

NATIONAL QUALITY FORUM

Measure Evaluation 4.1 January 2010

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The sub-criteria and most of the footnotes from the [evaluation criteria](#) are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all **yellow highlighted** areas of the form. Evaluate the extent to which each sub-criterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the sub-criteria (**yellow highlighted areas**).

Steering Committee: Complete all **pink** highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few sub-criteria as indicated)

(for NQF staff use) NQF Review #: PSM-044-10	NQF Project:
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Radiation Dose of Computed Tomography (CT)	
De.2 Brief description of measure: The measure has two components. Part A is an outcome measure; Part B is a process measure.	
Both would work together towards improving quality and allowing hospitals and imaging facilities to conduct ongoing quality improvement.	
Part A: radiation dose associated with computed tomography (CT) examinations of the head, neck, chest, abdomen/pelvis and lumbar spine, obtained in children and adults.	
Part B: The proportion of CT examinations where a measure of dose is included in the final medical report	
1.1-2 Type of Measure: outcome	
De.3 If included in a composite or paired with another measure, please identify composite or paired measure	
De.4 National Priority Partners Priority Area: safety	
De.5 IOM Quality Domain: safety	
De.6 Consumer Care Need: Staying Healthy	

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>Public domain only applies to governmental organizations. All non-government organizations must sign a</i>	A Y <input type="checkbox"/> N <input type="checkbox"/>

<p><i>measure steward agreement even if measures are made publicly and freely available.</i></p> <p>A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: agreement signed and submitted</p> <p>A.4 Measure Steward Agreement attached: 1txNQFMeasureStewardAgreement_020309_Final-1.pdf</p>	
<p>B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section</p>	<p>B</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.</p> <p>► Purpose: public reporting, quality improvement</p>	<p>C</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.</p> <p>D.1 Testing: Yes, fully developed and tested</p> <p>D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes</p>	<p>D</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (<i>if submission returned</i>):</p>	<p>Met</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>Staff Notes to Reviewers (<i>issues or questions regarding any criteria</i>):</p>	
<p>Staff Reviewer Name(s):</p>	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
<p>Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.</p> <p><i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)</i></p> <p>1a. High Impact</p>	<p>Eval</p> <p>Rating</p>
<p>(for NQF staff use) Specific NPP goal:</p>	
<p>1a.1 Demonstrated High Impact Aspect of Healthcare: affects large numbers, frequently performed procedure</p> <p>1a.2</p> <p>1a.3 Summary of Evidence of High Impact: 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 75 million in 2007. Integrating CT into routine care has improved patient health care, and CT is widely considered among the most important advances in medicine. However, CT delivers much higher radiation doses than do conventional diagnostic x-rays. For example, a chest CT typically delivers more than 400 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</p>	<p>1a</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

National Council 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 recent gross errors in the use of CT and its associated radiation dose- identified in several California hospitals including Cedar's Sinai and in Huntsville Alabama - 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 evidence has linked exposure to low-level ionizing radiation at doses used in medical imaging to the development of cancer.

Recognizing that potential risks associated with CT, The FDA has recently announced plans to increase their oversight of radiation from CT - including their call that 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.

In 2009, approximately 1 in five patients underwent a CT , and thus the number of people who are be impacted by the quality and safety of CT is extremely high.

1a.4 Citations for Evidence of High Impact: 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

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.

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."

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

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.

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

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.

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

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

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Radiologists 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. Furthermore, since information on radiation is reported differently across the different types of CT machines, it is difficult for radiologists to standardize their practice. Currently, radiologists do not know the typical radiation doses received by their patients. Almost certainly non-radiologists who are conducted CT studies also do not know the radiation doses delivered to their patients.

Creation of a simple standard for collection of radiation dose information would help facilities understand their current practice, 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, its the first step towards trying to compete on a measure of safety and I envision facilities will begin to do all they can to lower the doses they use.

The measure will lead to the creation of diagnostic reference levels, this will lead to dose awareness and inevitable improvements as it will enable physicians to consider dose as an important measure.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

Although CT delivers high doses of radiation, there is currently very 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.

However, several small snapshots of radiation exposure associated with CT exist, and all have found dramatic and unacceptably high variation in radiation dose. For example, our work published in the Archives of Internal Medicine 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

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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.

As another example, Dr. Hausleiter led an international study on one type of CT - coronary CT - and also documented dramatic variation in dose between facilities and patients.

The American College of Radiology has a relative small and new CT Accreditation Program that has been in existence for several years, 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.

The American College of Radiology Dose Index Registry, a new project still in its infancy, has begun collecting dose data from 8 CT machines across the country, and also found dramatic variation in dose. The Chair of the American College of Radiology Dose Index Registry, Dr. Morin, notes in his very strong letter of support accompanying this submission, 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." He goes onto say in his letter of support "I am strongly supportive of the quality metric you are submitting to the National Quality Forum focused on quantifying the radiation associated with Computed Tomography. 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 program where data are collected from actual CT scans conducted across the country, and 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."

Lastly, 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 hav not yet been published. However, preliminary results demonstrated that even for phantom studies (ie studies conducted on sophisticated plastic dummies where standardized settings are used) there was dramatic variation in dose

1b.3 Citations for data on performance gap:

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

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.

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.

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.

1b.4 Summary of Data on disparities by population group:

no data exist

1b.5 Citations for data on Disparities:

1c. Outcome or Evidence to Support Measure Focus

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1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*): The risk of radiation induced cancer, is proportional to the level of radiation exposure. Reduction in radiation exposure will be associated with reduction in cancer risk (BEIR VII reference documenting the association between radiation exposure and adverse effects including cancer, 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

Although radiation dose information is not currently collected in the US, programs exist in many European countries, Canada and Asia, for collecting the dose information using the indices specified in this measure. They have found the doses can be reduced through data collection and reporting. These programs have collected and reported dose information for many years, largely using voluntary programs, and this has resulted in a lowering of typical radiation dose. The most well known and published program is run through the National Radiological Protection Board (NRPB) in the United Kingdom. The most recent report, NRPB-W67, describes a snapshot of patient CT dose. (Doses from Computed Tomography (CT) Examinations in the UK - 2003 Review. Shrimpton PC et al. National Radiological Protection Board, Chilton, Didcot, Oxon, ISBN 0 859515567, <http://www.mendeley.com/research/nrpbw67-doses-from-computed-tomography-ct-examinations-in-the-uk-2003-review/>) The doses described in this report are on average approximately 50% lower than the doses used in the US (as documented in our Archives paper, the ACR accreditation data and the ACR dose registry data).

The near absence of widely collected data on current doses in the US, agreed upon standards for how the CTs should be programmed (meaning how these complex machines should be instructed to conduct the examinations), or an agreed upon metric whereby data could be collected and analyzed across facilities has led to the current situation where each facility decides on how to set up their individual CT scans. Further, the absence of widely published guidelines for acceptable ranges of dose in the US would make it difficult for an institution to know if they are doing well in minimizing this important harm of CT.

Oversight of CT is limited and highly fragmented, with no single organization assigned responsibility to ensure the standardization of CT dose when used in clinical practice. For example, while the FDA monitors the manufacture of CT machines, they do not assess how they are used in routine practice and they do not collect information on actual clinical practice. However, the FDA, have recently highlighted in their white paper on minimizing radiation dose the pressing need to collect dose information associated with the most common types of diagnostic CT and to use these data to generate standards for targeted dose.

The endorsement of a single measure of radiation dose by the NQF dose could have a profound effect on quality. An endorsement of a single quality measure, would allow facilities to begin assembling and evaluating their doses; would allow facilities to identify outlier doses and whether their typical doses fall within acceptable ranges, to share doses across facilities, and geographic areas, and to start to compete to lower dose. Further, if facilities began collecting these data, they could voluntarily share them with central quality improvement organizations to start generating diagnostic reference levels for CT.

1c.2-3. Type of Evidence: cohort study, observational study, systematic synthesis of research

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*):

There is extensive epidemiologic and biologic evidence that links exposure to ionizing radiation with promoting the development of lethal cancer, and in particular, cancer that involves the hematological system, breast, and thyroid. The evidenced comes from several sources, including studies of the Japanese atomic-bomb survivors. Even at low doses of radiation, atomic-bomb survivors were at a significantly increased risk of developing cancer. The dose associated with a single CT imaging examination is in the same range as the lower doses received by some of the Japanese survivors who were found to have a significantly increased risk of cancer. The second line of evidence comes from epidemiological studies of medically irradiated populations who were irradiated for both malignant and benign disease. Following

high-dose radiotherapy for malignant disease, an elevated risk of radiation-related second cancers has been observed and this increased risk of second primary malignancies is particularly high among survivors of childhood cancer who received therapeutic doses of radiation. The relatively common use of radiation for benign disease in the mid 1900s (1940-1960), sometimes resulted in a substantial relative risk of developing cancer. For example, cancers of the thyroid, salivary gland, central nervous system, skin, and breast have been associated with radiotherapy for tinea capitis, enlarged tonsils or thymus, and benign conditions of the head, neck, and breast. The risk of thyroid cancer is 5 - to 40-fold higher after childhood radiotherapy for benign conditions. Children who underwent cardiac catheterization to evaluate congenital anomalies were found to have twice the expected number of cancers later in childhood. Lastly, radiation-associated cancer risk and cancer-prone disorders may interact; so some patients with a genetic disposition might be at particularly high risk of developing malignancy at even relatively low exposure of medical radiation. The third line of evidence comes from an increased risk of cancer specific mortality associated with the occupational exposure to medical ionizing radiation. Radiologists and technologists have been found to be at increased risk of cancer mortality.

The literature on the health effects of exposure to ionizing radiation is best summarized in the BEIR VII phase 2 report (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

The BEIR VII committees, the most widely cited source on the topic, concluded after an exhaustive review of the literature that no dose of radiation should be considered completely safe, and attempts should be made to keep radiation doses as low as possible. As part of their report, The BEIR VII report presented the best risk estimates for exposure to low-dose, radiation in human subjects, which largely rely in large part on results of the Life Span Study (LSS), the study of the 120,000 survivors of the atomic bombings in Hiroshima and Nagasaki Japan. Organ specific radiation doses are linked with organ specific risks of cancer and cancer mortality. Researchers have used these data to estimate the risk of exposure to a single medical imaging study. For example, Einstein and colleagues estimated the risk of cancer associated with the radiation exposure from a single 64-slice computed tomography coronary angiography was as high as a 1/114. We found in our Archives paper that the risk of cancer could be as high as 1/80.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom*):

The evidenced is considered compelling for a strong association between radiation exposure and cancer risk. The risk is based on a large number of observational studies and case control studies, and using the criteria of the UK National Health Service would be classified as A, consistent data from cohort studies.

1c.6 Method for rating evidence:

1c.7 Summary of Controversy/Contradictory Evidence: There is controversy regarding the exact quantification of the risk associated with radiation associated with medical imaging. There is no controversy regarding that there is risk of cancer associated with medical radiation. All radiology professional organizations (such as the American College of Radiology, ACR) , physics professional organizations (such as American Association of Physicists in Medicine) and oversight organizations (such as National Council on Radiation Protection and the FDA) have endorsed the goal of lowering radiation dose from CT. See the American College of Radiology published a White Paper on Radiation Dose in Medicine (Amis SE, et al, JACR 2007).

1c.8 Citations for Evidence (*other than guidelines*): 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. There are hundreds of references cited within this comprehensive summary

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*):

<p>1c.10 Clinical Practice Guideline Citation: 1c.11 National Guideline Clearinghouse or other URL:</p> <p>1c.12 Rating of strength of recommendation (<i>also provide narrative description of the rating and by whom</i>):</p> <p>1c.13 Method for rating strength of recommendation (<i>If different from USPSTF system, also describe rating and how it relates to USPSTF</i>):</p> <p>1c.14 Rationale for using this guideline over others:</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Importance to Measure and Report</i>?</p>	1
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	1 Y <input type="checkbox"/> N <input type="checkbox"/>
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
<p>Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)</p>	Eval Rating
2a. MEASURE SPECIFICATIONS	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p> <p>2a. Precisely Specified</p>	
<p>2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): Part A: Radiation Dose, quantified using DLP, CTDIvol; within anatomic area, age, and machine-type strata Part B: The proportion of CT scans of one of the included anatomic areas with a measure of radiation dose reported in the final approved report. (The reported measure can be DLP, CTDIvol or Effective Dose.)</p> <p>2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): The metric is based on cross sectional analyses, and the numerator and denominator have same time period. The length of time needed to accrue a sufficient number of CT scans to generate sufficient precision for Part A will vary by the size of the facility, and will vary from 1 day to one year, but in general will be within one month. The sample size to generate sufficient precision in the adult category is 100 CTs within each anatomic and machine type strata. The sample size to generate sufficient precision in the child category is 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).</p> <p>All of the data are stored with the CT images 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 (probably a day or two)</p> <p>For Part B, the length of time to accrue a sufficient number of CT scans will be very short, as there are no separate strata.</p> <p>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): Part A: Radiation dose distribution for CTDIvol and DLP will need to be recorded for a consecutive sample</p>	2a- specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

of CT examinations within anatomic area, age and machine type strata. The mean, median, and percentiles in dose distribution (min, 5%, 10%, 25%, 50%, 75%, 90%, 95%, max) for CTDIvol and DLP. Because these values can vary by the type of machine, these need to be recorded for each machine type within a facility. A simple excel spread sheet will be made available for facilities that would like to use this to calculate descriptive statistics, based on entering raw CTDIvol and DLP CT dose data.

These data can be extracted from the CT examinations in several ways. These numbers can be 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 recently 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 in the future, this will simplify even further the collection and reporting of these dose data.

The strata for this measure include:

Anatomic area strata: head, chest, abdomen/pelvis and lumbar spine

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

CT machine (manufacturer, type)

Part B. The proportion of CT examinations (of the head, chest, abdomen/pelvis, and lumbar spine) with at least one measure of radiation dose included in final approved report. The measures that can be reported are DLP, CTDIvol and Effective Dose. It would be optimum if all three were reported.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured*):

Part A and Part B: Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis and lumbar spine.

2a.5 Target population gender: Female, Male

2a.6 Target population age range: all ages

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator*):

Part A and Part B. Numerator and denominator time windows are equivalent and as needed for assembling of at least 100 studies within each anatomic area and machine type strata for adults. and 50 studies (or one year of data) for anatomic area and machine type strata for children. (Fewer CT scans are conducted in children thus the lower volume of studies suggested in these groups)

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions*):

Part A and Part B: Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis and lumbar spine.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population*): Part A and Part B. CT examinations conducted in anatomic areas not included above (such as CTs of the extremities).

Note: among examination types not to be included in adults are "limited abdomen" or "limited pelvis" studies. In children, all abdomen and pelvis CT scans are included in the abdomen/pelvis category.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions*):

Most abdominal CT scans in adult patients include scanning of the abdomen and pelvis as one contiguous area. If examinations are conducted limited to the abdomen or limited to the pelvis, these should not be included- this would require creation of two additional anatomic area strata, and is not felt to add sufficient value to warrant inclusion.

For children, a CT scan more commonly might involve scanning a limited area (so these limited studies are

more frequent). Further, it could be more difficult to distinguish whether an examination was one of these limited types or include both abdomen and pelvis together in children. Thus it is not feasible to divide these categories in children. Thus in children all abdomen and pelvic scanning should be included when calculating this measure in children.

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions*):

Anatomic area strata: head, chest, abdomen/pelvis (as a single contiguous region) and lumbar spine.

These were chosen based on being the most common CT examination types conducted in the US.

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 (a social networking campaign to measure and reduce exposures in children, correspondence, with Dr. Donald Frush, Professor, Pediatric Radiology, Duke University, leader Image Gently Campaign.)

CT machine (manufacturer, type)

Geographic location where studies done (zip code or state)

2a.12-13 Risk Adjustment Type: no risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method*):

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score:

2a.20 Interpretation of Score:

2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps*):

2a.22 Describe the method for discriminating performance (*e.g., significance testing*):

Each facility can compare their performance to their previous year's performance. The average doses would be expected to decrease each year. Further, facilities can compare their performance (50%, 75%, 95%) to diagnostic reference levels. The 75% distribution in dose is generally used to set diagnostic reference levels (ideal upper limit targets).

The concept of diagnostic reference levels is that they can be used as tool to decrease average dose exposure to the population and create dose awareness. They are typically set based on collectin of dose data across a large number of patients and facilities, and the cutoff of the 75% distribution is usually set as the upper limit of typical dose. In Europe, and the UK, these are used to encourage physicians to consciously choose the dose levels prescribed and physicians must document when they choose to exceed the reference dose values.

Thus these reference values are not upper limits for radiological examinations (these do not mandate an absolute upper limit to exposures) but averages, and have been used largely to identify facilities where the dosage is typically to high.

These diagnostic reference levels currently do not exist in the U.S. However, the data collected as part of the proposed measure will likely lead to the creation of these levels. Several organizations have in fact tried to set diagnostic reference levels in the US, but have had difficulty in that there were few data to use to assemble these values (see letter of support from Dr. Bushberg describing the NCRP's efforts in this area.) In practice, once these values are created, facilities compare their values to these thresholds, and

facilities that routinely exceed these performance levels are encouraged to evaluate the settings they are using when setting up their CTs to assess if they are appropriate and necessary, or if they can be reduced.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):*
 Part A: 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)

Part B: This measure includes all reports (no strata) and a minimum of 100 reports is adequate

2a.24 Data Source *(Check the source(s) for which the measure is specified and tested)*
 electronic Health/Medical Record

2a.25 Data source/data collection instrument *(Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):*
 Part A: 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), printed CT images, or information stored in the medical record
 Part B: Electronic Health/Medical Record.

2a.26-28 Data source/data collection instrument reference web page URL or attachment:

2a.29-31 Data dictionary/code table web page URL or attachment:

2a.32-35 Level of Measurement/Analysis *(Check the level(s) for which the measure is specified and tested)*
 Facility/Agency

2a.36-37 Care Settings *(Check the setting(s) for which the measure is specified and tested)*
 Hospital, Ambulatory Care: Hospital Outpatient, Ambulatory Care: Office, Ambulatory Care: Clinic, Ambulatory Care: Emergency Dept, all settings

2a.38-41 Clinical Services *(Healthcare services being measured, check all that apply)*
 Clinicians: Physicians (MD/DO), Imaging

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size):* A sample of 100 subjects within each strata will yield highly precise estimates of dose, and these measures of dose are highly correlated with external measurements of dose.
 A sample of 50 subjects in the child strata will yield a reasonably precise estimate of dose.

2b.2 Analytic Method *(type of reliability & rationale, method for testing):*
 Part A: Basic descriptive statistics (min, 5%, 10%, 25%, 50%, 75%, 90% 95%, max).
 Part B: Proportion

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted):*
 These indices and descriptive statistics, for the specific specified indices (DLP, CTDIvol, and effective dose) are used by the several European countries, Canada, The UK to estimate, measure, report and standardize dose and have been validated with respect to both validity and reliability. They are also used by the ACR as part of their accreditation process and dose registry project. The external test of reliability have demonstrated that the measured indices of the machine output that they reflect, with respect to radiation, are correlated with actual doses received by a phantom in the machine. The two indices of CTDIvol and DLP

2b
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<p>reflect different parameters. The CTDIvol reflects the settings used to create the scan, whereas the DLP also includes the region imaged, so that a longer scan length will be reflected by a higher DLP, but an equivalent CTDI vol.</p> <p>The American Association of Physicists in Medicine have just convened a task force entitled Comprehensive Methodology for the Evaluation of Radiation Dose in X-Ray Computed Tomography, Report of AAPM Task Group 111: The Future of CT Dosimetry February 2010 (https://www.aapm.org/pubs/reports/RPT_111.pdf) specifically describing the validity of the indices proposed in this measure</p> <p>The idea of facility monitoring of CTDIvol and DLP was the core recommendation of the FDA /CDRH-Center for Devices and Radiological Health initial public communication following the disclosure of the Cedars-Sinai over-exposures associated with CT brain perfusion, and the concept of facility development and compliance with locally established diagnostic reference levels (DRLs) is discussed in the FDA white paper on dose reduction Initiative to "Reduce Unnecessary Radiation Exposure from Medical Imaging." Thus the FDA is on the record as favoring facility monitoring of CTDIvol and DLP.</p>	
<p>2c. Validity testing</p> <p>2c.1 Data/sample (<i>description of data/sample and size</i>): The sample of 100 subjects within each strata will yield highly precise estimates of dose in adults The sample of 50 subjects within children's strata will yield a reasonably precise estimate of dose (smaller sample sizes under 50 will also provide reliable estimates of means/medians if the full numbers cannot be assembled.)</p> <p>2c.2 Analytic Method (<i>type of validity & rationale, method for testing</i>): Part A: Basic descriptive statistics Part B: Proportion</p> <p>2c.3 Testing Results (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>): The sample size estimates were based using our published data, and data published by the UK National Radiological Protection Board.</p>	<p>2c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2d. Exclusions Justified</p> <p>2d.1 Summary of Evidence supporting exclusion(s):</p> <p>2d.2 Citations for Evidence:</p> <p>2d.3 Data/sample (<i>description of data/sample and size</i>):</p> <p>2d.4 Analytic Method (<i>type analysis & rationale</i>):</p> <p>2d.5 Testing Results (<i>e.g., frequency, variability, sensitivity analyses</i>):</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (<i>description of data/sample and size</i>):</p> <p>2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>):</p> <p>2e.3 Testing Results (<i>risk model performance metrics</i>):</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>

<p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:</p>	
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): Part A: Diagnostic reference levels are typically set at the 75% distribution, although facilities/programs can set other levels depending on the equipment available. Adequacy is usually set as a dichotomous interpretation of adequate (below 75%) or inadequate. For example, the American College of Radiology set the threshold for passing accreditation at the 75% cut off - facilities that submit CT scans with dose levels above these cutoffs are failed unless adequate justification and explanation is provided. However, the mean/median dose is clearly a continuous measure, and differences in the mean are meaningful as well.</p> <p>Each type of test will have a specific value. For example, for a head CT, The UK sets the diagnostic reference level at a CTDIvol of 57, for an abdominal CT the diagnostic reference level at a CTDIvol of 14, and for a chest CT a diagnostic reference level of 22.</p> <p>Part B: Dose information is currently reported rarely. This is a continuous measure, and the higher the number the better.</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (<i>type of analysis & rationale</i>): The measure is initially proposed for internal quality efforts, and thus reduction in average doses over time is the goal.</p> <p>In the near future it is hoped that these will lead to public reporting and creation of these diagnostic reference levels. At that time, deviation in average doses in comparison to diagnostic reference levels, or differences in median by more than one standard deviation for norms that are geographically based; or creation of more complex rules, for example that 95% of studies should be below the diagnostic reference levels, or that any study above the diagnostic reference level will need physician justification.</p> <p>The norms should be geographically based to reflect the variation in patient size/weight in different regions of the country. This is described under potential limitations</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (<i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance</i>):</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (<i>description of data/sample and size</i>):</p> <p>2g.2 Analytic Method (<i>type of analysis & rationale</i>):</p> <p>2g.3 Testing Results (<i>e.g., correlation statistics, comparison of rankings</i>):</p>	<p>2g C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>):</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:</p>	<p>2h C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met?</p>	<p>2 C <input type="checkbox"/></p>

<p>Rationale:</p>	<p>P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>3. USABILITY</p>	
<p>Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>3a. Meaningful, Understandable, and Useful Information</p>	
<p>3a.1 Current Use: not in use but testing completed</p>	
<p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not publicly reported</u>, state the plans to achieve public reporting within 3 years):</p>	
<p>The measure is initially submitted for internal quality control improvement efforts. However, it is hoped that public reporting will follow very soon in the future.</p>	
<p>The measures proposed are currently not widely collected and as such there is no organization that currently has oversight for collection, analysis or public reporting . However, the task of assembling radiation data for public reporting could be led by any number or organizations, including the American College of Radiology, the National Council on Radiation Protection, the American Association of Physicists in Medicine, and The FDA (with appropriate legislative mandate), all of whom are active in this area, and all of whom have called for precisely the types of data that this measure would help create. Letters of support have been submitted with this measure and public reporting could be conducted by any of these groups. For example, a letter of support has been submitted from Dr. Jerry Bushberg, Scientific Vice-President and member of board of directors of the National Council on Radiation Protection and Measurement's (NCRP), and chair the NCRP scientific advisory committee on Radiation Protection in Medicine. He describes a scientific committee led by Dr. James Brink (Chair of Radiology at Yale University), that has been created to try to summarize current doses associated with CT, but that come up short as it has been difficult to assemble the type and scope of data that the committee needs. He points out that the measure would directly help them with this important effort of obtaining current dose data, so that diagnostic reference level data can be created. The implication is that this organization might be willing to take the role in collating these data for reporting purposes. A letter of support is also submitted from the FDA, and the ACR, two additional organizations that could take the lead in public reporting.</p>	
<p>The concept of diagnostic reference levels (typically set at the 75% distribution in the dose) is that they can be used as tool to decrease average dose exposure to the population and create dose awareness. Thus the collation of the data collected in the measure would allow the creation of these diagnostic reference levels. In Europe, they force physicians to consciously choose the dose levels prescribed and document when they choose to exceed the reference dose values. Thus these reference values are not upper limits for radiological examinations (these do not mandate an absolute upper limit to exposures) but averages, and have been used largely to identify facilities where the dosage is typically to high. If the reference dose values for an individual exam is exceeded, as long as long as that can be justified, it is acceptable.</p>	
<p>The benefits of DRLs can be seen in the U.K., where they have guided radiation reduction efforts since the early 1990s, and overall have been estimated to have reduced doses by 50%.</p>	
<p>In summary, the format of this measure has been created specifically with an intention of pubic reporting, and every attempt will be made to engage one of the professional groups described above or the FDA to take responsibility for public reporting. As a last resort, I will work with individual state radiation protection boards to at a minimum engage them in public reporting at a state level.</p>	
<p>3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u>, state the plans to achieve use for QI within 3 years):</p>	
<p>These exact indices are used by many European countries and the UK in their quality improvement</p>	
<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>	

<p>programs. For example, the NRPB (the National Radiological Protection Board) in the UK has been collecting these indices for CT for many years. The American College of Radiology Collects data on CTDivol for similar assessment</p> <p>Testing of Interpretability (<i>Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement</i>)</p> <p>3a.4 Data/sample (<i>description of data/sample and size</i>): Comparable data are widely used by the National Radiological Protection Board in the UK and have led to dose reduction. Comparable data have been used by the ACR and reported to physicians. In our research, published in the Archives of Internal Medicine, these data were reported to the four facilities that participated in study, and several used these data to initiate quality safety committees and efforts to reduce dose.</p> <p>3a.5 Methods (<i>e.g., focus group, survey, QI project</i>):</p> <p>3a.6 Results (<i>qualitative and/or quantitative results and conclusions</i>):</p>	
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures: Part A: none Part B: measure is similar to endorsed measure of Fluoroscopy. However it is distinct. these are two very different examinations (the type of test is different, the machinery is different, the indications are different, the populations who undergo the tests are different.) What is similar is the measurement of radiation and the reporting of that radiation as a measure of quality.</p>	
<p>(for NQF staff use) Notes on similar/related <u>endorsed</u> or submitted measures:</p>	
<p>3b. Harmonization If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population):</p> <p>3b.2 Are the measure specifications harmonized? If not, why? Part A: NA Part B: The metric (proportion of exams with dose reporting) is harmonized with the similarly endorsed measure for fluoroscopy, although this new measure relates to CT whereas the approved measure applies to Fluoroscopy, a completely separate examination type. Quality on CT has no direct relationship to quality on fluoroscopy.</p>	<p>3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: There is no measure currently endorsed for CT, so this is a new, distinct and valuable measure</p> <p>5.1 Competing Measures If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), describe why it is a more valid or efficient way to measure quality:</p>	<p>3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p style="text-align: center;">4. FEASIBILITY</p>	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (<u>evaluation criteria</u>)</p>	<p><u>Eval Rating</u></p>

<p>4a. Data Generated as a Byproduct of Care Processes</p> <p>4a.1-2 How are the data elements that are needed to compute measure scores generated? data generated as byproduct of care processes during delivery,</p>	<p>4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4b. Electronic Sources</p> <p>4b.1 Are all the data elements available electronically? (<i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i>) No</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers. The data elements are available electronically by some data systems and for others the information is available on he CT images stored in PACS, but the data has to be retrieved by reviewing the images directly. However, by the end of 2010,all CT scans will have the capacity to export the data electronically, based on agreements between the Medical Imaging Technology Alliance (MITA) and the FDA.</p>	<p>4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4c. Exclusions</p> <p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</p>	<p>4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p> <p>4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. 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, but not for different size adults) nor for different protocols. These two issues will be addressed separately</p> <p>PATIENT SIZE</p> <p>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.</p> <p>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. 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.</p> <p>The validity of the proposed measure dose not require consideration 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.</p>	<p>4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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 are included.

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 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
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<p style="text-align: center;">Multiphase head CT 7-30 mSv</p> <p>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)</p> <p>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 multiphas study, at 15 mSv.</p> <p>For the sake of this example, each facility will conduct 100 head CTs over the course of a week.</p> <p>f 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.)</p> <p>However, if we would compare the average dose per head CT, 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]</p> <p>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.</p>	
<p>4e. Data Collection Strategy/Implementation</p> <p>4e.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/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:</p> <p>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).</p> <p>The last proposed index, 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 (xrays, fluoroscopy, angiography, nuclear medicine, etc), making it an easy measure to understand and compare between different types of tests. The provided excel spread sheet will allow input of DLP and CTDIvol and a method whereby effective dose can be automatically calculated.</p> <p>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 that allow the input of technical parameters to generate these values.</p>	<p style="text-align: right;">4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>There may be a small number of CT scans where these data are simply missing, but their exclusion from both the numerator and denominator will have no significant bearing on the overall distribution of the dose indices. Similarly, there may be a small number of reports that can not be identified, but the exclusion from the numerator and denominator for Part B will have no bearing on this measure.</p> <p>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 a month , 6 months or a year to generate sufficient data within each anatomic area/age/machine type category.</p> <p>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 CT DIvol 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.</p> <p>If facilities strive to achieve a high rate of reporting the radiation dose data (part B) it would be easy in the future to compile the data for part A by review of the radiology reports.</p> <p>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 will have this feature by the end of 2010, and they will provide a method whereby this is available to a proportion of existing scanners. When this feature is active (a few current scanners, all future scanners) generating these metrics will be extremely simple.</p> <p>4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): Data collection will require minimal effort. Facilities could immediately begin to use the data they collect to assess their performance and comparison to existing international standards, and used to contribute to a dose registry that would generate local standards. The measure would thus provide rapid feedback.</p> <p>4e.3 Evidence for costs: The data to complete this measure are readily available and the costs should be minimal, based on collating that information.</p> <p>4e.4 Business case documentation:</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
RECOMMENDATION	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/></p>
CONTACT INFORMATION	
<p>Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization University of California San Francisco 350 Parnassus Street, Suite 307 San Francisco California 94117</p>	

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<p>Co.5 Submitter If different from Measure Steward POC Rebecca Smith-Bindman, Professor, Radiology and Biomedical Imaging, Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Sciences rebecca.smith-bindman@radiology.ucsf.edu 415-377-7957- University of California San Francisco</p>
<p>Co.6 Additional organizations that sponsored/participated in measure development I have developed this measure on my own, but sought input from a large number of individuals. Three have provided letters of support included in this application, including letters from individuals from the NCRP, ACR, and FDA.</p>
<p>ADDITIONAL INFORMATION</p>
<p>Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. Letters of support are 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.</p>
<p>Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 Year the measure was first released: Ad.7 Month and Year of most recent revision: Ad.8 What is your frequency for review/update of this measure? Ad.9 When is the next scheduled review/update for this measure?</p>
<p>Ad.10 Copyright statement/disclaimers:</p>
<p>Ad.11 -13 Additional Information web page URL or attachment: Attachment Bushberg_NQF.pdf</p>
<p>Date of Submission (MM/DD/YY): 05/18/2010</p>