Optimizing Radiation Use during Fluoroscopic Procedures: Proceedings from a Multidisciplinary Consensus Panel

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Diagnostic and interventional fluoroscopic procedures have dramatically improved patient care. They have helped minimize the need for more invasive surgical procedures and consequently reduced the morbidity and mortality of numerous diseases. However, in recent years, the rapid increase in the overall use of ionizing radiation has renewed concerns about the risks of radiation exposure in medical imaging (1–19) (Fig 1). The data indicate that diagnostic and interventional fluoroscopic procedures are major contributors to this increase in per capita exposure (18,19). Fluoroscopic procedures carry a risk of permanent skin injuries as well as possible risk future cancer induction (20–22). The heightened interest in the risks associated with ionizing radiation prompted the Society of Interventional Radiology (SIR) Foundation to convene a panel of experts who would investigate how to best balance the risks and benefits of fluoroscopic procedures. The meeting's goal was to develop a comprehensive strategy for optimizing the use of ionizing radiation during fluoroscopic procedures. The premise is that ionizing radiation is a resource used during fluoroscopic procedures and optimal use satisfies the medical purpose but avoids excess or unproductive exposure.

MEETING ORGANIZATION

The SIR Foundation announced interest in developing a consensus panel for radiation use in March 2010. Interested parties were invited to develop and submit proposals for a national meeting. Proposals were reviewed in June 2010 and, based on previously specified criteria, an individual (J.R.D.) was selected to lead the panel. In consultation with the SIR Foundation leadership, the panel lead developed a list of experts in radiation dose optimization, medical physics, registry development, and health care policy. Fourteen of these experts were invited and agreed to serve on the panel and included interventional radiologists ($n = 8$), diagnostic radiologists ($n = 2$), medical physicists ($n = 2$), a radiologic technologist, and an expert in registry development. In addition, officials from the Food and Drug Administration, Agency for Healthcare Research and Quality, National Council on Radiation Protection and Measurements, The Joint Commission, and Department of Defense were invited and agreed to participate in the panel discussions.

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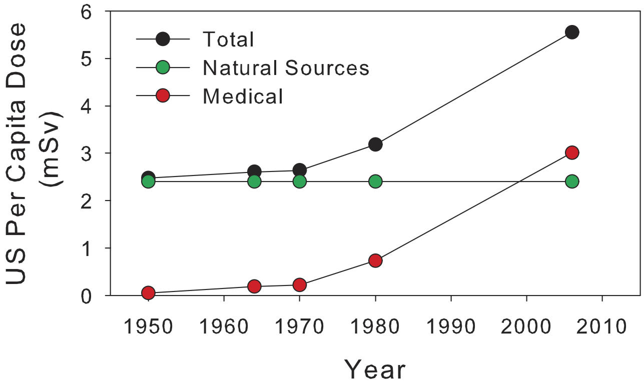

Figure 1. Trends in United States for per-capita exposure to ionizing radiation. Before 1970, the predominant source of ionizing radiation was from natural sources, but the rapid increase in medical imaging since then has doubled the per-capita exposure (18). Although this dose and the resultant risks are spread unevenly throughout the population, the increasing number and complexity of fluoroscopic procedures prompts evaluation of how to optimize radiation use during these procedures (19).

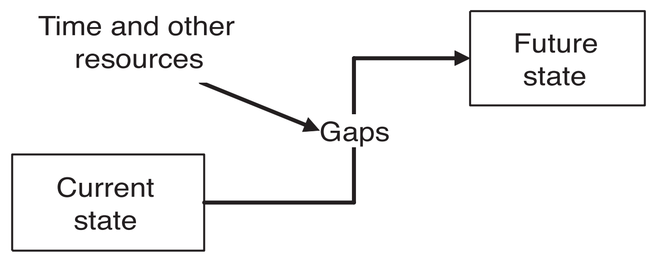

Figure 2. Process improvement from an investment perspective. The descriptions of the current state and desired future state provide insight into what gaps must be bridged. Time and other resources are then invested in improvement projects to bridge those gaps.

Before the meeting, the participants were given an agenda describing the structure and intent of the meeting. The structure of the meeting differed from earlier SIR Foundation Research Consensus Panels as the goal of this meeting was to select priorities for process improvement rather than to develop a research agenda. As illustrated in **Figure 2** , process improvement begins with an assessment of the current state, delineation of the desired future state, and assessment of the gaps between the two. The meeting, therefore, had three parts: (i) introductory presentations that described the current state, (ii) moderated roundtable discussion of desired future state, and (iii) discussion of the gaps between the two.

Table 1. Presentations to the Panel

Improving health care: radiation use as a priority
Adults as a priority (beginning with CT): Image Wisely campaign
Children as a priority: Image Gently campaign
Data-driven improvement: American College of Radiology registries
Improving tools for health care: role of the Food and Drug Administration
Improving health care processes: role of Agency for Healthcare Research and Quality
Data and system-based approaches to optimizing performance during fluoroscopic procedures
Collecting and analyzing data on radiation use during fluoroscopic procedures
DICOM-SR: new format for reporting radiation use during fluoroscopic procedures
NCRP process for developing reference levels

Note.—DICOM-SR = Digital Imaging and Communications in Medicine structured reporting; NCRP = National Council on Radiation Protection and Measurements.

DATA COLLECTION: DESCRIPTION OF THE CURRENT STATE

The current state and ideas for the future state were described in a series of presentations to the panel (**Table 1**). The overarching need for improvement in health care was described and the current process drivers were discussed. As large-scale improvement efforts in computed tomography (CT) are already under way (10,23), these projects were reviewed with particular attention to learning what key strategies might prove beneficial when attempting to optimize radiation use during fluoroscopic procedures. The role of registries and federal oversight was reviewed (24). Finally, systems-based approaches that build upon previous work in data collection and analysis were presented (25–34).

The overall status of the current state and contrasting view of the desired future state are summarized in **Figure 3** . Radiation use during fluoroscopic procedures varies widely and this variation reflects how patient attributes, operator experience, available equipment, and working environments differ from procedure to procedure (35–38). Other industries have confronted similar instances in which process inputs are highly variable but have been far more successful in producing results that exhibit minimal variation. Analysis of the current state found examples in which two- to eightfold reductions in radiation use were possible without sacrificing the diagnostic or therapeutic efficacy of fluoroscopic procedures (39,40). Finally, optimization efforts in radiology have been slow and sporadic rather rapid and continuous.

RESULTS: DESIRED ATTRIBUTES OF THE FUTURE STATE

The panel discussed the benefits of optimized doses and reduced variation. One of the fundamental goals of radiation protection is optimization (33,41). This means that the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors. This strategy recognizes the need to optimally balance the risks versus the benefits of ionizing radiation. As

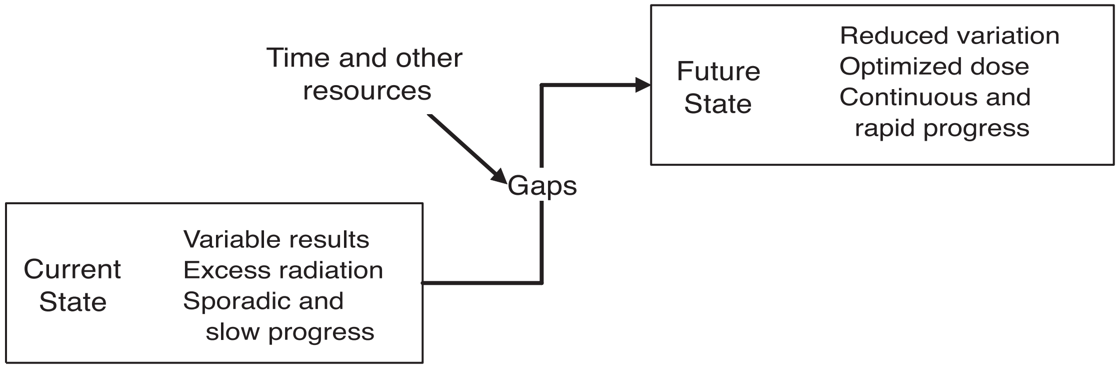

Figure 3. Assessment of the current and desired attributes for the future state.

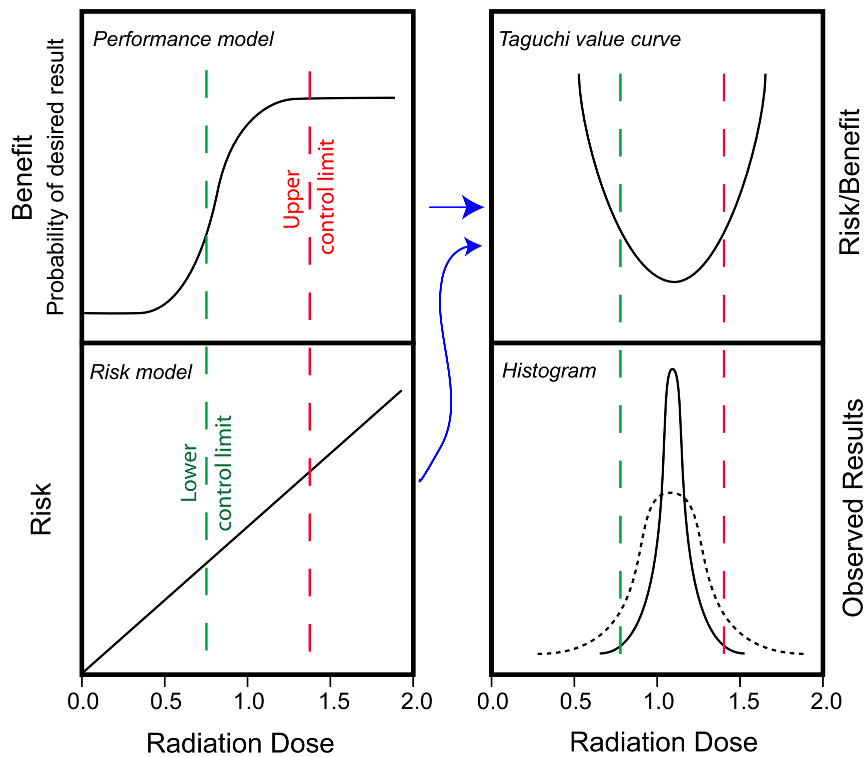

Figure 4. Modeling radiation use during fluoroscopic procedures. The performance model indicates that the probability of the procedure to achieve its intended goal is linked to radiation dose. The use of little or no ionizing radiation means that the desired outcome has little chance of success. Conversely, at some point, little is gained from increasing the dose. The linear, no-threshold risk model reflects the current understanding of damage caused by ionizing radiation. The resulting risk/benefit model (Taguchi value curve [42]) suggests that there is an optimal point at which the risk is counterbalanced by a measurable benefit. Deviations from that optimal point decrease the value provided. The histogram illustrates how trigger values or control limits can be used to focus investigative efforts on results that significantly deviate from the optimal point. (Figure adapted from Duncan and Evens [33] and Jacobs and Duncan [34]). (Available in color online at *www.jvir.org*.)

shown in **Figure 4** (33,34,42), excessive reduction in radiation dose could result in a nondiagnostic study or a failed intervention. This analysis also illustrates the importance of reducing unnecessary variation and specifying values that trigger investigations into determining factors that might have led to the need to use more or less radiation to accomplish a specific task.

DISCUSSION: GAP ANALYSIS

The panel then discussed a data-driven strategy for continuous process improvement (**Fig 5**). The keys to this effort include the creation of a fluoroscopy registry in which dose metrics would be routinely collected from patient procedures. The observed values at an individual facility would be compared with national reference levels and the results used to plan and implement changes. The success or failure of those changes will become evident from continued data collection and analysis.

Creating such a feedback loop will require convincing key stakeholders that change is needed and developing the necessary change agents. The Image Gently and Step Lightly initiatives have enrolled numerous radiologists who

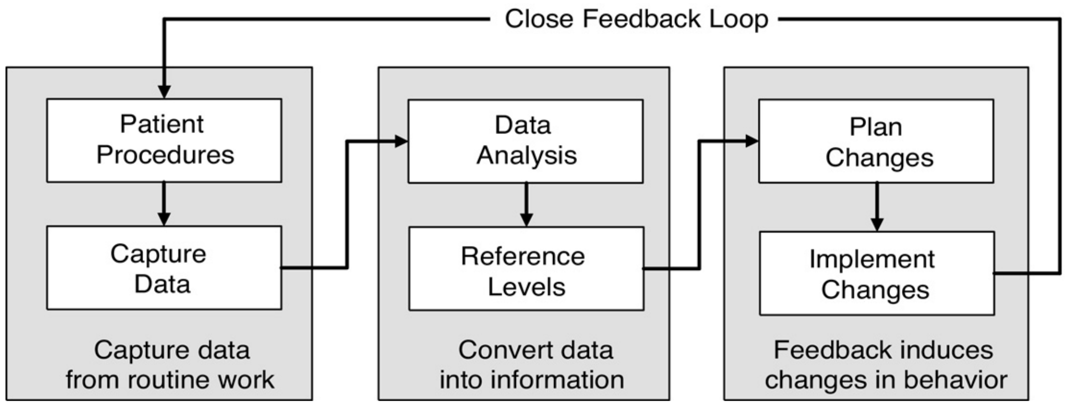

Figure 5. Data-driven feedback loop for continuous improvement.

Table 2. Improvement Process: Resources, Phases and Leverage Points (9–12,23,25,26,33,41,44–51)

Resource	Initial Construction	Continued Operations	Leverage Points*
Change agent	Develop argument	Communicate to large audience	Image Gently (9,10), Step Lightly (11,12), Image Wisely (23), optimization (33,41)
Registry	Define variables and data elements; develop local databases, create national registry, processes for data inflow	Receive data, store data, respond to queries, improve data capture	Radiology structured dose reports (DICOM-SR) (50,51), RIS and hospital informatics, PQRI (44,45), California legislation
Analysis	Recruit and train analysts, develop algorithms that provide benchmarks	Run algorithms, improve algorithms	OPPE (46), Maintenance of Certification (47–49)
Feedback	Generate reports on relative performance, create reporting channels	Provide feedback to frontline teams, improve feedback	Pay for performance (25,26), public reporting

* When planning any change, one ideally should leverage earlier work to help meet a future need. As a result, earlier work and an understanding of future needs can be considered "leverage points."
Note.— DICOM-SR = Digital Imaging and Communications in Medicine structured reporting; OPPE = Ongoing Professional Practice Evaluation; PQRI = Physician Quality Reporting Initiative; RIS = Radiology Information Systems;

pledge to serve as change agents for pediatric imaging. The decrease in CT use in pediatric centers suggests that imaging behavior has changed (43). The Image Wisely campaign hopes to expand this successful model to adult imaging. As shown in **Table 2** (9–12,23,25,26,33,41,44–51), the improvement process will also benefit from earlier work on the development of standardized radiation metrics such as Digital Imaging and Communications in Medicine structured reporting (50,51). As this loop is repeated, and knowledge gained, the results must be disseminated so that others may benefit from the process (52).

SUMMARY

Optimizing radiation use during fluoroscopic procedures is a key aspect of adding value to these procedures. The multidisciplinary panel acknowledged that patients are and will remain the key stakeholders in the improvement process. The panel recommended development of a multidisciplinary registry that will continually capture and analyze data from fluoroscopic procedures in an attempt to improve the safety of these procedures while maintaining their benefit. Although the SIR Foundation is well positioned to initiate this effort, long-term support will require working with a variety of patient advocacy groups and federal agencies.

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