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REVIEW

Ethics in Interventional Radiology: A Case-Based Primer

Sara Silberstein[1] · Michelle M. Shnayder-Adams[2] · Eric J. Keller[3] · Mina S. Makary[4]

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Abstract As the field of interventional radiology assumes a larger role in patient care, the specialty has a growing responsibility to recognize and understand ethical dilemmas within the field. We present a case-based primer on common ethical issues in IR, including requests for potentially inappropriate procedures, surrogate decision making, informed consent, and managing conflicts of interest and procedural complications. This primer is intended to be used as a guide for discussion-based training in ethics in IR while inspiring further research in applied ethics in IR.

Keywords Ethics · Futility · Informed consent · Conflict of interest · Complications · Interventional radiology

Introduction

As interventional radiologists (IRs) have adopted a more "clinical" identity," they have assumed more responsibility in patient management. With this evolving role, IRs have an even greater obligation to understand the ethical challenges specific to their specialty [1]. Although medical schools have incorporated ethics into their curricula, there is little consensus regarding educational content and objectives [2]. Furthermore, medical ethics education tends to treat clinicians as a monocultural group. Though some ethical issues are common across specialties, each specialty has a distinct culture with unique ethical challenges and varying navigation strategies [3, 4]. This ethics primer serves as a practical approach to applied ethics in IR by introducing a common language with which to discuss ethical issues (Table 1) and by presenting four representative ethical cases. With each case, we offer ethical considerations, potential courses of action, and questions for future discussion.

Requests for Potentially Inappropriate Procedures

A 78-year-old male with history of alcohol cirrhosis presents for evaluation of a 20.5 cm hepatocellular carcinoma with satellite lesions and bone metastases after an ablation. The patient is experiencing significant pain. He is referred to IR for radioembolization treatment.

Ethical Considerations:

IRs often receive consults for procedures that seem to have little to no chance of achieving meaningful benefit. Navigating these requests can be challenging due to limited abilities to definitively prognosticate, practice politics and

✉ Sara Silberstein
silbers@amc.edu

[1] Albany Medical College, 75 New Scotland Avenue, Albany, NY 12208, USA

[2] Division of Vascular and Interventional Radiology, Department of Radiology, University of Michigan Hospital, Ann Arbor, MI, USA

[3] Division of Vascular and Interventional Radiology, Department of Radiology, Stanford University School of Medicine, Stanford, CA, USA

[4] Division of Vascular and Interventional Radiology, Department of Radiology, The Ohio State University Wexner Medical Center, Columbus, OH, USA

Table 1 Key ethics terminology for the interventional radiologist

Key ethics term	Definition
Advance directive	A written document stating a patient's personal health care preferences. An advance directive is different than a living will, which is sometimes contained within an advance directive
Best interest standard	An acceptable standard with which to make decisions on behalf of a patient; when patient preferences are not know, this standard allows surrogates to act in the best interests of the patient based on the information available
Coercion	An external force that prompts the patient to make a decision that they would not otherwise have made in the absence of that influence
Competency	A legal determination made by a court declaring an individual's global capacity to make decisions for themselves without the need for a legal guardian
Conflict of interest	The perception that an individual has competing interests that may bias one's actions, regardless of the individual's intentions and/or actual behaviors
Decision-making capacity	A patient's cognitive and emotional capacity to make a given medical decision at a particular time for a particular reason. It is requisite for informed consent, but it is not a legal determination
Default surrogate	The individual to whom the responsibilities of becoming a surrogate decision maker fall when a patient lacks capacity and when there is no pre-appointed medical power of attorney, based on regional laws
Disclosure	The sharing of information such as professional and personal associations or potential conflicts of interest that may impact an audience's interpretation of information and how it is presented
Goals of care	The communicated goals, preferably reached through a shared decision-making process between patient/surrogate decision maker and treating physician(s)
Medical futility	Medical care that does not further the goals of care
Medical power of attorney	A legally appointed health care proxy documented in writing
Moral distress	The emotional state that arises when one knows and/or desires to act in accordance with a particular moral or ethical code, but situational constraints prevent them from doing so
Potentially inappropriate procedure	A description of medical interventions that may accomplish the patient's goals of care, but which the clinician believes should not be performed due to sufficient competing ethical considerations
Reasonable patient standard	An ethical concept acknowledging the objectivity and variability inherent in disclosures of informed consent discussions; it suggests providers should, at a minimum, share with patients what a reasonable lay person would want to know
Substituted judgment	Making decisions on behalf of a patient based on what the patient would desire
Shared decision making	The collaboration between patient/surrogate decision maker and provider in which the provider shares pertinent information about the patient's medical indications, treatment options, risks, benefits, and alternatives in a manner appropriately tailored to the patient/surrogate's health literacy level, preferences, and needs to help them make an informed decision aligned with their personal goals of care and preferences
Surrogate decision making	Making medical decisions on behalf of a patient lacking capacity
Therapeutic non-disclosure	Withholding information from a patient to protect them from the adverse effects of knowing that information

referral networks, and the diversity of patients' and families' values, cultural preferences, and perceptions of benefits and risks (Fig. 1). Figure 1 shows factors related to the interventional radiologist, the patient, the procedure, and the cultural environment, which all contribute to IRs' perceptions of futility and whether they perform a potentially inappropriate procedure.[1]

Truly futile interventions, those that unequivocally do not further goals of care, are widely considered unethical and should not be performed [5]. However, many requests are not unequivocally futile, which is why multi-society position statements have advocated for use of the term potentially inappropriate procedures to acknowledge the tentative and value-laden nature of these assessments. This refers to "treatments that have at least some chance of accomplishing the effect sought by the patient, but [which] clinicians believe that competing ethical considerations justify not providing them" [5, 6].

Understanding whether a request is potentially inappropriate or futile relies heavily on understanding the goals of care, the communicated goals between patient/surrogate decision maker and treating physician(s). For example, radioembolization in the example case is unequivocally not going to be curative in a patient with extra-hepatic metastatic disease, but it could shrink the dominant mass and potentially decrease pain.

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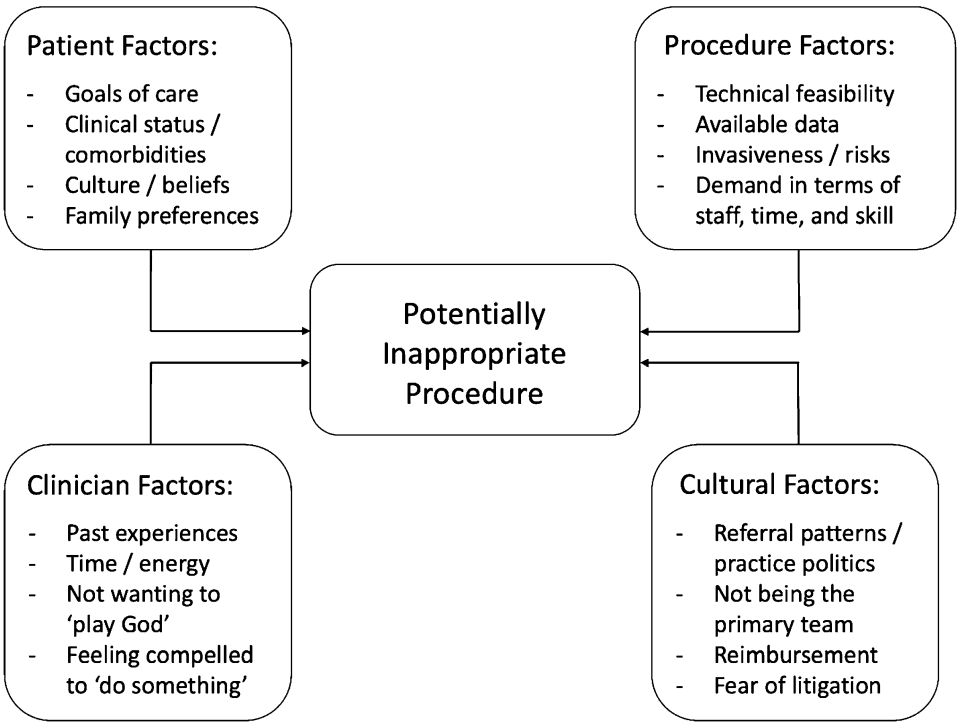

Fig. 1 Factors impacting whether a potentially inappropriate procedure is performed. Reprinted by permission from Springer Nature: Springer Nature CardioVascular and Interventional Radiology "Perceptions of Futility in Interventional Radiology: A Multipractice Systematic Qualitative Analysis," Keller, E.J., Rabei, R., Heller, M., et al., Copyright 2020

Courses of Action:

1. *Talk to the requesting clinician/team to clarify goals of care and consider a multidisciplinary discussion with the patient/family*. Interviews with referring clinicians suggest they prefer that IRs first ascertain from them whether they have already clarified goals of care with the patient/family. If not, the IR should suggest such a conversation prior to proceeding and offer to participate in a multidisciplinary discussion with the primary team and patient/family [7].
2. *If disagreement persists, consider third-party mediation and consult your institution's policy on refusal to treat if available*. Palliative care or ethics committee consultants are examples of potential mediators, though availability of such resources will differ across institutions and regions. Hospital tumor boards provide important platforms for multidisciplinary collaboration in oncology cases. Multi-society position statements also provide a stepwise approach for situations in which clinicians and patients/families disagree. Increasingly, institutions have policies in place for these situations [8].[2]
3. *Be wary of the adverse effects of providing care perceived as futile*. Providing care perceived as futile has been independently linked to moral distress and burnout [10].

Questions to Consider:

1. What would be a feasible workflow to enable documented goals of care discussions to occur prior to potentially inappropriate IR procedures? What should IR's role be in these discussions?
2. Can you recall a scenario in which you have been asked to perform a potentially inappropriate procedure? How did you respond?

Surrogate Decision Making

An 84-year-old female with Alzheimer's dementia and multiple admissions for anorexia and failure to thrive is referred for gastrostomy tube placement. According to her family, she "has good days and bad days." When you meet her, she says she does not want any type of feeding tube. Her living will from ten years ago stipulates she will have no invasive procedures. Her daughter is her medical power

[2] The Society of Critical Care Medicine (SCCM) Ethics Committee established a framework for approaching potentially inappropriate interventions in the critical care setting. The committee recommends the following approach to manage such cases, which may provide some helpful guidance: (1) enlisting expert consultation to continue negotiation during the dispute-resolution process; (2) giving notice of the process to surrogates; (3) obtaining a second medical opinion; (4) obtaining review by an interdisciplinary hospital committee; (5) offering surrogates the opportunity to transfer the patient to an alternate institution; (6) informing surrogates of the opportunity to pursue extramural appeal; and (7) implementing the decision of the resolution process [9].

of attorney (POA) and says her mother is confused and the procedure needs to be done.

Ethical Considerations:

In the American healthcare landscape, ethically and legally, patients have a right to determine what happens to them, and if they cannot or do not want to make the decision, someone can do so on their behalf (surrogate decision making) [11, 12]. Notably, this does NOT apply if the patient is competent, has capacity, and wants to make the decision. Competency is a global legal status in that someone is either legally competent to make healthcare decisions or they have been found to be incompetent by a court and appointed a legal guardian to make decisions on their behalf [13]. Conversely, decision-making capacity is both time- and situation-dependent and can be determined by any qualified healthcare professional. In the example case, the patient may not have capacity to make the decision at hand on one of her "bad days," but the clinician must assess her current capacity to make the decision before automatically deferring to surrogate decision making. If she can demonstrate an understanding of the situation at hand—the risks, benefits, and alternatives of the decision—and convey coherent reasoning for her decision, then the decision should be respected.

If a patient lacks capacity, one should first consider whether the patient has any advance directives, such as a living will that indicates their end-of-life preferences, or whether they have appointed a preferred surrogate decision maker or "proxy," such as a healthcare power of attorney or healthcare representative. If the patient has no advance directives or pre-appointed surrogates, states and countries tend to have specific laws in place as to whether all next of kin have equal priority in surrogate decision making or whether certain relationships take priority in determining default surrogates (e.g., a spouse before a cousin) [12]. Prior to accepting a surrogate's decision, one should ensure that the decision is free of coercion/ulterior motives and that the person is attempting to convey *what the patient would want*, not necessarily what they would want (substituted judgment). If no appropriate surrogate can be found, it is then appropriate to defer to the best interest standard, where clinicians may proceed with the decision believed to be in the patient's best interest.

Courses of Action:

1. *Clarify the current decision-making capacity of the patient*. If this determination is unclear, psychiatry or ethics consultants may be helpful.
2. *If lacking capacity, consider advance directives and pre-appointed surrogates*. Patients' advance directives and surrogates (pre-appointed or otherwise) do not always agree. These situations can be complex and require weighing the validity of the information at hand. Is the daughter using appropriate substituted judgment? Perhaps there is evidence that the patient's preferences changed since making the living will. Does a G-tube qualify as an "invasive procedure"? Often ethics consultation, if available, can be helpful in these situations.
3. *Be familiar with local laws regarding default surrogates*. If no advance directives or appropriate pre-appointed surrogate exists, defer to local laws regarding default surrogates, which vary (Table 2).
4. *Seek assent, even if the patient lacks capacity*. Assent refers to agreement with a decision despite not being able to legally consent. Even if a patient lacks capacity, clinicians should still seek their agreement with the plan to the greatest degree possible.

Questions to Consider:

1. Do you feel comfortable assessing a patient's capacity? How and when do you do this in your clinical workflow?
2. If a patient lacks capacity, where can you find information on advance directives and surrogates? Are you familiar with local laws on default surrogates?

Informed Consent

A 43-year-old man with Budd Chiari has occluded portal, hepatic, and splenic veins. He is referred for a transjugular intrahepatic portosystemic shunt (TIPS). The plan is to percutaneously access the superior mesenteric vein for recanalization and then do the TIPS. The trainee is sent to "get consent." She has only seen a couple TIPS procedures and tells the patient that it is a major procedure with risk of bleeding, infection, and damage to surrounding structures. She does not realize the planned approach is not routine and does not mention this to the patient.

Ethical Considerations:

Informed consent is central to the patient-clinician relationship and a foundational concept in medical ethics [14, 15]. Despite its ubiquity and importance, research suggests consent practices often fall short of theoretical ideals [16]. Ideally, consent is an ongoing conversation/agreement between the patient/family and care team, which empowers the decision maker with sufficient information on the risks, benefits, and alternatives to make informed decisions free of coercion [17]. It should not be understood as doing whatever the patient wants or only doing what the clinician thinks is best but rather as making a balanced, shared decision. Although documentation of consent is important, it is not final or binding. People get to change their minds, and physicians owe patients a chance to do so,

Table 2 Additional resources for the interventional radiologist

Interactive map for state surrogate decision-making laws "Who Decides When a Patient Can't? Statutes on Alternate Decision Makers." *N Engl J Med.* 2017 Apr 13; 376(15):1478–1482. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5527273/
State-specific advance directive forms "Links to State-Specific Advance Directive Forms." American Bar Association. February 2020. Published Online. https://www.americanbar.org/content/dam/aba/administrative/law_aging/2018-lnks-to-st-spcifc-advnc-drctv-frms.pdf
Multi-society guideline for consent in IR
American College of Radiology. ACR-SPR practice guideline on informed consent for image-guided procedures. 2011; Available at: https://www.sirweb.org/globalassets/aasociety-of-interventional-radiology-home-page/practice-resources/standards_pdfs/final_acr_doc7109ed01.pdf
Information for patient about image-guided procedures
Smith, A. et al., What are MIIPs? The Interventional Initiative website. 2016. Accessed February 26, 2021. http://theii.org/miips/procedures
IR-focused resources for navigating challenging situations in end-of-life care
Applied Ethics in IR working group. IR Ethics & Palliative Care. Society of Interventional Radiology website. 2019. Accessed February 26, 2021. http://rfs.sirweb.org/ir-ethics/
Analysis of requests for potentially inappropriate procedures in IR with suggested workflow Keller, E.J., et al., *Perceptions of Futility in Interventional Radiology: A Multipractice Systematic Qualitative Analysis.* Cardiovasc Intervent Radiol, 2021. **44**(1): p. 127–133. https://doi.org/10.1007/s00270-020-02675-3

particularly if new information arises. Patients' needs and preferences vary with differences in health literacy, numeracy, languages, cultures, and learning styles [16]. Some people prefer as much information as possible while others defer to their clinicians or family [18]. It can also be challenging to determine what information is important to convey. Should the patient be able to decide wire type or embolization material? What about the choice to use a novel or non-routine approach? These challenges may be particularly salient for IRs given that patients and other clinicians tend to have a lower baseline understanding of what IRs do, and it is not uncommon for IRs to trial new approaches during a case [15].

A final consideration posed in the case is who obtains consent. Ideally, the conversation would be between the patient and the clinician performing the procedure, the patient would develop a robust understanding of the risks, benefits, and alternatives, and the conversation would take place in a non-coercive setting in a language in which the patient is fluent. This can be challenging in a busy practice, particularly in the inpatient setting, but practices should avoid having inexperienced trainees or clinicians who will not be performing the procedure obtain consent. Consent conversations should not take place in the procedure room or in other settings that may make the patient feel that they cannot say 'no,' outside of emergent situations. See Table 3 for a summary of informed consent practices tailored to the interventional radiologist.

Courses of Action:

1. *Ensure the person obtaining consent is equipped to do so*. The provider obtaining consent should have a robust understanding of the procedural plan, risks, benefits, and alternatives and be part of the team performing the procedure.
2. *Consider what information is essential to convey about the procedure and how best to meet the patient's needs and preferences*. When first meeting the patient, it can be helpful to gauge their understanding of the clinical situation and whether they would like anyone else to be present or removed from the room. This enables a quick assessment of their health literacy, baseline understanding, and preferences. When necessary, a translator should be offered. Consider the information you would want to know about the procedure if you or a loved one was the patient. Attempt to convey this information in a manner respective of the patient's needs and preferences.
3. *Give patients time and space to make a decision when possible*. It can be helpful to sit rather than stand at the bedside. Ask whether they have questions, require some time alone to decide, or need you to repeat anything.
4. *Consider using decision support aids*. Decision support aids are handouts, videos, or other materials that provide information on a healthcare decision in a digestible format. These resources have repeatedly been found to increase patient understanding and satisfaction and are currently being developed for IR by a non-profit organization called the Interventional Initiative (Table 2) [19].

Questions to Consider:

1. How do you assess your patients' needs and preferences regarding consent? How do you decide what

Table 3 Summary of ideal informed consent practices from literature

1. Assess the patient's preferences and capacity to make an informed decision.
   a. Competency is a global assessment determined by a court with an appointed surrogate. Capacity can vary from day to day and decision to decision and can be determined by any clinician. To have capacity, one must be able to understand the options, appreciate how the option relate to one's self, express a choice, and explain one's reasoning.
   b. If the patient lacks competency or capacity, one should assess whether advance directives and surrogate decision makers are available. Priority should be given to advance directives. Note that surrogate decision-making laws vary from state to state.
   c. Patients have the right to decline information or have another person make the decision on their behalf.
2. Provide information regarding the patient's clinical condition, treatment options, the risks and benefits of those options, and the clinician's recommendation.
   a. Information regarding risks and benefits should be accurate and reflective of the performer's skill.
   b. Information should be provided by the person performing the treatment.
   c. Information should be presented in a manner that takes into consideration the patient's health literacy and numeracy as well as cultural beliefs and preferences.
   d. Information should be provided in the patient's native language with the assistance of a certified translator as needed.
   e. Decisional aids should be considered as useful tools to support informed decision making.
   f. Universal consents should be avoided, i.e., having a patient consent to a list of possible procedures that may occur during their hospitalization.
3. Remember that informed consent is not a single conversation but an evolving agreement between the patient and clinician that should be documented.
   a. Patients have a right to change their mind at any point and should be allowed to do so.
   b. New information that becomes available should be shared, e.g., if someone else will be performing the procedure or a significantly different device/approach will be used.
   c. Informed consent should be well documented, including who was present, what was discussed, the decision made, and when this occurred.

information about the procedure is important to discuss?
2. Who routinely obtains consent in your practice? Where does this occur?

Conflicts of Interest (COI) and Complications

An IR prefers to use Company X's IVC filter because she feels familiar with its deployment and thinks it results in fewer complications than other filters. Over time, she establishes a relationship with Company X, giving paid talks on her experiences with their filter and running some small trials funded by them. She later sees a 51-year-old man with newly diagnosed renal cell carcinoma and obtains his consent for cryoablation. The initial plan was to use the practice's routine cryoablation system, but a representative from Company X is present for the procedure and suggests trying their new cryoablation system. She does so and the liver and renal pelvis are damaged. The patient develops a urinoma requiring drainage, but does well overall.

Ethical Considerations:

This case raises a few different issues including conflicts of interest, managing complications, and how these relate to informed consent. Relationships with industry have been instrumental to the development of new medical technologies, devices, and, to a degree, the specialty of IR itself. COIs are also ubiquitous in healthcare and expand beyond financial relationships [20, 21]. The ethical issue here is not the relationships themselves but the potential bias they can create. [3, 20, 22, 23] Would the patient in the case have received better care if the clinician did not have a relationship with Company X? This is why many codes of ethics recommend taking steps to minimize COIs and disclose existing COIs so people can be aware of potential biases [24]. Some challenges with current common approaches to COIs are that they often rely on self-disclosure, people are limited in their abilities to identify their own biases, and, at times, disclosure can be falsely equated with bias resolution [21, 24–27]. Thus, it is important to routinely reflect upon one's relationships, perhaps with the assistance of colleagues, to identify and manage potential biases.

The case also raises questions about what to tell patients regarding both the potential COI and when a complication occurs, regardless of whether a COI was present. Ideally, clinicians should disclose potential biases during the consent process, particularly if it is reasonable to assume that it could affect the patient's decision. Beyond these

considerations regarding consent, patients tend to view clinicians as more trustworthy when they disclosed potential COIs compared to when they did not [28, 29]. Likewise, when a complication occurs, physicians owe patients and families support and honest explanations [3]. Some clinicians may worry about the legal ramifications, particularly in more litigious medical communities, but studies suggest that lack of disclosure tends to be a primary reason patients sue clinicians when a complication occurs [23].

Courses of Action:

1. *Minimize bias in clinical decision making and be wary of the limits of self-disclosure*. There is no need to avoid all relationships with industry, but thoughtful reflection on how one manages potential biases from these relationships is crucial. Given limited ability to identify one's own biases and the ubiquitous nature of COIs, it may be helpful to establish means for colleagues to help each other identify and manage potential bias, financial or otherwise.
2. *Disclose relevant potential biases during the consent process, presentations, and research*. People deserve a chance to weigh the information providers share with them in light of providers' biases. This may require more than a disclosure slide at the beginning of a talk. When having informed consent discussions with patients, consider what a reasonable person would want to know to make an informed decision (reasonable patient standard) [30].
3. *Provide patients and families an explanation and support when a complication or error occurs, unless it would cause undue harm*. Generally, patients and families deserve an explanation of what happened, why it happened, and next steps, both in terms of their care and of preventing future errors if applicable. A rare exception is if disclosure of certain information would cause undue harm.[3]

Questions to Consider:

1. What are potential biases associated with your professional relationships? How do you manage this potential bias?
2. What do you tell patients and families when a complication or error occurs? What support or resources does your practice have to help you navigate these situations professionally and personally?

[3] e.g., a physician may exercise therapeutic non-disclosure to protect the patient from the emotional harms that may result from learning certain information about his medical indication and/or treatment if such harms are a salient threat.

Conclusion

A wide array of ethical challenges can arise in IR practice. As the specialty evolves, it is important to consider these challenges and specialty-specific perspectives on how best to navigate them. This primer attempts to provide a common language and practical approach to salient ethical issues in IR practice, including requests for potentially inappropriate procedures, surrogate decision making, informed consent, and managing conflicts of interest and complications. Questions are used to stimulate discussion and relevant citations are provided for further reading. It is our hope that this work will serve to guide discussion-based training in applied ethics in IR while inspiring further research in this area.

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Declarations

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical Approval No IRB approval was needed for the creation of this work. All cases presented are fictionalized.

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