STANDARDS OF PRACTICE

Society of Interventional Radiology Quality Improvement Standards for Image-Guided Percutaneous Drainage and Aspiration of Abscesses and Fluid Collections

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ABBREVIATIONS

PDAFC = percutaneous drainage or aspiration of abscesses and abnormal fluid collections, QI = quality improvement

INTRODUCTION

Image-guided percutaneous drainage or aspiration of abscesses and abnormal fluid collections (PDAFC) has become the diagnostic and therapeutic treatment of choice for a wide variety of fluid collections. The procedures have resulted in reduced morbidity and mortality and have helped to reduce length of hospital stay and hospital costs (1–18). This Society of Interventional Radiology (SIR) Quality Improvement (QI) Guideline outlines the specifications and principles for performing high-quality PDAFC.

The procedures may be performed with ionizing radiation for image guidance, including fluoroscopy or computed tomography (CT), or with nonionizing radiation modalities such as ultrasound (US) or magnetic resonance imaging. Nonionizing radiation guidance is preferred when appropriate. Optimal performance of PDAFC requires knowledge of anatomy and pathophysiology, familiarity with percutaneous techniques (eg, needle, guide wire, and drainage catheter use), and knowledge of the advantages and disadvantages of one imaging modality versus another for any particular drainage procedure. As with any invasive therapy, the patient is most likely to benefit when the procedure is performed in an appropriate environment and by qualified physicians.

This standards document is intended to be used in QI programs to assess percutaneous drainage procedures. The most important processes of care are (i) patient selection, (ii) performing the procedure, (iii) monitoring the patient, and (iv) longitudinal postprocedural management of the drain if one was placed. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

This standard is updated from the adult (17) and pediatric (19) versions to include more recent techniques and references, including the use of percutaneous drainage for pancreatic necrosectomy and standardization of success, adverse event, and threshold rates. Full information about the SIR Standards Division and QI methodology is provided in **Appendix A** (available online on the article's Supplemental Material page at *www.jvir.org*). Information about the search terms and process is provided in the executive summary (**Appendix B** [available online on the article's Supplemental Material page at *www.jvir.org*]).

CLINICAL BACKGROUND ON DISEASE STATE

Fluid collections in the abdomen and pelvis, infected or otherwise, can occur in and affect nearly every organ, and the etiology of these collections is remarkably diverse; an extensive discussion of these locations and causes is beyond the scope of this document. A brief overview of etiologies includes benign cystic disease; infectious causes from bacterial, fungal, mycobacterial, or parasitic organisms; postsurgical seromas or lymphoceles; perforation or rupture and leakage from hollow viscus or conduits; and collections formed secondary to inflammatory states or diseases. Whether removal of infected or inflammatory contents, relief from extrinsic compression, or management of fistulae is required, image-guided percutaneous drainage has offered a rapid, safe, and effective alternative to surgical drainage or decompression, with reductions in morbidity, mortality, and hospital costs (1–18,20–37).

DEFINITIONS

Image-guided percutaneous drainage is defined as the placement of a catheter with the use of image guidance to provide continuous drainage of a fluid collection by using access pathways that may be transorificial (eg, transrectal, transvaginal, peroral) or transcutaneous. It includes localization of the fluid collection under imaging guidance and placement of one or more catheters into the collection, and may also include catheter maintenance and eventual removal of the catheter(s). It may be performed during a single session or as a staged procedure during multiple sessions.

Image-guided percutaneous aspiration is defined as evacuation or diagnostic sampling of a fluid collection by using a catheter or needle during a single imaging session, with removal of the catheter or needle immediately after the aspiration.

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Appendices A–C, Figure E1, and Table E1 can be found by accessing the online version of this article on *www.jvir.org* and clicking on the Supplemental Material tab.

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INDICATIONS

Because of variability in the presentation of abscesses and fluid collections, the indications for PDAFC must be stated in general terms enumerated at the end of this section. A collection may be detected by physical examination but typically is discovered by an imaging study. Additional studies may be helpful before the procedure to confirm the presence or nature of the fluid collection and to evaluate the feasibility of a percutaneous procedure.

Diagnostic aspiration may be the only means of determining whether a fluid collection is infected.

Although fever, leukocytosis, malaise, anorexia, or other systemic symptoms indicate the possibility an infection, these signs and symptoms may be absent in elderly, very ill, or immunocompromised patients. If material that appears infected is obtained or if the operator suspects the presence of infection, a drainage catheter may then be placed.

There is a spectrum of disease complexity. Examples of more complex situations include multiple or multiloculated abscesses, abscess caused by Crohn disease, pancreatic abscesses, a drainage route that traverses bowel or pleura, infected hematoma, and tumor abscess (22,26,28,29,31,34,35,37). Articles have reported curative or partially successful percutaneous drainage in patients with these complex situations. However, one should expect that percutaneous drainage in such cases will have a lower chance of success, be more technically difficult, require longer periods of time for drainage, involve more drainage or drain manipulation procedures or the use of adjunct fibrinolytic agents, have a higher likelihood of recurrence, and have a higher rate of complications.

For the treatment of necrotizing pancreatitis, percutaneous pancreatic abscess drainage with a combination of large catheters has been described (25,27,32,33,37). Alternatively, a "step-up approach," or percutaneous drainage of the pancreatic abscess collection followed by video-assisted retroperitoneal debridement along the route of the retroperitoneal drainage catheter, has been reported to reduce complications and mortality compared with open necrosectomy (25,33).

For other abscesses that are incompletely drained after PDAFC, some have reported success with adjunctive intracavitary fibrinolytic agents and/or adjunctive procedures such as upsizing to a larger catheter or one with more side holes (20,21,23). Decisions regarding percutaneous versus surgical drainage of complex collections should be made in concert with other physicians involved in the patient's care. Some have advocated the possibility of draining abscesses with the use of needles alone (24,30,36). However, catheter drainage may still be needed in selected cases, and the overall utility of needle drainage of abscesses awaits further study.

PDAFC should be performed for one of the following indications:

- Suspicion that the fluid is infected or the result of an abnormal fistulous communication;
- Need for fluid characterization;
- Suspicion that the collection is producing symptoms sufficient to warrant drainage; or
- Need for an adjunctive procedure to facilitate the improved outcome of a subsequent intervention (eg, paracentesis before liver intervention, access to a cyst for drainage and sclerosis).

Overall Procedure Threshold

The threshold for these indications is 98%. When fewer than 98% of procedures are for these indications, the department will review the process of patient selection.

Contraindications

There are no absolute contraindications. However, there are relative contraindications, and, as for all patients considered for this procedure, the relative benefits and risks of the procedure should be weighed carefully. These relative contraindications should be addressed and corrected or controlled before the procedure when feasible. The relative contraindications for PDAFC include:

- Significant coagulopathy that cannot be adequately corrected;
- Severely compromised cardiopulmonary function or hemodynamic instability;
- Lack of a safe pathway to the abscess or fluid collection;
- Inability of the patient to cooperate with, or to be positioned for, the procedure; and
- Patient refusal of procedure.

For the pregnant or potentially pregnant patient, the document "Radiation Management for Interventions Using Fluoroscopic or Computed Tomographic Guidance during Pregnancy: A Joint Guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe with Endorsement by the Canadian Interventional Radiology Association" (38) is recommended.

Risk Stratification

Contraindications listed in the previous section should be minimized when possible, and the relative risks and benefits of each clinical presentation should be weighed on an individual basis. As more relative contraindications such as a lack of a safe access route cannot be avoided, it is expected that the technical and clinical success rates of the procedure may decrease and the incidence of adverse events will increase. However, these average rates should remain below the suggested standards.

PROCEDURE TYPES AND SUBSETS

Image-guided drainage or aspiration of abdominopelvic fluid collections is a broad category of similar procedures, depending on indication, chosen route of access with or without organ transgression, the choice to leave an indwelling drainage catheter, and postprocedural management. However, for QI purposes, PDAFC may be considered one type of procedure with no subsets.

Pediatric Procedures

Several factors differentiate drainage of abscesses and fluid collections in children, including etiologies, need for sedation/analgesia, and increased concerns for radiation safety (19). The indications, contraindications, and techniques are similar to adult practice, with some modifications. The smaller body habitus of children improves visualization of collections with imaging and allows for much greater use of US, thereby reducing radiation exposure (19). If the use of ionizing radiation is required, the techniques can be modified to reduce exposure, such as low-dose CT protocols, pulsed fluoroscopy, and last image hold (19,39).

The most common indication for percutaneous abscess drainage in children is in the setting of perforated appendicitis (40). Percutaneous drainage of appendiceal abscesses in the acute setting decreases the risk of recurrent appendicitis or interval appendectomy and reduces postoperative complications if interval appendectomy is required (41). For deep pelvic abscesses, transrectal drainage can be performed in children with the use of a similar technique to that in adults; however, in smaller children, an endorectal probe may be too large and may require visualization through a transabdominal window or use of an endovaginal probe (42,43).

Compared to the adult population, the role of percutaneous drainage of intraabdominal abscesses in Crohn disease is less well defined, but it can be performed with high clinical and technical success rates, allowing early resumption of immunosuppressive treatment and reducing the requirement for surgery (44).

There are currently limited data in regard to percutaneous drainage of solid organ collections in children, but small studies have reported the procedure to be safe and effective, with high technical and clinical success rates (45).

Table 1. Success Rates and Thresholds (3–9,11,13–16, 18–24,26,28–32,34–37)

Outcome	Reported Rate (%)	Suggested Threshold (%)
Successful diagnostic fluid aspiration: aspiration of fluid adequate for diagnostic characterization	93–100	89
Successful drainage: curative and partial success	62–100	76

Quality Improvement

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% adverse events), all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing QI programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt an internal review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure, eg, major adverse events. Individual adverse events may also be associated with adverse event–specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when adverse events exceed a (maximum) threshold, a review should be performed to determine causes and to implement changes if necessary. For example, if the incidence of sepsis is one measure of the quality of image-guided percutaneous drainage or aspiration, values in excess of the defined threshold of 4% should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the adverse event. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for an indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own QI program needs.

TECHNICAL SUCCESS RATES

Curative drainage is defined as complete resolution of infection requiring no further operative intervention. In the majority of reviewed studies, curative drainage has been achieved in more than 80% of patients (1–18,20–37). Partial success is defined as adequate drainage of the abscess with surgery subsequently performed to repair an underlying problem or as temporizing drainage performed to stabilize the patient's condition before surgery. Partial success varies in reviewed literature, but generally occurs in 5%–10% of patients (1–18,20–37). It should be noted that, in certain conditions, the expectation of drainage is to serve as a "bridge" until definitive surgical treatment can be performed, as in the cases of some patients with ruptured appendicitis complicated by the development of an intraabdominal abscess or abscesses. For the purposes of these standards, this is considered partial success even though the treatment plan may include staged interventions consisting of percutaneous abscess drainage to be followed by definitive surgical therapy for underlying disease. Failure occurs in 5%–10% of cases, and recurrence in 5%–10%. These results are similar for abdominal and chest drainage procedures (1–18,20–37). However, clinical success rates will depend on the proportion of collections drained in patients with relative contraindications, the complexity of the collections, and the severity of the underlying medical problems.

Success rates may be improved by tailoring the size of drainage catheter to the consistency of the fluid collection. For example, simple fluid can be adequately drained with an 8-F catheter. More viscous or purulent collections may be less prone to obstruction with a larger catheter (≥ 10 F) (46).

Table 2. Specific Adverse Event Rates and Suggested Thresholds (3,4,15,16,18–24,28,31,34,36,40)

Specific Major Complication	Reported Rate (%)	Suggested Threshold (%)
Septic shock	0–2	4
Bacteremia requiring significant new intervention	0–3	5
Hemorrhage requiring transfusion*	0–13	8
Superinfection (includes infection of sterile fluid collection)	0–5	7
Bowel transgression requiring intervention	0–2	2
Pleural transgression requiring intervention (abdominal interventions)	0–1	2
Pneumothorax/hemothorax/pleural effusion requiring further intervention (chest procedures)	0–12	14

*Includes data in which adjunctive intracavitary fibrinolytic therapy is used.

Table 3. Overall Adverse Event Rates (1,14,15,18,19,24,28,30,36)

Overall Procedure	Reported Rate (%)	Suggested Threshold (%)
All major adverse events resulting from adult and pediatric percutaneous drainage procedures	0–15	15

Adult and pediatric technical success rates are summarized in **Table 1** (3–9,11,13–16,18–24,26,28–32,34–37), and are supported by the weight of the literature evidence and panel consensus.

ADVERSE EVENTS

Specific adult and pediatric major complication rates and suggested thresholds are summarized in **Table 2** (3,4,15,16,18–24,28,31,34,36,40), and are supported by the weight of the literature evidence and panel consensus. Overall adult and pediatric adverse events associated with PDAFC are reported to occur in approximately 0%–15% of patients (**Table 3**) (1,14,15,18,19,24,28,30,36).

Published rates for individual types of adverse events (**Appendix C** [available online on the article's Supplemental Material page at *www.jvir.org*]) (47) are highly dependent on patient selection and may be based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Generally, the adverse event–specific thresholds should therefore be set higher than the adverse event–specific reported rates listed here. It is also recognized that a single adverse event can cause a rate to cross above an adverse event–specific threshold when the adverse event occurs within a small patient volume, (eg, early in a QI program). In this situation, the overall procedure threshold is more appropriate for use in a QI program. In **Tables 2** and **3**, all values are supported by the weight of literature evidence and panel consensus.

CATHETER MAINTENANCE

Catheters draining abscesses or fluid collections are typically anchored to the skin with the use of nonabsorbable suture or adhesive devices. Although

there is limited evidence within the literature, and protocols may be institution-dependent (48,49), the consensus of the authors is that drainage catheters should be flushed every day with 5–10 mL normal saline solution to maintain patency of the catheter, as the fluid being drained is often highly viscous and prone to cause catheter obstruction. In addition, removal of the catheter may be considered when a sinogram or other imaging modality such as CT or US (50) demonstrates diminished collection size, the patient exhibits clinical improvement, and/or when the catheter drains < 10 mL for several days.

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APPENDIX A. SIR STANDARDS DIVISION PREAMBLE AND METHODOLOGY FOR QUALITY IMPROVEMENT STANDARDS

Preamble

The mission of the Society of Interventional Radiology (SIR) is to improve patient care through image-guided therapy. The Society was founded in 1973, and is recognized today as the primary specialty society for physicians who provide minimally invasive image-guided therapies. The standards division of SIR provides evidence-based clinical practice documents to ensure patient safety and enhance the delivery of patient care. Standards division members are leaders in the field of interventional radiology from the private and academic sectors of medicine who dedicate the vast majority of their professional time to performing interventional procedures, and, as such, they represent a broad expert constituency of the subject matter under consideration for standards development. The standards division currently produces the following types of documents.

Clinical Practice Guidelines/Practice Parameters

These are statements that include recommendations intended to optimize patient care and assist physicians in clinical decision-making. They are developed by using a rigorous methodology involving a systematic review of the literature and assessment of the evidence.

Competence and Training Statements

These are statements that make recommendations on training and competencies required for a given clinical topic, procedure, or therapy. Recommendations are supported by evidence when available and/or expert consensus.

Quality Improvement Standards

These are statements that combine the recommendations of clinical practice guidelines (where available) and performance measures to provide guidance on clinical quality improvement in interventional radiology practice.

Position Statements

These are statements that reflect the opinion of SIR concerning areas of evolving clinical practice and/or technologies. Position statements are evidence-based whenever possible, but, because the scope usually involves a developing clinical practice or technology, the body of evidence may not be robust, and an independent panel of experts, usually multidisciplinary, may be convened for document development.

Reporting Standards

These are statements that define a set of standardized data elements to be used in data-collection efforts for describing processes and outcomes of interventional radiologic procedures. The purpose of reporting standards is to facilitate professional agreement on common vocabulary/definitions and to permit comparison of data across studies or combination of data from studies for further analysis.

Methodology for Quality Improvement Standards

Topics for standards document development are solicited through an annual survey that allows SIR members the opportunity to submit topics for consideration. The proposed quality improvement topics are approved and prioritized by the executive council. A recognized expert or group of experts is identified to serve as the principal author or writing group for the document. Additional authors or societies may be sought to increase the scope, depth, and quality of the document dependent on the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases, such as Medline (via PubMed) and the Cochrane Library. A critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. All documents have adopted an updated methodology for evidence grading and assessment of strength of recommendation (**Appendix C**) (1,2) to fulfill Institute of Medicine standards for guidelines development. Accepted definitions of the hierarchical classification of evidence, commonly used by systems such as Oxford and Grading of Recommendations Assessment, Development and Evaluation, are included, and an assessment of the strength of recommendation is defined to assist in clinical decision-making (1,2). Similar classification systems are used by other specialty practice societies such as the American College of Cardiology/American Heart Association (3). The level-of-evidence assessment will be used to create the evidence tables that inform the standards documents. For documents that incorporate clinical recommendations, the strength of recommendation will be used to denote how well the recommendation is supported by systematic evidence. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds. Threshold values are determined by calculating the standard deviation of the weighted mean success and adverse events reported in all relevant trials with a sample size of approximately 50 patients or greater. Calculated threshold values represent 2 standard deviations above or below the mean for adverse event and success rates, respectively.

When the evidence of literature is weak, conflicting, or contradictory, a modified Delphi technique may be used to enhance effective decision-making (4,5), and consensus for the threshold value is reached when 80% of panelists are in agreement. Reported adverse event–specific rates in some cases reflect the aggregate of adverse events of varying severities. Thresholds are derived from the national benchmarks from the National Quality Registry for interventional radiology when available, a critical evaluation of the literature, and evaluation of empiric data from the members of the standards division.

The draft document is critically reviewed by the writing group and members of the standards division by telephone conference call or face-to-face meeting. Comments are discussed by the members of the standards division, and appropriate revisions are made to create the final document before peer review, approval by the SIR Operations Committee, and publication.

SIR Standards Documents are developed to improve quality of care for patients; however, there are other ongoing national quality improvement efforts such as the Centers for Medicare and Medicaid Services (CMS) Quality Payment Program (*https://qpp.cms.gov*). Reportable measures for the CMS Quality Payment Program will change from year to year. To see if there are reportable measures that pertain to this quality improvement standard, please refer to the current CMS measures. CMS measures and access tools to help with reporting of performance measures can be found through the American College of Radiology (*https://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Qualified-Clinical-Data-Registry*) and SIR (*https://www.sirweb.org/practice-resources/quality-improvement2/ir-quality-registry/*). The interventional radiology quality registry permits the collection of performance measures for image-guided interventional procedures, and participating facilities and physicians will receive reports based on aggregated benchmarks to facilitate patient safety and quality improvement efforts. The interventional radiology registry also provides participants opportunities to fulfill CMS Physician Quality Reporting System reporting requirements and gain maintenance of certification credit from the American Board of Radiology.

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APPENDIX B. EXECUTIVE SUMMARY

In August 2017, the work group members discussed the scope of the planned document, the Society of Interventional Radiology template, and the previous document. Image-guided aspiration and drainage of fluid collections by using various modalities, including fluoroscopy, ultrasound, computed tomography, and magnetic resonance imaging, have become the treatment of choice for a wide variety of fluid collections because of the minimally invasive nature of these techniques, which have substantially reduced morbidity and mortality while reducing hospital stay and hospital costs. Since the publication of the adult and pediatric quality improvements guidelines for percutaneous drainage or aspiration of abscesses and abnormal fluid collections (PDAFC), the indications for these procedures have expanded, eg, percutaneous drainage for pancreatic necrosectomy in adults and percutaneous drainage of solid-organ fluid collections in children. Thus, it was the authors' goal to revise the adult and pediatric PDAFC documents, emphasizing the current literature of the foregoing points and to combine them into one quality improvement document.

Starting in September 2017 with periodic updates through October 2019, the work group members performed a PubMed search combining all of the terms of group A with those of group B:

Group A	Group B
Percutaneous	Abscess
Drainage	Seroma
Imaging guidance	Fluid collection
Aspiration	Pancreatitis
	Appendicitis
	Pelvis
	Abdomen
	Fibrinolytic
	Hematoma

The search yielded 49 citations that were English-language publications from 1988 to 2016 and were one of the following:

- Prospective randomized controlled study
- Prospective nonrandomized study
- Case series
- Retrospective study
- Review article or metaanalysis if the literature in a particular area was limited

These references are included in the attached evidence tables and were used to update the document. The working group assembled a plenary draft, and, after review by the work group members, a final draft was constructed, which was forwarded to the Society of Interventional Radiology Standards Committee for review and comment by the nonvascular and pediatric workgroups.

APPENDIX C. ADVERSE EVENT CLASSIFICATION

Part A: Adverse Event Description

This is a descriptive narrative of adverse event (including sedation and anesthesia) and severity characterization. This part is suitable for scientific use (presentations, publications) as well as for adverse event reviews within a practice, practice group, facility, or specialty.

1. Mild adverse event: no therapy or nominal (ie, nonsubstantial) therapy (ie, postprocedural imaging performed and fails to show manifestation of adverse event); near-miss (eg, wrong site of patient prepared but recognized and corrected before the procedure, wrong patient information entered for procedure);
2. Moderate adverse event: moderate escalation of care, requiring substantial treatment, eg, intervention (description of intervention and result of intervention) under conscious sedation, blood product administration, extremely prolonged outpatient observation, or overnight admission after an outpatient procedure not typical for the procedure (excludes admission or hospital days unrelated to adverse event);
3. Severe adverse event: marked escalation of care, ie, hospital admission or prolongation of existing hospital admission for $>$ 24 hours that is atypical for the procedure, inpatient transfer from regular floor/telemetry to intensive care unit, or complex intervention performed requiring general anesthesia in previously nonintubated patient (generally excludes pediatric cases or in circumstances in which general anesthesia would primarily be used in lieu of conscious sedation, eg, in mentally challenged or severely uncooperative patients);
4. Life-threatening or disabling event, eg, cardiopulmonary arrest, shock, organ failure, unanticipated dialysis, paralysis, or loss of limb or organ; and
5. Patient death or unexpected pregnancy abortion.

*The Society of Interventional Radiology Adverse Event Severity Scale is intended to approximate the surgical Clavien–Dindo scale and the National Cancer Institute Common Terminology Criteria for Adverse Events scale. The Society of Interventional Radiology scale is tailored toward the procedures and adverse events encountered in interventional radiology practices. The grading of interventional oncology adverse events can selectively incorporate relevant adverse event grading definitions published in the current Common Terminology Criteria for Adverse Events for oncologic interventions, which may be particularly relevant in the context of research publications. All adverse events occurring within 30 days of a procedure should be included in the adverse event description and analysis, regardless of causality, in the interest of objectivity. The adverse event scale itself does not assess operator performance.

Modifier. M = multiple adverse events, each of which is counted and evaluated separately if possible.

Part B: Adverse Event Analysis

The following part pertains to adverse event analysis. It is designed to enable a confidential and constructive review of any adverse event within an interventional radiology practice or practice group. Applicability for scientific publications is limited, and there is none for other public use. The following content is meant to provide a strictly confidential, legally nondiscoverable, nonpunitive, objective, consistent, and clinically constructive analytic guide that may result in quality-improvement measures to advance the quality of patient care in interventional radiology.

Causality

Category 1. Adverse event not caused by the procedure

Category 2. Unknown whether adverse event was caused by the procedure

Category 3. Adverse event caused by the procedure

Patient and Procedural Risk Modifier

Category 1. High-risk patient and technically challenging procedure

Category 2. High-risk patient (eg, American Society of Anesthesiologists status 4, uncorrectable coagulopathy, poor functional status [Eastern Cooperative Oncology Group performance status 3/4], polypharmacy/polyintravenous therapy and transfusion, septicemia, hemodynamic instability, recent catastrophic event/intensive care unit admission/major surgery or

interventions) or low-risk patient and technically challenging procedure (eg, transjugular intrahepatic portosystemic shunt creation with occluded portal vein, percutaneous biliary drain placement in nondilated biliary system)

Category 3. No modifier

Adverse Event Preventability

Category 1. Rarely preventable, ie, well described and "typical" for the procedure and occurring despite adequate precautionary and preventive measures

Category 2. Potentially preventable

Category 3. Consistently preventable, eg, inappropriateness of procedural indication (may use checklist below)

Adverse Event Management

Category 1. Most operators would have handled the adverse event similarly

Category 2. Some operators would have handled the adverse event differently

Category 3. Most operators would have handled the adverse event differently

Examples of Consistently Preventable Event

- Wrong patient
- Absolute contraindication for procedure
- Wrong side for procedure
- Wrong procedure
- Wrong medication/contrast agent/blood product (dose/administration route)
- Exposure to known allergens
- Intraarterial placement of catheter meant to be intravenous or nonvenous placement of inferior vena cava filter
- Ferromagnetic devices contraindicating performance of magnetic resonance imaging
- Failure to follow up or communicate laboratory, pathology, or radiology results
- Use of known malfunctioning equipment or patient monitor system
- Lack or inappropriate use of monitoring equipment during sedation

LEVEL OF EVIDENCE

A HIGH QUALITY EVIDENCE

Types of Evidence	Characteristics of Evidence
Multiple RCTs	Homogeneity of RCT study population
Systematic reviews or meta-analyses of high-quality RCTs	Intention-to-treat principle maintained
RCT data supported by high-quality registry studies	Appropriate blinding
	Precision of data (narrow CIs)
	Appropriate follow-up (consider duration and patients lost to follow-up)
	Appropriate statistical design

B MODERATE QUALITY EVIDENCE—Randomized Study Design

Types of Evidence	Characteristics of Evidence
≥ 1 RCTs	RCTs with limitations (eg, < 80% follow-up, heterogeneity of patient population, bias, etc)
Systematic reviews or meta-analyses of moderate-quality RCTs	Imprecision of data (small sample size, wide CIs)

C MODERATE QUALITY EVIDENCE—Nonrandomized Study Design

Types of Evidence	Characteristics of Evidence
Nonrandomized trials	Nonrandomized controlled cohort study
Observational or registry studies	Observational study with dramatic effect
Systematic reviews or meta-analyses of moderate quality studies	Outcomes research
	Ecological study

D LIMITED QUALITY EVIDENCE

Types of Evidence	Characteristics of Evidence
Observational or registry studies with limited design and execution	Case series
Systematic reviews or meta-analyses of studies limited by design and execution	Case-control studies
	Historically controlled studies

E EXPERT OPINION

Types of Evidence	Characteristics of Evidence
Expert consensus based on clinical practice	Expert opinion without explicit critical appraisal or based on physiology, bench research, or "first principles"

STRENGTH OF RECOMMENDATION

Strong Recommendation	Moderate Recommendation	Weak Recommendation	No Recommendation
Supported by high quality evidence for or against recommendation	Supported by moderate quality evidence for or against recommendation; new research may be able to provide additional context	Supported by weak quality evidence for or against recommendation; new research likely to provide additional context	Insufficient evidence in the literature to support or refute recommendation

CI = confidence interval; RCT = randomized controlled trial.

Figure E1. Level of evidence and recommendation classification system.