STANDARDS OF PRACTICE

Society of Interventional Radiology IR Pre-Procedure Patient Safety Checklist by the Safety and Health Committee

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PREAMBLE

The National Patient Safety Goals program was established by The Joint Commission in 2002 to help accredited organizations address areas of concern regarding patient safety in the United States. The Universal Protocol, adopted by The Joint Commission in 2003, is included in the National Patient Safety Goals to prevent wrong person, wrong procedure, and wrong site surgery in all surgical and nonsurgical invasive procedures (1). These guidelines have been applied specifically to the practice of interventional radiology (IR) (2); however, a pre–procedure checklist tailored to IR may further improve patient safety and outcomes.

Recent interest has evolved in developing a surgical or time-out checklist to reduce morbidity and mortality caused by human errors. For example, Haynes et al (3) demonstrated that implementation of a 19-item surgical checklist adopted from the World Health Organization (4) reduced the rate of death associated with surgery from 1.5% to 0.8% in a global population. Inpatient complications also were reduced from a baseline of 11% to 7%. Corso et al (5) showed that use of a 20-item time-out checklist derived from the Cardiovascular and Interventional Radiological Society of Europe (6) eliminated adverse events associated with IR procedures in the first year of use. Such positive results with the use of checklists have also been confirmed in other studies (7–9).

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However, other studies have failed to duplicate significant improvements in patient safety following widespread implementation of pre-procedure checklists (10,11). These failures could reflect issues with checklist design or its implementation. A well-designed checklist should include items that effectively address the underlying failure modes for the adverse events that occur in any particular operational environment. In addition, the checklist should be designed to facilitate reliable execution of the control strategy for those failure modes. Creating a checklist that addresses the cause of every conceivable adverse event would result in a checklist so long as to be impractical. Rather, patient safety is better served by allowing local teams to build a checklist from a list of items that matches the operational requirements of their working environment and case mix. A series of potential checklist items is provided along with their rationale.

PRE-PROCEDURE CHECKLIST

The pre-procedure checklist is a list of pertinent items to review before the start of a procedure and can include the components of the Universal Protocol to remain compliant with The Joint Commission standards. Such a list may disclose patient allergies, use of contrast agent, prophylactic antibiotics, sedation plan, laboratory values, need for blood products, review of prior imaging, specimen collection, radiation or magnetic resonance (MR) imaging safety precautions, need for special medications or equipment, additional safety concerns, and nonstandard items for review ("sidebar"). An example of a pre-procedure checklist is shown in the **Table**.

UNIVERSAL PROTOCOL

The Joint Commission Universal Protocol is a requirement for hospital accreditation in the United States and includes pre-procedure verification, site marking, and time-out. The pre-procedure verification process verifies the correct patient, correct procedure, and correct site and is an ongoing process of gathering information before the procedure. Site marking is performed when there is more than one possible location for a procedure, such as different limbs, organs, or level of the spine, and when performing the procedure in a different location would negatively affect quality or safety (1). The time-out is performed immediately before the start of the procedure and involves the patient (whenever practical) and immediate members of the procedure team, including physicians, radiology technologists, and nurses. The time-out should be initiated by a designated member of the team and be standardized. During the time-out, the team members agree at a minimum on correct patient identity, correct procedure, and correct site.

Table. Pre-Procedure Checklist

Pre-Procedure Checklist	Patient Label
Patient identifiers (at least 2)	
Patient name	
Patient date of birth	
Patient medical record number	
Procedure(s)	
Site mark	
Allergies	
Contrast agent	
Antibiotics	
Administration time	
Sedation plan	
Minimal sedation	
Moderate sedation	
Deep sedation	
General anesthesia	
Laboratory tests	
INR	
Platelets	
PTT	
Creatinine	
Last dose of anticoagulation	
Blood products	
Type and screen	
Prior imaging	
Specimen collection	
Radiation safety	
Staff protective and monitoring equipment	
Optimize low dose radiation	
Patient protection	
MR imaging safety	
MR-compatible equipment and instruments	
Patient and staff screening	
Need for special equipment	
Disposable items	
Nondisposable equipment	
Procedural-related medications	
Additional safety concerns	
Sidebar	
Consent confirmation	
Patient radiation history	
Pregnancy test result	
Procedure sterility classification	
Prophylactic allergy premedication confirmation	

INR = international normalized ratio; PTT = partial thromboplastin time.

PATIENT ALLERGIES

Various agents are used during IR procedures; local anesthetics, opioids, anxiolytics, contrast agents, and prophylactic antibiotics are frequently administered. Use of latex gloves is also common if the institution is not a latex-free environment. The most common agents responsible for anaphylactic reactions during surgical and medical procedures are muscle relaxants and latex, followed by antibiotics and induction agents (12). The major emphasis on managing a patient's allergies is prevention (13,14), and reviewing a patient's allergies before the start of the procedure can help avoid minor or major reactions with potential morbidity.

CONTRAST AGENT

Use of radiocontrast media in IR has many benefits in localizing pathology, guiding treatment, and confirming treatment response. However, a major morbidity associated with intravascular radiographic contrast use is contrast-induced nephropathy, which is reported as the third most common cause of acute tubular necrosis in patients admitted to the hospital (15). Very few published studies have a suitable control group to permit the separation of contrast-induced nephropathy from post-contrast acute kidney injury, which may occur regardless of whether contrast medium is the cause of renal deterioration (16). Although more recent literature questions whether contrast-induced nephropathy exists (17,18), we treat it as a real but rare entity and recommend exercising caution when using intravascular radiographic contrast media in patients with preexisting renal disease.

For intravascular angiography, physicians may elect to use a hypo-osmolar agent, such as iopamidol (Isovue; Bracco Diagnostic Inc, Monroe Township, New Jersey), or an iso-osmolar agent, such as iodixanol (Visipaque; GE Healthcare, Princeton, New Jersey), owing to the less harmful effects on renal function compared with hyperosmolar agents (19,20). A less costly option with a hyperosmolar agent, such as iohexol (Omnipaque; GE Healthcare), may be favorable for nonvascular cases.

ANTIBIOTICS

Antibiotic prophylaxis for an IR procedure is commonly administered to prevent infection in vascular and nonvascular cases. Although there are no published multicenter randomized trials evaluating antibiotic prophylaxis during IR procedures, recommendations have been set forth by the Society of Interventional Radiology (SIR) regarding the use of prophylactic antibiotics in IR (21). The choice of antimicrobial agent depends on the type of procedure as well as the patient's renal and hepatic function and allergies.

SEDATION PLAN

An accurate sedation plan reduces patient movement, pain perception, and anxiety, allowing for a safe, comfortable, and successful procedure (22). There is high variability in the complexity and magnitude of injury incurred with various IR procedures, and the sedation plan can be influenced by many patient variables, including, but not limited to, patient age, patient positioning during the procedure, body mass index, Mallampati score, American Society of Anesthesiologists physical classification score, surgical or medical comorbidities, allergies, current medications, psychosocial history, and oral intake restrictions according to institutional guidelines. A medical assessment before a procedure is therefore critical in deciding on a sedation plan for a particular patient. Practice parameters for sedation and analgesia in radiologic care have been further described by the American College of Radiology and SIR (23).

The American Society of Anesthesiologists recognizes four levels of sedation: minimal sedation (anxiolysis), moderate sedation/analgesia (conscious sedation), deep sedation/analgesia, and general anesthesia (24). The benefits of the type of sedation must be weighed against the risks and discussed with the patient. The sedation plan should also be reviewed with the IR team before the start of the procedure.

LABORATORY TESTS/BLOOD PRODUCTS

Routine hematologic evaluation of patients is common for many IR procedures to reduce the risk of bleeding, sedation, and infectious complications. Recommendations for the use of blood products and other hemostatic agents in IR have been described by Patel et al (25). A patient's biochemical profile may be useful before the administration of intravascular contrast media in select patients. Liver function tests are also routinely evaluated before hepatic embolization treatments and transjugular intrahepatic portosystemic shunt procedures.

PRIOR IMAGING

Review of prior medical imaging studies can be very helpful in guiding a particular procedure, such as in localization of an infected fluid collection for percutaneous drainage or in identification of a migrated intravascular foreign body for endovascular retrieval. This review may decrease procedural time, reduce use of contrast agent, and prevent complications. Some fluoroscopy units may also allow for display of the patient's prior imaging study on the in-room monitors for continuous review during a procedure.

SPECIMEN COLLECTION

Collecting specimens for diagnostic purposes may sometimes require special media for storage (or transportation) or need specific personnel for determining a preliminary diagnosis or adequate tissue sampling. Awareness of the IR team before the procedure allows for appropriate collection of storage media and/or adequate notification of the pathologist or cytotechnologist. This in turn helps reduce procedural time delays and ensures optimal timing of tissue sampling.

RADIATION SAFETY

IR procedures with fluoroscopy and computed tomography guidance expose patients and health care workers to ionizing radiation that can be harmful in large or cumulative doses (26,27). A collaborative approach to radiation safety is recommended to achieve the lowest dose to all involved. Staff should have appropriate personal protective equipment, including fitted lead aprons, thyroid shields, and leaded eye wear. Static and mobile shielding devices may also be incorporated into IR suites to decrease radiation exposure (28).

The "Image Wisely" campaign for adults has been developed to raise awareness of opportunities to eliminate unnecessary imaging examinations and to lower the amount of radiation used in medical imaging (29). The campaign website contains various educational materials for different radiation protection issues, including technical principles for IR procedures. For dose reduction strategies in pediatric patients, the "Image Gently, Step Lightly" campaign website includes a procedural checklist to maximize radiation safety during interventional procedures (30). A few of the main points of the checklist include stepping lightly on the fluoroscopy pedal, the use of low-dose pulsed fluoroscopy, tight collimation to exclude radiosensitive organs, and the use of last image hold and electronic zoom. The use of patient shielding is not recommended on a regular basis; however, shielding is commonly used for pediatric patients and for potentially pregnant patients. This may include extragonadal shields and/or fetal monitoring for patients known to be pregnant.

Appropriate monitoring and analysis of prior radiation dose is necessary for long-term regulation of radiation exposure. For staff members, the International Commission on Radiological Protection recommends two dosimeters—one at the collar level and one under the apron—for an accurate assessment of radiation dosage (31). For patients, prompt review and recording of dose is imperative (30). Using these tools, statistical analyses with established systems for feedback are a proven method for long-term reduction of ionizing radiation dose (32).

MR IMAGING SAFETY

MR imaging has become a promising tool in guiding both diagnostic and therapeutic procedures. An important advantage of MR imaging is the lack of ionizing radiation. MR imaging also provides enhanced soft tissue contrast; is able to measure and quantify flow, diffusion, and perfusion; and allows for evaluation of temperature changes (33,34).

However, all operating equipment used within the MR imaging field must be nonmagnetic, and all instruments should be MR compatible. Electrical conductive materials (eg, wires associated with electrocardiogram monitoring or radiofrequency grounding pads) should be kept from touching the patient's skin. Internal policies and procedures specific to MR imaging–guided interventional procedures need to be implemented to ensure safe operation, including appropriate screening of patients and all staff personnel before entering Zone 3 (35). The "ACR Guidance Document on MR Safe Practices: 2013" is an excellent resource that provides recommendations on procedures, personnel qualifications and training, and site access restrictions (36).

NEED FOR SPECIAL EQUIPMENT

Use of fluoroscopy, ultrasound, and computed tomography is routine in IR; however, special equipment for certain procedures is sometimes necessary. This may include disposable items, such as specific vascular stents, thrombectomy catheters, or detachable coils, or nondisposable items, such as intravascular ultrasound, rheolytic devices, percutaneous ablation equipment, or endoscopic instruments for cholangioscopy. Procedural-related medications (eg, heparin, alteplase) may also be required. Adequate planning for these items can properly ensure appropriate equipment is available before the start of the case.

ADDITIONAL SAFETY CONCERNS

This element of the checklist is used to address any specific safety concern related to the patient. There are cultural and professional hierarchies that may lead to nonphysician providers on the medical team feeling apprehensive or embarrassed about speaking up when the physician naturally takes the leadership role. Allotting time for anyone on the IR team to speak about a safety concern by simply asking, "Does anyone have any other concerns?" may help avoid communication errors and improve safety attitudes and teamwork.

SIDEBAR

This is a catch-all category where nonstandard items are reviewed. This may include patient positioning, changes to the IR consultation, consent confirmation, the patient's radiation history, pregnancy test result, procedural sterility classification, or prophylactic allergy premedication confirmation. Depending on the procedure and institution, additional items of concern can be discussed here.

DISCUSSION

When reliably implemented, checklists lead to improved patient outcomes (37–39). Checklists are a tool that reduces reliance on memory, improves team communication, and increases situational awareness among team members (40). However, similar to any new tool, using checklists to improve patient care requires careful design and effective implementation. The description of potential checklist items presented here is intended to help teams construct checklists that meet the needs of their patients. Implementing a checklist requires teamwork and change management.

For most teams, The Joint Commission Universal Protocol is a required component of the pre-procedure time-out. Other items are meant to reduce complications related to IR procedures. The checklist is designed to be reviewed with the physician, nurse, and technologist when the patient is in the IR room before the start of the procedure.

In an era of fully electronic medical records, we encourage the use of electronic checklists for several reasons. First, default patient information can be loaded before the start of the case to help streamline operations. Second, data can be linked and tracked for future reference, such as a patient's prior radiation exposure. Third, electronic checklists may help reduce paper checklist errors, as demonstrated in the aviation industry (41).

Checklists should also be designed to promote compliance. The items listed in the checklist should be individualized to the needs of the institution and should be kept simple ($\leq$ 10 items). The checklist should be allowed to evolve over time with the addition or removal of items needed to address specific issues for a particular institution. A

checklist that is too complex, time-consuming, or redundant will likely not be followed well (42). Monitoring, analysis, and feedback may also improve compliance of appropriately using the checklist (43,44). Gottumukkala et al (43) demonstrated that the use of an audiovisual recording system and continual feedback led to substantial improvements in time-out performance over a 3–year period in the pediatric IR suite.

CONCLUSIONS

The pre-procedure checklist is not a panacea but is designed to promote communication and enhance teamwork in an effort to improve patient safety. As stated in the Boeing quick reference handbook, "checklists cannot be created for all conceivable situations and are not intended to replace good judgement" (41). We understand that trial and feedback of such a checklist are necessary for validation and hope that future studies will assess the usefulness of the checklist in regard to patient outcomes.

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