Patient radiation dose audits for fluoroscopically guided interventional procedures

Stephen Balter^{a)}

Department of Radiology and Department of Medicine, Columbia University, New York, New York 10032

Marvin Rosenstein^{b)}

Clarksburg, Maryland 20871

Donald L. Miller^{c)}

Department of Radiology, F. Edward Hébert School of Medicine, Uniformed Services University, Bethesda, Maryland 20814

Beth Schueler^{d)}

Department of Radiology, Mayo Clinic and Foundation, Rochester, Minnesota 55905

David Spelic^{e)}

Division of Mammography Quality and Radiation Programs, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20903

(Received 15 December 2010; revised 20 January 2011; accepted for publication 31 January 2011; published 28 February 2011)

Purpose: Quality management for any use of medical x-ray imaging should include monitoring of radiation dose. Fluoroscopically guided interventional (FGI) procedures are inherently clinically variable and have the potential for inducing deterministic injuries in patients. The use of a conventional diagnostic reference level is not appropriate for FGI procedures. A similar but more detailed quality process for management of radiation dose in FGI procedures is described.

Methods: A method that takes into account both the inherent variability of FGI procedures and the risk of deterministic injuries from these procedures is suggested. The substantial radiation dose level (SRDL) is an absolute action level (with regard to patient follow-up) below which skin injury is highly unlikely and above which skin injury is possible. The quality process for FGI procedures collects data from all instances of a given procedure from a number of facilities into an advisory data set (ADS). An individual facility collects a facility data set (FDS) comprised of all instances of the same procedure at that facility. The individual FDS is then compared to the multifacility ADS with regard to the overall shape of the dose distributions and the percent of instances in both the ADS and the FDS that exceed the SRDL.

Results: Samples of an ADS and FDS for percutaneous coronary intervention, using the dose metric of reference air kerma ($K_{a,r}$) (i.e., the cumulative air kerma at the reference point), are used to illustrate the proposed quality process for FGI procedures. Investigation is warranted whenever the FDS is noticeably different from the ADS for the specific FGI procedure and particularly in two circumstances: (1) When the facility's local median $K_{a,r}$ exceeds the 75th percentile of the ADS and (2) when the percent of instances where $K_{a,r}$ exceeds the facility-selected SRDL is greater for the FDS than for the ADS.

Conclusions: Analysis of the two data sets (ADS and FDS) and of the percent of instances that exceed the SRDL provides a means for the facility to better manage radiation dose (and therefore both deterministic and stochastic radiation risk) to the patient during FGI procedures. © 2011 American Association of Physicists in Medicine. [DOI: [10.1118/1.3557868](https://doi.org/10.1118/1.3557868)]

Key words: interventional procedure, skin injury, dose audit, diagnostic reference levels, quality improvement

I. INTRODUCTION

A major goal of the quality program for all forms of x-ray imaging is to minimize radiological risk without degrading clinical performance. Auditing of actual radiation use within and among facilities, using an appropriate and well-defined process, is essential.¹ Because of the many differences between diagnostic x-ray procedures and fluoroscopically guided interventional (FGI) procedures, different processes are needed to manage these two types of x-ray imaging.

The diagnostic reference level (DRL) process is designed to reduce the risk of stochastic effects and is a well-established quality tool for diagnostic radiography and computed tomography (CT).^{2,3} It is applicable to highly standardized, routinely performed diagnostic radiography examinations. Proper use of the DRL process depends on the highest practicable uniformity in patient or phantom size and procedure type among all of the facilities contributing data. The use of DRLs has yielded reductions in the average levels

of radiation observed for noninvasive x-ray imaging procedures.⁴

DRLs help facilities avoid radiation doses to patients that do not contribute to the medical imaging task.^{5,6} However, they do not apply to individual patients or individual instances. Also, they are a guide to what is achievable with current good practice, rather than optimum performance, and are neither limits nor thresholds that define competent performance of the operator or the equipment.⁷ A value of the dosimetric quantity for an imaging task that is less than the DRL does not guarantee that the task is being performed optimally.⁸

The International Commission on Radiological Protection (ICRP) has stated that (a), in principle, DRLs could be used for FGI procedures to help manage patient doses and avoid unnecessary stochastic radiation risks, but because of a very wide distribution of patient doses even for a specified protocol, a potential approach is to take into consideration the complexity of the FGI procedure; and (b) that DRLs are not applicable to deterministic effects from FGI procedures.^{3,5}

Regarding (a), the conventional DRL methodology is not well-suited to FGI procedures because FGI cannot be standardized in the same way as diagnostic radiography and CT examinations. Radiation dose in FGI is strongly affected by procedure complexity due to patient anatomy, lesion characteristics, and disease severity.^{9–12} There is a wide variation in the dose delivered by FGI procedures. Other causes are related to equipment selection and configuration differences. There is also wide variability in the skill sets of the operators performing the procedures.^{13–16} As a result, there is a wide variation in radiation dose for instances of the same procedure. Patient radiation doses from a single FGI procedure performed at a single facility have been shown to vary by several orders of magnitude.¹⁷ It is impractical to define a specific FGI procedure of standardized complexity performed by a standardized operator on a standard-size patient.

Regarding (b), the DRL process is designed to manage stochastic risk and does not provide an adequate means to manage deterministic risk. Because some instances of FGI procedures result in deterministic injuries to patients, control of deterministic risk is an essential component of the quality process for FGI procedures.

We present a new method to characterize and analyze the overall dosimetric performance for FGI procedures including the effects of equipment factors, procedure protocols, procedure complexity, and operator performance. It requires a more complete data collection process than that used for diagnostic radiography and CT, a more detailed presentation of the data set, and use of a trigger value (related to the need for patient follow-up) for the evaluation of high-dose cases.

II. REVIEW OF DIAGNOSTIC REFERENCE LEVELS

The DRL process requires the use of a uniform measurement protocol by all of the participating facilities. Chest radiography is an excellent example of the type of radiological examination for which the DRL process is well-suited.^{5,18–20}

DRLs for radiography are specific to a particular projection, such as a posteroanterior (PA) chest radiograph. The projection is standardized and can be performed on a phantom or on a “standard” patient in a defined weight range (typically 65–75 kg). A number of facilities contribute data to form a reference distribution. Each facility contributes a *single data point* that represents the amount of radiation used when a standard PA chest radiograph is performed using the facility’s usual radiographic technique on a standard patient or phantom. Depending on the protocol, the data point could be a single measurement performed on a standard phantom or the average of measurements for a small number of patients in a defined weight range. Some protocols require testing in the single room most commonly used for the examination. Other protocols allow testing in each room used for the examination and then either reporting the results separately for each room or reporting a facility average value.

The nationwide evaluation of x-ray trends (NEXT) survey program is an example of a method currently in use in the U.S. for collecting radiation dose data suitable for DRL analysis. NEXT is a collaboration between the Conference of Radiation Control Program Directors (CRCPD) and the U.S. Food and Drug Administration (FDA) to document trends in patient dose for selected diagnostic x-ray and CT examinations.^{21,22} For radiography examinations, defined phantoms for specified projections are used to collect entrance air kerma measurements from the most frequently used imaging equipment at each surveyed facility. Each facility uses standardized procedures and equipment and contributes one dosimetric data point. The NEXT adult chest phantom, for example, has an x-ray attenuation equivalent to that of an adult patient chest with a posteroanterior dimension of approximately 22 cm. Image quality is also evaluated under typical clinical conditions using two sets of test objects to capture data on low contrast and high contrast (detail) imaging performance.

This process has been extended to fluoroscopy in NEXT by collecting air kerma rate data using a standard phantom²³ and the facility’s typical fluoroscopic settings. This evaluation process provides important information about the technical performance of the fluoroscopic system. However, it is insensitive to factors such as patient mix and operator performance.

III. DOSE MEASUREMENT FOR FLUOROSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

Specific dose metrics have been developed for use in evaluating patient radiation dose from FGI procedures, and dose measurement tools have been integrated into FGI systems since the late 1990s.^{24–27} Estimation of peak skin dose is ideal for prevention or mitigation of deterministic effects, but no automated system is available as of 2011. Currently, patient radiation dose can be assessed for an FGI procedure using air kerma-area product (P_{KA}) or reference air kerma ($K_{a,r}$) (i.e., the air kerma at the reference point).^{24,25,28,32} In this paper, P_{KA} and $K_{a,r}$ refer to the cumulative value for the

FIG. 1. Definition of $K_{a,r}$. The quantity $K_{a,r}$ is the cumulative air kerma at the reference point, free-in-air (i.e., without backscatter). The locations of the reference point, focal spot, and isocenter are indicated for an isocentric system such as a C-arm fluoroscope. For these systems, the default reference point is on the central ray 15 cm distant from the isocenter toward the x-ray tube (Ref. 25).

FGI procedure. The default reference point for large/isocentric C-arm fluoroscopes is along the central ray, 15 cm from the isocenter toward the x-ray tube.^{24,25} The reference point location may differ for these systems and always differs for other fluoroscopic geometries (including typical operating room C-arm systems). The actual location of the reference point on any system is found in the system's instructions for use.

Interventional departments should store all available dose metrics (e.g., $K_{a,r}$, P_{KA} , fluoroscopic time, and number of fluorographic images) in a retrievable database.^{28–30} Accessible multiparametric dosimetric data facilitates the departmental radiation dose investigations discussed below.

$K_{a,r}$ (Fig. 1) is the most useful metric for auditing FGI radiation use because it can be used to analyze both overall performance and the likelihood of a deterministic effect.³¹ $K_{a,r}$ has been shown to correlate reasonably well with peak skin dose and is recommended for use as an analog of peak skin dose when skin dose estimates are not available.²⁸ $K_{a,r}$ estimation capability is present in all International Electrotechnical Commission (IEC) 60601-2-43 (Refs. 24 and 25) compliant interventional fluoroscopes, all fluoroscopes sold in the USA since June 2006,³² and in some other systems. It has been available on some interventional fluoroscopy units in the U.S. since the mid-1990s. $K_{a,r}$ also has other advantages for FGI dose audits, as noted in Sec. IV. P_{KA} is often appropriately used for DRL analysis. It is less suitable for FGI procedures because P_{KA} values cannot be used directly to evaluate the risk of skin injury.³¹ A high value of P_{KA} may result from a high value of skin dose applied to a small skin area or a low value of skin dose applied to a large skin area.

Many interventional fluoroscopes store detailed data in their service logs. In many cases, data are recorded for each irradiation event (fluoroscopic foot-pedal activation, cine run, or DSA run). In addition to event-specific P_{KA} and $K_{a,r}$, these data usually include details of the system settings, system geometry (e.g., beam angles and SID), and technical factors (e.g., kV, mA, and number of frames). There are current efforts to standardize the export of these dosimetric data in an open format as a radiation dose structured report (RDSR).³³ This would allow calculation of an estimate of peak skin dose. Limited availability of the RDSR began in 2010. So far, there are no commercial implementations of skin dose estimates based on this technology.

IV. ADVISORY DATA SETS (ADSs) FOR FLUOROSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

The facility's overall dosimetric performance for FGI procedures, which incorporates the effects of equipment function, procedure protocols, procedure complexity, and operator performance, can be characterized and analyzed, but this requires collection of more data than required for the DRL process and a more detailed presentation of the resultant data set. The proposed audit process for FGI procedures is called the advisory data set process.³⁰ The key components are as follows:

An ADS that is obtained by collecting dosimetric data for *all of the instances* of a specific procedure performed at a large number of facilities. All of the data in an ADS must be collected using fluoroscopic systems with the same reference point location.

The ADS for a specific procedure consists of the distribution of the $K_{a,r}$ values for all of the instances of that procedure done in all of the facilities in the pool.^{10,16,34} It is necessary to use all available data for FGI procedures because of the wide variability in radiation dose, even for instances of the same procedure performed at the same facility.¹⁷ Random subsampling may be necessary when assembling the ADS to avoid excessive influence from a few high-volume facilities.¹⁰

A facility data set (FDS) that consists of the dosimetric data ($K_{a,r}$) for all of the instances of the same procedure at an individual facility. A facility evaluates its clinical performance by assembling all of the instances of the procedure into an FDS. A minimum of 50 instances is recommended for adequate statistical power.¹⁶ The FDS reference point definition must match the reference point definition of the corresponding ADS.

The substantial radiation dose level (SRDL) is a facility-selected value used to trigger patient follow-up for possible deterministic injury.³¹ The SRDL value is based on the imaging system geometry, the radiobiology, and the effects of radiation on the skin, not on the relative performance of the local facility or a group of facilities.^{29,35} It is intended to ensure that patients who receive a high radiation dose are not lost to follow-up. For isocentric C-arms, the Society of Interventional Radiology and the Cardiovascular and Inter-

TABLE I. Distribution by $K_{a,r}$ bin of a sample advisory data set and a sample facility data set for percutaneous coronary intervention. (This data set is provided as an example. Numerical values are only for illustration and cannot be used for any other purpose.)

$K_{a,r}$ bin range (Gy)	Advisory data set $n=2,546$		Facility data set $n=1,697$	
	Percent in bin	Cumulative percent	Percent in bin	Cumulative percent
0.0–0.5	1.22	1.22	0.53	0.53
0.5–1.0	6.17	7.38	3.65	4.18
1.0–1.5	15.36	22.74	7.96	12.14
1.5–2.0	17.95	40.69	13.38	25.52
2.0–2.5	15.79	56.48	15.03	40.54
2.5–3.0	12.10	68.58	12.79	53.33
3.0–3.5	9.86	78.44	10.55	63.88
3.5–4.0	5.85	84.29	9.13	73.01
4.0–4.5	4.67	88.96	6.54	79.55
4.5–5.0	3.61	92.58	4.77	84.33
5.0–5.5	2.79	95.37	4.48	88.80
5.5–6.0	1.34	96.70	3.24	92.04
6.0–6.5	1.18	97.88	2.12	94.17
6.5–7.0	0.67	98.55	1.59	95.76
7.0–7.5	0.67	99.21	1.06	96.82
7.5–8.0	0.27	99.49	0.88	97.70
8.0–8.5	0.20	99.69	0.65	98.35
8.5–9.0	0.04	99.73	0.41	98.76
9.0–9.5	0.08	99.80	0.41	99.18
9.5–10.0	0.04	99.84	0.29	99.47
10.0–10.5	0.04	99.88	0.18	99.65
10.5–11.0	0.04	99.92	0.06	99.71
11.0–11.5	0.08	100.00	0.12	99.82
11.5–12.0	0.00	100.00	0.00	99.82
12.0–12.5	0.00	100.00	0.06	99.88
12.5–13.0	0.00	100.00	0.00	99.88
13.0–13.5	0.00	100.00	0.00	99.88
13.5–14.0	0.00	100.00	0.00	99.88
14.0–14.5	0.00	100.00	0.00	99.88
14.5–15.0	0.00	100.00	0.12	100.00
>15.0	0.00	100.00	0.00	100.00

ventional Society of Europe recommend, and the National Council on Radiation Protection and Measurements (NCRP) suggests, a $K_{a,r}$ of 5 Gy.^{29,30} (For interventional radiology procedures, a $K_{a,r}$ of 5 Gy usually yields a peak skin dose of approximately 3 Gy.^{29,31}) Lower values have also been suggested as a more conservative alternative.³⁶ Biological sensitivity to radiation varies between individual patients. In addition, beam movement varies from procedure to procedure. Therefore, there is no implication that values above the SRDL will always cause an injury or that lower values will never cause an injury.

Examples of an ADS and an FDS for percutaneous coronary intervention (PCI) (i.e., coronary angioplasty) are shown in Tables I and II and Figs. 2–4. Note that although these data are derived from *real procedures*, they are only for *illustration and cannot be used for any other purpose*. These distributions are approximately log-normal, as is typical for almost all FGI procedures. Procedures with a $K_{a,r}$ above 5

TABLE II. Percentiles for the distributions of the advisory data set and the facility data set for percutaneous coronary intervention. (This data set is provided as an example. Numerical values are only for illustration and cannot be used for any other purpose.)

Percentile	$K_{a,r}$ advisory data set (Gy)	$K_{a,r}$ facility data set (Gy)
1	0.5	0.6
5	0.9	1.1
10	1.1	1.4
20	1.4	1.8
25	1.6	2.0
30	1.7	2.2
40	2.0	2.5
50	2.3	2.9
60	2.6	3.3
70	3.1	3.8
75	3.3	4.1
80	3.6	4.5
90	4.7	5.7
95	5.4	6.8
99	7.3	9.3
Arithmetic mean	2.6 Gy	3.3 Gy
Percent of values ≥ 5 Gy	7.4%	15.7%

Gy (the facility-selected SRDL in this example) are indicated by the cross-hatched bars. The same distribution can be described numerically by the percentage of procedures exceeding fixed $K_{a,r}$ values (Table I) or by the $K_{a,r}$ at fixed percentiles of the distribution (Table II). In this example, 7.4% of the procedures exceeded the facility-selected SRDL for this procedure. Note that the instances that exceeded the SRDL fall within a log-normal distribution, but are not predicted by a Gaussian distribution. Also note that because of the high-

FIG. 2. Sample ADS for PCI. Instances with a $K_{a,r} > 5$ Gy are indicated by the cross-hatched bars. In this ADS example, 7.4% of the instances exceeded the facility-selected SRDL for this procedure. This data set is provided as an example. Numerical values are only for illustration and cannot be used for any other purpose.

FIG. 3. Sample FDS for PCI. Instances with a $K_{a,r} > 5$ Gy are indicated by the cross-hatched bars. In this FDS example, 15.7% of the instances exceeded the facility-selected SRDL for this procedure. This data set is provided as an example. Numerical values are only for illustration and cannot be used for any other purpose.

dose tail, the mean $K_{a,r}$ of a typical dose distribution is greater than the median $K_{a,r}$.

An advantage of using $K_{a,r}$ as the dose metric for FGI dose audits is the ability to identify individual instances that exceed the facility-selected SRDL. The numerical value for the SRDL should be set at a level that is low enough to alert the facility to all patients who might experience a skin effect and high enough to permit reasonable and efficient management of patient follow-up. The expected impact of a specific SRDL on follow-up volume can be estimated from the percentage of $K_{a,r}$ values in the ADS that exceed the facility-selected value.

Another advantage of using $K_{a,r}$ as the dose metric is that simplified patient management can be considered for those procedures that do not meet the potentially high radiation dose criterion.³⁰ As defined by the NCRP, a potentially high radiation dose procedure is one for which $>5\%$ of instances of that procedure results in $K_{a,r} > 3$ Gy (or $P_{KA} > 300$ Gy cm²).³¹ A facility's experience is determined by reviewing the FDS for each procedure.

An example of an FDS is shown in Fig. 3 and Tables I and II for the same procedure shown in Fig. 2 and the tables. Instances with a $K_{a,r} > 5$ Gy are indicated by the cross-hatched bars. In this FDS example, 15.7% of the instances exceeded the facility-selected SRDL for this procedure.

The first step in the audit process is a comparison of the FDS median with the 75th percentile of the ADS (Table II). (The FDS mean value should *not* be used because it can be strongly influenced by the high-dose tail of the distribution.) An investigation should be undertaken if the local median exceeds the 75th percentile of the ADS. Investigation may also be desirable if the local median is below the 25th or above the 50th percentile of the ADS. Low radiation usage might be attributable to incomplete instances, inadequate image quality, or superior dose management. High radiation usage might reflect poor equipment or incorrect equipment

FIG. 4. Graphic comparison of the ADS and FDS distributions. Numerical comparisons are discussed in the text.

settings, suboptimal procedure performance, operator inexperience, or high clinical complexity. For the example shown in Table II, the median $K_{a,r}$ of the FDS is 2.9 Gy. This is greater than the ADS median of 2.3 Gy but less than the ADS 75th percentile of 3.3 Gy. The facility's overall performance is acceptable, but the reasons for radiation usage in excess of the ADS median should be evaluated and understood.

The second step in the audit process is to determine the percentage of local facility instances that exceed the facility-selected SRDL. Local percentages that are considerably above or below that observed for the ADS should be investigated with respect to clinical results and reported skin injuries. If the local frequency is greater than the ADS frequency, further analysis is performed to evaluate the cause. This additional analysis focuses first on the equipment, next on procedure protocols, and lastly on the operators (see below). This sequence is recommended because equipment faults are easiest to evaluate and correct, while operator performance is the most difficult process to analyze and influence.^{29,30,36}

The percentage of local instances of the procedure that exceed the facility-selected SRDL is determined from the ADS and FDS, as shown in Table I and depicted in Fig. 4.

(In the example presented in this paper, the facility-selected SRDL is 5 Gy; 7.4% and 15.7% of procedures exceed this SRDL for the ADS and FDS, respectively.) The reasons for this difference need to be analyzed and appropriate actions should be taken to minimize the potential for deterministic injuries.

A visual overview of the percentage of instances performed with low doses can be helpful. Figure 4 illustrates this using both binned and continuous distributions. Compared to the ADS, the facility performed fewer instances with a $K_{a,r} < 2$ Gy. An investigation is appropriate. Reasons might include equipment calibration or clinical case mix.

The third step is to ensure that there is adequate follow-up on each patient whose radiation level dose exceeds the local SRDL. The goal is to efficiently detect and manage all patients with deterministic skin changes or injuries.

V. INVESTIGATION OF RADIATION DOSE

Investigations are warranted whenever the FDS is noticeably different from the ADS. This is especially important in two circumstances: When the facility's local median $K_{a,r}$ for a particular procedure exceeds the 75th percentile of the ADS and when, for a particular procedure, the fraction of instances with patient doses that exceed the facility-selected SRDL is considerably greater for the FDS than for the ADS.

Fluoroscopic equipment configuration and procedure protocols should be examined first. In each room, fluoroscopic dose rate and fluorographic dose per image should be measured using the default settings and other settings commonly used at the facility. These measurements should be compared to equipment based DRLs using standard phantoms and a defined measurement protocol. In each room where local values exceed the DRL, equipment dose settings should be reduced and/or dose-reduction techniques employed (e.g., added spectral filtration and lower fluoroscopy pulse rates). In addition, if phantom air kerma or air kerma rate values differ from one procedure room to another in a facility, procedure air kerma data can be analyzed on a room-by-room basis to identify specific equipment that requires investigation.

Whenever dose-reduction techniques are implemented, resultant image quality and clinical performance must also be evaluated. It is essential that the operator's ability to adequately visualize the relevant anatomy is not compromised. If dose reduction to acceptable values cannot be accomplished without impairing the clinical mission, equipment repair, upgrade, or replacement may be necessary.

If equipment settings are found to be appropriate, operator performance parameters should be examined next. These parameters include, among others, fluoroscopy time and the number of fluorographic images acquired. These data should be acquired in the same fashion as the $K_{a,r}$ data. If these parameters are excessive, operator education is needed. This can be further evaluated by a review of procedure parameter information for individual operators to determine if additional training and mentoring are needed.

The FDS may differ from the ADS if a facility's patient population differs from the reference population. Corresponding differences in patient dose are expected.³⁷ Since the patient entrance air kerma for fluoroscopy and fluorography increases nearly exponentially with body-part thickness, patient size has a substantial effect on $K_{a,r}$ and P_{KA} . In addition, increased body-part thickness reduces image quality, resulting in the need for increased fluoroscopy time and an increased number of acquired images. Various normalization models have been described, including dividing data into weight ranges or using a normalization factor derived from phantom measurements.³⁸

A high volume of complex cases may also result in median FDS values exceeding the 75th percentile of the ADS or larger than expected numbers of instances with patient dose values exceeding the local SRDL. Procedure complexity depends on such factors as patient anatomy, location, anatomy, number and severity of the lesion(s) being treated, and number of problems encountered during the FGI procedure. Increased complexity often results in increased fluoroscopy time and patient dose.^{11,12,16} The ICRP and the International Atomic Energy Agency recommend that complexity be considered for FGI procedures.^{3,10} Unfortunately, the criteria for determining complexity are procedure-specific and have been developed only for a few specific cardiac interventional procedures.^{10,34} The development of complexity criteria for other procedures should be strongly encouraged. Alternatively, the data for different types of facilities (e.g., academic medical centers and community hospitals) could be analyzed separately to provide an ADS tailored to each type of facility. This method would take into account variations in different types of practice, including differences in average procedure complexity and in the use of trainees.

VI. DISCUSSION

At present, very limited data are available to generate an ADS for any interventional radiology procedure.³⁷ A concerted effort to gather the necessary data and create these data sets will be needed before this dose management tool is widely applicable. The FDA recently called for creation of such a database in the U.S.³⁹ New fluoroscopy systems in the U.S. have been required to display $K_{a,r}$ since mid-2006, so the number of installed units is now sufficient to permit nationwide data collection.

The values derived from an ADS or FDS are not intended for use in a regulatory manner and are not maximum values for individual instances of a procedure. Interventional procedures are performed by or under the direction of a physician who continuously monitors patient risk and benefit. Placing a limit on dose could harm a patient by requiring that an instance of a procedure be terminated prematurely. As the ICRP has noted, dose limits are not appropriate for medical exposures of patients.³ If a procedure is halted before the clinical goal is achieved, all of the radiation administered increases the patient's radiation risk but provides no clinical benefit.

It is expected that if this methodology is widely utilized for quality improvement, median ADS values will decrease over time. In the United Kingdom, DRLs for diagnostic radiography examinations decreased 20% between the 1995 and 2000 reviews.⁴⁰ This suggests that data gathering and determination of ADS values will need to be a continuing process, repeated at regular intervals.

If there is concern for deterministic injuries in other areas of medical imaging where multi-institutional data on all instances of a specific procedure (e.g., head CT) are collected, the ADS process could be extended to those areas. The selection of radiation metrics and reference point locations would be a function of the type of procedure. The use of a SRDL provides an alert for those instances of a procedure that might induce deterministic injury.

ACKNOWLEDGMENTS

This article was developed as part of the work of National Council on Radiation Protection and Measurements Scientific Committee 2-3 and expands the materials presented in Report 168. The work of SC 2-3 was funded by NCI under Grant No. 5R 24 CA 074296.

^{a)} Author to whom correspondence should be addressed. Electronic mail: sb2455@columbia.edu

^{b)} Electronic mail: smmr@msn.com

^{c)} Electronic mail: donald.miller@med.navy.mil

^{d)} Electronic mail: schueler.beth@mayo.edu

^{e)} Electronic mail: david.spelic@fda.hhs.gov

¹ D. C. Spelic, R. V. Kaczmarek, and O. H. Suleiman, "Nationwide evaluation of x-ray trends survey of abdomen and lumbosacral spine radiography," *Radiology* **232**, 115–125 (2004).

² ICRP, "Report 103: The 2007 recommendations of the International Commission on Radiological Protection," *Ann. ICRP* **37**(2–4), (2007).

³ ICRP, "Report 105: Radiation protection in medicine," *Ann. ICRP* **37**(6), 1–63 (2007).

⁴ D. Hart, M. C. Hillier, and B. F. Wall, "National reference doses for common radiographic, fluoroscopic and dental x-ray examinations in the UK," *Br. J. Radiol.* **82**, 1–12 (2009).

⁵ ICRP, "Diagnostic reference levels in medical imaging: Review and additional advice," *Ann. ICRP* **31**(4), 33–52 (2001).

⁶ B. F. Wall and P. C. Shrimpton, "The historical development of reference doses in diagnostic radiology," *Radiat. Prot. Dosim.* **80**, 15–19 (1998).

⁷ IAEA, "International basic safety standards for protection against ionizing radiation and for the safety of radiation sources," International Atomic Energy Agency, Vienna, Safety Report Series No. 115, 1996.

⁸ E. Vano and L. Gonzalez, "Approaches to establishing reference levels in interventional radiology," *Radiat. Prot. Dosim.* **94**, 109–112 (2001).

⁹ G. Bernardi, R. Padovani, G. Morocutti, E. Vano, M. R. Malisan, M. Rinuncini, L. Spedicato, and P. M. Fioretti, "Clinical and technical determinants of the complexity of percutaneous transluminal coronary angioplasty procedures: Analysis in relation to radiation exposure parameters," *Catheter. Cardiovasc. Interv.* **51**, 1–9 (2000).

¹⁰ IAEA, "Establishing guidance levels in x ray guided medical interventional procedures: A pilot study," International Atomic Energy Agency, Vienna, Safety Report Series No. 59, 2009.

¹¹ A. Peterzol, E. Quai, R. Padovani, G. Bernardi, C. J. Kotre, and A. Dowling, "Reference levels in PTCA as a function of procedure complexity," *Radiat. Prot. Dosim.* **117**, 54–58 (2005).

¹² T. Vehmas, "Radiation exposure during standard and complex interventional procedures," *Br. J. Radiol.* **70**, 296–298 (1997).

¹³ N. W. Marshall, C. L. Chapple, and C. J. Kotre, "Diagnostic reference levels in interventional radiology," *Phys. Med. Biol.* **45**, 3833–3846 (2000).

¹⁴ A. I. Stratis, P. L. Anthopoulos, I. P. Gavaliatsis, G. P. Ifantis, A. I. Salahas, I. P. Antonellis, A. G. Tavernarakis, and M. I. Molfetas, "Patient

dose in cardiac radiology," *Hellenic J. Cardiol.* **50**, 17–25 (2009).

¹⁵ E. M. Paisley, J. P. Eatough, P. J. Mountford, G. Frain, and J. Pickerill, "Patient radiation doses during invasive cardiac procedures categorised by clinical code," *Br. J. Radiol.* **77**, 1022–1026 (2004).

¹⁶ S. Balter, D. L. Miller, E. Vano, P. Ortiz Lopez, G. Bernardi, E. Cotel, K. Faulkner, R. Nowotny, R. Padovani, and A. Ramirez, "A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures," *Med. Phys.* **35**, 673–680 (2008).

¹⁷ I. A. Tsalaftas, H. Goni, P. N. Maniatis, P. Pappas, N. Bouzas, and G. Tzortzis, "Patient doses from noncardiac diagnostic and therapeutic interventional procedures," *J. Vasc. Interv. Radiol.* **17**, 1489–1498 (2006).

¹⁸ European Commission, "RP-109: Guidance on diagnostic reference levels (DRLs) for medical exposures," Radiation Protection (1999) (http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/109_en.pdf).

¹⁹ ACR, "ACR practice guideline for diagnostic reference levels in medical x-ray imaging," American College of Radiology, Reston (2008) (http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/reference_levels.aspx).

²⁰ M. Rosenstein, "Diagnostic reference levels for medical exposure of patients: ICRP guidance and related ICRU quantities," *Health Phys.* **95**, 528–534 (2008).

²¹ CRCPD, "Nationwide evaluation of x-ray trends (NEXT): Tabulation and graphical summary of 2001 survey of adult chest radiography," Conference of Radiation Control Program Directors, 2005 (unpublished), Publication No. E-05-2.

²² CRCPD, "Nationwide evaluation of x-ray trends (NEXT): Tabulation and graphical summary of 2002 abdomen/lumbosacral spine survey," Conference of Radiation Control Program Directors, 2006 (unpublished), Publication No. E-06-2b.

²³ CRCPD, "Nationwide evaluation of x-ray trends (NEXT): Protocol for 2008–2009 survey of cardiac catheterization," Conference of Radiation Control Program Directors, 2009 (unpublished), Publication No. E-09-2.

²⁴ IEC, "Medical electrical equipment—Part 2–43: Particular requirements for the safety of x-ray equipment for interventional procedures," IEC 60601-2-43 (2000) (<http://webstore.iec.ch/>).

²⁵ IEC, "Medical electrical equipment—Part 2–43, 2nd edition: Particular requirements for the safety of x-ray equipment for interventional procedures," IEC 60601 (2010) (<http://webstore.iec.ch/>).

²⁶ S. Balter, B. A. Schueler, D. L. Miller, P. E. Cole, H. T. Lu, A. Berenstein, R. Albert, J. D. Georgia, P. T. Noonan, E. J. Russell, T. W. Malisch, R. L. Vogelzang, M. Geisinger, J. F. Cardella, J. St George, G. L. Miller III, and J. Anderson, "Radiation doses in interventional radiology procedures: The RAD-IR study. Part III: Dosimetric performance of the interventional fluoroscopy units," *J. Vasc. Interv. Radiol.* **15**, 919–926 (2004).

²⁷ D. L. Miller, S. Balter, P. E. Cole, H. T. Lu, B. A. Schueler, M. Geisinger, A. Berenstein, R. Albert, J. D. Georgia, P. T. Noonan, J. F. Cardella, J. St George, E. J. Russell, T. W. Malisch, R. L. Vogelzang, G. L. Miller III, and J. Anderson, "Radiation doses in interventional radiology procedures: The RAD-IR study: Part I: Overall measures of dose," *J. Vasc. Interv. Radiol.* **14**, 711–727 (2003).

²⁸ D. L. Miller, S. Balter, L. K. Wagner, J. Cardella, T. W. Clark, C. D. Neithamer, Jr., M. S. Schwartzberg, T. L. Swan, R. B. Towbin, K. S. Rholl, and D. Sacks, "Quality improvement guidelines for recording patient radiation dose in the medical record," *J. Vasc. Interv. Radiol.* **15**, 423–429 (2004).

²⁹ D. L. Miller, S. Balter, P. E. Cole, H. T. Lu, A. Berenstein, R. Albert, B. A. Schueler, J. D. Georgia, P. T. Noonan, E. J. Russell, T. W. Malisch, R. L. Vogelzang, M. Geisinger, J. F. Cardella, J. S. George, G. L. Miller III, and J. Anderson, "Radiation doses in interventional radiology procedures: The RAD-IR study: Part II: Skin dose," *J. Vasc. Interv. Radiol.* **14**, 977–990 (2003).

³⁰ S. Balter, N. A. Detorie, and M. Mahesh, "Federal regulations (effective June 2006) require dose monitors on all new fluoroscopes: How will this help clinicians keep track of patient dose?," *J. Am. Coll. Radiol.* **4**, 130–132 (2007).

³¹ IEC, "PAS 61910-1: Radiation dose documentation. Part 1: Equipment for radiography and radioscopy" (2007) (<http://webstore.iec.ch/>).

³² NCRP, "Report 168: Radiation dose management for fluoroscopically-guided interventional procedures," NCRP Report No. 168, 2010.

³³ IAEA, "Patient dose optimization in fluoroscopically guided interventional procedures," International Atomic Energy Agency, Vienna, Technical Document Series No. 1641, 2010.

- ³⁴S. Balter, J. W. Hopewell, D. L. Miller, L. K. Wagner, and M. J. Zelefsky, "Fluoroscopically guided interventional procedures: A review of radiation effects on patients' skin and hair," *Radiology* **254**, 326–341 (2010).
- ³⁵M. S. Stecker, S. Balter, R. B. Towbin, D. L. Miller, E. Vano, G. Bartal, J. F. Angle, C. P. Chao, A. M. Cohen, R. G. Dixon, K. Gross, G. G. Hartnell, B. Schueler, J. D. Statler, T. de Baere, and J. F. Cardella, "Guidelines for patient radiation dose management," *J. Vasc. Interv. Radiol.* **20**, S263–273 (2009).
- ³⁶ACR, "Technical standard for management of the use of radiation in fluoroscopic procedures" (2008) (http://www.acr.org/SecondaryMainMenuCategories/quality_safety/RadSafety/RadiationSafety/standard-manage-radiation.aspx).
- ³⁷D. L. Miller, S. Balter, B. A. Schueler, L. K. Wagner, K. J. Strauss, and E. Vano, "Clinical radiation management for fluoroscopically guided interventional procedures," *Radiology* **257**, 321–332 (2010).
- ³⁸D. L. Miller, D. Kwon, and G. H. Bonavia, "Reference levels for patient radiation doses in interventional radiology: Proposed initial values for U.S. practice," *Radiology* **253**, 753–764 (2009).
- ³⁹FDA, "Initiative to reduce unnecessary radiation exposure from medical imaging" (2010) (<http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm>).
- ⁴⁰D. Hart, M. C. Hillier, and B. F. Wall, "Doses to patients from medical x-ray examinations in the UK-2000 review," NRPB-W14 (2000) (http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947421571).