

Guidelines for Establishing a Quality Assurance Program in Vascular and Interventional Radiology

Society of Interventional Radiology Standards of Practice Committee
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ENSURING quality care in vascular and interventional radiology is the primary goal of the SIR Standards of Practice Committee. To achieve this goal, the Committee has previously defined the qualifications of physicians performing the procedures and the facilities that are required for safe diagnostic and interventional procedures. The next focus is on the assessment of quality care; this is done by identifying important aspects of care, defining acceptable standards for each of these areas, and designing a system to monitor and evaluate the care given.

Such a program is mandated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO medical staff regulations 3.11 requires that "... there is a mechanism to assure the same level of quality of patient care by all individuals with delineated privileges in a given medical institution." Within a diagnostic radiology department, JCAHO requirements DR.4.2.1.2.1.1 further states "... These criteria are used by the diagnostic radiology department/service or by the hospital's quality assurance program in the monitoring and evaluation of patient care services..." Thus, the program must be based on objective criteria that can define quality care and these criteria must be applied to all individuals with the de-

fining privileges within an institution. The JCAHO has published guidelines on how to establish and maintain a Quality Assurance program to monitor and evaluate the quality and appropriateness of care. We will briefly review the essential elements of such a program and then show how these elements may be applied in interventional radiology.

ESSENTIAL STEPS IN MONITORING AND EVALUATION

There are ten steps needed in designing a program. There are:

1. Assign responsibility for the Monitoring and Evaluation (M&E) Program.
2. Delineate the scope of the care provided.
3. Identify important aspects of care.
4. Identify indicators related to the important aspects of care.
5. Establish the thresholds for evaluation related to the indicators.
6. Collect and organize data.
7. Evaluate care when thresholds are reached.
8. Take action to resolve identified problems.
9. Determine whether care or service has improved or has improved and document improvement.
10. Communicate relevant information to the facility-wide Quality Assurance program.

The SIR Standards of Practice Committee has designed the following M&E program, which meets the JCAHO requirements. The program includes evaluation of 3 areas of current concern: diagnostic angiography, percutaneous transluminal angioplasty (PTA) and other percutaneous revascularization procedures, and percutaneous nephrostomy. These procedures were chosen because they are either high-volume or high risk. The Committee strongly believes that all practitioners must meet a minimum standard with regard to case selection, technical success, and complication rates.

This program may be used as outlined or modified to meet the needs of the individual institution. While it monitors three areas of practice, other areas may be added using the same format. The complication and technical success rates are based on literature data. However, the reference used in each section served only as guides, and the thresholds given do not reflect any single author's experience.

MONITORING AND EVALUATION

1. Responsibility

The Chairman of the Department of Radiology is responsible for the Quality Assurance Program for the entire department. He/she designates the Chief of Vascular and Interventional Radiology as responsible for the monitoring and evaluation in the section, and that individual will evaluate care

Procedure	Reason for Evaluation	Important Aspect of Care
Diagnostic Angiography	High Volume	Appropriateness Safety
PTA	High Risk	Appropriateness Efficacy Safety
Percutaneous Nephrostomy	High Risk	Appropriateness Safety

and report the results to the department at the monthly meeting. Each practitioner who performs procedures in the section has the responsibility to ensure that all his/her procedures are properly recorded and that any complications are reported. The special procedures nurse is responsible for maintaining the records on procedures and complications.

2. Scope of Care

The Vascular and Interventional Radiology Section is responsible for all diagnostic angiography performed in the department. In addition, all interventional radiology procedures are performed by this section. These interventional procedures include, but are not limited to, the following: percutaneous transluminal angioplasty or other percutaneous revascularization procedures in peripheral, cerebral, renal, and visceral arteries; transcatheter embolization; percutaneous vena cava filter placement; infusion of chemotherapy, vasopressin, or fibrinolytic agents; biliary interventional procedures; percutaneous nephrostomy, percutaneous renal stone extraction and other genitourinary procedures; abscess and fluid drainage; and percutaneous aspiration biopsy. These procedures are used to diagnose and treat a wide variety of disease processes, although atherosclerosis, cancer, biliary and renal stone disease, and post-operative complications are the most common problems addressed.

The section includes the department's radiologists with privileges in these procedures, other physicians who perform procedures have privileges within the Department of Radi-

ology, the special procedures technologists, and the special procedures nurses. The services of the section are scheduled five days a week, with emergency services available 24 hours a day as needed. The vast majority of the procedures are occasionally done on extremely ill patients. Procedures are done on both inpatients and outpatients. The patient population served is that of the hospital and its medical staff.

3. Important Aspects of Care

The department staff has determined that the following procedures will be monitored. The most important aspects of care are given in **Table 1**.

4&5. Indications and Thresholds for Important Aspects of Care

DIAGNOSTIC ANGIOGRAPHY

Aspects of Care: Appropriateness

Indicators:

Indications for diagnostic angiography include:

1. Evaluation of vascular disease, for diagnosis and staging
2. Evaluation of malignant disease, for diagnosis and staging
3. Evaluation of gastrointestinal bleeding
4. Preoperative planning for portosystemic shunts
5. Evaluation of benign conditions, for diagnosis and preoperative planning

Threshold: See Quality Improvement Guidelines for Diagnostic Arteriography (J Vasc Interv Radiol 2002; 13:1-6) included in this supplement on pages S283-S288.

Aspects of Care: Safety

The following complications are the indicators of the safety of diagnostic angiography. If the threshold levels are exceeded, a review will take place. For threshold values see Singh et al.

Indicators:

Puncture site complications

- Hematoma (requiring transfusion, surgery or delayed discharge)
- Occlusions
- Pseudoaneurysm
- Arteriovenous fistula
- Contrast extravasation

Non-puncture site complications

- Distal emboli
- Unintended dissection/occlusion of selected vessels

Contrast reactions

- All idiosyncratic reactions
 - Major reactions (respiratory symptoms)
 - Contrast-related death
 - Non-idiosyncratic reactions (hypertension, nausea, vomiting, bradycardia)
- Contrast-induced renal failure (Increase in serum creatinine by 50% or by 1 mg/dL within 48 hours of the procedure resulting in an abnormal serum creatinine level.)
 - Transient
 - Permanent

References

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PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

Renal, iliac, femoropopliteal and tibial angioplasties are the highest volume procedures currently. Visceral, venous, and dialysis access dilations are not included in this program.

This section covers balloon angioplasty, laser-assisted angioplasty, atherectomy and any other devices used for percutaneous revascularization. They all will be reviewed using the same criteria for appropriateness, efficacy and safety.

Aspects of Care: Appropriateness

Indicator:

Percutaneous transluminal balloon angioplasty and other forms of percutaneous revascularization are done for the following indications:

Peripheral (includes iliac, femoropopliteal and tibial)

- A. Presence of one of the following:
 1. Intermittent claudication, which limits lifestyle and is documented by appropriate non-invasive tests
 2. Ischemic rest pain
 3. Ischemic ulceration or other tissue loss
- B. And one of the following:
 1. One or more short (<10 cm in length), hemodynamically significant arterial stenoses, with definable continuous runoff below
 2. Short segment (<10 cm in length) occlusion with definable continuous runoff below
 3. More extensive disease than the above in patients who are

Table 2

Angioplasty Site	Threshold Technical Success
Iliac	95%
Superficial Femoral and Popliteal	90%
Tibial and Peroneal	80%
Renal (Atherosclerotic)	*
Renal (Fibromuscular Dysplasia)	*

* See also Martin et al, *J Vasc Interv Radiol* 2002; 13:1069-1083.

- poor operative risks or who lack suitable bypass material
4. Stenosis associated with a bypass graft

Renal

- A. Presence of one of the following:
 1. Suspected renovascular hypertension supported by clinical and laboratory data
 2. Renal insufficiency (abnormally elevated serum creatinine)
- B. And one of the following:
 1. Short segment hemodynamically significant atherosclerotic stenosis of the main or segmental renal arteries
 2. Typical angiographic appearance of fibromuscular dysplasia
 3. Ostial stenosis or renal artery occlusion in a patient who is a poor operative risk
 4. Stenosis associated with a bypass graft

Threshold: When fewer than 95% of cases are for the above indications, a review will be done. See also Quality Improvement Guidelines for Angiography, Angioplasty, and Stent Placement in the Diagnosis and Treatment of Renal Artery Stenosis in Adults (*J Vasc Interv Radiol* 2002; 13:1069-1083).

Aspects of Care: Efficacy

The success rates in **Table 2** are the indicators of the efficacy of these procedures. Technical success is defined as residual stenosis of less than 20% and either improvement in the ankle-brachial index of at least 0.2 or residual gradient of <10 mm Hg by direct

measurement. When these success rates are not met, a review will be undertaken.

Aspects of Care: Safety

Indicators:

When the following complications and corresponding thresholds are exceeded, a review will be done (**Table 3**).

For contrast reactions and contrast-induced nephropathy, please see the diagnostic angiography section.

References

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Table 3

Indicators	Threshold
Emergency surgery	<3.0%
Severe bleeding or hematoma (requiring transfusion, surgery, or delayed discharge)	<4.0%
Puncture site occlusion	<0.5%
Angioplasty site occlusion	<3.0%
Distal embolization causing tissue damage	<0.5%
Vessel perforation requiring surgery	<0.5%
Vessel perforation, no surgery required (Laser angioplasty)	<15.0%

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PERCUTANEOUS NEPHROSTOMY

Aspects of Care: Appropriateness

Indicators:

Percutaneous nephrostomy is done for one of the following indications:

- Relief of renal obstruction where there is impaired renal function or infection.
- To allow percutaneous access to the kidney, for antegrade ureteral stent placement, removal of urinary stones, dilation or incision of structures, or removal of foreign bodies.
- To allow access for urodynamic studies.
- For urinary diversion in the presence of urinary leaks.
- To drain renal abscesses.
- To allow access for the infusion of chemotherapeutic or other drugs.
- Prophylactic placement prior to ESWL of large renal stones, where a retrograde stent cannot be placed.

Threshold: Percutaneous nephrostomy should be done for one of the previous indications. For threshold values, see Quality Improvement Guidelines for Percutaneous Nephrostomy (*J Vasc Interv Radiol* 2001; 12:1247–1251) included in this supplement on pages S277–S281. When the threshold levels are exceeded, a review will be undertaken.

Aspects of Care: Safety

The complications listed below are the indicators of the safety of percutaneous nephrostomy. For threshold values, see Quality Improvement Guidelines for Percutaneous Nephrostomy (*J Vasc Interv Radiol* 2001; 12: 1247–1251). When the threshold levels are exceeded, a review will be undertaken.

Indicator:

- Bleeding requiring transfusion
- Fever (No pyonephrosis present)
- Fever (Pyonephrosis present)
- Septic Shock
- Major urothelial injury (requiring other intervention)
- Tube dislodgment

References

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6. Data Collection

The data source will consist of the logs of the vascular and interventional procedures done in the radiology department, regardless of the specialty of the operating physician. This case log will include the patient's name, hospital number, operating physician, date indication, and the specific procedure done. They will be listed by procedure type.

A separate complication log will be maintained, and will contain the patient data and a brief summary of the details of the complication.

All records and case logs will be monitored as part of the department's confidential peer review file.

7. Evaluation

All complications will be presented by the staff physician responsible and the circumstances of the event will be discussed at the monthly Radiology Quality Assurance Meeting. In addition, every six months the cumulative data will be presented at the department meeting. Complications that exceed the thresholds will be discussed, both for individual staff and the department as a whole. The complications of all physicians performing these procedures in the department will be monitored in the same manner. Similarly, when the thresholds for efficacy and appropriateness are not met, a review will be done (see next section.)

8. Action to Improve Care

When complications are presented at the monthly meeting, they will be classified as avoidable or unavoidable by the staff. Means of preventing repeated avoidable complications will be discussed and agreement will be reached.

The review done each six months will be divided into the three areas of greatest concern: appropriateness, efficacy, and safety. When appropriateness thresholds are exceeded, either by an individual or by the department as

a whole, the specific cases will be discussed. The indications may need to be broadened as a result of the review. Alternatively, reemphasis of the consensus view for procedural indications will occur.

When efficacy or safety thresholds are exceeded, the review will focus on the specific cases, the general expertise of the practitioners involved, the overall patient population served, and the equipment related issues. A specific plan of action will be formulated. This may involve alteration of thresholds because of the patient population, further continuing medical education courses for some practitioners or voluntary limitation of privileges. The

plan will be implemented by the chief of Interventional Radiology, and he/she will monitor the results of the actions taken.

Where there is repeated or gross failure of an individual to meet the standards outlined by the department, and there is not sufficient improvement after the above actions, following the hospital's medical staff bylaws and procedures, involuntary limitations of privileges may be considered.

9. Follow-up of Actions Taken

The problem area will be reviewed at subsequent meetings, after action has been taken. The chief of Inter-

tional Radiology will report each 6 months until the thresholds are no longer exceeded. This report will be recorded in the department's QA meeting minutes.

10. Reporting

As defined in the institutional quality assurance plan, the results of the department meetings will be reported to the Hospital Quality Assurance Committee. The specific actions taken will be included, as will the results of previous actions. If there are any specific recommendations for altering the hospital privileges of any of the medical staff, based on the accumulated data, these will be presented.