas not included above (such as CTs of the extremities or lumbar spine). In adults approximately 16% of CT scans fall in these excluded areas. In children, approximately 23% of CT examinations fall into excluded areas.

Further, combined areas, such as head and chest, should not be included in the scans collected.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category.

De.1. **Measure Type:** Outcome

S.23. **Data Source:** Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Registry

S.26. **Level of Analysis:** Facility, Health Plan, Integrated Delivery System

**IF Endorsement Maintenance – Original Endorsement Date:** Aug 15, 2011 **Most Recent Endorsement Date:** Aug 15, 2011

**IF this measure is included in a composite, NQF Composite#/title:**

**IF this measure is paired/grouped, NQF#/title:**

De.4. **IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?** No

## 1. Evidence, Performance Gap, Priority – 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 subcriteria to pass this criterion and be evaluated against the remaining criteria.***

**1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form**
a0739_MeasSubm_Evidence_2-10-14-1--2-.docx

**1b. Performance Gap**

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

1b.1. **Briefly explain the rationale for this measure** *(e.g., the benefits or improvements in quality envisioned by use of this measure)*
Radiologists and other physicians such as cardiologists, orthopedists, urologists and other medical specialists determine how the CT tests are performed. However, there are few national guidelines on how these studies should be conducted and, therefore, there is great potential for practice variation that could introduce unnecessary harm from excessive radiation dosing. Several publications, including our own, have demonstrated 20-50 fold variation in doses when a patient goes to different facilities to obtain a CT (Smith-Bindman, JAMA IM 2009 and JAMA 2012 and Miglioretti JAMA Pediatric 2013). Furthermore, since information on radiation is reported differently across the different types of CT machines, it is difficult for physicians to standardize their practice. Currently, physicians do not know the typical radiation doses received by their patients. This tool provides the framework for measurement – the first step towards quality improvement.

Creation of a simple standard for collection of radiation dose information would help facilities understand their current practice, would allow understanding changes in practice over time (Keegan, JACR 2014) would allow comparisons to local and national standards, and would indicate to facilities whether their is a need to improve. There is currently a high level of interest in this area - facilities are being asked by their patients and governing boards to report whether they are performing CT safely - and this measure is an ideal starting point for facilities to assemble this information to answer these questions. If facilities collect dose information, it is the first step towards trying to compete on a measure of safety and to lower the doses they use.

The measure will lead to the creation of diagnostic reference levels, and UCSF and numerous professional organizations will contribute to their creation. This will lead to dose awareness and inevitable improvements as it will enable physicians to consider dose as an important measure.

There are few diagnostic reference levels In the U.S. that are currently reflective of current practice. The American College of Radiology has published reference levels based on their CT certification program but this includes a very small number of self-selected scans from facilities who participate in the certification program (McCullough, JACR 2011). Because these references are based on so few and self selected examination, they may not reflect actual current practice. Goske has published Diagnostic Reference Ranges in children, also based on a relatively small number of studies (< 1000).

1b.2. **Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.** *(This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, 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 included). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*
There is currently little information on current doses associated with CT across the nearly 10,000 CT scanners that are in operation in the US. In an article entitled "What are the National Radiation Doses?" published in 2006 in the American College of Radiology Journal, Dr. Morin, Editor of the Medical Physics Column, and a physicist with many years of experience focused on understanding and quantifying the radiation associated with medical imaging noted that the doses associated with medical imaging studies – including CT - are simply not known.

Several snapshots of radiation exposure associated with CT exist, and all have documented dramatic and unacceptably high variation in dose. For example, our work published in the Archives of Internal Medicine (now JAMA IM) in December of 2009, found for the 11 most common types of CT examinations conducted (including the study types included in the proposed measure) there was profound variation in dose between institutions, and even within the same institution, dramatic variation in dose between patients. For example, for a routine head CT there was a 20-fold variation in dose between the patient who received the highest and lowest dose. In more recent work, conducted among several large integrated health care systems, we have found doses can vary 50 fold

across patients and facilities for the same examinations (Smith-Bindman, JAMA, 2012; Miglioretti, JAMA Pediatrics, 2013; see Tables 2 and 3, "Change in radiation dose metrics over time using the NQF measure format", from Keegan et al. JACR 2014 article in attachments).

Dr. Hausleiter led an international study on one type of CT - coronary CT - and also documented dramatic variation in dose between facilities and patients. This examination type is less common, and thus not included in this patient outcome measure. There remains considerable variation in radiation dose for other types of imaging tests, such as nuclear medicine studies, however currently the majority of radiation dose for medical imaging comes from CT, therefore this measure is limited to CT.

The American College of Radiology has a relatively small and new CT Accreditation Program, and these results (presented at National Radiologic Society of North American meetings) have also found dramatic variation in dose for the most common types of examinations - CT of the head and CT of the abdomen. Data in radiation dose in children was sparse, but here too shows dramatic variation in dose.

The American College of Radiology Dose Index Registry, has collected dose data from hundreds of medical facilities and they too have found dramatic variation in dose. The Chair of the American College of Radiology Dose Index Registry, Dr. Morin, notes in his strong letter of support that accompanied the original submission of this measure, that the data collected through the Dose Registry project "demonstrate the current and dramatic variation in dose indices we have seen through the registry, highlighting the need for quality improvement in this area... This is an extremely important topic which addresses a real safety concern, given the large number of patients who undergo CT every year. There is much higher than acceptable variation in the dose indices associated with CT, and there is currently (…) no simple metrics for facilities to know how they are doing with respect to other facilities. Measuring and reporting a dose index in a simple and consistent fashion are extremely important first steps toward reducing variation, and thereby improving the safety and quality of CT imaging."

The FDA, in collaboration with individual states, collect data on different types of medical imaging studies and the associated radiation. They last collected data in 2005 (these data have not yet been formally published.) However, presentation of the results at national meetings demonstrated that even for phantom studies (i.e. studies conducted on sophisticated plastic dummies where standardized settings are used) there was dramatic variation in dose. This work is not currently collecting data on current practices.

**1b.3. If no or limited performance data on the measure as specified is reported in 1b2, 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.**
See: Tables 2 and 3 ("Change in radiation dose metrics over time using the NQF measure format") from Keegan et al. JACR 2014 article referenced below and submitted in attachments.

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology : JACR. Mar 2014;11(3):309-315. http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf

Calvert C, Strauss KJ, Mooney DP. Variation in computed tomography radiation dose in community hospitals. Journal of pediatric surgery. Jun 2012;47(6):1167-1169.

Dorfman AL, Fazel R, Einstein AJ, et al. Use of Medical Imaging Procedures With Ionizing Radiation in Children: A Population-Based Study. Arch Pediatr Adolesc Med. Jan 3 2011.

Einstein AJ, Henzlova MJ, Rajagopalan S. Estimating risk of cancer associated with radiation exposure from 64-slice computed tomography coronary angiography. JAMA 2007;298:317-23.

Hausleiter, J., T. Meyer, et al. (2009). "Estimated radiation dose associated with cardiac CT angiography." JAMA 301(5): 500-7.

Miglioretti D, Johnson E, Vanneman N, Smith-Bindman R, al e. Use of Computed Tomography and Associated Radiation Exposure and Leukemia Risk in Children and Young Adults across Seven Integrated Healthcare Systems from 1994 – 2010. JAMA Pediatrics Published online June 10, 2013 joli:101001/jamapediatrics2013311 2013.

Miglioretti, YX Zhang, E Johnson, N Vanneman, R Smith-Bindman. Personalized Technologist Dose Audit Feedback for Reducing

Patient Radiation Exposure from Computed Tomography. In press Journal of the American College of Radiology 2014.

Nationwide Evaluation of X-ray Trends: NEXT 2005-2006. This presentation was given by David Spelic, physicist with the Food and Drug Administration (FDA), to the 39th Conference of Radiation Control Program Directors (CRCPD) annual meeting, held in Spokane Washington, May 21-24, 2007.

Morin, R. L. (2006). "CT dosimetry--an enigma surrounded by a conundrum." J Am Coll Radiol 3(8): 630.

Morin, R. L. (2006). "What are the national radiation doses?" J Am Coll Radiol 3(12): 956.

Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. Arch Intern Med 2009;169:2078-86.

Smith-Bindman R. Is computed tomography safe? N Engl J Med 2010;363:1-4.

Smith-Bindman R. Environmental causes of breast cancer and radiation from medical imaging: findings from the Institute of Medicine report. Arch Intern Med 2012;172:1023-7.

Smith-Bindman R, Miglioretti DL, Johnson E, et al. Use of diagnostic imaging studies and associated radiation exposure for patients enrolled in large integrated health care systems, 1996-2010. JAMA 2012;307:2400-9.

1b.4. **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.** *(This is required for endorsement maintenance. 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 subcriterion on improvement (4b.1) under Usability and Use.*

There are two principle areas on known, or suspected, disparity. The first involves children as compared with adults. In general, it is believed that the harm of radiation with respect to the potential to cause future cancer is proportional to the radiation per unit of tissue. Because children are smaller than adults, and because doses have not been reliably reduced in children, the same radiation dose will be more harmful in children because of their smaller size. This has been known for many years (Brenner, NEJM 2007) and in fact the FDA issued a warning in 2012 asking physicians to lower the doses they use in children; however, there is no evidence that this has been widely done. We found profound variation in doses used in children (Miglioretti, JAMA Pediatric 2013), and a related abstract found that while exams in pediatric hospitals tend to use lower dose technique, doses used on children in adult hospitals (where most CT scans in children occur) are not tailored. Image Gently, a large social marketing campaign, has focused attention on this issue, but there is no evidence that this effort has resulted in any meaningful reduction in dose.

The second potential area of disparity has to do with socioeconomic status. In general, newer technologies of CT allow dose to be reduced, and public hospitals are less likely to have these newer machines. To support this hypothesis, I have just completed a large 15-center randomized trial where we collected dose across institutions (several manuscripts in press). Three of the county hospitals had the three highest doses, and on average delivered doses of radiation for routine CT that were 4-5 times higher than the best performing hospitals in the sample (Submitted for publication).

1b.5. **If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.**

**1c. High Priority** (previously referred to as High Impact)

The measure addresses:

- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

1c.1. **Demonstrated high priority aspect of healthcare**

Affects large numbers, Frequently performed procedure

1c.2. **If Other:**

**1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare. List citations in 1c.4.**

The use of diagnostic imaging has increased dramatically over the past decade, contributing to medical exposure to ionizing radiation. The largest growth has been in the utilization of computed tomography (CT). The total number of CT examinations performed annually in the United States has risen from approximately 3 million in 1980 to nearly 80 million today. Integrating CT into routine care has improved patient health care. However, CT delivers much higher radiation doses than do conventional diagnostic x-rays. For example, a chest CT typically delivers more than 1000 times the radiation dose of chest x-ray. Further, radiation exposure from individual CT examinations has also increased, in part due to the increased speed of image acquisition allowing vascular, cardiac, and multiphase examinations, all associated with higher doses. Thus, greater utilization of CT and higher exposure per examination has resulted in a substantial increase in the US population's exposure to radiation from medical imaging. The National Counsel on Radiation Protection reported that the US population's exposure to radiation from medical imaging increased 600 fold over the last 20 years.

Further, recent research conducted by our group has documented significant variation in the radiation doses associated with specific CT examinations, between facilities and patients, raising concerns that the doses may be higher than necessary and potentially un-safe. Further several egregious errors in the use of CT and its associated radiation dose– identified in several California hospitals including Cedar's Sinai and in Huntsville, Alabama where doses were delivered that were as high as radiation used to treat brain cancer – further highlighted concerns about the radiation doses that can be delivered (either deliberately or accidentally through CT) can be extremely high. These errors led to levels of radiation exposure comparable to those delivered by radiation therapy for brain cancer

Exposure to ionizing radiation is of concern, because extensive evidence has linked exposure to ionizing radiation at doses used in medical imaging to the development of cancer. While there are some uncertainties in the exact quantification of risk, the overwhelmingly supported view is that it is prudent to limit radiation to the degree possible.

Recognizing the potential risks associated with CT, The FDA has recently announced plans to increase their oversight of radiation from CT – including their call that for facilities to begin to assess the radiation used in examinations, and call for creation of diagnostic reference levels. The US House of Representatives, Energy and Commerce Committee, Subcommittee on Health has sponsored hearings specifically focused on radiation associated with medical imaging, with discussion of possible legislative oversight. The Joint Commission has issued a radiation sentinel event and has incorporated several requests for the radiation dose to be included in its most recent hospital accreditation metrics.

The measure as specified could enhance all of the efforts by providing a simple measurement tool and standard.

Of note, three of the measurements, CTDIvol, DLP and Effective Dose have been extensively tested and validated. The newly added metric, SSDE, is essentially an adjustable CTDIvol that takes into account patient size. It was developed by a collaboration of medical physicists, but has not been validated as a facility-level measure of dose. However, including SSDE has enhanced enthusiasm for this measure and thus this application for renewal the metric has been added.

In 2009, 10% of patients underwent a CT annually, and thus the number of people who are be impacted by the quality and safety of CT is extremely high.

**1c.4. Citations for data demonstrating high priority provided in 1a.3**

Board of Radiation Effects Research Division on Earth and Life Sciences "Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Washington, D.C.: The National Academies Press, 2006.

Bogdanich, Walt. "At hearing on radiation, calls for better oversight." NY Times. February 26, 2010

Calvert C, Strauss KJ, Mooney DP. Variation in computed tomography radiation dose in community hospitals. Journal of pediatric surgery. Jun 2012;47(6):1167-1169.

Caoili, E. M., R. H. Cohan, et al. (2009). "Medical decision making regarding computed tomographic radiation dose and associated risk: the patient´´s perspective." Arch Intern Med 169(11): 1069-71.

Dorfman AL, Fazel R, Einstein AJ, et al. Use of Medical Imaging Procedures With Ionizing Radiation in Children: A Population-Based Study. Arch Pediatr Adolesc Med. Jan 3 2011.

Einstein AJ, Henzlova MJ, et al. "Estimating risk of cancer associated with radiation exposure from 64-slice computed tomography coronary angiography. JAMA. Jul 18 2007;298(3):317-323."

Fletcher JG, Kofler JM, Coburn JA, Bruining DH, McCollough CH. Perspective on radiation risk in CT imaging. Abdom Imaging. Feb 2013;38(1):22-31.

Food and Drug Administration (2009) FDA Makes Interim Recommendations to Address Concern of Excess Radiation Exposure during CT Perfusion Imaging.

Goske MJ, Strauss KJ, Coombs LP, et al. Diagnostic reference ranges for pediatric abdominal CT. Radiology. Jul 2013;268(1):208-218.

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology : JACR. Mar 2014;11(3):309-315.

Mathews J, Forsythe A, Brady Z, al. e. Cancer risk in 680?000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. BMJ. 2013;346 doi: http://dx.doi.org/10.1136/bmj.f2360

McBride, D. (2009). "Radiation may be unnecessary for children with leukemia." ONS Connect 24(10): 29.

McBride J, Paxton BE, et al. (2009 American Roentgen Ray Society, Annual Meeting in Boston, MA, April 26-30.). CT Scans: Most Doctors Lack Knowledge of Radiation Exposure Risks.

McCollough C, Branham T, Herlihy V, et al. Diagnostic reference levels from the ACR CT Accreditation Program. Journal of the American College of Radiology : JACR. Nov 2011;8(11):795-803.

Medical Radiation: An Overview of the Issues: US House of Representatives, Energy an Commerce Committee Hearing - Subcommittee on Health, Friday, 26 Februrary 2010. Testimony of witnesses and discussion can be found on web site: http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1910:medical-radiation-an-overview-of-the-issues&catid=132:subcommittee-on-health&Itemid=72

Medicine ABoI. U.S. Physician Groups Identify Commonly Used Tests or Procedures They Say are Often Not Necessary. 2012; http://www.abimfoundation.org/News/ABIM-Foundation-News/2012/Choosing-Wisely.aspx. Accessed Last accessed on: 5/15/2013, 2012.

Mettler, FA Jr (2009). "Overview of Medical Usage Patterns Radiation Exposures from Imaging and Image Guided Interventions." Eighth Annual Gilbert W. Beebe Symposium. Wednesday, December 9, 2009, The National Academies Washington, D.C.

Mettler, FA Jr Thomadsen BR, et al. "Medical radiation exposure in the U.S. in 2006: preliminary results. Health Phys. Nov 2008;95(5):502-507."

Mettler FA Jr., Huda W, et al. "Effective doses in radiology and diagnostic nuclear medicine: a catalog. Radiology. Jul 2008;248(1):254-263. ."

Mettler, F. A., Jr., B. R. Thomadsen, et al. (2008). "Medical radiation exposure in the U.S. in 2006: preliminary results." Health Phys 95(5): 502-7.

Miglioretti DL, Johnson E, Williams A, et al. The use of computed tomography in pediatrics and the associated radiation exposure and estimated cancer risk. JAMA pediatrics. Aug 1 2013;167(8):700-707.

Miglioretti DL, Zhang Y, Johnson E, et al. Personalized Technologist Dose Audit Feedback for Reducing Patient Radiation Exposure From CT. Journal of the American College of Radiology : JACR. Mar 2014;11(3):300-308.

National Council on Radiation Protection and Measurements "NCRP Report No 160, Ionizing Radiation Exposure of the Population of the United States.

Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Lancet. Aug 4 2012;380(9840):499-505.

Schindera ST, Odedra D, Raza SA, et al. Iterative Reconstruction Algorithm for CT: Can Radiation Dose Be Decreased while Low-Contrast Detectability Is Preserved? Radiology. Jun 20 2013.

Smith-Bindman, R., Lipson J, et al. (2009). "Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. " Arch Intern Med 169(22): 2078-2086.

Smith-Bindman, R., D. L. Miglioretti, et al. (2008). "Rising use of diagnostic medical imaging in a large integrated health system." Health Aff (Millwood) 27(6): 1491-502.

Steenhuysen, J. (Februrary 26, 2010). "US experts seek more overgsight of medical radiation: Equipment makes need national dose standards." Retrieved March 31, 2010, from http://www.reuters.com/article/idUSN2610991020100226.

Zablotska LB, Bazyka D, Lubin JH, et al. Radiation and the risk of chronic lymphocytic and other leukemias among Chornobyl cleanup workers. Environ Health Perspect. Jan 2013;121(1):59-65.

1c.5. **If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful.** *(Describe how and from whom their input was obtained.)*

## 2. Reliability and Validity—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 subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

**2a.1. Specifications** The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. **Subject/Topic Area** *(check all the areas that apply):*

De.6. **Cross Cutting Areas** *(check all the areas that apply):*
Safety

S.1. **Measure-specific Web Page** *(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.)*

S.2a. **If this is an eMeasure**, HQMF specifications must be attached. Attach the zipped output from the eMeasure 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)
**Attachment:**

S.2b. **Data Dictionary, Code Table, or Value Sets** *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*
**Attachment:**

S.3. **For endorsement maintenance**, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.

1. An additional metric of CT radiation dose – SSDE, Size Specific Dose Estimate has been added to this measure. This is a small variation to a metric already approved (CTDIvolCivil). It differs from CTDIvol in that it adjusts for patient size.

This metric was created by physicists and the American Association of Physicists in Medicine (AAPM (American Association of Physicists in Medicine). AAPM Report No. 204 - Size-specific dose estimates (SSDE) in pediatric and adult body CT examinations. American Association of Physicists in Medicine;2011).

While it has not undergone rigorous testing, there is widespread interest in this measure, particularly in children, diagnostic reference ranges have been generated in children using this metric (Goske MJ, Strauss KJ, Coombs LP, et al. Diagnostic reference ranges for pediatric abdominal CT. Radiology. Jul 2013;268(1):208-218).
We have found it yields similar results to the other metrics (Keegan et al, JACR 2014), and importantly, this metric has broad stakeholder support.

2. The number of anatomic areas where results are presented has been reduced form 4 to 3.

We had originally included four anatomic areas (head, chest, abdomen and pelvis and lumbar spine.) Spine has been deleted as this is less frequent, and not conducted at all institutions.

Limiting the measurements to head, chest and abdomen/pelvis includes over 80% of all CT scans conducted in the US (84% of adult scans and 77% of child scans are done of these areas.)

S.4. **Numerator Statement** *(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)*
*IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.*
Radiation Dose, quantified using the distribution in four dose metrics (DLP, CTDIvol, SSDE, ED); within anatomic area, age, and machine-type strata. SSDE only pertains to abdomen scans.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only generates dose metrics for a single metric, there is a lot of information and performance information to be gleaned.

CTDIvol will reveal the settings used per small scan length. This is directly generated by most modern CT scanners.

DLP reflects both the dose per small scan length, but also the length of scan that is conducted, and is defined as CTDIvol x scan length. This is directly generated by most modern CT scanners.

Effective dose takes into account the total amount of radiation emitted from the machine as well the radio-sensitivity to developing cancer in the area radiated. The measure thus combines both radiation dose and future cancer risk. The metric is the only one that can be combined across types of studies and anatomic areas and is thus useful for dose monitoring dose surveillance and facility performance (see Smith-Bindman, Radiology, 2011).

While there are many different ways to calculate Effective Dose, and many current dose monitoring software products can do this automatically, a simple rule of thumb can be used to convert DLP to Effective dose in adults (see Huda, below). In the brain, given typical machine settings that are used, the DLP can be converted to Effective Dose by multiplying DLP measured in mGy-Cm by 0.002 to yield Effective Dose measured in milli-Sieverts. Effective Dose of CT scans though the chest can be estimated by multiplying the DLP measured in mGy-cm by .017 to yield Effective Dose measurements in mSv; and Effective Dose of abdominal and pelvis CT can be estimated by multiplying DLP by 0.18. It is not clear that using greater precision in the quantification of effective dose is necessary for the quality improvement purposes outlined in this measure.

Additional relevant citations for effective dose

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

**S.5. Time Period for Data** *(What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)*
The metric is based on cross sectional analyses, and the numerator and denominator have the same time period. The length of time needed to accrue a sufficient number of CT scans to generate sufficient precision will vary by the size of the facility, but for average sized practices, will include review of data from several months. The sample size to generate sufficient precision in the adult category is 100 CTs within each anatomic and machine type strata. More than this number can be included for example if data are automatically generated, they can be generated for a fixed time interval (see Keegan JACR 2014, Miglioretti JACR 2014). The sample size to generate sufficient precision in the child category is smaller, 50 in children within each strata. The sample sizes is lower in children (and can be lower still in the child categories if the facilities do not evaluate sufficient children within a year to meet this minimum of 50 per strata), because CT is used less often in children. Of not, facilities do not need to collate data in all categories, only ones relevant to their practice.

All of the data are stored with the CT images and stored electronic data (within DiCom Headers) and the dose data can be collected retrospectively for all patients at one time by reviewing existing records. Thus all of the data can be abstracted in a single time period of review.

**S.6. Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, 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 S.2b)*
*IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.*
Radiation dose distribution for the four metrics (CTDIvol, DLP, SSDE, Effective Dose) need to be recorded for a consecutive sample of CT examinations within anatomic area, age and machine type strata. The mean, median, and percentiles in dose distribution (min, 5%, 25%, 50%, 75%, 95%, max) for each measure need to be generated. Because these values can vary by the type of machine, these need to be recorded for each machine type within a facility. ED can be calculated using simple conversion factors for DLP as described above (a multiplication of DLP yields an effective dose) or using more sophisticated programs now readily available to do so within dose monitoring software programs.

These data can be extracted from the CT examinations in several ways. These numbers can written down directly from the CT scanner itself at the time of the examination; they can be written down from the PACS (computer terminal where images are reviewed and stored); or can be written down from the medical record if the facility stores these data as part of the medical record (a minority of facilities currently do this.) The CT manufacturers have agreed (through MITA, Medical Imaging and Technology Alliance, the professional trade association of imaging manufacturers) to make these data electronically available through export from the CT machines to a local server), and these data can also be collected electronically from the PACS, Radiology Information System, EPIC program if the data are exported there, or using any number of dose monitoring software programs allowing the collection and reporting of these dose data. The easiest way to collect these data is through one of the 6 or so commercial software programs, and several free-ware programs that enable directly extracting CT dose information from the PACS. We have published in a recent paper (Keegan, JACR 2014) several examples of techniques for dose extraction that can be completed even by even a small facility.

The strata for this measure include:
Anatomic area strata: head, chest, abdomen/pelvis
Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)
CT machine (manufacturer, type)

NOTE: The SSDE was developed as a metric for adjusting for size. However, it does not completely adjust for size and analysis within age strata are still needed among children to account for the different doses that are used and should be used for infants to obese children. Further, there have been no large-scale studies validating SSDE as a measure of quality and thus it is still import to assess dose within size strata in children to assure quality.

**S.7. Denominator Statement** *(Brief, narrative description of the target population being measured)*
Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis

S.8. **Target Population Category** *(Check all the populations for which the measure is specified and tested if any):*
Children's Health, Senior Care

S.9. **Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, 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 S.2b)*
Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis

S.10. **Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*
CT examinations conducted in anatomic areas not included above (such as CTs of the extremities or lumbar spine). In adults approximately 16% of CT scans fall in these excluded areas. In children, approximately 23% of CT examinations fall into excluded areas.

Further, combined areas, such as head and chest, should not be included in the scans collected.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category.

S.11. **Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, 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 S.2b)*
Most abdominal/pelvis CT scans in adult patients include scanning of the abdomen and pelvis as one contiguous area. If examinations are conducted limited to one region, these should also be included, as it is difficult/impossible to define what areas would be considered limited.

S.12. **Stratification Details/Variables** *(All information required to stratify the measure results including the stratification variables, definitions, 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 with at S.2b)*
Anatomic area strata: head, chest, abdomen/pelvis

These were chosen based on being the most common CT examination types conducted in the US, comprising >80% of all CT scans, and because dose varies by these groups.

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

These patient age groups were chosen based on the variation of CT settings and resulting radiation dose based on patient size (and age is frequently used as a marker for size.) The ICRU (International Commission on Radiation Units and Measurements) uses these child size categories, they correspond to available phantoms, and they are the ones found to be most reliable through the Image Gently Campaign

CT machine (manufacturer, type)

Geographic location where studies done (zip code or state)

Other strata are not needed

S.13. **Risk Adjustment Type** (Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)
No risk adjustment or risk stratification
If other:

S.14. **Identify the statistical risk model method and variables** *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)*

**S.15. Detailed risk model specifications** *(must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)*
*Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.*

**S.15a. Detailed risk model specifications** (*if not provided in excel or csv file at S.2b*)

**S.16. Type of score:**

If other:

**S.17. Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

**S.18. Calculation Algorithm/Measure Logic** *(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*

**S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment** *(You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

**S.20. Sampling** *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*
IF a PRO-PM, identify whether (and how) proxy responses are allowed.
For adult categories, 100 patients within each strata will provide minimum sample size.

For child categories, 50 patients within each strata is more feasible and will provide adequate sample size. (One year of data should be extracted if the minimum cannot be met within a shorter time interval).

**S.21. Survey/Patient-reported data** *(If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.)*
IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.

**S.22. Missing data** (specify how missing data are handled, e.g., imputation, delete case.)
Required for Composites and PRO-PMs.
The dose metrics are occasionally not available for a particular scan. These can be deleted from the numerator and denominator, although should be exceedingly rare (< 1/1000 examinations).

**S.23. Data Source** *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*
*If other, please describe in S.24.*
Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Registry

**S.24. Data Source or Collection Instrument** *(Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.)*
IF a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration.
Electronic CT images (captured from the CT console at the time of scanning or harvested from the PACS (Picture Archiving Communication System - the computerized systems for reviewing and storing imaging data), Radiology Information System, EPIC, printed CT images, or information stored in the medical record. Further numerous software products are now available for capturing these data (Bayer, GE, etc.) and several free ware programs are also available. Of note, a recent California law requires the reporting

of several of the dose metrics outlined in this measure in the patient medical record, and as a results, many software companies have provided techniques for collating these data.

S.25. **Data Source or Collection Instrument** *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

S.26. **Level of Analysis** *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*
Facility, Health Plan, Integrated Delivery System

S.27. **Care Setting** *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*
Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Ambulatory Care : Outpatient Rehabilitation, Ambulatory Care : Urgent Care, Hospital/Acute Care Facility, Imaging Facility
If other:

S.28. **COMPOSITE Performance Measure** - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

**2a. Reliability – See attached Measure Testing Submission Form**
**2b. Validity – See attached Measure Testing Submission Form**
b0739_MeasSubm_MeasTesting_2-10-14-2-.docx

## 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.

**3a. Byproduct of Care Processes**

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. **Data Elements Generated as Byproduct of Care Processes.**
Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Other
If other: The two of the specified metrics (CTDIvol and DLP) are generated as part of clinical CT examinations. The two additional metrics can be easily calculated from these two primary metrics and these calculations are done within existing software products or can be done manually, or using various additional approaches.

**3b. Electronic Sources**

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. **To what extent are the specified data elements available electronically in defined fields?** *(i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)*
ALL data elements are in defined fields in a combination of electronic sources

3b.2. **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 other than electronic sources.**

3b.3. **If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.**
**Attachment:**

**3c. Data Collection Strategy**

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs

associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. **Describe what you have learned/modified 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.**
**IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those whose performance is being measured.**
Two of the dose indices that are specified (DLP and CTDIvol) are available on nearly all (>95%) of CT scans conducted in the US. The FDA collects dose data on a sample of imaging examinations every year as part of a collaborative effort with states called the NEXT survey. The last year data were collected on CT exams was in 2005. These data are collected based on phantom studies (ie CTs conducted on sophisticated plastic phantoms rather than patients, thus providing data different from, although complimentary to, the proposed metric). However, as part of that survey the FDA documented that he vast majority of CT machines in operation will document DLP and CTDIvol. (Unpublished, information provided by Dave Spelic, FDA). Given the adoption of uniform standards described above, this number should be higher today.

Effective Dose, can be calculated easily by multiplying the DLP by a factor specific to patient age (child or adult) and anatomic area (head, chest, abdomen/pelvis, spine) and is thus easily calculated from the DLP. The usefulness of effective dose (even though it is similar to DLP) is that it is a measure that can be calculated from all radiologic tests associated with ionizing radiation (X-rays, fluoroscopy, angiography, nuclear medicine, etc.), making it an easy measure to understand and compare between different types of tests. The multiplication for adults are provided above, and there are several conversion factors that can be used for children.

SSDE can be calculated manually, and is currently calculated by many vendors who developed software to extract radiation dose metrics from CT machines or PACS. Thus this metric is almost as available as the other metrics.

Thus nearly all facilities that perform CT examinations can collect the specified indices outlined in this measure. There could be a small number of facilities that have only very old CT scanners that do not routinely record this information, yet even for these, there are simple excel based programs – such as IMPACT CT, or CT EXPO - that allow the input of technical parameters to generate these values.

There may be a small number of CT scans where these data are simply missing (probably < 1/1000 examinations) but their exclusion from both the numerator and denominator will have no significant bearing on the overall distribution of the dose indices.

A busy facility center can abstract data on scans that were conducted over a few days to have sufficient sample size, whereas smaller centers may to compile data from several months to generate sufficient data within each anatomic area/age/machine type category.

On a practical level, these data are readily available and easy to assemble. Specifically, a medical chart abstractor or technologist would need to record the CTDIvol and DLP data from a review of the CT images on a PACS scanner, CT console, or medical record. These data are thus captured from displayed values on the CT operator console or otherwise electronically harvested.

If facilities strive to achieve a high rate of reporting the radiation dose data in the medical records it would be easy in the future to compile the data for this measure using data in the medical records.

Lastly, the CT manufacturers have agreed to uniformly adopt the same standard for reporting the radiology dose data (called the Dose SR [standard report]) and all new machines have had this feature since the end of 2010, providing a method whereby this is available to a proportion of existing scanners. With this feature, generating these metrics will be extremely simple.

3c.2. **Describe 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)*.

## 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.

**4a. 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.

4.1. **Current and Planned Use**

*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 performance improvement.*

| Planned | Current Use (for current use provide URL) |
|---|---|
| Public Reporting<br><br>Quality Improvement with Benchmarking (external benchmarking to multiple organizations)<br><br>Quality Improvement (Internal to the specific organization) | |

4a.1. **For each CURRENT use, checked above, provide:**

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

4a.2. **If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons?** (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

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

**4b. Improvement**

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b.1. **Progress on Improvement. (Not required for initial endorsement unless available.)**

**Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:**

- **Progress (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**

We have used the NQF method of assessing facility level and provider level radiation dose metrics and have demonstrated substantial improvements in dose over time (Keegan, 2014) and as the result of a randomized trial of an educational intervention and process whereby technologists were shown their performance using the dose summary that was designed to follow the NQF measure (Miglioretti, 2014).

4b.2. **If no improvement was demonstrated, what are the reasons? 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.**

**4c. Unintended Consequences**

The 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).

4c.1. **Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.**

There are two potential limitations of the proposed measures that need to be described. CT radiation dose will vary by patient size, and the specific protocols used, and yet we are not suggesting the dose indices be collected in separate strata for size (other than for children) nor for different protocols. These two issues will be addressed separately.

PATIENT SIZE

One factor that influences the radiation dose in CT is patient size. In general higher doses are used in large patients in order to maintain the same image quality as can be achieved with lower doses in smaller patients. It simply takes higher doses of radiation to penetrate (get through) larger sized patients. Thus the recorded radiation doses in part will reflect the size of the patients seen.

If a facility sees a very high proportion of obese patients, their doses will be higher than a facility that sees very thin patients. This issue will be important when facilities compare their dose indices to normative data (to the diagnostic reference level data), as they should compare their actual data to data of facilities that assess similar patients. This is the reason that facilities should note the state where their facility is located if they submit their data to a national organization. Diagnostic reference levels should be generated at a local enough level (state, or region of the country) so they are most useful and relevant with respect to the size of patients scanned. Thus diagnostic reference data should reflect geographic differences and be appropriate to the typical patients seen in a given area, as called for in the FDA white paper on radiation safety. Thus if patients tend to be larger in the Northwestern states, the diagnostic reference levels may be higher in that region. As long as a given facility is compared to the correct area, this would have no impact unless a facility differs profoundly from the other facilities in its geographic region. Of note, the differences in patient size will only have a relative small impact on dose (around a two fold difference between the smallest and largest adult patients,) whereas variation in dose by 20-50 fold have been seen unrelated to patient size (Smith-Bindman, JAMA 2012; Smith-Bindman, JAMA IM 2009; Miglioretti, JAMA Pediatrics 2013; and Miglioretti, JACR 2014). Thus, while the current metrics does not perfectly account for size, size is a small contributor to dose, in comparison to much larger, unexplained and unjustified variation.

Thus the validity of the proposed NQF measure dose not require consideration individual level adjustment of patient size. Facilities (even without consideration of external data) can compare their own data from one year to their data from prior years, and unless there is a profound shift in the weight of their patients, this will have no impact on their data. Facilities should still perform in-depth analysis of patient's who receive high radiation doses (perhaps above the 75% distribution at their own institution) to determine if those doses were appropriate and justified, or if they could have been reduced.

Further, none of the quality control programs in existence and described above (UK, European or American College of Radiology Programs) assess patient weight in conjunction with CT dose measures. It is simply not feasible, and would make it far more difficult for facilities to assemble dose data, as this information is not recorded as part of the radiology medical record, and is typically not available anywhere for most patients seen in outpatient settings. Difference in patient size is only one factor contributing to dose, and likely accounts for only a small amount of the large variation in dose within and between facilities.

The issue of the validity of this measure without consideration of patient size was vetted with a large number of physicists. There was widespread agreement that this measure as specified was highly valuable. Three letters of support (from the ACR, NCRP and FDA) supporting the measure as specified were included with the initial submission of this NQF measure when it was first approved.

CT PROTOCOLS

The way CT studies are conducted (the "protocols" using the language of CT) leads to the radiation doses patients will receive. These are the specific instructions the radiologist or other physician and technologists program into the CT machine at the time of

scanning. The instructions include how large an area to scan, how many times to scan each area and the settings of kVp and mAs to use. If a larger anatomic area is imaged, the dose the patient receives will be higher. If a multiphase study is done (meaning a single anatomic area is imaged many times) the dose will be higher than if a single-phase study is done. If a facility chooses to use multiphase protocols frequently, or to scan large anatomic areas frequently, their doses will be higher than facilities that try to minimize the area imaged or number of scans taken. The type of scans done in Los Angeles California and Huntsville Alabama that led to the extreme radiation dose exposures for CT, were perfusion scans, a type of scan where a small area of the brain is imaged dozens, and sometimes hundreds of times.

The two ways to collect and compare CT dose index information would be first to compare doses WITHIN the specific study type - thus compare doses for routine single phase studies and compare doses for multiphase studies, or second to compare typical doses for all patients who undergo a CT within a single anatomic area (ignoring considering of the specific protocol used).

The latter method is far more practical. It's a large amount of work to determine the specific protocol, why a study was done, whether it was routine or not, how many phases were used, and it is simply not practical to have a data abstractor or technologist necessarily know how distinguish the study type. However, I also strongly believe this latter method is far more valid, reproducible and a reliable measure of quality. This is particularly true as there are no evidenced based guidelines about when particular protocols should be used. In particular the multiphase, higher dose protocols are not clearly indicated in particular clinical situation, studies have not shown they lead to improved diagnoses or quantified the potential harm in their use, and differences reflect practice variation more than any objective criteria of the need for these multiphase, studies. That's not to say that these higher dose protocols don't have any value – but only that decisions about when to use different protocols are more based on physician preferences that patient outcomes, and choosing to frequently use these higher dose protocols should be reflected in the radiation dose quality metrics generated at a facility.

To highlight this issue, a concrete and very realistic example has been provided below of two facilities and their choice regarding imaging patients with head CT. Keep in mind that the question a patient, a referring clinician, a radiologist, a hospital administrator or payer might wonder is what is the dose Ms. Smith will likely receive if she goes to a particular facility for a head CT.

Two facilities (A and B) will have different doses for different exam types and will have a different distribution of how often the different exam types are used.

For the sake of this example, we will estimate that a basic head CT has a dose of 2-3 mSv and a multiphase head CT has a dose of 15-20 mSv (numbers from our Archives paper)

| | |
|---|---|
| Basic head CT | 2-3 mSv |
| Multiphase head CT | 7-30 mSv |

For the sake of this example, we will estimate that facility "A "uses the basic head CT for most of their patient's (95%) and that facility "A" the dose for the basic head CT is 2.5 mSv, and is 20 mSv for a more complicated head CT (like a perfusion scan).

At facility "B" they use the basic head CT less often (50%) and use the more complicated head CT more often (also 50%.). Their dose for the basic head CT 2 mSv (lower at this facility as they use the much higher dose, multiphase study more often, so can get away with lowering the dose on the routine study). They also have a lower dose for the multiphase study, at 15 mSv.

For the sake of this example, each facility will conduct 100 head CTs over the course of a week.

If the two facilities were compared WITHIN study type, facility "B" would appear to be doing a better job at dose reduction, as they have a lower dose for a simple head CT (2 mSv versus 2.5 mSv) and have a lower dose for a multiphase head CT (15 mSv versus 20 mSv). And yet this facility is using the higher dose multiphase protocol far more often.

Thus if we would compare the average dose per head CT (which is the clinical quality question a patient and payer would care about), it would be far lower at facility "A" Facility "A" has an average dose of 3.4 mSv [(95 low dose studies * 2.5 mSv) + (5 high dose studies*20 mSv)/100] whereas facility "B" has an average dose that is substantially higher at 8.5 mSv [(50 low dose studies * 2 mSv) + (50 high dose studies*15 mSv)/100].

Thus the dose patients receive will be driven by the choice of protocol more than the dose within protocol and doing comparisons

only within protocol with mask real and important differences. Thus comparing overall exposure within anatomic area is not only more feasible, it is more appropriate if the goal is to identify facilities where the typical doses are simply too high. The facility could then explore why their doses are high.

## 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.

**5. Relation to Other NQF-endorsed Measures**
Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.
YesYes

5.1a. **List of related or competing measures (selected from NQF-endorsed measures)**
0740 : Participation in a Systematic National Dose Index Registry

5.1b. **If related or competing measures are not NQF endorsed please indicate measure title and steward.**
0740 : Participation in a Systematic National Dose Index Registry
The steward is the American College of Radiology0740 : Participation in a Systematic National Dose Index Registry
The steward is the American College of Radiology

**5a. Harmonization**

The measure specifications are harmonized with related measures;
**OR**
The differences in specifications are justified

5a.1. **If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):**
**Are the measure specifications completely harmonized?**

5a.2. **If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.**

**5b. Competing Measures**

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);
**OR**
Multiple measures are justified.

5b.1. **If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):**
**Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)**
The ACR Dose Index Registry and this measure each collect similar dose metrics - DLP, CTDIvol, SSDE are specified in each. I believe Effective Dose only specified in this measure.

The ACR provides benchmarking to organizations that belong to their registry (it is a fee based system) and do not publish benchmarks publicly. I do not believe they benchmark by anatomic area, but rather by protocol as described above, with the inherent weakness of not distinguishing organizations that use multiphase studies frequently or rarely.

The UCSF measures encourages facilities to analyze their own data using a simple standard, and benchmarks are currently being published using data from a large number of institutions using the measure specifications. Further, institutions can track their own performance over time using this measure. The ACR Dose Index Registry and this measure each collect similar dose metrics (DLP and

CTDIvol are specified in each).

The ACR provides benchmarking to organizations that belong to their registry (it is a fee based system) and do not publish benchmarks publicly.

The UCSF measures encourages facilities to analyze their own data using a simple standard, and benchmarks are currently being published using data from a large number of institutions using the measure specifications. Further, institutions can track their own performance over time using this measure.

## Appendix

**A.1 Supplemental materials may be provided in an appendix.** All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.
Attachment **Attachment:** NQFAttachments_21214-635321278149646536.pdf

## Contact Information

Co.1 **Measure Steward (Intellectual Property Owner):** University of California San Francisco
Co.2 **Point of Contact:** Rebecca, Smith-Bindman, Rebecca.smith-bindman@ucsf.edu, 415-353-4946-
Co.3 **Measure Developer if different from Measure Steward:** University of California San Francisco
Co.4 **Point of Contact:** Rebecca, Smith-Bindman, Rebecca.smith-bindman@ucsf.edu, 415-353-4946-

## Additional Information

Ad.1 **Workgroup/Expert Panel involved in measure development**
**Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
Letters of support were included from three individuals with leadership positions in radiation safety who strongly support the measure as specified, with active leadership positions in the NCRP, ACR and FDA.

**Measure Developer/Steward Updates and Ongoing Maintenance**
Ad.2 **Year the measure was first released:** 2011
Ad.3 **Month and Year of most recent revision:** 02, 2013
Ad.4 **What is your frequency for review/update of this measure?** two years
Ad.5 **When is the next scheduled review/update for this measure?** 01, 2014

Ad.6 **Copyright statement:**
Ad.7 **Disclaimers:**

Ad.8 **Additional Information/Comments:**