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EXPERT CONSENSUS DOCUMENT

SCAI/ACCF/HRS/ESC/SOLACI/APSIC Statement on the Use of Live Case Demonstrations at Cardiology Meetings

Assessments of the Past and Standards for the Future

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"Teaching in those days was chiefly by the didactic lecture in a large clinic, a method that was windy and wordy during which time the students heard much, saw little, and did nothing."

—William J. Mayo, MD

Preamble

Patient-based teaching has been used since the earliest days of medical education and continues to be used today for educating medical students, physicians, nurses, and other medical personnel. Patient demonstrations have evolved from bedside teaching, to the surgical amphitheater, to recorded medical procedures, and finally to broadcast live case demonstrations. With current telecommunication capabilities, it is possible to transmit medical procedures worldwide in real-time. Because of their perceived educational benefit and in parallel with advances in transmission technology, the use of live case demonstrations at medical meetings has grown to include adult and pediatric interventional and electrophysiology procedures. Many feel live broadcasts are an effective educational tool, especially for new technical procedures that cannot be learned by self-study or didactic presentations. However, as live case transmissions have proliferated, issues have been raised about patient safety, the ethics of live broadcasts, and their value as an educational tool. Both interventional cardiology and electrophysiology are rapidly evolving fields with changing educational needs, and many of the cases transmitted focus on newer therapies that have not been formally tested in randomized trials. The repeated demonstration of untested therapies has the potential to dilute their educational value and lead physicians into believing the therapy is advantageous in the absence of appropriately controlled clinical trials. This educational approach may not be an appropriate model for advancing patient care. Cases that feature unapproved new devices may be interpreted as more promotional than educational. Live demonstrations of endoscopy, bronchoscopy, and dental procedures are being done, but there are no published guidelines from the related professional societies (1–3). The American Association for Thoracic Surgery and the Society of Thoracic Surgery has published a statement on live broadcasts of thoracic and cardiovascular surgery (4). Broadcasts to the general public were prohibited, recorded broadcasts, either edited or unedited, were deemed preferable to live surgery broadcasts and they recommended national and international cardiothoracic societies consider prohibiting live broadcasts to large audiences at their annual meetings.

Because of the growth of live case transmissions and these concerns, the Society for Cardiovascular Angiography and

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This statement is endorsed by the Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, the Heart Rhythm Society, European Heart Society, Sociedad Latino-americana de Cardiologia Intervencionista and the Asian Pacific Society of Interventional Cardiology Foundation.

Conflict of interest: Detailed in Appendix A.

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Interventions (SCAI), the American College of Cardiology Foundation (ACCF), the Heart Rhythm Society (HRS), the European Society of Cardiology (ESC), the Sociedad Latinoamericana de Cardiología Intervencionista (SOLACI), and the Asian-Pacific Society of Interventional Cardiology (APSIC) formed this writing committee to review live case demonstrations. The writing committee included Jessica W. Berg, JD, MPH, Professor of Law and Bioethics, Case Western Reserve University, who provided counsel on legal and ethical issues. Although not officially involved, the Accreditation Council for Continuing Medical Education (ACCME) was consulted to ensure all policies and concerns of the ACCME were considered and the Food and Drug Administration (FDA) was used as a resource. Finally, to incorporate a patient perspective, the writing committee engaged Mended Hearts, Inc., a national non-profit organization that provides support to patients with heart disease and advocacy for patient related policies and legislation. In developing this document, it was appropriate to involve physicians with considerable experience in live broadcasts so that their knowledge could be included. However, their inclusion introduced possible bias and a conflict of interest, as these individuals are regarded as proponents of live case demonstrations. Therefore by intent, the writing committee also included physicians who had minimal or no past association with live case demonstrations. All writing committee members were required to disclose any real or potential relationship that could be perceived as a conflict of interest (Appendix A).

The SCAI was the convening organization for this document and thus provided the primary staff support. As the convening organization, the policies and procedures of the SCAI for document development and reporting relationships with industry (RWI) were used although each of the participating organizations followed their own internal processes for peer review. SCAI requires that all authors disclose any affiliations they consider relevant and important with any organization that to the author's knowledge has a direct interest, particularly a financial interest, in the subject matter or materials under consideration. Such affiliations include, but are not limited to, employment by an industrial concern, ownership of stock, membership on a standing advisory counsel or committee, membership on the board of directors, or being publicly associated with a company or its products. Other areas of real or perceived conflict of interest to be reported include honoraria, consulting fees, grants or funds from such corporations or individuals representing such corporations. The final version of the document was peer reviewed by individuals selected by the sponsoring organizations, but disclosure of RWI from the peer reviewers was not requested.

The History of Live Demonstration Cases

Interventional Cardiology

In response to this developing subspecialty, new educational methods were required to train the growing number of physicians seeking these skills. This educational process began much like the early days of surgery, with pioneering experts traveling to learn from others and to teach practicing physicians (5). This educational process affected Dr. Andreas Gruentzig, who performed the first percutaneous transluminal coronary angioplasty (PTCA) in 1977 (6). Gruentzig's work received rapid worldwide acclaim and he was soon inundated with training requests. The vast number of requests could not be accommodated by individual onsite tutorials. Less than 1 year after his first PTCA, Gruentzig addressed this training dilemma by conducting the first live case demonstration course in Zurich, Switzerland. Over the next 2 years, hundreds of physicians including many future leaders in interventional cardiology attended his live demonstration courses and witnessed the successes, limitations, and complications of PTCA. Gruentzig's concept was to create an "audience presence" in the catheterization laboratory, so those observing could see, hear, interact, and experience all aspects of the case as it was performed. Gruentzig developed not only a medical procedure, but he also transformed physician training by pioneering the live case demonstration that has now been embedded in interventional physician education for more than 30 years.

In the 1980s, along with the growth of PTCA, live demonstration courses became an integral part of continuing medical education (CME) for interventional cardiologists. Indirectly, the educational value of these courses was validated by the many U.S. hospitals that required attendance at such courses to obtain and maintain interventional privileges. In the 1990s, as interventional cardiology grew, so did the size of live demonstration courses. Audience response systems augmented the participants' educational experience, and moderated panel discussions during live broadcasts stimulated educational discussion. Now, interventional cardiology has broadened to include treatments for structural heart disease and peripheral vascular disease. This evolution has brought pediatric and adult interventional cardiologists closer together and has increased their collaboration with surgeons and radiologists in the cardiac catheterization laboratory, leading to "thematic" live case courses blending experts across specialties. In many ways, the growth of interventional therapeutics has been intertwined with live case physician training to disseminate evolving techniques and new procedures, for the purpose of improving operator skills and patient outcomes. For the past several years, there have been approximately 50 live case educational events per year worldwide, many of which have been sponsored by national and international organizations.

Electrophysiology

Live case demonstrations are now a component of many major electrophysiology meetings. The first live case at the annual scientific sessions of HRS occurred in 2000 for an audience of over 1,000 electrophysiologists. Since then, live cases have been a regular feature at the HRS annual scientific sessions and HRS now produces internet broad-

casts of live cases as part of their web-based educational programs. Live cases were also included in 10 different international and domestic electrophysiology meetings co-sponsored or endorsed by HRS in 2008. These cases demonstrated device implantation techniques and complex catheter-ablation procedures.

Pediatric and Adult Structural Heart Disease

The Pediatric Interventional Cardiac Symposium (PICS) in 1997 was the first large meeting where live cases were performed on children and adults with congenital heart disease. Attendance at meetings with a focus on pediatric interventions has steadily grown, as have the number and locations of these meetings.

Rationale, Benefits, and Risks of Live Cases for Educational Purposes

Ultimately, the justification for live broadcast case demonstrations should be based on answers to three critical questions.

What is the Educational Value of Live Case Demonstrations?

Education for medical professionals is offered in many formats including written materials, lectures, and patient based demonstrations. Although some aspects of interventional cardiology and electrophysiology can be acquired from reading or didactic teaching, critical aspects of procedures are difficult to learn without direct observation, explanation and ultimately, "hands-on" experience. Even for established procedures, seeing how other physicians manage clinical situations has educational value for experienced physicians and can help them gauge their performance. There are several proposed benefits of broadcast case demonstrations. First, they provide an opportunity for a large audience to observe procedures with expert commentary, thereby providing education to more individuals than could be reached by experts traveling to centers where cases are performed. However, because case demonstrations represent only one component of the entire CME process, it is difficult to quantify their added value. No specific metrics exist to assess the impact of live case courses on physician skills or patient outcomes. Thus, opinions concerning the educational value of live demonstrations are subjective and may simply reflect the biases of various stakeholder groups. There has been little research examining the educational value of live cases in interventional cardiology or electrophysiology. A single study published nearly 20 years ago examined live demonstrations of PTCA from the perspective of the operators performing the cases and those observing the cases, but those data may not be relevant today (7). Although no contemporary data have been published that assess the educational value of live case broadcasts, course evaluations received from physicians indicate that live case demonstrations are a popular component of meetings. These evaluations could be interpreted as validating their educational value, or alternatively be interpreted by critics as meaning they are more entertainment than education. Second, healthcare providers can obtain a better understanding of the indications for complex procedures, which may help them explain the details, risks, and benefits to future patients as part of informed consent. Third, allied health professionals who support physicians in the performance of these procedures can benefit by observing procedure planning and resource requirements. Fourth, viewing the technical aspects of procedures and the related discussions may help basic and clinical scientists, engineers and inventors. Unmet needs can be identified, leading to innovation in device development. Fifth, live case demonstrations of unapproved devices currently being evaluated within approved research protocols can increase awareness of the studies among investigators and potential investigators, and may aid in the recruitment of subjects. Finally, the demonstration of newly approved devices or devices under investigation provides physicians with insight into the future, thus helping to integrate new therapies with existing strategies to enhance clinical practice.

Are There Alternatives to Live Case Demonstrations?

For teaching interventional and electrophysiology procedures, pure didactic modalities cannot substitute for an actual demonstration of the procedure. Both live and edited videotaped formats can provide the educational value noted above and enhance the educational experience beyond didactic teaching.

There are several potential advantages to the videotaped case format. Time sensitive scheduling and case duration issues are more manageable, thus creating less pressure for operators and staff and reducing possible hazards created by time constraints. The videotaped case format permits interruptions, which easily allows moderator/panel discussion without changing the case flow. Ideally, a videotaped case is presented such that it mimics real world decision-making and permits interaction between the moderators and audience. Properly edited cases can focus audience attention on critical teaching elements while omitting more time-consuming or routine portions of the procedure. For example, ablations to treat ventricular tachycardia can be time consuming, but an edited videotaped format allows critical parts of the case to be viewed in a pre-specified time period, while ensuring key teaching points are not eliminated. Finally, videotaped cases reduce the burden of identifying appropriate cases for transmission on a particular date, as cases can be prerecorded and subsequently broadcast.

Conversely, there are disadvantages of edited videotaped cases as a surrogate for live case transmissions. One perceived disadvantage is that videotaped cases are necessarily "scripted" and could be edited to favor optimal case outcomes or other subjective biases. These alterations may provide an unrealistic or inaccurate perception of procedural

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Table I. Potential Concerns Related to Live Surgical Cases

- Increased infection risk associated with individuals who are unfamiliar with sterile technique and the placement of filming equipment in the procedure room
- Disruption of the operating theatre by audiovisual technicians and equipment, which may interfere with treatment
- Time delays to accommodate transmission schedules
- Hurried procedures due to transmission time constraints
- Performance of cases outside of regular working hours
- Changes in case strategies to accommodate the educational process or pre-specified case transmission schedules
- Distractions to the site operators associated with maintaining a dialogue with moderators or panelists, or as part of providing an educational experience
- Exposing visiting operators to an unfamiliar clinical environment and patient care team, without proper review of the planned case

Adapted from Sade et al. (4).

details. Inadvertently, this same problem can occur with live cases if the transmission is truncated to meet broadcast schedules. If truncation occurs, efforts should be made to return to the case or provide an update to the audience regarding the outcome and difficulties encountered. Videotaped cases do not allow real-time bi-directional communication with the operators, thus eliminating the element of observer "presence" in the procedure room and preventing exposure to spontaneous problem solving and decision making, features that are a unique and valued educational aspect of live case transmissions. However, it is unlikely the spontaneous problem solving in any one live case would address more than a few of the many complex issues that might arise during a procedure. In some educational courses, hybrid demonstrations combining a moderator and a panel of experts with both live and videotaped portions are an excellent option that has been used effectively for lengthy electrophysiology procedures and may be appropriate for some interventional procedures. Procedure simulation is also maturing as a modality to teach and evaluate procedure skills.

Whether the case is broadcast live or videotaped for later viewing, it is essential to use an experienced production team that is familiar with the necessary requirements and restrictions imposed by the medical environment. Proper preparations, high quality and reliable equipment and, in some cases, even rehearsals may be necessary to optimize transmissions and enhance the educational experience for the audience.

What Are the Risks and Benefits to Patients Participating in Live Cases?

Patient Risks

The utmost priority during any procedure, whether in routine clinical care or as part of a demonstration course, is patient safety and completion of a successful procedure. Therefore, it is critical to examine whether live case transmissions pose new or unacceptable risks to patients. Several concerns have been raised about surgical procedures that are broadcast live for demonstration (4) (Table I). Some of these concerns are more relevant to live surgical than interventional or electrophysiology case transmissions. Infection risk is increased with an open surgical field versus percutaneous procedures. Moreover, the limited field-of-view intrinsic to a surgical site often requires specialized ceiling and/or head-mounted cameras with custom lighting, whereas the signal from the imaging platforms used during interventional procedures (X-ray, ultrasound, etc.) can be captured directly from in-room monitors. Time constraints associated with surgical procedures are more problematic, as prolonged general anesthesia or cardiopulmonary bypass time may increase patient risk. Interventional and electrophysiology procedures frequently use local anesthesia and conscious sedation, allowing easier adjustment of critical times without incurring undue patient risks. However, there are other concerns unique to interventional and electrophysiology cases. For example, support personnel wishing to not disrupt the live transmission could be less apt to inform the operator of changes in vital signs during the procedure. Moreover, a possible increase in contrast agent use and x-ray exposure to satisfy the live case broadcast deserves more investigation. The interventional and electrophysiology case environments are less rigid than operating rooms and allow for easier interaction with the operators, but caution is still necessary to prevent this interaction from becoming excessive and detrimental to the procedure. The environment for a visiting operator may also be less threatening in an interventional setting, because the equipment and clinical surroundings are often more generic. Nevertheless, if communication barriers are significant and adequate case preparation is not enforced, guest operators may pose unnecessary risks. More serious risks may develop if the planned case strategy is altered without reason to satisfy the live case requirements. This might include the unplanned use of specific devices or modifications of optimal patient care practices, resulting in delays in treatment or prolongation of the procedure. If such changes occur and pose a hazard to a patient or cause an adverse outcome, a formal review of the case by the institution where the case originated should occur after the broadcast.

Data on the outcomes of live case demonstrations are limited to what is shown during the transmission and there are no reports of 30-day mortality or morbidity. Over the past 20 years, the Transcatheter Cardiovascular Therapeutics (TCT) conference has broadcast 928 live cases from 101 clinical sites, both inside and outside the United States (8). Two procedure-related deaths occurred, despite the fact that many of these cases were in high-risk patients or in patients with complex anatomy. In one case, a distal coronary guide wire perforation occurred at the end of a complex intervention on a patient receiving a glycoprotein IIb/IIIa inhibitor. Attempts to place a covered stent were unsuccessful, emergency surgery was performed and the patient died of complications following surgery. The other death occurred shortly after placement of a percutaneous aortic valve when the patient developed severe mitral regur-

gitation and profound pump failure. The mortality rate for TCT cases is 0.21% (95% CI, 0.03% to 0.88%) and this is well within acceptable standards for such procedures (9). Complications from 186 carotid stent procedures performed at three high-volume centers during 22 live educational courses between 2001 and 2008 were recently reported (10). The combined primary endpoint of death, myocardial infarction, or minor/major strokes occurred in 3.2% of patients, an incidence no different than that reported in major clinical trials (11). Because data on clinical outcomes during and after live case transmissions are scarce and no long-term follow-up data exist, the writing committee proposes a national and international registry of all live case broadcasts be established. In this way, more information on the safety and educational value of live case broadcasts could be obtained (Appendix B). Information could be collected during or shortly after the live case, or by reviewing taped or archived cases following the meeting. An alternative would be to task those responsible for quality assurance at each host institution to submit independent information on the cases performed and outcomes. In addition, the option of a pre and post-case quiz to determine how well the educational goals were met by the live demonstration should be considered. Ultimately, the institutional ethics and quality assurance committees at the facility where the case originates are the final internal monitors of the live case process and patient outcomes.

Patient Benefits

The primary purpose of case demonstrations is for education and to improve the knowledge of physicians, which should improve care and thereby help patients. Objective evidence of direct patient benefits from participation in a demonstration case does not exist. Certain features of the live case process deserve mention, but there is no evidence these features improve patient outcomes. First, patients for live cases are carefully screened and the planned treatment strategy is often reviewed and performed by the most experienced operators at the transmission site. Having the most experienced operators perform case may improve the outcome for the individual patient. However, their experience may not translate to the larger population of physicians performing this procedure and could potentially harm patients if physicians later attempt procedures beyond their capabilities. Second, more than one expert operator usually performs live case procedures, to minimize distractions and maximize the dual goals of optimal patient care and educational benefit. Third, some live cases are selected to demonstrate a new technology or technique. Providing patients who participate in the case demonstration access to these new therapies may improve their clinical outcome, but access to new therapies that might benefit a patient should not be contingent upon live case participation. Fourth, visiting operators can benefit patients by virtue of their special skills, but must be oriented to the different work environment. Patients should be informed if a guest operator will participate in their case, and they should understand the status of the guest operator (i.e., temporary hospital privileges and state licensure) and any implications related to malpractice insurance coverage. Finally, the moderator and panelists can provide their aggregate knowledge and experience to the operator, which has the potential to benefit the patient undergoing the demonstration procedure. There have been anecdotal situations where the moderator or panelists observe a nuance or use their collective experience to advise the operator about technique or device selection. The potential downside, however, is that suggestions derived from individual experiences can vary from panel to panel and result in conflicting comments that may distract the operator, thus shifting focus from the patient to the panel. Although there may be some patient-benefit related to the features cited above, it would be inappropriate to emphasize any of these in an attempt to convince a patient to participate in a live case demonstration.

Benefits to a population of patients may result from the dissemination of educational information to practicing physicians who, in turn, apply that knowledge to their own patients. This benefit is limited to the use of approved devices to which the practicing physician has access or an understanding of devices under investigation, which may require referral of a patient to another center. Improved physician training that results in better skills and judgment can benefit patient care beyond the confines of any single transmitted case. In addition to enhanced training, patient participants in live cases may experience societal rewards or altruism from assisting with the advancement of medical knowledge in the spirit of helping physicians and other patients.

Patient Rights and Informed Consent for Live Case Demonstrations

Any alteration of the physician-patient care process must be carefully scrutinized to ensure that all aspects of patient rights, preferences and confidentiality are protected. In addition to informed consent for the medical procedure, a separate informed consent for participation in the case demonstration is necessary. This document, specific to the live case broadcast, should be generated by the site and approved by the local institutional review board, ethics committee, or committee that approves consent documents (Appendix C). The patient must be informed of potential risks and benefits of the live case demonstration and informed that some of the risks are unknown and benefits, if any, unproven. Once the patient has agreed to the medical procedure, having someone other than the physician operator obtain consent for the live broadcast provides some distance and may limit the patient's feeling of obligation to participate. The additional participation of a third-party patient advocate in this consent process may be appropriate. As with other teaching procedures, patients must understand that the primary purpose of the live case demonstra-

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tion is physician education, rather than a direct therapeutic benefit for them. The informed consent process should occur in a non-pressured environment with adequate time for discussion. If a patient declines the live broadcast, no other part of their care or relationship with the physician should be affected. Patients should maintain the right to terminate their participation in the broadcast at any time up to and during the broadcast. Patient privacy regulations such as the Health Insurance Portability and Accountability Act in the United States, as well as local hospital policies, apply to these activities. Document translation into the patient's native language is required. Additional burdens relating to protection of patient rights and confidentiality apply to live case demonstrations. Presentation of the patient history must be devoid of specific patient references or identifiers, and facial anonymity should be preserved. Patients are never introduced to the viewing audience and any durable product of the case demonstration must remain unidentified.

A vital aspect of patient rights is preservation of the physician's ethical code of conduct to always act in the best interest of the patient. Good judgment and standards of ethical conduct must not become blurred by the enthusiasm or energy surrounding a live case transmission. Unfortunately, there is variability among live demonstration courses and all possible protections are not uniformly applied. Moving forward, the integrity of these educational events will depend on following a robust code of conduct, ultimately resulting in accreditation of live case broadcasts. The writing committee proposes that each course have independent live case monitors to assess adherence to the code of conduct proposed in this document, and that their assessments be reviewed as part of the overall course review. If deviations in case conduct occur, a corrective action plan should be developed. Moreover, as part of the required course assessment by the audience, specific questions should be included to assess the appropriateness of the educational goals for the case, objectivity of the operators, moderator and panelists, protection of patient rights and any conflicts of interest that may have influenced patient care irrespective of whether or not they were disclosed to the audience.

The Ethics of Broadcast Demonstrations and Conflicts of Interest

Questions about a variety of ethical issues surround live case transmissions. Several of these fall under the broad category of "commercialism." Critics have commented that live cases are simply a public spectacle rather than good physician education. Indeed, broadcasts of surgical, interventional and other medical procedures are available as webcasts and on public video sharing websites and, in some settings, appear to be for marketing purposes rather than for CME (12,13). The broadcast of medical procedures can have educational value for the public and raise awareness of important health issues. However, there should be no tolerance for overt or covert commercial involvement or nonprofessional behavior in broadcast demonstrations that distort the pure educational mission. Understandably, the broadcast format may feature charismatic physician educators and the real time aspect does create a sense of drama. Nevertheless, all individuals involved must conform to the highest standards of ethical conduct and professional demeanor. In the United States, live cases should occur within the framework of a CME meeting, thereby minimizing potential conflicts of interest and fostering a balanced presentation.

Live case broadcasts may place ethical codes of conduct in conflict with the goals of physician education and training. Even the most prepared and thoughtful operator cannot assure patients with complete certainty that there are no added risks associated with broadcast demonstrations. To fulfill the physician's ethical code of conduct, there must be a reasonable assurance that the demonstration case format itself adds minimal risk of harm to the patient. A benefit-to-harm assessment should be a requisite component of physician participation in all educational activities involving patients to maintain the highest ethical standards. Participating patients should have no expectation of direct benefit.

Conflicts of Interest and the Performance of Live Cases

A conflict of interest exists in any situation in which an individual or business is in a position to exploit a professional or official activity for personal or commercial benefit. A conflict of interest can exist even if no improper act results from it, as it can create an appearance of impropriety that can undermine confidence in the conflicted individual or organization. Over the past 10 years, there has been increasing scrutiny of relationships between physicians or institutions and industry. Many documents and codes of conduct have been developed by professional organizations, government agencies and industry to provide guidance (14–25). Potential conflicts of interest related to live case demonstrations are problematic because of the possibility that professional judgment about patient welfare could be clouded by the opportunity for economic or other personal gain during the live case demonstration. Institutions acting as the host for live cases may also be subjected to these same conflict issues. Some potential conflicts are more easily recognized than others, but all must be addressed to the extent feasible.

A conflict of interest exists if the physician has a financial interest in a product being demonstrated or other financial relationships with an industry sponsor (26). Although the physician in question may be the best individual to demonstrate the device, financial relationships must be clearly disclosed to the audience and the patient before the case demonstration. One mechanism to manage disclosure would require all potential conflicts to be reported to an independent committee that determines whether the conflict of interest should be mitigated through other safeguards. Physicians performing live case demonstrations may also gain enhanced personal prestige and possibly increased

patient referrals. Presumably, physicians chosen for live case demonstrations are selected because of their expertise and teaching skills. Live case demonstrations should not have marketing intent or be perceived as a "commercial" for a particular physician or their home institution. Although it is appropriate to acknowledge support from the host facility at the beginning of the case, elaborate introductions meant to highlight the host facility are inappropriate. Excessive branding of the host facility or a commercial sponsor by logos placed in the viewing field or branded attire is inappropriate. Any financial arrangements between the CME provider, the production company for live cases, the operating physicians, and the host institution must be clearly disclosed. The present practice of briefing showing a slide listing conflicts at the start of a presentation is inadequate for a full understanding of the audience. There are legitimate additional expenses incurred by facilities that support live cases, and reimbursement for these expenses is appropriate; however physicians and institutions should not profit financially from their participation in live cases. The production and transmission of live demonstration cases is expensive and may not be supported by attendee registration fees alone. Accordingly, the cost of many professional medical meetings is heavily underwritten by industry funding through indirect educational grants (20,23). Pharmaceutical and medical device companies develop new therapies that benefit millions of patients, but it must be recognized that these companies have a responsibility to their stockholders who expect positive financial returns on their investments. The relationship between live case transmissions and industry funding of educational symposia can pose a conflict of interest. Device and drug manufacturers can potentially benefit from the mention of their products during live case demonstrations. However, it is contrary to ACCME regulations for the organizers of a meeting to accept money from industry earmarked for any particular activity within the meeting (17). ACCME standards for commercial support require that any contributions from industry be given in an unrestricted manner to the organization sponsoring a meeting, and that a separate program committee determines the scientific content and format of the meeting (17,20,22). A program committee should have the sole authority to select the program topics, speakers, demonstration cases, as well as case operators, moderators and panelists, and the committee should be blinded to the industry sponsors and the amount provided. If possible, the program should be finalized by the organizing committee in advance of requests for commercial support, to avoid even the potential for conflict. To the extent possible, those involved with live cases should mention products in a generic fashion (e.g., a coronary guidewire, angioplasty balloon or ablation catheter) without the brand name assigned by a manufacturer. Statements by physicians indicating that this product is their favorite for a particular purpose must be avoided, because such statements can be interpreted as a product endorsement. Likewise, panel members and the moderator of the live case demonstration should refrain from asking questions that require the identification of specific brand name products. However, in certain situations only one specific product made by one company will work, whereas other products in the same general class are unsuitable. For physician education, mention of the vendor and brand name of this unique product is appropriate with an explanation of why use of this specific product is necessary. Efforts to identify companies and products by camera angles clearly intended to show names or logos are inappropriate. There is no obvious reason for representatives of a company to have involvement in a live case demonstration. Before performing a live case demonstration, the operators should have enough experience with the equipment used that additional technical support from company representatives is unnecessary. Understanding the desire to have everything go well during the transmission, it is understandable to have technical support personnel on standby to assist if an equipment malfunction occurs, but they should have no active role in the procedure.

One of the most challenging issues is when a new product is being developed and showcased in a live case being transmitted in the United States, to create interest before FDA approval and general commercial release. Consultation with the FDA is required to ensure that appropriate controls are in place. After making a substantial investment in the development of a product, companies are interested in creating an immediate demand for it. In this circumstance, the desire to provide funding for a live case demonstration featuring their product is understandable. However, such targeted funding is specifically prohibited by the ACCME (17). Finally, multiple stakeholders can have conflicts of interest rooted in the desire to have a meeting be financially successful. Success requires good attendance, which may be inversely related to the amount of the registration fee and directly associated with funding from industry. Featured promotion of live cases in mailings and electronic media about the meeting content has inherent marketing intent to increase meeting attendance, which in turn benefits the meeting organizers and industry sponsors.

Special Considerations and Device Use in Live Case Demonstrations

Procedure, Patient, and Operator Selection

Appropriate case selection for a live transmission is crucial for the educational value of the broadcast and for preserving patient safety. Two trends should be noted in live interventional cases. First, there has been an emphasis on showing start-to-finish live cases to mimic the real-world situation rather than selected portions. For long procedures, this can be accomplished with a combination of videotaped and live portions, taking care that key steps are not excluded. There may be an occasional role for shortened live case vignettes, but only when the educational objective is designed to

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Table II. Goals for Case and Patient Selection for Live Demonstrations

- The rationale and indications for the procedure should be identified and explained to the audience before starting the case. These should fit within established guidelines or appropriate use criteria.
- The case strategy should be reviewed in advance of the broadcast and reflect the consensus of all available experts. Ideally, the case strategy should also be reviewed in advance with the case moderators, so that teaching objectives are understood.
- The case should have well-defined teaching objectives that have a high likelihood of being completed in the allotted time.
- Cases should be of medium to high complexity such that the educational lessons appeal to a broad audience with varying degrees of experience.
- Very high-risk scenarios should be avoided, as there is a greater chance of complications that may require the operators undistracted attention.
- The demonstration of new devices or evolving treatment strategies may be appropriate, but these procedures should be performed only by operators with the greatest amount of experience with the new device.
- Avoid non-standard techniques just for the sake of demonstrating a new device or treatment strategy. Avoid undue emphasis on performing cases simply to highlight a new device.
- Avoid sensational or "oddity" cases which will have little educational value to the practicing physician.

demonstrate an isolated technique and not the complete case. Second, many courses or segments within courses now feature specific themes developed around procedure types, patient characteristics or devices. Clustering content thematically helps case operator and discussant selection, and can focus the educational experience for the audience. Other aspects of live case and patient selection are shown in Table II.

The ideal characteristics for live case operators include technical expertise, an ability to educate, and calmness under stress. An operator may not possess all of these attributes, thus it has become common to enlist operator teams to meet these characteristics. This approach emphasizes the division of activities, such that one operator can focus on the procedure, while another operator responds to dialogue from the moderator and discussants. This approach is important to prevent procedure times from becoming longer than those expected in a similar case under routine clinical circumstances. Operators should not be placed in situations where case complexity or required tasks are unfamiliar, regardless of the moderator or discussant recommendations.

Specific Case and Device Situations

The live case environment mandates strict adherence to many requirements. FDA-approved devices are permitted for live case transmissions, but so-called off label use of these devices requires further clarification. Many devices in standard clinical practice are used beyond the confines of labeled indications. As live case demonstrations should be relevant to daily practice, off-label device use may be acceptable, but live case presentations should not be viewed as a forum to encourage off-label use. Promotion of off-label use can be a disincentive for industry and investigators to complete the clinical studies needed to demonstrate a device's safety and effectiveness for FDA approval. Off-label device use during live cases should be identified for the audience and be confined to uses that are usually considered reasonable standard practice.

Medical devices that have not been approved by the FDA and are under clinical investigation cannot be used during live case transmissions broadcast from the United States unless approved more than 30 days in advance by the FDA. Currently, approval is on a case-by-case basis, through a formal process for each unapproved device and educational event. In some situations, the FDA has agreed that live case exposure of a device undergoing clinical investigation might stimulate improved trial enrollment. In contrast, the FDA has also declined to approve some requests, citing the severity of the patient's illness, device complexity, the potential for increased patient risk, nearly complete clinical trial enrollment, or inadequate time to review the submitted documentation. Approval has been a difficult issue for cases transmitted from abroad, as there are different regulatory bodies in the host country and the FDA has no direct jurisdiction. However, regulatory requirements do exist in many countries, some of which are relevant to case demonstrations (27).

Special Considerations for Pediatric and Adult Congenital Heart Disease Cases

As there are only a few devices approved by the FDA for use in patients with congenital heart disease, the majority of devices and catheters used for these interventions, whether in daily practice or for live demonstration, are used "off-label" (28). No stents are currently approved for management of branch pulmonary artery stenosis or coarctation of the aorta and no balloon catheter has been approved for angioplasty in children. Furthermore, electrophysiologists lack certain approved cardiovascular devices to treat heart rhythm disorders in pediatric patients. The paucity of approved devices for congenital heart disease treatment and restrictions on the demonstration of devices under evaluation is a dilemma for those wishing to educate physicians treating these patients.

Because of smaller patient size and the complexity of their anatomy, performing interventions in pediatric patients requires additional skills and live case demonstrations should only be done by physicians with considerable experience. Interventions in educational courses should be done with the goal of educating practicing interventional pediatric cardiologists about the management of common cases rather than rare and complex interventions that they may not encounter during their practice. Furthermore, infants and small children are at increased risk of hypothermia, blood loss, radiation exposure and complications due to the intervention. Anesthesia support is recommended, especially in the very young. Delays in the performance of the case must be avoided to prevent heat loss, prolonged anesthesia use and other complications. Demonstration cases should be selected based on their educational value, avoiding very complex, rare, or time-consuming cases.

Occasionally, a hybrid approach with collaboration between a surgeon and the interventionalist or electrophysiologist may be the best option. Cases benefiting from this approach should be done in a hybrid laboratory that meets all requirements of an operating room. However, the hybrid environment mandates increased awareness of all of the concerns expressed about live surgical case demonstrations (4) (Table I). Using two experienced operators is essential, with one focused only on patient care. As many cases are unique and there are few standard approaches, a dialogue between the operators, moderator, and panelists is especially helpful, but is subject to the same concerns as noted for adult cases. Because of the unique concerns regarding the pediatric age group, live case demonstrations of high-risk procedures will rarely be justified.

During the discussion with the family and child about the conduct of the live case, it is important to explain the environment of the live case, potential hazards, and complications. The consent form should outline all potential risks of performing the procedure as a live demonstration. For very young children, permission is obtained from the parents. Verbal assent of children in addition to written permission of the parents is required as the child gains capacity, and full written consent may be appropriate from children closer to the age of maturity. Children who have the capacity to assent have the right to refuse filming of the procedure or refuse to participate in any type of demonstration case.

Managing Live Case Complications

Complications may develop that must be managed immediately. The opportunity to observe the real-time decision process after adverse events provides a powerful learning experience. However, these are the very circumstances where patient safety is most jeopardized and rapid reaction is critical to the outcome. Several common sense rules apply when a complication occurs during a live broadcast, and there should be a clear "chain-of-command" within the procedure team, production team and the moderator that is established before the case. First and foremost, proper management of complications takes priority over all educational objectives, and no aspect of the live case process should interfere with clinical care. Minor complications can be managed during a continuous broadcast, as long as the operators are comfortable that the necessary steps can be taken and the moderator/panelist discussion is nonintrusive. For such complications, the judgment of case operators and management suggestions from the moderator or panelists can enhance the educational experience. However, at the first sign of clinical instability, it is best to manage a life-threatening complication "off camera" without the stress of live case conditions and audience observation. The decision to terminate a live case transmission should come from the operator with collaboration from the moderator, but the operator's decision is always final. Occasionally, interruption of the case can be temporary and it may be continued later, once clinical stability is reestablished. Whether the case remains "live," identifying what went wrong, how to avoid a similar complication and discussing how to manage a complication is valuable education for the audience. In the event of an important complication, a formal case review should be initiated by the host institution following the procedure.

Moderator-Driven Panel Discussions

During the evolution of live courses, there has been a transition from "operator-driven" to "moderator-driven" discussions. Initially, the most experienced physicians were the operators themselves, and the bulk of teaching dialogue was unidirectional from the operator to the audience. This approach placed the burden of both technical and educational content on the operator. Over time, emphasis has shifted to the selection of an experienced moderator and a multidisciplinary panel of discussants, thus producing a bidirectional dialogue. As such, operators focus more on the technical aspects of the case while the moderator/panelists facilitate educational discussions. The effectiveness of live case teaching can be diminished by excessive discussions, which can delay or interrupt optimal case flow. The ideal moderator-driven live case presentation will have a comfortable cadence, with the moderator directing questions and comments to the site operators and modulating discussion such that case flow is maintained and patient safety is preserved. The moderator must also assess presentation bias and conflicts of interest, protect patient confidentiality, and engage the expert panelists to be certain that different points of view are expressed. Panelists should not disrupt the case flow established by the moderator, should not speak simultaneously, and should await recognition by the moderator before interrupting the case flow. Finally, the moderator should reinforce the primary role of the case operators in determining case strategy, only interceding if key decision points have educational value. This more active and vital role of the case moderator is essential to enhancing the educational value of live case transmissions, while also relieving excessive burden on the case operators. The moderator and panelists should receive and acknowledge written instructions regarding their roles and conduct during a live case.

Controls for the Internet Broadcast of Case Demonstrations

With improved internet broadband technologies, there has been a proliferation of internet-based offerings utilizing live cases. There are several potential advantages of such internet-based courses. Specifically, internet-based live cases allow a larger and more international audience to participate. With the elimination of attendee travel costs, this approach may be a more cost effective way to educate physicians. By archiving the content, physicians are able to view the live case and panel discussion at more convenient times. Given the openness of the web, internet broadcasts

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Table III. Code of Conduct for Live Case Demonstrations

Patient Safety

1. Patient safety and completing a successful procedure are the highest priorities.
2. Performing the case as a "live or taped case demonstration" must not pose a meaningful additional risk to the patient.
3. Cases should be performed with a primary operator focused on the procedure and the patient, and a secondary operator to assist and interact with the case moderator.
4. A pre-planned strategy for the case should be used and not altered except for clinical necessities.
5. Patients should be carefully screened before participation in live case demonstrations.
6. The planned treatment strategy should be reviewed and supervised by the most experienced operators at the transmission site.
7. Visiting operators should be properly oriented to the laboratory before performing any live demonstration cases, and should work with an operator familiar with the daily operation of the laboratory. Patients should be informed if a guest operator will participate in their case. The host institution should review the status of the guest operator (i.e., temporary hospital privileges and state licensure) and any implications related to malpractice insurance coverage.
8. Serious complications should be managed "off-camera" so the operator's only focus is patient care.
9. Because of the unique concerns in the pediatric age group, live case demonstrations of high-risk procedures are rarely justified.

Patient Privacy

1. Patients should not be identified and care is necessary to ensure their name is not inadvertently disclosed on display monitors. This confidentiality is especially important in the pediatric age group, as children may be especially sensitive to potential embarrassment.
2. Within the U.S., HIPAA regulations should always be enforced, but there are also privacy and confidentiality protections outside of HIPAA that must be addressed.

Informed Consent

1. The operating physician or a physician familiar with the procedure must inform the patient of potential risks and possible benefits of the medical procedure that will be performed. Separately, the risks and benefits of participation in a live case demonstration should be discussed, emphasizing that the live broadcast is for educational purposes and is not designed to provide direct benefit to the patient. Furthermore, the patient should be informed that the possible risks from participation in a live broadcast demonstration have not been studied and some may be unknown and the benefits, if any, are unknown.
2. Once the patient has agreed to the medical procedure, having someone other than the physician operator obtain consent for the live broadcast provides some distance and may limit the patient's feeling of obligation to participate. The additional participation of a third party patient advocate in the consent process may also be appropriate.
3. The patient must sign the standard informed consent document for the procedure and a specific site-generated informed consent document that explains the potential risks/benefits of the live case format. These two consent processes should be done separately.
4. Patients should understand that the purpose of the live case demonstration is educational and is not designed to provide a direct therapeutic benefit. Any benefit they receive would be incidental.
5. The informed consent process should occur in a non-pressured environment with adequate time for explanation and discussion. While the supervising physician should provide an explanation of the risks and benefit, a neutral third party may obtain the actual consent so the patient feels less obligated to participate.
6. Patients may withdraw from live case participation at any time without penalty.
7. If a new device or therapy under investigation as part of an approved research protocol is used in a live case, the patient should understand that their ability to receive the new therapy is not dependent on their participation in the live case.

Conflict of Interest

1. Educational meetings should have a conflict of interest oversight committee composed of individuals with no relationship to the meeting organizers, participants or sponsors. All financial relationships between physicians participating in live case presentations and industry must be clearly disclosed to this committee. Any conflict of interest must be clearly disclosed to the audience and the patient involved in the procedure.
2. Live case demonstrations should not be used as marketing or commercial opportunities for either the physician or the host institution.
3. Excessive branding by the host facility or a commercial sponsor, for example via banners placed in the viewing field or branded attire worn by the physicians and assistants is not permitted.
4. Financial arrangements between the CME provider, the physicians involved and the hosting institution should be fully disclosed to the conflict of interest committee.
5. Physicians performing live cases should mention products only in a generic fashion if possible, unless clinically relevant.
6. Panel members and the moderator of the live case demonstration should refrain from asking questions that require the identification of specific products.

Regulatory Considerations

1. Within the U.S., if a non-FDA approved device, drug or therapeutic strategy is utilized for the case, specific approval from the FDA is required in advance.
2. Common off-label device use during live cases should be disclosed and noted for the audience; unconventional off label use should be discouraged during live case teaching activities.

Educational Imperatives

1. The specific educational goals of the case should always be noted for the audience before starting.
2. Whenever possible, cases used for demonstration purposes should be based on indications that match guidelines or appropriate use criteria recommendations, which should be identified for the audience. Since guidelines and appropriate use criteria are not all-inclusive, cases performed outside of these recommendations should also be identified.
3. At the conclusion of each case, the case moderator should provide a declaration of the educational messages to the audience.
4. Attendees of live case demonstrations should submit an assessment of the experience that is designed to determine the educational value of the live case demonstrations.

CME indicates continuing medical education; FDA, Food and Drug Administration; and HIPAA, Health Insurance Portability and Accountability Act of 1996.

may allow physicians to see new technologies that may not yet be available in their country. Lastly, internet-based courses may enhance interaction among meeting participants by means of real-time electronic communication, including the possibility that attendees may be able to interact with other attendees in a real-time learning atmosphere. In addition to all of the recommendations for live cases discussed in this document, internet broadcasts have a

unique challenge related to content access. Given the possibilities for the promotion of new devices or procedures to patients that may be taken out of proper context, and without the background understanding of a true risk versus benefit analysis, it is recommended that internet-based broadcasts be restricted to healthcare providers and be performed in the setting of a CME course. Furthermore, the use of a device under investigation could be interpreted as commercial promotion of an unapproved product, which is not permitted under the Code of Federal Regulations, Title 21 CFR 812.7 (29). Internet broadcasts involving live cases should not be used for promotion of a medical device or drug, institution, or individual physician and external links to industry websites should not appear.

International Considerations

The practice of medicine and the delivery of healthcare vary widely around the world. Regulatory processes and privacy protections like those in the United States are different in many countries but do exist (27). There is less concern about the performance of live case demonstrations in some countries and special consents may not be consistently used for live case demonstrations. Therefore, complete adoption of the principles set forth in this statement in all countries may be challenging, but should be considered to improve live case demonstration broadcasts.

Code of Conduct for Live Case Demonstrations

Based on the considerations in this document, a general code of conduct for live case demonstrations is T3 presented in Table III. Further recommendations of the writing committee are to establish an ongoing registry of live cases to collect objective information for the purpose of better understanding their educational value, assessing both acute and long-term patient outcomes, monitoring operator and course behavior, and reviewing feedback from the audience participants.

Conclusions

Live case demonstrations have evolved over the past 30 years and have become an integral and accepted part of education for the practicing physician specializing in interventional cardiology and electrophysiology. However, data examining the educational value and patient risks of this teaching method are sparse. Along with the proliferation of courses and the ability to broadcast such activities worldwide, concerns have been raised about the appropriateness of live case demonstrations, particularly regarding patient safety, conflicts of interest, and the ethics of these events. After evaluating the pros and cons of live case demonstrations and the available data, the writing committee cannot determine if the educational benefits of live case demonstrations outweigh any potential negative consequences. It is not the intent of this statement to endorse or proscribe live case demonstrations. Rather, it is the hope of this writing committee that the principles set forth in this statement will provide guidance to those engaged in this activity, will help to ensure patient safety and privacy, and will lead to the highest educational value possible. Professional organizations should consider adopting these recommendations for live case demonstrations performed as part of meetings they promote.

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APPENDIX A. CONFLICTS OF INTEREST FOR MEMBERS OF THE WRITING COMMITTEE

Writing Committee Member	Participation in Organization of a Course With Live Case Broadcasts Within the Past Year	Received Compensation in an Amount >$10,000 From Involvement in a Live Case Broadcast	Research Grant	Speakers Bureau/ Honoraria >$10,000 Per Year	Stock Ownership	Board of Directors	Consultant or Advisory Board Member
Alexander Abizaid, MD, PhD	Yes	No	No	No	No	No	• Abbott • Boston Scientific • Cordis
Jessica W. Berg, JD, MPH	No	No	No	No	No	No	No
John Day, MD	Yes	No	No	No	No	No	• Boston Scientific Corp. • Irvine Biomedical Inc. • St. Jude Medical • St Jude Medical Corp.
Gregory J. Dehmer, MD	No	No	No	No	No	No	No
John S. Douglas, Jr., MD	Yes	No	• Abbott • Boston Scientific • Johnson & Johnson • Medtronic • The Medicines Co.	No	No	No	No
Roger Hall, MD	No	No	• Cordis • Eli Lilly	No	No	No	• Astra Zeneca
Martin B. Leon, MD†	Yes	No	No	No	No	Yes†	• Abbott Vascular Angioscore • Boston Scientific • Medtronic
Ziyad M. Hijazi, MD*	Yes	No	No	No	Yes	No	• Coherex Medical (non-paid) • Jena Inc. • NuMED Inc. • Sadra Medical (non-paid)
Frank Marchlinski, MD	Yes	No	No	No	No	No	No

Writing Committee Member	Participation in Organization of a Course With Live Case Broadcasts Within the Past Year	Received Compensation in an Amount >$10,000 From Involvement in a Live Case Broadcast	Research Grant	Speakers Bureau/ Honoraria >$10,000 Per Year	Stock Ownership	Board of Directors	Consultant or Advisory Board Member
Seung-Jung Park, MD	Yes	No	• Abbott Vascular • Cordis • Medtronic	No	No	No	No
Jeffrey J. Popma, MD	No	No	• Abbott • Abiomed • Boston Scientific • Cordis • Medtronic	No	No	No	• Abbott • Boston Scientific • Cordis

*Dr. Ziyad Hijazi reports that he is the course director of PICS and president of the PICS Foundation; a non profit organization and he receives no monetary compensation for these roles. †Dr. Martin Leon reports he is Founder and Chairman Emeritus of the Cardiovascular Research Foundation an independent, 501(c)3 nonprofit organization. He also reports he is Founder and Director of the Transcatheter Cardiovascular Therapeutics (TCT) meeting.

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APPENDIX B. PROPOSED BASIC STRUCTURE AND ROUGH OUTLINE OF DATA ELEMENTS FOR A LIVE CASE REGISTRY

Structure

1. Courses with live case broadcasts would be required to register the cases presented with a central registry.
2. Funding for this registry would come from a modest fee paid by each course on a per case basis.
3. In the U.S., participation in this registry would be a requirement for course approval by the ACCME.

Data Elements

1. Educational goals of the case
   a. Rationale for this case
      i. Features new device
      ii. Features new treatment strategy
      iii. Anatomic theme (e.g., SVG treatment, bifurcation lesion)
      iv. Clinical theme (e.g., diabetics, elderly)
   b. Other
2. Case demographic data
   a. Site of case performance
   b. Case operators
   c. Moderator
   d. Panelists
3. In-hospital outcome
   a. Mortality (Y/N)?
   b. Complications (list specific)
   c. One-month or longer follow-up
4. Audience assessment
   a. Any compromise in patient privacy observed (Y/N)?
      i. Specify
   b. Any compromise in patient safety (Y/N)?
      i. Specify
   c. Any conflict of interest observed (Y/N)?
   d. Any inappropriate product branding or commercialism noted (Y/N)?
   e. Did the operator(s) or discussants appropriately indicate that the devices used were:
      1) investigational or approved; and
      2) if approved whether device use was on or off-label?
   f. Was this case useful in improving your knowledge/skills (Y/N)?
   g. Was the behavior of the operator(s) appropriate and objective (Y/N)?
   h. Was the behavior of the moderator appropriate (Y/N)?
   i. Was the behavior of the panelists appropriate (Y/N)?
5. Patient participant survey (completed following the live case)
   a. Was the information provided as part of the informed consent to the live broadcast accurate (Y/N)?
   b. Is there any other information you would have liked to be told about the live broadcast before participation? (Y/N)? If yes, describe
   c. Do you feel you received good care during the procedure (Y/N)?
   d. Are you satisfied with your experience as a live case patient (Y/N)?
   e. Would you do a live case again or advise a friend to do so (Y/N)?
   f. Did you suffer any complications (Y/N)?

APPENDIX C. SAMPLE INFORMED CONSENT DOCUMENT FOR LIVE CASE PARTICIPATION

The informed consent form for a live case demonstration should delineate the potential risks associated with the live case, such as longer procedure times, starting delays due to transmission requirements and the potential for operator distraction. The document should include a statement that the live case is not designed to provide the patient with a direct therapeutic benefit but rather may provide educational benefit to physicians and subsequently to the patients they treat. Disclosure of the estimated size and composition of the audience and any conflicts of interest of the physicians or facilities involved should be included.

Sample Consent Form for Live Case Demonstrations

Consent for Live Video Transmission of Procedure

Participation Duration: approximately _____ hours

Purpose:

You are being asked to allow you or your child's _____ [insert name of procedure here] to be either videotaped and/or shown in a live, real-time format to attendees in a medical education course. The name of this course is _____. The estimated number of individuals viewing your procedure will be _____ and the audience will be composed of physicians, other allied health professionals (nurses, technologists, etc.) and other individuals who may be in the medical device or drug industry. This meeting is not open to the public and your procedure will not be shown to the general public.

If you sign your name below, you agree to have your or your child's medical procedure filmed and/or be shown live for this purpose. In addition, it is possible that portions of your or your child's procedure or the entire procedure will be shown later to medical professionals who could not attend the conference. In addition to the filming, your or your child's medical history will be reviewed with the conference attendees so they understand why the procedure is being performed.

We will make every effort to not film or show your or your child's face or disclose your or your child's name in any way during the procedure. Should your or your child's face or other identifying data be inadvertently included in the live presentation, the subsequent video will be edited to remove such frames.

It is important that you or your child understand that you/he or she are not required to agree to this filming and there are no penalties for refusal to participate. By agreeing to be filmed, you or your child permit your physicians the limited right to only use the videotape of your procedure for educational and training purposes and to improve the quality of healthcare.*

*If a registry is developed, a separate consent form may be required and should provide relevant information as appropriate.

Risks:

In addition to the risks identified in the procedure consent form, additional risks of the filming may include:

- Prolonged procedure time
- Additional personnel present in the room where your procedure is performed
- Possible loss of privacy if identifying information is inadvertently disclosed
- Possible unknown risks, such as the distraction of the physician performing the procedure

Potential Benefits:

The primary benefit of the filming is for physician training and education. The filming is not designed to provide you or your child with any direct therapeutic benefit.

Right to Withdraw:

You or your child may withdraw the consent at any time by notifying your physician. Your or your child's care will not be affected in any way if you or he/she withdraw consent for the filming or decline to participate.

Questions:

If you or your child have any questions please contact your physician. [Insert specific contact information here:]

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Consent:

I hereby consent to have my procedure filmed and/or shown live, and to be used in the future for the training or education of physicians.

Name of Subject	Signature	Date & Time
Signature of Individual Obtaining Consent		Date & Time
Signature of Witness		Date & Time
Parent, Guardian or Legal Representative Signature		Date & Time