

Patient Safety Framework for Mitigating Risk in Interventional Radiology

RECOMMENDATIONS OF THE INTERVENTIONAL RADIOLOGY TASK FORCE



Created: 2017

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ABOUT THIS DOCUMENT

The recommendations for Patient Safety Framework for Mitigating Risk in Interventional Radiology were developed under the auspices of the Academic Medical Center Patient Safety Organization (AMC PSO) Interventional Radiology Task Force. These consensus recommendations are for informational purposes only and should not be construed or relied upon as a standard of care. The AMC PSO recommends institutions review these guidelines and accept, modify or reject these recommendations based on their own resources and patient populations. Additionally, institutions should continue to review and modify these recommendations as the field continues to evolve.

EXECUTIVE SUMMARY

A 65-year-old male was admitted for treatment of lymphoma. On hospital day 5, the patient developed an acute change in mental status that worsened over the day; he was unable to tolerate a lumbar puncture at the bedside. In Interventional Radiology (IR), the patient required incremental doses of Ativan for the management of his altered mental status and acute agitation. The incremental doses of medication were obtained from the inpatient unit, but administered by the IR nurse. The patient arrested and expired during the procedure.

In an effort to proactively address emerging risks associated with changes in healthcare delivery, the Academic Medical Center Patient Safety Organization (AMC PSO) convened the Interventional Radiology Task Force to arrive at a set of literature-supported, consensusbased patient safety guidelines for considerations for Interventional Radiology procedures.

With advancements in technology and minimally invasive approaches to interventional procedures, procedural areas such as interventional radiology suites, cardiac catheterization labs and endoscopy units effectively function as satellite operating rooms. Opportunities exist to align and standardize practice to reflect this evolution. The Task Force began with a review of the latest literature, scientific evidence, guidance documents and opinion statements from relevant sources. Further insights were gathered from AMC PSO member subject matter experts from Interventional Radiology, Anesthesiology, Nursing, medical trainees, risk management, and patient safety.

What follows is a document that reflects the aim, mission and consensus opinion of the Task Force. It offers guidance for patient safety experts in their efforts to provide the safest possible care to patients.

INTRODUCTION

Procedural areas are high volume, diverse, fast-paced units that are rapidly growing due to advances in technology and the increased demand for outpatient and non-surgical treatments.

Common ambulatory procedural areas include endoscopy suites, cardiac catheterization laboratories, pain management clinics, radiology suites, as well as clinic-based procedural areas found in dermatology, rheumatology, and orthopedic clinics. Traditionally, these areas are administered and managed by individual departments with no central coordination and limited multidisciplinary oversight in the hospital, making a review of unanticipated events, shared learning, and implementation of improvement or corrective action extremely challenging. The lack of centralized governance for procedural areas thus creates a serious problem when attempting to create standardized protocols and training opportunities aimed at reducing risk. The lack of centralization also reinforces the misconception that procedures in non-operating room locations must be less risky, and do not need the same strict safety protocols and oversight as the operating rooms. Studies have demonstrated the heightened risk of an adverse event occurring in remote procedure areas.

The 2013 CRICO benchmarking report (*Malpractice Risks of Routine Medical Procedures*) provided a detailed account of malpractice litigation related to procedures occurring outside of an operating room. Claims ranged substantially in severity from death and serious injury to more minor events, such as intravenous infiltration. Lack of communication was identified as a major theme in this analysis. On detailed review, some events were preventable. A lack of consistent safety practices in diverse areas responsible for invasive procedures was also noted.

The increase in patient risk in procedural areas stems from multiple issues, including increases in patient-related factors/patient acuity, staff training and education, remote settings, production pressure and emphasis on efficiency. There is an increase in 'low risk' procedures being performed on high-risk patients. In addition, unlike most surgeons and anesthesiologists in operating rooms, staff in procedural areas are less likely to have had significant team-based safety training. Also, many procedural physicians are highly specialized and routinely perform high-risk procedures, but may have limited experience or expertise in 'crisis' management or utilizing team resources in the event of a serious or life-threatening event. In busy ambulatory procedural areas, procedures may be inherently lower risk, but the volume can be staggering, adding to the complexity of delivering safe care.

DEFINITIONS

Hybrid Room

A multipurpose procedural suite jointly accessed by both IR and surgical teams and specifically designed for use as both an OR and interventional procedure room.

Warm Handoff

A verbal exchange of patient care information between two members of the health care team that occurs during transitions of care, allowing for synopsis and verbal confirmation by the receiver.





Introduction of New/Rare Procedures/Technologies

CONSIDERATIONS

- A lack of systems to introduce new and evolving procedures or technologies to the organization and to key stakeholders can increase risk.
- Anesthesiologists and key care team members may be unfamiliar with the risks associated with new or established procedures.
- Missed opportunities may exist to adequately assess associated monitoring, sedation, training and oversight requirements.
- There are risks associated with the increased morbidity and complexity of patients.

RECOMMENDATIONS

Evaluate the effectiveness of organizational structures to provide oversight of new procedures and technologies (or variations of established procedures) and to facilitate multidisciplinary input, education and review as they are introduced. (i.e., opportunities may exist for expanded education and communication).

Potential approaches include:

- O Charter a multidisciplinary committee to oversee the introduction of new/adapted procedures/ technologies.
- O Review credentialing and privileging processes. Credentialing should be guided by patient safety and quality improvement principles in this area.
- O Define what is considered a "new" procedure vs. a "variation" of an established procedure.
 - Consider the creation of an expedited process for variations on a similar procedure.
 - Consider the creation of a pathway for urgent procedures that require expedited approval (include how to address orientation of staff).



Pre-assessment & Clinical Decision-making

CONSIDERATIONS

- Who requests the procedure?
 - Is the procedure appropriate for the patient and condition?
 - Is there clarity on what the procedure involves?
 - Are the comorbidities and stability of the patient considered?
 - Has the urgency of the procedure been assessed?
 - Does the patient or health care proxy understand the risks, benefits, and nature of the procedure, including alternative treatments?
- Is the training/skill set/credentialing of team members performing the procedure assessed and appropriate?
 - Particular attention should be placed on familiarity with established but infrequently performed procedures.
- What level of monitoring is required and who makes this determination/how is this determined (trigger, algorithm, etc.)?
 - Is sedation required for the patient?
 - Are there indications for the consideration of involvement of Anesthesiology?
 - Is prone positioning anticipated or required for this procedure?
 - What are the patient's recent medications?
 - Are there any lab abnormalities?

RECOMMENDATIONS

- O Establish a multidisciplinary process for IR, Anesthesiology and Intensive Care Unit (ICU) leadership to develop standards for sedation and/or anesthesia planning and monitoring in IR.
- O Collaborate with Nursing, Anesthesiology and ICU leadership to develop a standard approach to the support of a patient's sedation and/or anesthesia and related monitoring needs by ensuring the availability of appropriately trained providers.
 - Empower team members.
 - Use escalation protocols to activate the "chain of command."
- O Engage patients and families in shared medical decision-making as part of the informed consent process. Ensure an understanding of procedural risks, benefits and alternatives.
- O As part of the pre-procedural assessment, establish a standard process for obtaining input from the referring service on the patient's clinical status and current/potential monitoring needs. The assessment should inform decision-making relative to the following matrix, with involvement of Anesthesiology and/or Critical Care as appropriate.

CASE	PLANNED	EMERGENT
Simple	IR Core Team	IR Core Team
Complex	Anesthesiology	Anesthesiology vs. Critical Care

- O Once indications for Anesthesiology involvement are identified, determine appropriate allocation of resources.
 - Formal Anesthesiology consultation is *recommended* for:
 - Patients with/at high risk for airway compromise.
 - **Any** patient who the nurse/IR team member is uncomfortable sedating.
 - Anesthesiology presence should be *considered* for:
 - Clinically complex or high risk patients that require prone positions.
 - Escalation procedure should be activated if there is disagreement on the care plan between Anesthesiology and the core IR team.
- O Establish a process for IR clinician review of procedural requests to facilitate:
 - Evaluation of patient risk (especially in complex patients).

- Selection of the most appropriate procedure.
- Input on when a "consult" vs. an "order" is appropriate.
- Identification of cases where direct provider-toprovider communication between the referring service and IR provider is recommended.
- O The IR schedule is dynamic and should be reviewed prior to starting the day's schedule to support planning *and* prior to each case starting.
- O Consider collaborating with IT and/or the EHR vendor to generate an IR schedule patient report pre-populated with key clinical information from the EHR for each patient. Color reports may assist providers in visually identifying key information, including:
 - Allergies
 - Recent relevant medication(s)
 - Relevant lab results with critical/abnormal results highlighted
 - Other relevant/unique considerations (such as age, BMI, interpreter services needs, etc.)



No one realized that Ativan required monitoring as procedural sedation... and the nurse was busy assisting with the procedure."

— a Nurse Educator

Example of IR Schedule Dashboard

Image used with permission.

IR Radiant Schedule Visceral		Print	
Dete: Submit Date Visc	veral + Clínic Clínic ne Neuro Body Mamms MSK Nur	Anes ALL Nursing CT MR rsing Svc [All] Image: Labs Audit +Cane	
VISCERAL CASES			
North Tower Active Cases: 9			
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Acc #: G3477 🛛 🔗 Bed:		8/17/18 9.5 40.3 4.5 4.81 1.1 130 3.4 7/22/18 6.4 40.5 4.8 4.27 111 21 32 0.9 3.1 322 Previous Labs Available MELD (HD: 24 / 21 NaMELD (HD: 22 / 22 ALE): 2.89 (A1)	
Detail) Reports) OFlex) •)	D::: Liver Replaced By Transplant [V42;7:ICD-9-CM] Allergies: Ordering Comments/Notes: OP(BIOPSY TJES/SURG PATH IN	Visceral	
08:00 Ir Nt Rm14 ModSed L , O	percutaneous nephrostomy-nephrostogram,	Date WBC Hot Na K Cr INR Pit AST ALT TB Alb APh	
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OrderSets: 26yo WF DOB:	1991	4/28/17 4.6 37.8 142 4 0.91 259	
017		3/10/15 5.5 35.4 4.3 0.68 313	
Acc #: G3509 Bed:		12/16/14 8 0.68 289 15 12 0.2 3.9 68 8/31/14 8.9 0.55 288 Previous Labs Available	
		MELD / HD: 7 / 21 NsMELD / HD: 7 / 21 ALBI: -2.98 (A1)	

A patient required IR drainage of a liver abscess. Because of staffing limitations, narcotics are not available in IR. Hospital policy stated that medications are to be obtained from the Emergency Department. Due to lack of education on this policy, the process delayed the procedure for more than an hour."
—IR Nurse





CONSIDERATIONS

- What staffing resources are required?
 - If sedation is required, who is responsible for monitoring the patient?^{1,2}
- Are existing staff trained in critical care/certified in advanced cardiac life support?
- Are critical care nurses available?
- Who has overall accountability for the patient?
- Are there policies for activating Nursing and Anesthesia resources to assist with clinically complex patients, especially after hours?

RECOMMENDATIONS

- O Assess the role of Anesthesiology and Nursing flex staffing plans in meeting the clinically dynamic demands of procedural areas, such as IR.
 - After hours, an on-site leader with responsibility for allocation of staff and coordination of resources (e.g., nursing supervisor, patient flow coordinator, etc.) should be aware of procedures scheduled/underway in satellite procedural areas.

- O Structured nursing handoff tools provide key clinical information when transferring patients to (and from) the IR suite. Multidisciplinary IR procedural teams should reflect the dynamic care management needs of acute, clinically complex patients:
 - In addition to the core IR nurse, a qualified critical care provider (RN/NP/PA/MD) should be available to participate in the transport and management of *all* ICU level-of-care patients.
 - The qualified critical care personnel stays with the patient, unless excused by the IR Team and the patient can be safely managed in the IR suite by the core IR Team.
 - In consultation with the covering ICU provider, the appropriate ICU staff assists with the acute medical management (titrating drips, etc.) of the patient during the IR case.
- O In the scenario of unexpected deterioration of a patient's clinical condition during a procedure, the IR Attending, or Anesthesiologist, if present, is responsible for the ongoing medical management of the patient and remains at the bedside until a face-to-face transfer of care to a receiving service occurs.
- O Strengthen staff education and preparedness by establishing a schedule for mock IR codes, team training and drills.



Communication & Hand-Offs

CONSIDERATIONS

- A high percentage of add-on procedures poses additional challenges.
- The clinician performing the pre-procedure assessment may not be the provider performing the procedure. As such, mini-handoffs can be problematic.
- Unit-specific, organizational cultural barriers may exist that impede the promotion of huddles, briefings and other safety activities.
 - The lack of integration of procedural areas, such as IR, into executive and operations surgical services committees is a barrier to the adoption and promulgation of best practices and lessons learned in surgical services.

RECOMMENDATIONS

- O Team huddles are recommended and, if possible, should occur the day before or morning of scheduled procedures.
- O Triage of the IR board is a collaborative process requiring input from key stakeholders.
 - In consideration of the dynamic nature of the IR schedule, a licensed professional should be designated for active management and interval reassessment of the IR board.

Ca 52-year-old female with recent history of splenic rupture, splenectomy and cardiac arrest underwent an uncomplicated liver biopsy in IR. Approximately 5 hours later, the patient had a cardiac arrest and died. The RN recalls briefing the team during the time out that the patient was on Plavix. There was no synopsis or 'hearback' as part of the structured briefing. The team did not recall this and felt they would have approached the biopsy differently."



- O Pre-procedure briefings should be conducted:
 - For *all* IR procedures.
 - With key team members present.
 - Immediately prior to commencing the procedure.
- O Maintain situational awareness to recognize critical issues as they arise. Create a hard stop or a "stop and re-evaluate" process at critical points in the procedure.
 - Consider implementation of a mid-procedure safety pause for complex cases and for those lasting >2 hours. Led by a designated team member, this process facilitates an opportunity to reevaluate key procedural, clinical and patient considerations (such as equipment, supplies, medication, lab work, blood products, monitoring, patient positioning, the need for additional assistance, etc.).

- O Prior to the provider exiting the room, facilitate a final check-in or post-procedure debriefing with the team (e.g., what went well, specimen collection/labeling/ orders, and concerns/plan going forward).
- O Consider redesign of post procedure documentation and warm handoffs to include essential elements for handoff/transfer of care information back to the receiving clinical team (e.g., I-PASS).
 - Ensure documentation of best practices, such as "brief procedure notes" following all procedures (CMS Conditions of Participation (CoP): "Immediate Post-Op Notes" in surgical services).³
- O Conduct closed-loop RCA (collaborative case review) processes on adverse events to identify and mitigate communication and transfer-of-care vulnerabilities.



A Near Miss...

^C An IR physician was consulted for a procedure; shortly thereafter, a paper order was generated in IR. The procedure was performed, but the post-procedure documentation was not completed and the order was not acknowledged in the EHR. The next day, another physician noted the paper order requisition in the 'inbox.' Finding no electronic acknowledgement of the order and no post-procedure note in the record, the patient was requested to come to the IR suite for the procedure. The patient's nurse knew the patient had already had the procedure and actively intervened prior to the error reaching the patient."

—IR Provider



Production Issues

CONSIDERATIONS

Inpatient vs. Outpatient: These two groups of patients present unique challenges with different processes.

- What mechanisms are activated when an IR inpatient or outpatient develops clinical deterioration?
- How are accepting/receiving services identified and assigned?
- Is there an established, high reliability process to transfer patients from one service to another?
- What unit is a patient transferred to for further care?

Urgent and Emergent procedures pose unique challenges with respect to planning, staffing and monitoring.

RECOMMENDATIONS

- Timely assignment of appropriate level of care:
 - Patients scheduled for an elective procedure:
 - Anticipate resource needs plan ahead for patients who will require bed placement following the procedure.
 - Patients requiring an urgent procedure:
 - An assigned bed and admitting service should be identified before proceeding with the case.
 - Patients requiring an emergent procedure:
 - Case begins while a bed is being located.
 - Concurrently identify an admitting service and initiate a warm handoff.
- O Develop a protocol such that if a bed cannot be assigned, the patient is accepted by an appropriate monitoring unit, irrespective of whether the case was performed with Anesthesia services.
- O Develop explicit escalation protocols for all team members.



Institutional & Executive Leadership Issues

CONSIDERATIONS

- Staff support and resource allocation.
- Support for:
 - Re-education of staff to mitigate risks associated with attrition.
 - Policies around huddles, briefings, Universal Protocol, checklists, structured handoffs and activation of appropriate personnel, when needed.
 - Organizational clarity on IR as a consult service vs. an admitting service vs. a clinical support procedural area.
- Risk of lack of designated IR medical staff and administrative leadership on surgical executive and operations committees.
- Procedures framed as an "order" can create tension between the role of the Interventional Radiologist as a consultant vs. a "proceduralist."
- IR professional societies promote IR as an admitting service.⁴
 - Limitations:
 - Cross coverage at night/off hours.
 - Credentialing/maintenance of competency in general medical and surgical care (OPPE/FPPE).
- New IR residency training program accreditation requirements include requirements for IR as an admitting service with provision of outpatient clinic services.

RECOMMENDATIONS

- O Facilitate collaboration with Anesthesiology and ICU leadership.
- O Include designated IR medical staff and administrative leadership on the OR Executive Committee (or equivalent) to facilitate standardization, spread of best practices and escalation of issues to operations and medical staff leadership.
 - Alignment of leadership of surgical services and procedural areas is a key driver to facilitating high quality, standardized care delivery.
 - Organizational support is necessary to promote culture change and the adoption and adherence to Universal Protocol (i.e., huddles, briefings, site marking, time out, etc.)
- O Perform a risk assessment of procedural areas relative to overlap with surgical services, with attention to availability of supplies and potential for retained objects (guidewires, etc.).
 - Include Materials Management in both the risk assessment and the appropriate procedural area operations committee.
 - Promote the spread of best practices and learnings from surgical services (e.g., checklists, site marking, closing counts).

^{(C}IR environments pose a risk for loss of situational awareness and critical thinking in evolving situations."

—Hospital VP/COO

•• A patient had a non-tunneled dialysis catheter placed in the right internal jugular vein by Interventional Radiology. The IR Fellow was unfamiliar with this particular catheter. While accessing the catheter later the same day, the hemodialysis nurse noted that the venous port tubing was "dry." He was unable to remove the venous port cap. Inspection by the Attending revealed that a plastic stylet that comes pre-loaded inside the catheter and facilitates catheter placement had not been removed from the venous port following catheter placement."

— α Residency Director

•• A patient with a history of metastatic gastric cancer was admitted for the management of ascites due to portal vein stenosis from prior radiation. The plan was for palliative portal vein stent placement to decrease pain associated with the ascites. The guidewire from a femoral central line placed at end of the IR procedure in urgent response to hypotension was left in and discovered later in the ICU."

—ICU Nurse Manager

•• I activated a Rapid Response on a Saturday morning. The Rapid Response Team had no idea where IR was located!"

—Medical Assistant

- O IR as both an admitting and a consult service:
 - Clinical decision making of the Interventional Radiologist is critical in determining to which admitting service a patient will be assigned.
 - Patients admitted to the IR service may need supporting medical/surgical consults based on underlying conditions.
 - Conversely, handoff processes and post procedure care plans for patients admitted to medical/surgical services should facilitate appropriate engagement of the Interventional Radiologist in the aftercare of patients. These processes should specifically address access to IR expertise in the notification, assessment and multidisciplinary management of postprocedure adverse events.
 - Routine review of IR admitting and consult privileges as part of the OPPE and reappointment credentialing cycles.
- O Establish processes that triage patients to services appropriately resourced to meet their anticipated care needs.
 - Processes should seek to identify and account for inherent limitations of cross-coverage of services that may be unique to the facility (e.g., availability of in-house providers, mid-level provider coverage, ICU staffing model, clinical services cross-covered after hours by other clinical disciplines).
- O Adapt *Code Blue* and rapid response/trigger programs and incorporate IR mock drills.
- O Consider a team training program with simulation as a patient safety exercise.
 - Integration with surgical services team training through the OR Executive Committee (or equivalent) to facilitate standardization, spread of best practices and escalation of issues to operations and medical staff leadership.



Emerging Issue: Hybrid Rooms

The emergence of 'Hybrid Rooms' poses unique challenges relative to patient safety, regulatory, governance, staffing and training. When planning for the implementation of hybrid rooms, organizations should evaluate considerations such as:

- What is the physical location of the hybrid room?
- Is the hybrid room within the OR suite (hybrid operating room)?
- What Association of periOperative Registered Nurses standards apply, if any?
- Is there a defined process for delineating scheduling and use of the hybrid room by surgical vs. procedural area teams?
- How and by whom will non-elective cases be prioritized?

- Is there a defined process for case-by-case designation of a hybrid operating room? On what basis will this determination be made (type of procedure, open vs. closed, acuity/risk assessment, patient comorbidities, resource allocation, specialty, etc.)?
- Are staffing and resource allocation in compliance with regulatory standards?
- Is Anesthesia supervision in compliance with state and federal regulation, licensing requirements and accrediting body standards?
- Are mechanisms in place to ensure that staff 'floated' from IR to a hybrid operating room have documentation of the required orientation, certifications and competencies to provide care in a hybrid setting?



APPENDIX Interventional Radiology WHO Safety Checklist

BRIEFING AT TIME OF CONSENT WITH CIRCULATING RT/RN/MD/PA

- O Sedation/anesthesia plan
- O Labs/anticoagulants
- O Laterality addressed and site marking done prior to leaving HR if not image guided
- O Verify procedure against MD order, booking sheet, and consent
- O Airway assessment documented by MD and confirmed by RN sedation
- O ASA classification documented by MD and confirmed by RN sedation
- O Supplies/rep available for case, critical steps of the case discussed
- O Team reviews images and consult notes
- O RN has read history and all questions answered
- O Site marking done if not image guided
- O On-call nursing supervisor/ Anesthesia notified
- O Does patient have any electronic medical devices? If yes, discuss management

TIME OUT

- O Confirm all team members have introduced themselves by name and role
- O Has antibiotic prophylaxis been given within the last 60 minutes?
- O Allergies noted
- O Anticoagulants, if not previously addressed
- O Pulse oximeter and capnography in place—sedation
- O Proceduralist reviews what are the critical or unexpected steps, interventional plan with team if not done at brief
- O Document time out

DEBRIEF

- O Procedure recorded
- O Specimens labeled and verified
- O Patient disposition and orders
- O What went well; what did not go well
- O WHO audit complete

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About the AMC PSO

In 2009, the Patient Safety and Quality Improvement Act (PSQIA) was enacted to create a culture of safety by providing federal privilege and confidentiality protections for information that is assembled and reported to a PSO, or developed by a PSO, for the conduct of patient safety activities.

The act promotes the sharing of best practices and knowledge to continuously improve the quality of patient care. Before the PSQIA, legal protections for quality activities were limited in scope and existed only at the state level.

The PSQIA encourages voluntary reporting. Identification of common, systemic errors can be achieved more effectively through the aggregation of information reported from providers across the health care delivery system.

In 2010, the Risk Management Foundation of the Harvard Medical Institutions, Inc. formed a component entity, the Academic Medical Center Patient Safety Organization (AMC PSO) to function as a national convener of clinicians and health care organizations to collect, aggregate, and analyze data in a secure environment in an effort to identify and reduce the risks and hazards associated with patient care.

Our objectives:

- Create a bridge between themes driving malpractice activity and factors seen in real-time data with a particular focus on high-severity/high-significant events seen in root cause analysis (RCA)
- Convene member organizations in response to real-time events and bring context to patient safety issues by providing a secure venue for discussion
- Translate learnings gleaned from our convening sessions and data analyses into focused clinical interventions that can improve quality, reduce costs, and decrease liability
- Reach beyond data reporting and generate actionable responses that can inform the development of best practice recommendations
- Inform institutional patient safety efforts by pinpointing the areas of highest risk and vulnerability to help guide organizational patient safety initiatives



