

Developing a Clinical Pediatric Interventional Practice: A Joint Clinical Practice Guideline from the Society of Interventional Radiology and the Society for Pediatric Radiology

Kevin M. Baskin, MD, Mark J. Hogan, MD, Manrita K. Sidhu, MD, Bairbre L. Connolly, MB, Richard B. Towbin, MD, Wael E.A. Saad, MD, Josee Dubois, MD, MSc, Manraj K.S. Heran, MD, FRCPC, Francis E. Marshall, MD, Donald L. Miller, MD, Derek Roebuck, MBBS, Michael J. Temple, MD, FRCP, T. Gregory Walker, MD, John F. Cardella, MD, and members from the Society of Interventional Radiology Standards of Practice Committee and Society for Pediatric Radiology Interventional Radiology Committee

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 expert constituency of the subject matter under consideration for standards production.

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

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic, procedural, and clinical care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth later, the SIR and the Society of Pediatric Radiology caution against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question. The practitioner, in light of all the circumstances presented, must make the ultimate judgment regarding the propriety of any specific procedure or course of action.

An approach that differs from these guidelines does not, of itself, imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science but also the art of the promotion of health and the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of these guidelines is to assist practitioners in achieving this objective.

From the Department of Radiology (K.M.B.), Children's Hospital of Pittsburgh, University of Pittsburgh Medical Center, Pittsburgh; Department of Radiology (J.F.C.), Geisinger Health System, Danville, Pennsylvania; Section of Vascular and Interventional Radiology, Department of Radiology (M.J.H.), Nationwide Children's Hospital, The Ohio State University, Columbus, Ohio; Department of Radiology (M.K.S.), Seattle Children's Hospital, University of Washington, Seattle, Washington; Center for Image Guided Therapy (B.L.C., M.J.T.), Hospital for Sick Children, University of Toronto, Toronto, Ontario; Department of Medical Imaging (J.D.), Centre Hospitalier Universitaire Sainte-Justine, Montreal, Quebec; Department of Radiology (M.K.S.H.), British Columbia Children's Hospital, Department of Radiology (M.K.S.H.), Vancouver General Hospital Vancouver, British Columbia, Canada; Department of Radiology (R.B.T.), Phoenix Children's Hospital, Phoenix, Arizona; Department of Radiology (W.E.A.S.), University of Virginia Health System, Charlottesville, Virginia; Department of Radiology (F.E.M.), Riley Hospital for Children, Indiana University School of Medicine, Indianapolis, Indiana; Department of Radiology (D.L.M.), Uniformed Services University of the Health Sciences; Department of Radiology (D.L.M.), National Naval Medical Center, Bethesda, Maryland; Department of Radiology (D.R.), Great Ormond Street Hospital, London, United Kingdom; and Division of Vascular Imaging and Intervention (T.G.W.), Massachusetts General Hospital, Boston, Massachusetts. Final revision received and accepted July 18, 2011. Address correspondence to K.M.B., c/o SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033. E-mail: kevin.baskin@chp.edu

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This guideline document was developed and written collaboratively by the SIR and the Society of Pediatric Radiology. It consists in part of adaptations from the general Clinical Practice Guidelines for Interventional Radiology, with permission of the publisher (1). The special skills of the interventional radiologist include both major and minimally invasive procedures performed in whole or in part with image guidance. The terms “interventionalist,” “intervention,” or “interventional” will be used throughout this document to represent interventional radiology in its broadest sense, inclusive of all disease processes, body systems, means of access, imaging modalities, equipment, and devices concerned. However, jurisdictions may differ on a variety of issues, including requirements of informed consent, scope of practice of nonphysician providers, and procedural coding and reimbursement practices. It is recommended in all cases that local regulatory agencies, medical boards, and hospital administration be consulted regarding the specific parameters applicable to a given practice.

Pediatric interventional radiology is a clinical subspecialty of radiology whose focus spans the range of pediatric health and disease. This document has been prepared specifically for interventional radiologists who wish to develop within their practice a clinical focus on the treatment of children. Within this context, these guidelines are intended to be as inclusive as possible of all practice locations, inside and outside of the United States.

An interventionalist interacts directly with patients and their families and guardians and counsels them regarding diagnostic and therapeutic options for their medical conditions. Interventional care is a longitudinal continuum, beginning with an initial consultation either formalized in a clinic setting or originating from discussion with a referring clinician, defining a plan of care that may include a diagnostic or therapeutic intervention, through to eventual resolution of the clinical problem or establishment of an alternative care plan. To achieve these ends, it is often necessary for the interventional radiologist to see patients in clinical practice settings and to create and execute management plans (1,2).

In order to treat patients in a hospital setting, it is necessary that the interventionalist obtain the required hospital privileges. Furthermore, a clinical pediatric interventional radiology practice benefits from both appropriate procedural areas and traditional clinical office space. In addition to the necessary infrastructure requirements, there are benchmarks that define an interventional clinical practice. These benchmarks should be used as goals for developing the practice.

Depending on the clinical complexity of the case and the practice environment, a clinical interventional radiologist should be in a position to:

1. Independently accept referrals for diagnostic or therapeutic interventions as the responsible physician or as a consultant for the disease process;
2. Inform patients referred for services of the spectrum of diagnostic and therapeutic options that might benefit them and provide interventional treatment if they desire;
3. Establish treatment plans and implement them;
4. Admit patients who require inpatient services related to therapeutic interventions;
5. Consult specialists as indicated for opinions regarding aspects of care outside the regular scope of practice of the interventional radiologist;
6. Perform and bill for consultations for patients before and after planned or elective interventions; and
7. Provide longitudinal patient care.

The following guidelines should be used to develop an interventional clinical practice for inpatient and outpatient clinical services. Recommendations will include processes for dealing effectively with pediatric clinical care issues, handling referrals, the physician–patient relationship, scheduling of invasive procedures, staffing, clinic space, time dedicated to clinical duties, interventional suites and equipment needs, administrative and clerical services, practice development, and continuous quality improvement programs.

ISSUES IN PEDIATRIC CLINICAL CARE

Family-centered Care

Maintaining a family-centered approach is a core value of pediatrics (2) that should be fully supported by a pediatric interventional radiology practice and the hospital or health care system within which it operates. The foundation of family-centered care is a partnership between families and professionals that acknowledges and respects the integral role the family plays in the child’s wellbeing, illness, and recovery. It affects the time and detail required for sharing information and obtaining consent, permitting parental presence during certain procedures, scheduling, and the provision of family-suitable facilities (eg, waiting rooms, play areas, space), to mention just a few examples.

Consent and Assent

Informed consent has several essential features that must be provided or assured by the interventional radiologist (1). The patient or substitute decision-maker must understand the critical elements of the planned procedure, including its potential risks and benefits, expected outcomes, and the comparative risks and benefits of any alternatives. A detailed discussion of informed consent is beyond the scope of this document. When feasible, having this discussion at a time and place removed from the procedure will help the decision-maker be more relaxed and attentive, such as in a clinic setting, a multidisciplinary patient/family conference, or during a bedside visit. Ideally, the consenting individual will have full access to all relevant information in a form that is accessible and sensitive to the consenter’s language and comprehension.

The pediatric patient is often not legally capable of consent, although the age and conditions for consent vary from one jurisdiction to another. Even when the patient cannot legally consent, he or she should be afforded every opportunity to participate in the plan of care. The child who understands and assents to a procedure is more able to cooperate.

When parents or guardians wish to limit the child’s access to information about a medical condition or interventional procedure, the interventional radiologist must balance the parents’ decision with the child’s need for, or right to, information. Conflicts between parents and patients with regard to a plan of care can be very difficult to resolve, and may require the assistance of patient care representatives, medical ethicists, and legal staff.

Sedation, Analgesia, and Anesthesia

The sedation and analgesia needs of pediatric patients can vary widely and can be difficult to predict. A plan for patient comfort must be individualized to each patient and for each procedure, and may range from general anesthesia or intravenous or oral sedation to minimal anxiolysis. There are several models currently in use for the safe delivery of sedation, including the following:

1. Sedation administered by an interventional radiologist or other interventional radiologic clinical provider;
2. Sedation administered by an anesthesiologist, intensivist, or other specialist not involved in the primary procedure;
3. A hospital-wide sedation service; and
4. A combination of the aforementioned determined on a case-by-case basis.

There are published guidelines detailing the necessary requisites (3,4). There is general agreement that the sedation team must have the training, skills, and equipment necessary to resuscitate the patient.

The interventional suite must be capable of monitoring critically ill patients and patients under deep intravenous sedation and analgesia or general anesthesia. The ability to monitor heart rate, electrocardiography, venous and arterial pressures (noninvasively or invasively), and pulse oximetry must be available at minimum. The ability to measure simultaneous pressures from multiple inputs can be helpful during certain procedures. It is also useful to be able to create a permanent record of any selected physiologic parameter.

Radiation Protection

In order to adhere to the “As Low as Reasonably Achievable” principles of radiation protection, it is important to balance the need to limit radiation dose on a moment-by-moment basis against the need to image effectively and advance a successful procedure efficiently (5). A variety of free resources are available to assist in this process (and can be found at www.imagegently.com). Appropriate radiation protection in pediatric interventional radiology is important because of the increased sensitivity of children to radiation effects and the number of years of life during which to express any potential effects (6–8). It is also important to manage exposure of interventional staff and other participants (9–12). In brief, the radiation dose to the child may be reduced by carefully selecting such technical parameters as focal spot size, pulse width, pulse rate, field size, air-gap magnification, choice of screens, filter thickness and position, and antiscatter grid systems to match the size of the patient and the needs of the procedure. The operator should be judicious in the use of ionizing radiation, and should limit fluoroscopy time and the number of images obtained in angiographic and radiographic acquisitions. Appropriate use of nonionizing imaging modalities such as ultrasound during portions of suitable procedures may reduce the radiation dose. Additional dose reduction can be achieved through such software features as last image hold, storage of dynamic fluoroscopy, flexible automated detection systems, radiation-free patient positioning and collimation, and postprocessing magnification. Appropriate pediatric settings and protocols should be considered throughout the equipment work cycle, including at the time of purchase and equipment setup and during ongoing interventional radiology staff education (13–15). As recent Digital Imaging and Communications in Medicine standardization will make radiation dose information archival universal, it is important to assure that relevant information (eg, dose–area product or estimated skin entry dose) be reported in the medical record (16) and considered during the informed consent process (7,14).

CLINICAL TEAM

Each team member brings vital training and experience to the clinical interventional team. Team members need to work within and across conventional job descriptions to assist each other in meeting the demands of patient care, and to assure patient safety and comfort and procedural efficacy. They must also understand their specific individual roles in the care of the child. These include, but are not limited to, maintaining appropriate laboratory, imaging, and physiologic parameters (eg, body temperature, hydration, ventilation, and oxygenation); ensuring proper positioning, padding, and restraint; and correctly labeling and dosing medications so that the procedure is optimized to the individual. Appropriate pediatric life support certification (eg, Pediatric Advanced Life Support or equivalent) is strongly recommended.

Interventional Radiologists

Ideally, pediatric image-guided interventions should be performed by or under the supervision of a pediatric interventional radiologist or an interventional radiologist with a special interest in and experience with pediatric interventions. Again, in ideal terms, highly specialized procedures require an interventional radiologist with additional specific training and experience. For example, pediatric interventional radiologists with relevant experience in neurologic interventions may perform neurointerventional procedures in children or they may be performed by neurointerventional radiologists with relevant experience treating children. Hybrid solutions may be necessary when the volume of such procedures is not sufficient to maintain currency of specific skills by a single individual. For example, in some centers, an interventional neuroradiologist and a pediatric interventional radiologist may jointly perform head and neck and neurologic vascular interventions.

It is essential that interventional radiologists caring for pediatric patients be familiar with the relevant spectrum of pediatric disease, and be well versed in the principles of pediatric interventions and related care. Specific requirements for credentialing and privileges will vary from institution to institution.

Other Licensed Independent Practitioners

As part of the interventional team, other practitioners may assist the interventional radiologist in providing clinical care. These practitioners can help to improve the efficiency of the clinical practice, especially with regard to routine follow-up care in the hospital or in the office.

Hospitalist physicians. Partnership with pediatric hospitalists may assist the interventional radiologist in timely consultation, development of a management plan, and follow-up for complex medical problems in pediatric interventional patients (17).

Midlevel practitioners. Midlevel practitioners (eg, advanced practice nurses, nurse practitioners, and physician assistants) work within the scope of practice of their supervising physicians as regulated by law (18,19). These individuals are specifically trained to function in the inpatient and outpatient clinical settings and are equipped with the skills needed to perform clinical duties (20). They can perform histories and physical examinations, educate patients and families regarding informed consent (21), and participate with the interventional radiologist in forming a clinical assessment and plan. Within an interventional practice, midlevel practitioners may develop particular areas of expertise and may perform as a first-line resource to patients and families. They may triage problems, provide education, take off-hour telephone queries, and manage minor problems or complications. Their clinical training makes them valuable complementary members of the interventional clinical team.

A licensed independent practitioner employed by a radiology group can function as an independent member of the interventional team. In most settings, the licensed independent practitioner can perform selected interventional procedures, thereby increasing clinical productivity. There are clear differences in the way different midlevel practitioners can practice, as determined by various third-party payers, regulatory agencies, and health care centers. In some jurisdictions, appropriately trained nurses and radiologic technologists (ie, radiographers) can take on advanced roles in the interventional practice. Interventional radiologists are advised to consult with their local regulatory agencies and hospitals regarding the modes of practice that are acceptable in their regions.

Radiology practitioner assistants. Radiology practitioner assistants are advanced practitioners with extended training in radiologic technology. They have a much different scope of practice than nurse practitioners or physician assistants, and, like registered nurses, are not recognized as independent providers, but work under the direct supervision of the interventional radiologist.

Clinical Interventional Staff

Registered nurses and radiologic technologists play a critical role during interventional procedures; in addition, they can augment clinical services and provide care adjunctive to that provided by the practitioner. Many tasks require significant overlap of the roles of all team members. Other tasks are more specific to particular certification and training.

The role of the radiologic technologists and nurses frequently include other responsibilities, such as performing as a “scrubbed-in” assistant during interventional procedures, procedural coding, inventory management, and workflow management. Extended training with advanced skills may also be included, with appropriate credentialing or certification.

Interventional nurses. Nurses should be appropriately licensed with documented training and expertise in care of pediatric patients, although no specific certification pathway exists for pediatric interventional nurses. Nurses may administer intravenous sedation and analgesia under the supervision of the interventional radiologist or another physician or other licensed independent practitioner, within the credentialing standards of the institution and the scope of practice as defined by local authorities. Nurses frequently play a role in screening or triaging referrals, gathering laboratory values and historical information, speaking with family members, and assisting with research protocols. In the outpatient setting, adjunctive nursing care might include obtaining a history, systems review, and vital

signs; drawing blood; and providing patient education, telephone consultation, and follow-up with patients.

Radiologic technologists. Radiologic technologists should be certified and licensed and should have documented training and experience in pediatric interventional procedures. No specific single certification pathway currently exists for pediatric interventional radiologic technologists. Technologists bring expertise in radiation protection techniques and their application in children. With the increasing complexity of imaging equipment and postprocessing software, it is helpful if the interventional radiologic technologist has a working knowledge of various imaging modalities (eg, US, fluoroscopy, digital subtraction angiography, and rotational and conventional computed tomography [CT]) and associated software. With the heavy reliance on US in many pediatric interventional radiology practices, it is helpful if a technologist is available who is familiar with and able to optimize sonographic imaging.

Auxiliary Services

Auxiliary services can assist the patient and family, decreasing frustration and anxiety while improving satisfaction. For example, child life specialists or play therapists can significantly improve patient comfort and decrease reliance on pharmacologic therapies to achieve patient comfort and adequate immobility. They may help to engage patients with nonpharmacologic interventions (eg, distraction, imagery and visualization, hypnosis, lighting, music, décor, three-dimensional goggles, and DVD players) (22). This information has been extrapolated from the adult data, as there are no pediatric data available. Similarly, patient and family liaisons can facilitate accurate communication; update patients, families, and referring clinicians regarding delays and scheduling changes; and comfort families during procedures and recovery. All these measures have the ability to decrease perceptions of pain and anxiety, increase comfort and satisfaction, and decrease procedure time.

ADMINISTRATIVE SERVICES

Administrative support and coordination are most helpful when they align interventional radiology within the institution's clinical pathway. It is important that the hospital administration understands and supports the broader clinical nature of pediatric interventional radiology and how it differs from an entirely diagnostic service. The administrative resources required to run an inpatient and outpatient clinical practice effectively include transcriptional services, information technology, office management, dedicated interventional scheduling, and clinical documentation. In certain jurisdictions, coding, billing, insurance precertification, and compliance may require administrative resources and support. In addition, personnel who can perform data management and quality improvement are required.

A single individual may fill the responsibilities of more than one position. Often many of these services are already available within an institution and may therefore be expanded or modified to meet the additional requirements of the clinical service.

OUTPATIENT CLINIC

The outpatient interventional clinic should become a routine entry point to the interventional clinical practice. An outpatient clinic is important for facilitating longitudinal care, including monitoring and surveillance of disease progression or recurrence. Patients and referring physicians have general expectations of a clinical practice. It is instrumental to the growth and future success of an interventional service that it meets such expectations. In the outpatient clinic setting, the interventional radiologist and support staff should perform the following duties while providing evaluation and management services:

1. Determine an appropriate plan for diagnostic workup;
2. Determine need for and arrange consultation with other physicians;
3. Schedule interventional procedures;
4. Obtain informed consent and assent;
5. Order or prescribe appropriate medications and laboratory or imaging studies;
6. Provide follow-up care, including testing and evaluation after a procedure; and
7. Provide counseling visits.

Currently, provision of a full clinical service represents a culture change in practice for some interventional programs and in the perception of many administrators (23). Provision of this service requires acknowledgement and endorsement of the importance of this activity for good clinical care. Clinic visits for outpatients, like ward rounds for inpatients, are the medium through which longitudinal care is delivered and quality of care is achieved.

The interventional radiologist who is involved with the continuing care of a patient is following a conventional model of clinical care. The interventionalist is the health care professional most knowledgeable about interventional options and most capable of providing interventional management for a patient whose problem falls within the interventional radiologist's scope of practice.

Space and Equipment

Clinicians typically practice in a traditional physician office setting that includes standard amenities such as a receptionist, patient and family waiting area, and private consultation and examination areas. A successful clinical interventional practice will benefit from quality dedicated clinical space that will meet outpatient needs and expectations.

Office space for outpatient visits may be most economically achieved through an office-sharing arrangement within a hospital-owned clinic or in conjunction with another subspecialty clinic such as a general pediatric surgical clinic. If interventional radiologists and other colleagues offer special multidisciplinary services, such as treatment of vascular anomalies or feeding and nutrition, combining efforts in a multidisciplinary specialty clinic may help coordinate care more effectively and improve patient and family satisfaction.

There are potential advantages to establishing an office practice that is separate from the procedural area. These include increased awareness of the clinical interventional practice among other doctors in the clinic area, an increased understanding by potential referring doctors of the practice's level of commitment to longitudinal patient care, and an improved status with the hospital. The examination room(s) should be large enough to accommodate an examination table, a sink, enough chairs for the patient and at least one family member, a wheelchair or stroller if needed, as well as equipment and supplies appropriate to the pediatric population.

Time

Ideally, interventional clinics should be staffed with practitioners not concurrently scheduled to perform procedures. The time required for the clinical care of pediatric patients may differ from that required for adult patients, as additional time is needed for elicitation of history through parents or guardians, physical examination, obtaining consent, and educating the patient and relevant caregivers (eg, parents, guardians, blended families).

Time recommended for evaluating new pediatric interventional patients and providing adequate follow-up care for patients is in the range of 5–15 hours per week or more, as described later. The exact time required for nonprocedural evaluation and management encounters will vary depending on the size and nature of the practice.

The time (including physician and ancillary personnel time) allotted per clinic patient should be 45–60 minutes for each new patient and 20–30 minutes for each follow-up patient (1):

- Practices performing fewer than 1,000 procedures per year may require 5 hours per week;
- Practices performing between 1,000 and 3,000 procedures per year may require 5–15 hours per week; and
- Practices performing more than 3,000 procedures per year may require 15 hours or more of clinic time per week.

Communication of Clinical Care

Appropriate documentation of the outpatient clinic visit is imperative for patient care as well as for legal and billing purposes. It should include a signed and dated record of the initial evaluation and treatment plan and should document communications with the referring clinician. It should be coded according to local regulatory requirements and archived appropriately (24–28). A formal consultation report, as opposed to a radiography report, should be sent to the referring physician in a timely fashion.

Requirements differ depending on the patient and physician setting, and are often defined by the payer, health system, or national standards (24–26,29). The medical record must support the scope and level of service, and match assigned codes where applicable (24–28). In the United States, adherence to International Classification of Disease codes is required by the Health Insurance Portability and Accountability Act (24,29). These codes apply to inpatient services. In addition, Current Procedural Terminology codes are used to define evaluation and management encounters (24,25,27). The assigned codes depend upon physician status (treating vs consulting) and patient status (inpatient vs outpatient) (25). The codes also differ depending on the time involved in the clinical care and the complexity of the encounter (25,30). Different coding systems may apply in other jurisdictions. Proper coding is essential for appropriate billing and to assure legal and regulatory compliance (25,30). This information has been extrapolated from the adult data because there are no pediatric data available.

INPATIENT REQUIREMENTS

Admitting Privileges

It is no longer possible to merely perform technical procedures without providing ongoing clinical care to patients (31,32). Admitting privileges signify that the hospital acknowledges the clinical role of the interventional service and that the service is willing and able to assume the primary responsibility for patients within their scope of practice. It is essential for a clinical interventional radiology service that desires to admit patients that the hospital grants the same admitting privileges as those of the surgical and medical procedural services. Increasingly interventional radiologists have used these privileges to optimize patient care through personal inpatient management and treatment (33–36). A clinically competent interventional radiologist managing the patient minimizes gaps in continuity of care and potential risks inherent in the system of having different physicians performing the procedure and managing the patient (37,38). The interventional service is best informed about preprocedural workup and preparation, postinterventional care and management of related potential complications, and the appropriate timing of hospital discharge and outpatient follow-up of patients within their scope of practice. Therefore, the ability to accept patient referrals for admission and management is important to the effectiveness and long-term success of any clinical practice (31,39).

Ideally, the following patients may be admitted to the interventional service unless a medical condition exists or arises that is best managed by another service:

- Patients seen in consultation and believed to warrant elective inpatient interventional therapeutic procedures;
- Patients treated in the interventional suite who develop related complications warranting admission;
- Patients admitted strictly for interventional diagnostic tests or therapeutic procedures; and
- Urgent referrals from outpatient offices that require interventional services and then require admission.

The duties of the interventional radiologist should include daily clinical rounds (40). Patients to be seen by the interventional practitioners include:

- Any patient who is admitted to the interventional service, or who has a significant portion of his or her inpatient care managed by the interventional service, including patients with drains;

- Any patient with a clinical problem that is being managed by the interventional service in consultation; and
- All patients after a therapeutic intervention before discharge for same-day patients or within 24 hours of their procedure for inpatients.

The physician inpatient visit can be done in coordination with other interventional licensed independent practitioner visits. This strategy will insure the most efficient use of physician time and help reduce costs while maintaining the all-important personal contact provided to the patient by the interventional radiologist.

Training and Clinical Privileges

Specific training and experience in the performance of image-guided interventional procedures in children and in the provision of related clinical care, including sedation, analgesia, resuscitation, and radiation protection, are necessary prerequisites for the interventional radiologist committed to developing a pediatric service. There is no universal pathway to this end at this time. Training backgrounds, specialization, and subspecialization of pediatric interventional radiologists vary and include residency in diagnostic radiology and fellowships in pediatric interventional radiology, interventional radiology, pediatric radiology, neuroradiology, and neurointerventional radiology. Most current practitioners who answered a survey reported training in more than one of these areas (41).

The group of expert authors and reviewers of this document strongly recommend certification equivalent to the American Board of Radiology and adequate exposure to care of the pediatric patient, performance of interventional procedures in children, and experience with management of pediatric interventional care, within the scope of the individual interventional radiologist and within the boundaries of appropriate regulatory agencies.

Clinical privileges arise from the specific training, experience, certifications, and credentialing of the individual pediatric interventional practitioner. For pediatric interventional radiologists, such privileges may specify a wide variety of procedures, use of diagnostic imaging equipment for diagnostic and therapeutic procedures, and prescription and dispensing of radiographic contrast media, among other tasks.

The pediatric interventional service and its parent radiology department should work carefully to delineate and secure all appropriate clinical privileges commensurate with the interventional radiologists' training, experience, and certification. The health care institution, hospital, department, and pediatric interventional service share accountability to assure that all practitioners are operating within the legitimate boundaries of the specific clinical privileges they have been granted, and have the appropriate training, experience, certification, and credentialing for the performance of procedures (42).

Time Allotment for Inpatient Clinical Duties

Recommended time allocations include the total time spent by the physician, independent licensed practitioner, and any other ancillary staff that the interventional radiologist and hospital deem appropriate. The amount of time required for daily rounds and admissions will also vary with the size of the practice and procedure mix: practices with less than 1,000 procedures per year, 1–2 hours per day; practices with 1,000–3,000 procedures per year, 2–4 hours per day; and practices with more than 3,000 procedures per year, 4–6 hours per day (1). Practices performing large volumes of procedures such as arterial interventions, hepatobiliary procedures, treatment of vascular malformations, chemoembolization, radiofrequency and other ablative therapies, enteric access procedures, musculoskeletal procedures, and abscess/drain management usually require more admissions and inpatient care.

Call

The number of physicians who provide interventional services and have admitting privileges should be sufficient to provide 24-hour interventional call coverage. Coverage responsibilities include management of the clinical problems that fall within the interventional radiologist's scope of practice and appropriate referral or consultation when clinical problems

fall outside that scope. In some health care systems, arrangements for sharing responsibility between interventional radiologists and other clinicians have evolved. Local hospital factors and expertise will influence how such a system is arranged or organized.

To ensure a stable service, attention to call frequency demands is suggested to avoid unnecessary burnout and staff turnover. In smaller programs, the number of staff required for call coverage may exceed the need based solely on daytime case volume. Interim call support for a small or growing pediatric interventional service may be provided by cross-coverage by other individuals with similar training, certification, and experience performing interventional radiology procedures in children.

Scheduling of Interventional Procedures

It may be acceptable to schedule a few types of invasive diagnostic radiology procedures (ie, routine low-risk procedures in low-acuity cases), based on a direct request from a physician to booking personnel. Scheduling of more invasive diagnostic and therapeutic procedures should be by consultation with the interventional radiologist, and may necessitate a clinic or bedside visit. It is important to provide the opportunity for family discussion and to obtain informed consent. Complex consultations should result in a written or electronic documentation of evaluation and management recommendations, even if a specific interventional procedure is not recommended. Electronic scheduling processes can help practice efficiency and communication with the referring physicians (43).

INTERVENTIONAL SUITE REQUIREMENTS

Imaging Requirements

Unlike adult interventional practices, which are often subdivided by systems and modalities, pediatric interventional practices tend to be less partitioned, and the pediatric interventional radiologist tends to perform all image-guided procedures in the pediatric radiology department regardless of the imaging modality or modalities employed (44).

It is vital to the success of any pediatric interventional service to have high-quality imaging equipment and sufficient space for the equipment, personnel, and supplies necessary to safely and effectively complete a pediatric interventional procedure.

Angiographic or fluoroscopic equipment must be capable of accommodating the spectrum of pediatric patients, from 500 g to greater than 150 kg. This poses unique challenges with respect to table positions, location of the C-arm pedestal, positioning of monitors, accessibility of bedside controls, immobilization of the patient, integration of other imaging modalities during multimodality and multidisciplinary procedures, and incorporation of equipment necessary for safe delivery of sedation and general anesthesia. The x-ray-emitting equipment (fluoroscopy, digital subtraction angiography, CT) must be of high standard and appropriately modified for pediatric patients (as detailed in "Radiation Protection").

US is an essential component of a pediatric practice. US-guided procedures in children require high-quality equipment for the wide range of procedures and body sizes and target depths. Although CT is less commonly employed in pediatric practices compared with adult practices, access to a CT suite in reasonable proximity to the angiographic suite and adequately equipped and supplied for common CT-guided procedures should be available, ideally outfitted with CT fluoroscopic capability and staffed with technologists familiar with the imaging requirements for pediatric interventional procedures. Rotational (ie, three-dimensional) angiography and dynamic CT-capable angiographic suites may reduce reliance on freestanding CT suites for procedures requiring cross-sectional radiographic guidance.

Interventional Suite

In an ideal situation, a single pediatric interventional suite should have a digital angiographic unit (single or biplane) and a high-quality US unit. It should include vacuum suction and medical gases sufficient for general anesthesia. Ideally, air filtration and lighting should be of a standard suitable for an operating room and adapted to the needs of pediatric procedures. Entry to the room should be through a protected clean zone not

accessible to the general public. A dedicated scrub area should be available. Adequate electrical, medical gas, and monitoring hookups should be available for provision of general anesthesia or deep intravenous sedation and analgesia to the sickest patients in an intensive care unit. The room needs to be sufficiently large (as detailed later) to accommodate the movement of a bed, multiple teams of health care personnel, general anesthesia, patient monitoring, and support. Immediate access to the patient for emergency personnel should be assured at all times.

A pediatric "crash cart" with pediatric airway management supplies, resuscitation and intravenous reversal medications, and related supplies should be in the suite and familiar to all key personnel. Lock-protected narcotics and other medications common to interventional procedures should be readily accessible. Supplies sufficient for completion of most common cases should be at hand in the interventional suite, with reserve stocks and supplies for less usual procedures stored in close proximity.

Such an arrangement will commonly support the practice of one or two full-time equivalent pediatric interventional radiologists with a case-load of as much as 1,000–1,500 procedures per year and will ideally require no less than 56 m² (600 square feet) of space in the primary interventional suite.

As the practice grows to 1,500–3,000 procedures annually, an additional suite may be needed to support two or three full-time equivalent interventional radiologists, with a single-plane or biplane angiographic unit and a second dedicated high-quality US machine. A generalized pediatric practice performing 3,000–5,000 procedures annually may need to add a third suite with a single-plane angiographic unit and a third dedicated US machine to support three or four full-time equivalent interventional radiologists. Beyond 5,000 procedures annually, consideration may be given to adding a fourth suite. If facilities are constrained, a "minor procedure" suite may serve as an alternative to a fourth fully configured suite. A portable C-arm with a large (eg, 43-cm [17-inch]) detector and with software capable of dynamic vascular imaging, and a high-quality portable US machine, may also provide cost-effective alternatives to more expensive equipment if the potential reductions in flexibility and image quality can be tolerated. The ratio of patient volumes to the number and type of interventional radiology suites must reflect the nature of the specific pediatric practice.

Specialized practices may require additional imaging facilities at much lower procedure intervals. For example, practices with a large proportion of vascular malformation interventions, regional oncology interventions or neurologic interventions may fully utilize an interventional suite at a rate of only 400–500 procedures annually. Practices that more heavily depend upon general anesthesia under the supervision of an anesthesiologist will have significantly greater room time needs on a per-case basis. Alternative imaging modalities may also be useful for certain types of practice profiles, such as those requiring interventional magnetic resonance (MR) imaging, interventional positron emission tomography/CT, endoscopy or laparoscopy, and optical imaging, and will depend upon the particular features of an individual practice environment.

Patient Preparation Area and Recovery Room

To optimize utilization of hospital resources, space and personnel need to be allocated to accommodate inpatients and outpatients who are awaiting procedures or transport and to provide postprocedure and postsedation recovery for outpatients as well as for inpatients awaiting transfer. The amount of space should be two to four beds per interventional suite, depending on the types of cases and workflow in a particular practice. This could include space in a dedicated recovery area not necessarily in the radiology department, provided such space is allocated for and is staffed with personnel familiar with pre- and postprocedure care of pediatric interventional patients. Adequate space and privacy are required for interaction with the patient and caregivers, for obtaining informed consent if not already done, and for examination and correct site marking. As family-centered care is a fundamental guiding principle in a pediatric practice, appropriate provision for parents and family in the preparation area, waiting area, and recovery room is an important consideration.

Medical/Surgical Supply Inventory

The dedicated interventional suite must have sufficient space and a control mechanism to manage the large required inventory located close to the suite. Integration with central supply or surgical supply facilities within the institution facilitates economies of scale and decreases the administrative burden on interventional personnel.

The following items relevant to inventory should be considered when developing the modern-day interventional practice suite:

- Sufficient facility budgetary commitment to sustain the disposable equipment needs of the suite;
- Dedicated personnel responsible for inventory management and authorized to replenish stocks at reasonable par levels;
- An inventory control system, possibly with barcode or radiofrequency identification reading capability for high-end equipment and supplies; and
- Interventional radiologic representation on hospital committees focused on innovative procedures, new equipment, product purchasing, and quality assurance.

Nonradiographic Equipment

The modern interventional suite often requires other invasive and noninvasive equipment for nonradiographic imaging and interventions, such as radiofrequency ablation generators with associated probes, thrombolysis and thrombectomy devices, endovascular and endocavitary US devices, and battery-operated drills and associated hardware, to mention just a few. The particular equipment necessary to a given practice will depend upon the local practice profile, the referral base, opportunities for multidisciplinary collaboration, and the preferences and experience of the pediatric interventional radiologists.

Staffing Level

Nurse staffing levels should always be sufficient to provide at least one nurse for each procedure room to prepare, provide, and monitor patient care, as well as to perform other departmental activities such as quality assurance. When nurse-administered intravenous sedation and analgesia is provided under the supervision of the interventional radiologist, that nurse must have no other competing duties during the case. Such regulatory standards may increase the staffing needs of the interventional service. In addition, the recovery room should have at least one, and preferably two, nurses per patient bed specifically trained in postsedation or postanesthetic recovery of the pediatric patient. Regulatory standards within each jurisdiction will determine minimum staffing for each phase of recovery.

Radiologic technologist staffing levels should be sufficient to always provide at least one and preferably two technologists per procedure room to perform imaging functions as well as functions related to inventory, cleanup, room preparation, film or digital image processing, and data entry into inventory management, coding and billing, and quality assurance databases.

If a radiologic technologist or nurse is scrubbed in for procedures, the necessary number of staff per room will increase accordingly. To achieve consistent coverage, these staffing recommendations should be considered in light of local staffing factors and allow for adequate coverage for off-hours procedures, vacations, sick time, and educational leave.

In ideal circumstances, a pediatric interventional service will build a team of nurses and technologists that are dedicated to the interventional area. Many centers may try to have their staff cycle through MR imaging, CT, or fluoroscopy as part of the day-to-day work. This may dilute the experience of members of the interventional team and erode their confidence in performing more complex procedures.

The incorporation of independent licensed practitioners into pediatric interventional practices has been slow to occur, but successful interventional practices generally stabilize with approximately one midlevel practitioner for every two interventional radiologists.

PRACTICE DEVELOPMENT: EDUCATION AND COMMUNICATION

The overarching concern of the interventional radiologist is the patient's health and well being. A practice that does not anticipate and adapt to changes in its environment will not maintain the ability to deliver patient care. As part of both a medical and an economic enterprise, a successful interventional practice must plan its business and market its services reliably and effectively (45). This planning should be based on the needs and abilities of each practice.

In order to educate the patients and health-care professionals we serve, the interventional radiologist needs to effectively establish and highlight points of differentiation that offer real and lasting benefits over alternative options. Key advantages of interventional radiology may include decreased morbidity and invasiveness, a shorter duration of hospitalization, greater comfort, timeliness, and accessibility, and decreased cost. There are areas in which interventional radiologists provide added value such as salvage procedures for a transplant service, oncologic interventions, sclerotherapy of vascular anomalies, and percutaneous cecostomies, to name a few. Even in areas such as venous access in which the procedure may not be as obviously differentiated, the ability to demonstrate improved outcomes at lower cost may help sustain the pediatric interventional radiology practice.

Leadership participation in multidisciplinary and institution-wide care initiatives (eg, vascular access, vascular malformations, enteral feeding and nutrition programs, pain management, oncology, and palliative care) is very important and may help enhance the pediatric interventional radiologist's ability to provide the most comprehensive and high-quality care achievable and to maintain access to the relevant patient populations. Increasing awareness about clinical pediatric interventional radiology through a multipronged and multimedia approach to education could be beneficial. Broader educational and public health initiatives on a national or international scale, such as the Image Gently and Step Lightly campaigns (45–47), or multiinstitutional outcomes registries, can help establish the concept of pediatric interventional radiology by improving patient and family awareness of the role interventional radiologists play in patient care and by improving the awareness of potential referring clinicians of the added value of specific targeted procedures (48).

QUALITY IMPROVEMENT

An ideal pediatric interventional radiology practice develops plans of care based upon best practices and peer-reviewed outcomes data appropriate to the context of that practice and applicable to the given patient problem (49,50). For many situations, such information is not currently available in the published literature, and quality improvement in pediatric interventional radiology is therefore in its infancy (51). Within each interventional practice, quality assurance can be enhanced by conducting dedicated morbidity and mortality reviews (52), internal audits of key practices, identification and measurement of specifically chosen determinates and outcomes (53), and clinical research and reviews (54). In view of the stage of evolution and growth of the specialty at the time of this writing, it is necessary to establish a greater knowledge base, to perform outcomes analysis, and to establish standards. Therefore, evidence-based quality assurance can be best achieved through multiinstitutional studies, registries, and collaboration. Electronic databases which facilitate a quality assurance program are crucial (55). All of these are important approaches to maintaining and improving quality of care.

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SIR DISCLAIMER

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 towards 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.