

# Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record

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J Vasc Interv Radiol 2004; 15:423-429

**Abbreviations:** CD = cumulative dose, DAP = dose-area-product, FDA = Food and Drug Administration, IRP = interventional reference point, PSD = peak skin dose, TIPS = transjugular intrahepatic portosystemic shunt

## 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.

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DOI: 10.1097/01.RVI.0000126814.97605.C6

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, 10201 Lee Highway Suite 500, Fairfax, VA 22030.

## 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 dependent upon the magnitude of the project.

An in-depth literature search is performed with use of electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regards to 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 with a Modified Delphi Consensus Method (1,2). For the 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 Standards of Practice Committee members, either by telephone conference calling or face-to-face meeting. 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 Standards of Practice Committee, and appropriate revisions are made to create the finished standards document. Prior to its publication the document is endorsed by the SIR Executive Council.

## PATIENT RADIATION DOSE RECORDING

There are no federal regulatory requirements in the United States concerning recording or reporting of radiation dose data for interventional procedures. There are recommendations from the United States Food and Drug Administration (FDA) on this topic (3-5). Regulations or guidance at the state level are not uniform. Only a small number of states have addressed this issue. If state regulations exceed the requirements contained in this

document, practitioners are advised to follow the more stringent state regulatory guidelines. Existing guidelines and recommendations are shown in **Table 1**.

Fluoroscopically guided procedures are an essential part of the contemporary practice of medicine. In general, the risk of patient injury as a result of radiation exposure during these procedures is low. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin (16). The frequency of injury is unknown (17,18). Koenig and colleagues (16), in a comprehensive review published in 2001, reported data on radiation-induced skin injuries in 73 patients. Of these, 47 (64%) were results of coronary angiography and intervention, 12 (16%) were results of cardiac radiofrequency catheter ablation, seven (10%) were results of transjugular intrahepatic portosystemic shunt (TIPS) creation, three (4%) were results of neuroradiologic interventions, and the type of procedure was not specified for four patients. Some reported skin injuries have been associated with renal angioplasty, multiple hepatic/biliary procedures, or embolization (17–22).

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” (3). The International Commission on Radiological Protection (ICRP) has also recommended recording patient radiation dose in the medical record for certain procedures (6). Monitoring and recording patient dose data for all procedures can be valuable for quality-assurance purposes as well as for patient safety. Feedback to the operator may help to optimize radiation doses overall (23).

These guidelines 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.

## DEFINITIONS

*Absorbed dose:* The energy imparted per unit mass by ionizing radiation to matter at a specified point. The SI unit of absorbed dose is the joule per kilogram. The special name for this unit is the Gray (Gy).

*Air kerma:* The energy released per unit mass of a small volume of air when it is irradiated by an x-ray beam. For diagnostic x-rays, air kerma is the same as the absorbed dose delivered to the volume of air in the absence of scatter. Air kerma is measured in Gy.

*Biologic variation:* With respect to radiation, the differences among individuals in the threshold dose required to produce a deterministic effect, or the differences in degree of effect produced by a given dose. Biologic variation may be idiopathic or due to underlying disease. Different areas and types of skin also differ in radiosensitivity.

*C-arm fluoroscopic system:* A fluoroscopic system consisting of a mechanically coupled x-ray tube and image receptor. Such systems typically have two rotational degrees of freedom (left-right and cranial-caudal). Most such systems have an identifiable center of rotation called the isocenter. An object placed at the isocenter remains centered in the beam as the C-arm is rotated.

*Cumulative dose (CD):* The air kerma accumulated at a specific point in space relative to the fluoroscopic gantry (the interventional reference point) during a procedure. CD does not include tissue backscatter and is measured in Gy. CD is sometimes referred to as cumulative air kerma.

*Deterministic effect:* A radiation effect characterized by a threshold dose. The effect is not observed unless the threshold dose is exceeded. (The threshold dose is subject to biologic variation.) Once the threshold dose is exceeded in an individual, the severity of injury increases with increasing dose. Examples of deterministic effects include skin injury, hair loss, and cataracts.

*Dose:* As used in this document, “dose” is the same as the absorbed dose unless specified as “equivalent dose” or “effective dose.”

*Dose-area-product (DAP):* The integral of air kerma (absorbed dose to air) across the entire x-ray beam emitted

from the x-ray tube. DAP is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. DAP is measured in  $\text{Gy}\cdot\text{cm}^2$ .

*Effective dose:* The sum, over specified tissues, of the products of the equivalent dose in a tissue and the tissue weighting factor for that tissue. Effective dose is measured in Sieverts (Sv). Stochastic risk factors are usually stated relative to effective dose.

*Equivalent dose:* A quantity used for radiation protection purposes that takes into account the different probability of effects that occur with the same absorbed dose delivered by radiations with different radiation weighting factors. Effective dose is measured in Sv.

*Fluorographic image:* A single recorded image obtained using an image intensifier or flat digital panel as the image receptor. A digital angiographic “run” consists of a series of fluorographic images.

*Fluoroscopy time:* The total time that fluoroscopy is used during an imaging or interventional procedure.

*Interventional reference point (IRP):* For C-arm-type fluoroscopic systems with an isocenter, the IRP is located along the central ray of the x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot. The IRP is defined by International Electrotechnical Commission (IEC) standard 60601-2-43 (24).

*Isocenter:* For C-arm-type fluoroscopic systems, the point in space between the focal spot and the image receptor through which the central ray of the x-ray beam passes, regardless of beam orientation.

*Kerma:* Kinetic Energy Relaxed in Matter; the amount of energy transferred from the x-ray beam to charged particles per unit mass in the medium of interest. For diagnostic x-rays, this is equivalent to absorbed dose in the specified medium (eg, air, soft tissue, bone). Kerma is measured in Gy.

*Peak skin dose (PSD):* The highest dose at any portion of a patient’s skin during a procedure.

*Stochastic effect:* A radiation effect whose probability of occurrence increases with increasing dose, but whose severity is independent of total dose. Radiation-induced cancer is an example.

*Threshold dose:* The minimum radia-

**Table 1**  
Existing Recommendations for Recording Patient Dose

| Reference                         | Reference Type  | Procedures for which Dose Data Should Be Recorded   | When Dose Should Be Recorded  | Dose Metrics Recorded   |
|-----------------------------------|---|---|---|---|
| ICRP (6)                          | International guideline   | Determined by dose (presumed measured for all cases)  | PSD > 1 Gy if procedure likely to be repeated; PSD > 3 Gy if procedure not likely to be repeated          | PSD and location, skin dose map   |
| Spanish Statute (7)               | National law (Spain)  | Mandatory for all interventional procedures (eg, IR, cardiology); recommended for other fluoroscopic procedures   | Always  | DAP (minimum requirement); fluoroscopy time and number of images desirable  |
| FDA Advisory (4)                  | FDA advisory guideline (United States)                            | To be decided by each facility; should include TIPS and "percutaneous endovascular reconstruction"  | If skin dose equals or exceeds a threshold dose set by each facility (1–2 Gy suggested as threshold dose) | Skin dose; skin dose map or verbal description of site  |
| ACR (8)                           | ACR technical standard (United States)                            | Determined by fluoroscopy time or expected skin dose  | Fluoroscopy time > 10 min or expected skin dose > 2 Gy  | For automated dosimetry systems, dose data; for other systems, fluoroscopy time; if skin dose likely > 2 Gy, location of skin areas receiving dose > 2 Gy |
| CRCPD, 2001 (9)                   | CRCPD resolution (United States)                                  | "Procedures with a potential for producing radiation-induced injury"  | Not specified   | Not specified   |
| CRCPD, 2003 (10)                  | Suggested state regulations for radiation control (United States) | All   | All   | Fluoroscopy time, number of images (no specific requirement to include this in patient's medical record)  |
| Faulkner (11)<br>O'Dea et al (12) | Review<br>Observational study                                     | All<br>Greater than 0.01% chance of exceeding 6 Gy PSD if study not likely to be repeated; > 5% chance of exceeding 1 Gy PSD if study likely to be repeated at the same skin site | Always<br>All procedures meeting criteria   | PSD and DAP<br>PSD  |
| Waite and Fitzgerald (13)         | Observational study   | FGIPs   | Always for cerebral embolization; for all cases if easily available, otherwise periodic checks for FGIPs  | PSD and DAP for cerebral embolization, dap or automated PSD for all cases if easily available, otherwise periodic checks of PSD for FGIPs                 |
| Miller et al (14)                 | Observational study   | All, if integrated dosimetry available; otherwise, procedures with known potential for high dose (embolization, TIPS, renal/visceral artery PTA and stent placement)              | All, if integrated dosimetry available; otherwise, procedures with known potential for high dose          | PSD, CD, DAP (fluoroscopy time acceptable only if other metrics not available)  |
| Miller et al (15)                 | Observational study   | All if integrated dosimetry available; otherwise, procedures with known potential for high dose (all embolization, TIPS, angioplasty in abdomen or pelvis)                        | All, if integrated dosimetry available; otherwise, procedures with known potential for high dose          | PSD, CD, DAP  |

Note.—ACR = American College of Radiology; CRCPD = Conference of Radiation Control Program Directors; FGIP = fluoroscopically guided interventional procedure; ICRP = International Commission on Radiological Protection; PTA = percutaneous transluminal angioplasty.

tion dose at which a specified deterministic effect can occur. Threshold doses differ among individuals as a result of biologic variation. The threshold dose for skin injury also differs in different anatomic sites on the same individual.

Although practicing physicians should strive to achieve perfect compliance, in practice, all physicians will fall short of this ideal to a variable extent. Indicator thresholds may be used to assess the efficacy of ongoing quality-improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. When compliance rates fall below a minimum threshold, a review should be performed to determine causes and implement changes if necessary. If recording patient radiation dose data is one measure of the quality of radiation dose management, compliance rates lower than the defined threshold should trigger a review of policies and procedures within the department to determine the causes and implement changes to improve quality. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Because institutions and interventional fluoroscopic units vary widely in their ability to measure various metrics of patient dose, radiation dose data may be recorded with use of one or more of four different dose metrics: fluoroscopy time/number of fluorographic images, DAP, CD, and PSD. Therefore, setting universal thresholds is very difficult and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality-improvement program needs.

## GENERAL PRINCIPLES

### Dose Measurement

Radiation-induced effects may be divided into deterministic and stochastic effects. The likelihood of these effects in any individual patient cannot be predicted unless that patient's radiation dose is known. This is the principal reason for recording patient radiation dose. Monitoring and recording patient dose data can also be valuable for quality-assurance pur-

poses as well as for patient safety. Feedback to the operator may help to optimize radiation doses overall (23).

Patient radiation dose may be measured and recorded in different ways. There are four relatively standard methods for measuring dose during interventional fluoroscopic procedures. These methods differ in usefulness and availability. In the United States, one method is widely available, whereas the others vary in availability from relatively common to extremely uncommon. Note that none of these methods are applicable to dose measurements for CT fluoroscopy. Dose measurement and recording for CT fluoroscopy are not discussed in this document.

The simplest and most widely available measurements are fluoroscopy time and number of fluorographic images. These are analogues of dose; that is, they do not measure dose directly, and, by themselves, they are insufficient to determine patient dose. They are the least useful measures of patient dose. To estimate patient dose from fluoroscopy time and number of fluorographic images, the fluoroscopic dose rate and the dose per image must also be measured or estimated.

The next most commonly available dose measurement is DAP, which is a measure of the total radiation energy entering the patient. It is a good indicator of stochastic risk, and correlates with operator and staff dose (25,26). DAP meters may be integrated into the fluoroscopic unit or installed as add-on devices.

DAP is not an ideal indicator of deterministic risk. The principal deterministic risk to the patient is radiation-induced skin injury. The likelihood and severity of radiation injury at any point on the skin are related to the dose delivered to that portion of skin (17,27). DAP is a surrogate measure of skin dose. It does not correlate well with skin dose (13,28–33). A large dose delivered to a small skin area yields the same DAP as a small dose delivered to a large skin area.

The International Electrotechnical Commission introduced the concept of CD in 2000 (24). CD is the air kerma value at a specific point, the IRP, defined for fluoroscopic systems with an isocenter as a location along the central ray 15 cm from the system iso-

center in the direction of the focal spot. CD does not include tissue backscatter. Depending on the patient's size, the table height, and the angulation of the beam, the IRP may be outside the patient, may coincide with the skin surface, or may be inside the patient. CD is an approximation of the total radiation dose to the skin, summed over the entire body. During the course of virtually all interventional radiology procedures, the x-ray beam is moved periodically with respect to the patient, and is directed at different areas of the patient's skin. In general, therefore, estimates of the likelihood of radiation-induced skin injury that are based on CD tend to overstate this risk (15). CD is usually measured with a dosimeter integrated into the fluoroscopic unit. Relatively few fluoroscopic units incorporate CD measurement capability as of 2004, but this will change as International Electrotechnical Commission 60601-2-43-compliant interventional fluoroscopic systems are installed. As of March 2004, proposed FDA regulations require CD measurement capability for all new fluoroscopic equipment.

The likelihood and severity of radiation-induced skin injury to the patient as a whole are functions of the highest radiation dose at any point on that patient's skin—the PSD. Typically, no point on the patient's skin is within the irradiated field for the entire procedure. For this reason, the PSD is usually lower than the CD (15). It is desirable to measure PSD during interventional radiology procedures, but this has proved difficult in practice (34). PSD may be measured with a computerized analysis tool integrated into the fluoroscopic unit (35,36), with real-time point-measurement devices applied to the patient (37–39), with thermoluminescent dosimeters applied to the patient, or with dosimetric film interposed between the x-ray beam and the patient (40–42). PSD data derived from point measurement devices are likely to underestimate true PSD unless the measurement device is placed at the exact site of PSD. Exact placement of a point measurement device is unlikely because the PSD is usually confined to a small area of skin, the precise location of which is not known before the procedure (15,37,43).

PSD measurement may be accom-

panied by a display of a skin dose map. A real-time skin dose map is an extremely valuable tool for assisting the operator in minimizing skin dose (36). Dosimetric film may also be used to obtain a skin dose map, albeit not in real time (42,44). The skin dose map may also be added to the medical record at the conclusion of the procedure, thereby indicating not only the magnitude of the skin dose, but its location. This satisfies the most stringent interpretation of FDA, American College of Radiology, and international recommendations for recording skin dose (4,6,8).

A real-time skin dose map that indicates the site and magnitude of PSD is the ideal means for managing and recording patient radiation dose. Unfortunately, as of March 2004, this technology is not commercially available. Alternative methods of dose mapping, such as dosimetric film and thermoluminescent dosimeter arrays, are rarely used.

### Measurement Uncertainty

All statements of patient dose contain some degree of uncertainty. This results from uncertainties in the physical measurement of dose and further uncertainties when these measurements are used to estimate patient dose. Users of dose data should be aware of these uncertainties.

For example, fluoroscopy time can be accurately measured. However, important uncertainties in converting fluoroscopy time to patient dose include the varying effects of patient size, beam orientation, and the technical configuration of the fluoroscope.

Beam orientation and beam motion during the procedure have a profound influence on the precision of most dose metrics to estimate PSD. If the beam is fixed relative to the patient during the entire procedure, the conversion is relatively straightforward. However, if the beam never strikes the same portion of the patient's skin twice, PSD will be low. Virtually all clinical procedures are between these extremes (45).

In addition, even the most sophisticated dose-measurement instrumentation has unavoidable uncertainties related to variations in instrument response with changes in beam energy, dose rate, and collimator size.

Converting these measurements into skin dose introduces yet further uncertainties related to the patient's size and position relative to the beam. Finally, clinically available dose and DAP measurements ignore the effect of backscatter from the patient. Backscatter can increase skin dose 10%–40%, depending on the beam area and energy.

Methods for estimating PSD can be ranked from most reliable to least reliable. Peak (air) dose measuring software is the most reliable, followed by measurement of CD at a reference point, DAP, and finally fluoroscopy time combined with a count of the number of fluorography frames or images.

Measurement of peak (air) dose at the patient's skin is probably accurate to within  $\pm 50\%$  of the actual peak air dose. This means that a reported value of 2 Gy more precisely represents a skin dose value between approximately 1.3 Gy and 3.9 Gy (including the effect of backscatter). Dose data reconstructed from fluoroscopy time and number of fluorographic frames are much more uncertain and, after all corrections are factored in, are probably not more accurate than a factor of approximately +130% and –70% of the best estimated value. For example, a 2-Gy calculated peak air dose at the patient's skin, reconstructed from fluoroscopy time and number of fluorographic frames, is probably more precisely stated as between 0.6 Gy and 4.6 Gy. The uncertainties of estimates of PSD derived from CD or DAP are between these two extremes.

### How Dose Should Be Measured

The optimal method is measurement of PSD. Ideally, this would include real-time skin dose mapping as a means for managing patient radiation dose. In the absence of skin dose measurements, other dose metrics should be used. PSD and DAP are the most useful predictors for deterministic and stochastic injury, respectively. CD is an acceptable substitute if PSD is difficult to measure, but it does not correlate well with PSD in individual cases (15). Fluoroscopy time alone does not correlate with PSD (45). Monitoring fluoroscopy time alone also underestimates the risk of radiation-induced skin effects (12). Fluoroscopy

time and number of fluorographic images, used together, can provide a better guide to patient dose but are not themselves measures of dose. They do not provide sufficient information for dose calculations and are therefore suboptimal dose metrics. However, if none of the other metrics can be measured, fluoroscopy time and number of fluorographic images, along with the patient's height and weight, can be used for recording patient radiation dose until other means are available.

SIR recognizes that many practitioners have access only to interventional fluoroscopic equipment with minimal or no radiation dose measurement capabilities. Facilities should be encouraged to purchase interventional fluoroscopic equipment with state-of-the-art dose-measurement and dose-management capabilities and to upgrade existing interventional fluoroscopic equipment with after-market devices to improve dose-measurement capability. When deterministic effects are of concern, the most desirable capability is real-time skin dose mapping, followed by non-real-time skin dose mapping, PSD measurement, CD measurement, and, least valuable, fluoroscopy time and number of images. If stochastic effects are of concern, DAP measurement capability is also valuable.

### When Dose Should Be Recorded

Certain procedures are known to be associated with relatively high patient radiation doses (14,15). Patient radiation dose data should be recorded for all instances of these procedures. To simplify the categorization of high-dose procedures, SIR recommends that all embolization procedures, TIPS procedures, and arterial angioplasty or stent placement procedures anywhere in the abdomen or pelvis should be considered potential high-dose procedures (15). Patient radiation dose data should also be recorded for medium-dose procedures that are likely to be repeated (6). Medium-dose procedures may be defined as procedures with a CD of 1–3 Gy. Examples include biliary drainage, stroke therapy, and vertebroplasty (14). Other interventional radiology procedures such as pulmonary angiography, inferior vena cava filter placement, and venous access procedures are less

**Table 2**  
**Threshold Rates for Recording of Dose Metrics**

| Procedure Type   | Threshold (%) |
|--|---------------|
| High-dose procedures (all embolization procedures, TIPS, arterial angioplasty or stent placement at any site in the abdomen or pelvis) | 99            |
| Other fluoroscopically-guided interventional procedures (excluding CT fluoroscopy)   | 95            |

likely to result in high patient radiation doses (14,45). It is nonetheless desirable to record patient radiation dose data for these procedures. Recording patient dose data for all procedures makes it less likely that the process will be omitted inadvertently for high-dose procedures. In addition, monitoring and recording patient dose data can be valuable for quality-assurance purposes as well as for patient safety. Feedback to the operator may help to optimize radiation doses overall (23).

Published SIR guidelines for reporting and archiving of interventional radiology procedures do not specify where in the medical record radiation dose data should be recorded (46). Radiation dose data may be recorded in the immediate procedure note, the procedure worksheet, and/or the final report. Each institution should specify where this information is to be recorded in accordance with the needs of its own quality-improvement program and its medical record guidelines.

## DATA RECORDING

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, CD, DAP, or fluoroscopic time/number of fluorographic images (Table 2). In Table 2, all values were supported by the weight of literature evidence and panel consensus.

**Acknowledgments:** Dr. Donald L. Miller authored the first draft of this document and served as topic leader during the subsequent revisions of the draft. Drs. Stephen Balter and Louis Wagner made significant contributions to the content of this document. Dr. John F. Cardella is chair of the

SIR Standards of Practice Committee. Dr. David Sacks is Councilor of the SIR Standards Division. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are (listed alphabetically): Curtis W. Bakal, MD, Joseph Bonn, MD, Daniel B. Brown, MD, Patricia E. Cole, PhD, MD, Peter Drescher, MD, Neil J. Freeman, MD, Jeffrey D. Georgia, MD, Scott C. Goodwin, MD, Clement J. Grassi, MD, Ziv Haskal, MD, David M. Hovsepian, MD, Curtis A. Lewis, MD, MBA, Patrick C. Malloy, MD, Louis G. Martin, MD, J. Kevin McGraw, MD, Steven G. Meranze, MD, Kenneth Murphy, MD, Albert A. Nemcek, Jr, MD, Steven B. Oglevie, MD, Reed Ali Omary, MD, Nilesh H. Patel, MD, Dheeraj Rajan, MD, Parvati Ramchandani, MD, Anne C. Roberts, MD, Orestes Sanchez, MD, Gary P. Siskin, MD, Harry R. Smouse, MD, Patricia E. Thorpe, MD, Thomas M. Vesely, MD, Bret N. Wicmann, MD

## APPENDIX: METHODOLOGY

Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee member practices, and, when available, the SIR HI-IQ system national database.

Consensus on statements in this document was obtained with a modified Delphi technique (1,2).

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The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.