Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record for Fluoroscopically Guided Procedures

Donald L. Miller, MD, Stephen Balter, PhD, Robert G. Dixon, MD, Boris Nikolic, MD, MBA, Gabriel Bartal, MD, John F. Cardella, MD, Lawrence T. Dauer, PhD, and Michael S. Stecker, MD, for the Society of Interventional Radiology Standards of Practice Committee

ABBREVIATIONS

ACR = American College of Radiology, CRCPD = Conference of Radiation Control Program Directors, FDA = Food and Drug Administration, ICRU = International Commission on Radiation Units and Measurements, IEC = International Electrotechnical Commission, IRP = interventional reference point, Ka,r = total air kerma at the interventional reference point, NCRP = National Council on Radiation Protection and Measurements, PKA = kerma–area product, PSD = peak skin dose, RDSR = Radiation Dose Structured Report

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

This is the second edition of this document. It is a revision of the original document, which was published in 2004 (1) and reprinted in 2009 (2).

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending upon the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed regarding the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members using a Modified Delphi Consensus Method (Appendix) (3,4). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Revisions Subcommittee members of the Standards of Practice Committee, either by telephone conference calling or face-to-face meetings. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Subcommittee, and appropriate revisions are made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

From the Center for Devices and Radiological Health (D.L.M.), Food and Drug Administration, Silver Spring; Department of Radiology and Radiological Sciences (D.L.M.), F. Edward Hébert School of Medicine, Uniformed Services University, Bethesda, Maryland; Departments of Radiology and Medicine (S.B.), Columbia University; Department of Medical Physics (L.T.D.), Memorial Sloan–Kettering Cancer Center, New York, New York; Department of Radiology (R.G.D.), University of North Carolina, Chapel Hill, North Carolina; Department of Radiology (B.N.), Albert Einstein Medical Center, Philadelphia; Department of Radiology (J.F.C.), Geisinger Health System, Danville, Pennsylvania; Department of Diagnostic and Interventional Radiology (G.B.), Meir Medical Center, Kfar Saba, Israel; and Division of Angiography and Interventional Radiology (M.S.S.), Brigham and Women's Hospital, Boston, Massachusetts. Final revision received September 7, 2011; accepted September 8, 2011. Address correspondence to D.L.M., 3975 Fair Ridge Drive, Suite 400, North, Fairfax, VA 22033; E-mail: donald.miller@fda.hhs.gov

R.G.D. is an educational consultant for Bard (Covington, Georgia). None of the other authors have identified a conflict of interest.

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Food and Drug Administration, the Department of Health and Human Services, or the United States Government.

The initial version of this article first appeared in J Vasc Interv Radiol 2004; 15:423–429.

DOI: 10.1016/j.jvir.2011.09.004

Table 1. Recommendations for Recording Patient Dose from Fluoroscopically Guided Interventional Procedures (1,5,8–10,12,13)

Publication, Year	Publication Type	Fluoroscopic Procedures for which Dose Data Should Be Recorded
Present document	SIR quality improvement guideline	All
CRCPD Technical White Paper: Monitoring and Tracking of Fluoroscopic Dose, 2010 (10)	CRCPD guidance (United States)	All
NCRP Report 168, 2010 (9)	NCRP recommendation (United States)	All
ACR/SIR Practice Guideline for Reporting and Archiving of Interventional Radiology Procedures, 2009 (13)	ACR/SIR practice guideline (United States)	All
ICRP Publication 105, 2007 (12)	International guideline	Determined by dose (presumed measured for all cases)
SIR Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record, 2004 (1)	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 (8)	International guideline	Determined by dose (presumed measured for all cases)
US FDA Advisory, 1995 (5)	FDA advisory guideline (United States)	To be decided by each facility; should include TIPS and "percutaneous endovascular reconstruction"

Note.—ACR = American College of Radiology, CRCPD = Conference of Radiation Control Program Directors, FDA = Food and Drug Administration, ICRP = International Commission on Radiological Protection, Ka,r = total air kerma at the interventional reference point, NCRP = National Council on Radiation Protection and Measurements, PSD = peak skin dose, TIPS = transjugular intrahepatic portosystemic shunt.

PATIENT RADIATION DOSE RECORDING

As of 2011, there are no federal regulatory requirements in the United States concerning recording or reporting of radiation dose data for interventional procedures. There are recommendations on this topic from the United States Food and Drug Administration (FDA), the Conference of Radiation Control Program Directors (CRCPD), and national and international advisory bodies (5–10). Regulations or guidance at the state level are not uniform (11). Only a small number of states have addressed this issue. State regulations are typically updated periodically based on CRCPD guidance. If state regulations exceed the requirements contained in this document, practitioners should follow the more stringent state regulatory guidelines. Existing guidelines and recommendations are summarized in **Table 1** (1,5,8–10,12,13). The International Atomic Energy Agency issued its International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources in 1996 (14). This document, currently under revision, provides important safety guidance, but no specific recommendations on dose recording.

Fluoroscopically guided procedures are an essential part of the contemporary practice of medicine. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin (9,15). These injuries may be painful, disfiguring, and long-lasting (16). Koenig and colleagues (15), in a comprehensive review published in 2001, reported data on radiation-induced skin injuries in 73 patients. Of these, 47 (64%) were the result of coronary angiography and intervention, 12 (16%) were the result of cardiac radiofrequency catheter ablation, seven (10%) were the result of transjugular intrahepatic portosystemic shunt creation, three (4%) were the result of neuroradiologic interventions, and the type of procedure was not specified for four patients. Deterministic skin effects have been associated with renal angioplasty, multiple hepatic/biliary procedures, and embolization (8,17–20). In general, the risk of patient injury as a result of radiation exposure during these procedures is low. The frequency of deterministic skin effects is unknown (17,18), but for cardiac interventions has been estimated at less than 0.03% (21), although it is higher for some complex cardiac interventions, such as treatment of chronic total occlusions of the coronary arteries (22).

In a Public Health Advisory of September 30, 1994, the FDA recommended that "information permitting estimation of the absorbed dose to the skin be recorded in the patient's medical record" (5). The International Commission on Radiological Protection has also recommended recording patient radiation dose in the medical record for certain procedures (8). Monitoring and recording patient dose data for all procedures can be valuable for quality-assurance purposes as well as for patient safety (9,23–25). Feedback to the operator may help to optimize radiation doses overall (20).

The present document revises and updates recommendations made in the first edition of this guideline (1,2). The new recommendations are based on recent national guidelines and recommendations from the CRCPD (10), the National Council on Radiation Protection and Measurements (NCRP) (9), and the American College of Radiology (ACR) (13). The guidelines presented in this document are written for inclusion in quality-improvement programs used to manage radiation dose from fluoroscopically guided invasive and interventional procedures, excluding computed tomographic (CT) fluoroscopy. A measurable part of the radiation management process is the recording of patient dose. The outcome measure or indicator for this process is the compliance rate for data recording. Outcome measures are assigned threshold levels.

This document does not outline how these patient radiation dose data