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

**Measure Number** (*if previously endorsed*)**:** 0510

**Measure Title**: Exposure time reported for procedures using fluoroscopy

**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: Recording exposure dose or time for medical procedures using fluoroscopy.

Structure: Click here to name the structure

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.

The process of recording dose data for patients undergoing procedures using fluoroscopy will readily provide patient radiation history, which is essential in determining radiation-induced injury and enable appropriate, timely treatment. Monitoring and recording patient dose data is a distinct element in the radiation management process and is valuable for quality improvement and feedback to optimize radiation dose overall.

**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.*

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

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

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

1. Miller DL, Balter S, Dixon RG, et al. Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures. J Vasc Interv Radiol 2012; 23:11-18. [http://www.sirweb.org/clinical/cpg/PIIS1051044311012565[4].pdf](http://www.sirweb.org/clinical/cpg/PIIS1051044311012565%5b4%5d.pdf)
2. American College of Radiology (ACR), American Association of Physicists in Medicine (AAPM). ACR–AAPM Technical standard for management of the use of radiation in fluoroscopic procedures. <http://www.acr.org/~/media/ACR/Documents/PGTS/standards/MgmtFluoroProcedures.pdf>
3. American College of Radiology (ACR), Society of Interventional Radiology (SIR). ACR–SIR Practice guideline for the reporting and archiving of interventional radiology procedures. [online publication’. Reston (VA): American College of Radiology (ACR) 2009. <http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Reporting_Archiving.pdf>

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

Guideline 1, page : Adequate recording of dose metrics is defined as documentation in the patient record of at least one of the following for all interventional procedures requiring fluoroscopy (in descending order of desirability): skin dose mapping, PSD, Ka,r, PKA, and fluoroscopic time/number of fluorographic images.

Guideline 2, page 6: All available radiation dose data should be recorded in the patient’s medical record [6,11,12]. If cumulative air kerma or air kerma-area-product data are not available, the fluoroscopic exposure time and the number of acquired images (radiography, cine, or digital subtraction angiography) should be recorded in the patient’s medical record.

Guideline 3, page 4: If technically possible, all radiation dose data recorded by the fluoroscopy unit or computed tomography (CT) scanner should be transferred and archived with the images from the procedure. This should be performed electronically, with automatic transfer of the data from the fluoroscopy unit or CT scanner to a picture archiving and communication system (PACS). Archiving of radiation dose data is of particular importance if the procedure is likely to be repeated or if the patient has received a clinically important radiation dose.

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

Quoted recommendations were not graded.

**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.*)

Grading system not used.

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

**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*):

Guidelines, publications and advisories reviewed that support the measure focus:

* Conference of Radiation Control Program Directors. Technical White Paper: Monitoring and tracking of fluoroscopic dose. CRCPD Publication E-10-7. Frankfort, KY: Conference of Radiation Control Program Directors, 2010. Available at http://www.crcpd.org/Pubs/white\_papers.aspx.
* National Council on Radiation Protection and Measurements. Radiation dose management for fluoroscopically guided interventional medical procedures. Report No. 168. Bethesda, MD: NCRP, 2011.
* American College of Radiology. ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures. Reston, VA: American College of Radiology, 2009. Available at <http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv.aspx>.
* International Commission on Radiological Protection. Radiation protection in medicine. ICRP Publication 105. Ann ICRP 2007; 37:1–63.
* Miller DL, Balter S, Wagner LK, et al. Quality improvement guidelines for recording patient radiation dose in the medical record. J Vasc Interv Radiol 2004; 15:423–429.
* International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann ICRP 2000; 30:7–67.
* Food and Drug Administration. Public Health Advisory: avoidance of serious x-ray-induced skin injuries to patients during fluoroscopically guided procedures. Rockville, MD: Center for Devices and Radiological Health, 1994. Available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm063084.htm>.

Summary of recommendations:

|  |  |  |
| --- | --- | --- |
| **Publication, Year** | **Publication Type** | **Procedures for which**  **Dose Data Should Be Recorded** |
| SIR Quality Improvement guideline for recording patient radiation dose in the medical record for fluoroscopically guided procedures, 2012 | SIR quality improvement guideline | All |
| CRCPD Technical White Paper: Monitoring and Tracking of Fluoroscopic Dose, 2010 | CRCPD guidance (United States) | All |
| NCRP Report 168, 2010 | NCRP recommendation | All |
| ACR/SIR Practice Guideline for Reporting and Archiving of Interventional Radiology Procedures, 2009 | ACR/SIR practice guideline (United States) | All |
| ICRP Publication 105, 2007 | International guideline | Determined by dose (presumed  measured for all cases) |
| SIR Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record, 2004 | SIR quality improvement guideline | All cases of potentially high-dose procedures and all medium dose procedures that are likely to be repeated; desirable to record radiation dose for all other procedures |
| ICRP, Publication 85, 2001 | International guideline | Determined by dose (presumed measured for all cases) |
| US FDA Advisory, 1995 | FDA advisory guideline (United States) | To be decided by each facility; should include TIPS and “percutaneous endovascular reconstruction” |

**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?**

A literature search focused on patient radiation dose recording, primarily for procedures using fluoroscopy.

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

No grade assigned. Studies considered high quality were used to form the recommendations in the guideline. A critical evaluation of the literature with empirical data was conducted by an expert committee.

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

Guideline 1: When evidence of literature is weak, conflicting or contradictory, the clinical practice committee uses consensus for the parameter by using a modified Delphi consensus method. Consensus on statements in Guideline 1 was obtained without the need for a modified Delphi technique.

Guidelines 2 and 3: Process of Developing ACR Practice Guidelines and Technical Standards <http://www.acr.org/Quality-Safety/Standards-Guidelines/DevelopingProcess>

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: 1990-2011

**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*)

Included in the literature review for Guideline 1: Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures:

* 45 observational studies regarding potential harmful effects or injuries from procedures using fluoroscopy, or methods to derive dose and its significance to patient outcome.
* 27 references on methods, needs and guidance for recording and monitoring fluoroscopic dose.

**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*)

Not applicable.

**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*)

Guidelines reviewed uniformly agreed that recording and monitoring patient dose data for fluoroscopic procedures leads to improved health outcomes for the patient.

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

Studies evaluated the potential harmful (both stochastic and deterministic) effects to patients of radiation exposure from fluoroscopic procedures with conclusions that recording and monitoring dose data is an essential element in radiation dose management and optimization.

**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?**

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