Standards 2.0: Methodology Update

Alda L. Tam, MD, MBA, Laura Findeiss, MD, Michael D. Dake, MD, Jeremy D. Collins, MD, Raymond W. Liu, MD, Ziv J Haskal, MD, Suresh Vedantham, MD, Susan E. Sedory, MA, CAE, and M. Victoria Marx, MD

ABBREVIATIONS

CPG = clinical practice guideline, IOM = Institute of Medicine

In 2018, we mark the 30th anniversary of the inaugural publication from the Society of Interventional Radiology (SIR) Standards Division: "Guidelines for Establishing a Quality Improvement Program in Vascular and Interventional Radiology" (1). SIR took a prescient stance with the creation of the Standards Division, correctly anticipating the need to help physicians integrate evidence-based medical knowledge into daily practice and to ensure high-quality outcomes and patient safety in vascular and interventional radiology. To date, thanks to the unflagging efforts of our member volunteers over the decades, the Standards Division has published 24 Position Statements, 17 Practice Parameters, 32 Quality Improvement Standards, 26 Reporting Standards, and 9 Credentialing & Training Statements. The Division has also diligently maintained the repository of documents by reviewing them every 5 years and revising as necessary with current data. Lastly, the SIR Standards Division has served as the voice for interventional radiology on international consensus guidelines and multisociety consensus documents.

As with many specialty societies, the early documents were created using a simple consensus methodology; however, SIR Standards documents evolved in 1995 to incorporate methodologic elements, including the use of the Modified Delphi Consensus Method (2,3), which are required to comply with criteria set forth by the Agency for Healthcare Research and Quality National Guidelines Clearinghouse (4). Despite adherence to a rigorous scientific and consensus process, clinical practice guidelines (CPGs) developed by specialty societies were, and continue to be, the subject of general criticisms and concerns on the national stage (5–7), with many advocating for CPGs to be developed by public entities, such as the National Institutes of Health or the Agency for Healthcare Research and Quality (6). This public health issue was addressed when the US Congress assigned the Institute of Medicine (IOM) to develop a set of criteria for CPG development. The IOM recommendations were summarized in 2011 in "Clinical Practice Guidelines We Can Trust" (8) and "Finding What Works in Health Care: Standards for Systematic Reviews," (9) which redefined CPGs as follows: "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options."

Furthermore, the IOM recommendations stressed the importance of subjecting the scientific body of evidence on which CPGs were based to critical evaluation, the need for transparency in the methodology being used by the writing group, and a candid disclosure of conflict of interests with industry for the members involved in the CPG development (6). While it needs to be acknowledged that the IOM recommendations and proposed methodologies are themselves primarily consensus-based, rather than evidence-based, and their impact on clinical outcomes is as yet unknown (10), there has been widespread adoption of this new standard approach to CPG development. This has created a challenging environment for specialty societies, which may lack the infrastructure and financial resources to be compliant (6).

As we begin our tenure as an independent specialty, we have instituted several process changes within the Standards Division to meet the evolution in methodology of CPG development and to continue the Division's strong tradition of helping members optimize the quality of care for patients. The following process changes have been implemented:

1. Each fall, SIR will issue an **Annual Open Call for Topics** providing members with the opportunity to propose topics for guideline development via an online submission process. The suggested topics are reviewed and prioritized by the Chairs of the Standards Division and SIR leadership.
2. All documents have adopted **an updated methodology for evidence grading and assessment of strength of recommendation** (**Appendix A**; 11,12) to fulfill IOM standards for guidelines development. Accepted definitions of the hierarchical classification of evidence, commonly used by systems such as Oxford and GRADE, are included, and an assessment of the strength of recommendation is defined to assist in clinical decision making (11,12). Similar classification systems are used by other specialty practice societies, such as the American College of Cardiology/American Heart Association (10). 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. It should

From the Department of Interventional Radiology (A.L.T.), M.D. Anderson Cancer Center, Houston, Texas; Department of Radiology (L.F.), Grady Memorial Hospital, Atlanta, Georgia; Falk Cardiovascular Research Center (M.D.D.), Department of Cardiothoracic Surgery, Stanford University School of Medicine, Stanford, California; Department of Radiology (J.D.C.), Northwestern University Feinberg School of Medicine, Chicago, Illinois; Division of Interventional Radiology (R.W.L.), Massachusetts General Hospital, Boston, Massachusetts; Division of Interventional Radiology (Z.JH.), University of Virginia Medical Center, Charlottesville, Virginia; Mallinckrodt Institute of Radiology (S.V.), St. Louis, Missouri; Society of Interventional Radiology (S.E.S.), Fairfax, Virginia; and Department of Clinical Radiology (M.V.M.), Keck School of Medicine, University of Southern California, Los Angeles, California. Received May 21, 2018; accepted May 22, 2018. **Address correspondence to** A.L.T., c/o Elizabeth Himes, 3975 Fair Ridge Drive, Ste 400, North, Fairfax, VA 22033; E-mail: Alda.tam@mdanderson.org

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be noted that a recommendation with level C or D evidence does not necessarily imply that the recommendation is weak (10), as many important clinical questions may not lend themselves to clinical trials, and very clear clinical consensus may exist supporting the usefulness or effectiveness of a therapy (10). In fact, in an audit of the 3,271 recommendations from 19 CPGs developed by the American College of Cardiology/American Heart Association published in 2013, of the class I (strong) recommendations, only 11% were based on the highest level of evidence, and 46% were informed by evidence from limited data or expert opinion (10).

3. All documents have adopted the **New SIR Adverse Event Classification System (Appendix B)** (13). This new system was developed by members of the Standards of Practice Committee and introduced in 2017. It is designed to approximate the surgical Clavien-Dindo scale and the National Cancer Institute Common Terminology Criteria for Adverse Events scale. All adverse events occurring within 30 days of a procedure should be included. The system consists of 2 parts. Part A requires a descriptive narrative of the adverse event (including sedation and anesthesia) and severity characterization. Classification of the adverse event under Part A is suitable for scientific reporting as well as for adverse event reviews within a practice, practice group, facility, or specialty. Part B involves analysis of causality, which takes into consideration patient and procedural risk modifiers as well as adverse event preventability and management. It is designed to enable a confidential and constructive review of an adverse event within an interventional radiology practice or practice group (peer review). Applicability of Part B for scientific publication is limited, and there is none for public use (13).
4. Finally, thanks to a commitment from SIR leadership, support for the Standards Division will fundamentally shift toward the development of documents that will be helpful to the membership, impactful, and able to withstand methodologic scrutiny by payers, policymakers, and the medical community at large. Since 2007, aided in part by an Agency for Healthcare Research and Quality grant, the American Academy of Orthopaedic Surgeons has been making a concerted effort to improve the development of their CPGs and now offers consultative services to help other specialties create CPGs that meet IOM criteria. We are excited to announce that SIR is working with the American Academy of Orthopaedic Surgeons Evidence-Based Medicine Unit to develop a CPG on inferior vena cava filters. The purpose of this CPG will be to provide clinicians with evidence-based recommendations to assess the use of inferior vena cava filters in the treatment of patients with thromboembolic disease. The process began in April 2018 and is expected to be completed within 12–18 months.

Appendix A. Level of Evidence and Recommendation Classification System (11,12)

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
	Case-control studies
Systematic reviews or meta-analyses of studies limited by design and execution	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.

APPENDIX B: ADVERSE EVENT CLASSIFICATION (13)

Part A: Adverse Event (AE) Description

Descriptive narrative of adverse event (including sedation and anesthesia) and severity characterization. This part is suitable for scientific use (presentations, publications, etc) as well as for adverse event reviews within a practice, practice group, facility or specialty (13).

1. **Mild adverse event:** No therapy or nominal (non-substantial) therapy (post-procedural imaging performed and fails to show manifestation of adverse event); near miss (eg, wrong site of patient prepped, recognized and corrected prior to procedure, wrong patient information entered for procedure, etc)
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 post 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 h hospital admission that is atypical for the procedure, inpatient transfer from regular floor/telemetry to ICU or complex intervention performed requiring general anesthesia in previously non-intubated patient (generally excludes pediatrics or in circumstances where 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, loss of limb or organ
5. **Patient death or unexpected pregnancy abortion**

*The SIR Adverse Event Severity Scale is intended to approximate the surgical Clavien-Dindo scale and the NCI CTCAE scale. The SIR scale is tailored toward the procedures and adverse events encountered in IR practices. The grading of interventional oncology adverse events can selectively incorporate relevant adverse event grading definitions published in the current CTCAE for oncological 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 IR 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 non-discoverable, non-punitive, objective, consistent and clinically constructive analytic guide that may result in quality improvement measures to advance the quality of patient care in interventional radiology (13).

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, ASA 4, uncorrectable coagulopathy, poor functional status (ECOG 3 and 4), polypharmacy/polyintravenous therapy and transfusion, septicemia, hemodynamic instability, recent catastrophic event/ICU admission/major surgery or interventions) etc, OR low risk patient and technically challenging procedure (eg, TIPS with occluded portal vein, percutaneous biliary drain placement in non-dilated biliary system, etc)

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, see 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
- Intra-arterial placement of catheter meant to be intravenous or non-venous placement of IVC filter
- Ferromagnetic devices contraindicating performance of MR 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

ASA = American Society of Anesthesiologists; CTCAE = Common Terminology Criteria for Adverse Events; ECOG = Eastern Cooperative Oncology Group; ICU = intensive care unit; IVC = inferior vena cava; NCI = National Cancer Institute; TIPS = transjugular intrahepatic portosystemic shunt.

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