**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0740

**Measure Title**: Participation in a Dose Index Registry

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 1/17/2014

|  |
| --- |
| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

|  |
| --- |
| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Click here to name the process

Structure: Automated collection of dose information in a registry for monitoring, analysis and improvement

Other: Click here to name what is being measured

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

Infrastructure > benchmarks > protocol optimization > lower dose > higher patient safety

Dose index monitoring is still at an early stage and there are no clear benchmarks. The primary goal at this point is to facilitate participation by as many facilities as possible, and for this purpose, a participation measure is appropriate. There is evidence in medicine that registry participation improves outcomes, if that evidence is not convincing, we propose the participation measure as a means for infrastructure development with an eventual goal of evaluating dose index values against benchmarks.

The goal of the Dose Index Registry participation measure is to improve patient safety by helping facilities adjust their imaging protocols to obtain diagnostic images using the lowest reasonable dose. There is likely to be quality improvement simply with participation but the larger benefit in the role of an attestation measure is supporting the development of an infrastructure to provide richer means of dose index monitoring.

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

*Check systematic review for outpatient imaging efficiency measures – see if we can use the patient safety aspect material*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

1. ACR–AAPM PRACTICE GUIDELINE FOR DIAGNOSTIC REFERENCE LEVELS AND ACHIEVABLE DOSES IN MEDICAL X-RAY IMAGING Rev. 2013 <http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Reference_Levels.pdf>
2. The Joint Commission Sentinel Alert Issue 47 – Radiation risks of diagnostic imaging, August 24 2011 <http://www.jointcommission.org/sea_issue_47/>
3. The Joint Commission Standards: Revised Requirements for Diagnostic Imaging Services; prepublication December 30, 2013 <http://www.jointcommission.org/assets/1/6/PREPUB-12-20-2013-DiagImaging_AHC.pdf> Standard PI.02.01.01

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

Guideline #1:

Page 1:

The establishment of reference levels in diagnostic medical imaging requires close cooperation and communication between the clinical team of physicians who are responsible for the clinical management of the patient, the Qualified Medical Physicist responsible for monitoring equipment and image quality and estimating patient dose, and the radiologic technologist who is responsible for adherence to protocols. Adherence to this guideline should help to maximize the efficacious use of these procedures, optimize patient radiation dose and image quality, minimize radiation dose to staff, maintain safe conditions, and ensure compliance with applicable regulations. This is particularly important for children who are more vulnerable than adults to the potential risks of ionizing radiation.

Pg 7: Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director’s National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

Guideline #2: Page 3

***Right test***

7. Institute a process for the review of all dosing protocols either annually or every two years to ensure that protocols adhere to the latest evidence.

8. Investigate patterns outside the range of appropriate doses. Track radiation doses from exams repeated due to insufficient image quality or lack of availability of previous studies to identify the causes. Address and resolve these problems through education and other measures.

9. Record the dosage or exposure as part of the study’s summary report of findings.

In addition, The Joint Commission:

19. Endorses the creation of a national registry to track radiation doses as the start of a process to identify optimal and reference doses.

Guideline #4: Page 6

**Standard PI.02.01.01**

The organization compiles and analyzes data.

Elements of Performance for PI.02.01.01

A 6. For organizations that provide diagnostic computed tomography (CT) services: The organization compiles

and analyzes data on patient CT radiation doses and compares it with external benchmarks, when such benchmarks are available.

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

Guideline #1: Reference studies for the guideline were not graded.

Guideline #2: Reference studies for the guideline were not graded.

Guideline #3: No grade assigned.

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

Guideline #1: <http://www.acr.org/Quality-Safety/Standards-Guidelines/DevelopingProcess>

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

Evidence on the Benefits of registry participation:

1. Data from the Society of Thoracic Surgeons registries show that registry participation is associated with reductions in risk-adjusted mortality.

Ferguson TB Jr, Hammill BG, Peterson ED, DeLong ER, Grover FL; STS National Database Committee. A decade of change--risk profiles and outcomes for isolated coronary artery bypass grafting procedures, 1990-1999: a report from the STS National Database Committee and the Duke Clinical Research Institute. Society of Thoracic Surgeons. Annals of Thoracic Surgery 2002 February;73(2):480-9.

There are substantial observational data, especially in general and cardiac surgery, that clinical registries contribute significantly to improvement by providing high quality, risk adjusted data that are accepted as valid by providers (in contrast to administrative data) (Ferguson, Jr. et al., 2003; Grover et al., 1994; Grover, 1997; Grover et al., 2001; Hammermeister et al., 1994b; Hammermeister et al., 1994a; Khuri et al., 1998).

Evidence suggests that the feedback of results based on high quality data, rather than public reporting, is the common denominator for such improvement. This is evidenced by the superior and nearly identical “best in class” performance improvement achieved within the publicly reported New York Cardiac Surgery Reporting System and the totally confidential Northern New England Cardiovascular Disease Study Group (Peterson et al., 1998), both of which are based on clinical registry data, as well as results from a registry-based feedback program in Ontario (Guru et al., 2006).

1. Data from the Breast Cancer Surveillance Consortium (BCSC) show that among participating radiologists interpreting mammograms, there was an improvement in overall discrimination, a measure of the probability that a patient with cancer was assigned an assessment category for a higher likelihood of cancer than a patient without cancer. BCSC participants received periodic feedback reports and national benchmarks.

Ichikawa LE, Barlow WE, Anderson ML, Taplin SH, Geller BM, Brenner RJ, National Cancer Institute-sponsored Breast Cancer Surveillance Consortium. Time trends in radiologists' interpretive performance at screening mammography from the community-based Breast Cancer Surveillance Consortium, 1996-2004. Radiology 2010 July;256(1):74-82.

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

No grade assigned.

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: Click here to enter date range

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

Five observational studies.

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

Direction of effect on outcome:

In the United Kingdom, the Health Protection Agency (HPA) (formerly the National Radiological Protection Board [NRPB]) reported a 55% reduction in the 75th percentile of radiation patient dose following 20 years of use of and education about DRLs and achievable doses (ADs) [2]. Hart D, Hillier MC, Wall BF. *Doses to patients from radiographic and fluoroscopic x-ray imaging*

*procedures in the UK - 2005 Review. HPA-RPD-029; 2007*

[http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\_C/1194947413167.

Achievable dose (AD) can be used with DRLs to assist in optimizing image quality and dose. ADs are set at approximately the median (50th percentile) of the study dose distribution i.e., half of the facilities are producing images at lower doses and half are using higher doses. Further information on ADs is available in the recent National Council on Radiation Protection and Measurements (NCRP) Report 172 [6]. National Council on Radiation Protection and Measurement Diagnostic. Reference levels and achievable

doses in medical and dental imaging: recommendations for the United States. Bethesda, MD. NCRP Report #172; 2012.

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

Magnitude of effect:

Ionizing radiation has been used for diagnostic purposes in medicine for more than a century. The benefits are immense and certainly exceed the risks. The more recent development of equipment such as multi-detector row computed tomography and the increased utilization of x-ray and nuclear medicine imaging studies have improved the lives of our patients and, along with other new modalities, revolutionized the practice of medicine. However, this dramatic evolution of imaging has also resulted in a significant increase in the population’s cumulative exposure to ionizing radiation.

Over the past quarter century, there has been a rapid growth in both the number of diagnostic x-ray examinations and the introduction of newer, very valuable, but also relatively high-dose technologies. Use of Computed Tomography (CT) has risen considerably over the past several decades; in the past 10 years use of CT has increased nearly 700% (3,4). The total number of CT examinations performed annually in the United States has risen from approximately 3 million in 1980 to nearly 70 million in 2007. (1, 2) Additionally, radiation exposure from CT examinations has also increased, in part due to the increased speed of image acquisition allowing vascular, cardiac and multiphase examination, all associated with higher doses. Thus, greater use of CT has resulted in a concurrent increase in the medical exposure to ionizing radiation. (5)

This dramatic evolution of imaging has also resulted in a significant increase in the population’s cumulative exposure to ionizing radiation. (1) Although there is current debate that this will cause an increased incidence of cancer years down the line, the presumption is that it will.

It is worth noting that many (CT) scans and nuclear medicine studies have effective dose estimates in the range of 10 to 25 mSv for a single study, and some patients have multiple studies; thus, it would not be uncommon for a patient’s estimated exposure to exceed 50 mSv. In further validation of this concern, the International Commission on Radiological Protection has reported that CT doses can indeed approach or exceed levels that have been shown to result in an increase in cancer (1). CT exams account for about 5-15% of imaging exams using ionizing radiation but estimated to contribute 70% of effective radiation dose from all medical imaging [6].

Citations

1. Amis Es Jr, Butler PF, Applegate KE, et al; American College of Radiology. American College of Radiology white paper on radiation dose in medicine J AM Coll Radiol. 2007;4(5):272-284.

2. IMV Medical Information Division. CT Census Database and Market Summary Report. Greenbelt, MD: IMV;2008.

3.Medicare payment Advisory Commission. A Data Book: Healthcare Spending and the Medicare Program. June 2007. http://www.medpac.gov/documents/Jun08DataBook\_Entire\_report.pdf. Accessed January 29, 2010.

4.Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers - from NCI and SPR. www.nci.nih.gov/cancertopics/causes/radiation-risks-pediatric-CT.

5. Bindman-Smith 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 (22)2078-2085.

6. Brody AS, Frush DP, Huda W, et al. Radiation risk to children from computed tomography. Pediatrics 2007; 120:677-682.

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.8 OTHER SOURCE OF EVIDENCE**

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

**1a.8.1** **What process was used to identify the evidence?**

Literature review, guideline search.

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**

1. U.S. Food and Drug Administration Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 2010 <http://www.fda.gov/Radiation-emittingProducts/RadiationSafety/RadiationDoseReduction/default.htm> and <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm299368.htm>

Tracking Radiation Safety Metrics – Dose Registries

Dose registries would enable facilities to compare their radiation doses to those delivered in other facilities for the same exam, and such comparisons over time could assist in optimizing patient radiation doses for medical imaging. The goals of tracking imaging exams and the associated radiation exposure include: (1) providing information at the point-of-care for the referring practitioner (i.e. supporting justification); (2) promoting development and use of diagnostic reference levels (DRLs) (i.e. supporting optimization); (3) providing information for assessment of radiation risks; and (4) establishing a tool for use in research and epidemiology.

1. Lukasiewicz A, Bhargavan M, Coombs L, Ghita M, Weinreb J, Gunabushanam G, Moore CL. Radiation Dose Index of Renal Colic Protocol CT Scans in the United States: A Report from the American College of Radiology National Radiology Data Registry, Radiology, In press

This study used data from the ACR Dose Index Registry to explore variation in radiation dose indices across facilities for renal colic protocol CT studies (CT for kidney stones). The concusions of the study were that “Reduced-dose renal protocol CT is used infrequently in the United States. Mean dose index is higher than reported previously, and institutional variation is substantial.”

1. Goske MJ, Strauss KJ, Coombs LP et al. Diagnostic reference ranges for pediatric abdominal CT. Radiology 2013;268:208-18.

This study used registry data from six facilities to establish diagnostic reference levels for pediatric abdominal CT exams. This range provides a target dose estimate for a facility to not exceed in order to limit exposure to a vulnerable population, and a target minimum dose estimate to ensure diagnostic quality image.

1. Frush D, Denham CR, Goske MJ, Brink JA, Morin RL, Mills TT, Butler PF, McCollough C, Miller DL. Radiation protection and dose monitoring in medical imaging: a journey from awareness, through accountability, ability and action…but where will we arrive?J Patient Saf. 2013 Dec;9(4):232-8. doi: 10.1097/PTS.0b013e3182a8c2c4.

This study defines issues that are critical for patient safety and radiation dose monitoring. The paper states that “… we must be careful that what we select as a dose measure is as accurate as possible, is able to be modified to reflect the evolution in dose estimations, is suitable for both pediatric and adult patients, does not require manual input of data, and can be embraced by all stakeholders. The measures adopted and programs developed must have clearly defined objectives that are amenable to monitoring and modification. This is the very essence of a quality practice.”