Session 7. Iatrogenesis: Exploring Ethical Obligations

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Overview

Iatrogenesis may be defined as any adverse condition in a patient resulting from the application of a treatment by a physician, health care professional, or member of the medical team. These events contribute significantly to patient morbidity and mortality (Kohn et al). A substantial percentage of iatrogenic events are preventable. Iatrogenic events may or may not be the result of medical errors (Sharek and Classen; Klugelman et al). Harm may come to patients due to known complications of treatments such as chemotherapy as well as from failure of a patient to get appropriate care, from getting unnecessary care, from poor or impaired medical judgment, or from a physician failing to put the good of the patient ahead of his or her own. Iatrogenic events may be minor or life-threatening. Institutional or system failures, such as insufficient enforcement of standards for hand washing resulting in inappropriately high rates of health care–associated infections, may also result in iatrogenic events that harm patients.

Physicians and other health care professionals have a duty to do no harm. In settings where patients are at risk or are harmed, what are the responsibilities of the ethical physician to the patient? This module will discuss how the physician and health care system can demonstrate integrity and respect for persons as well as carry out their fiduciary responsibilities. It will provide ethical reflection on what levels of transparency and disclosure are appropriate. In addition it will explore the options available for an apology and identify avenues for repair of the relationship.

Instructor’s Guide

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Case Summary

A 7-year-old boy, with a relapse of acute myelocytic leukemia (AML), did not respond to any of his cancer treatments, including a bone marrow transplant (BMT). He was hospitalized to implement a research protocol with a new investigational drug for AML. A thorough process of informed consent and assent was followed and signed by the child and parents.

During the first 3 days of chemotherapy treatment the child had significant side effects including high fever and neuropsychiatric symptoms. The mother became very alarmed that something was wrong. On the fourth day the principal investigator was informed the entire study drug supply
had been given, contrary to the protocol instructions. Subsequent investigation revealed the pharmacy had received a new batch of the drug with the same appearance but a different concentration. A labeling error then led to administration of an excessive and nephrotoxic dose of the drug. The end result was cessation of any further experimental therapy. The child lost his “last-chance treatment.” He died a few weeks later in another hospital. Review of this event identified an error caused in part by insufficient staffing of the research pharmacy and failure to recheck medications prepared there.

This young child and his distraught parents had negotiated their way through the vicissitudes of daunting AML treatments, including BMT, only to see their hopes for recovery dashed by this iatrogenic event.

- What are the moral and legal implications of iatrogenesis?
- Was this iatrogenic event the responsibility of an individual or the result of a failure of systems within the hospital?
- What is the role of apology and repair in the setting of iatrogenesis?

Alternate Cases
1. A 17-year-old Hispanic girl was hospitalized for headaches and fever. She had an unremarkable neurologic examination. Subsequently it was noticed she had third cranial nerve palsy with diplopia. A computed tomography (CT) scan of the brain was read as compatible with cysticercosis; her spinal tap showed low blood glucose and mild pleocytosis. Cultures were negative, chest radiograph was normal, and her purified protein derivative was negative. Consultations were obtained with infectious disease specialists and a neurologist, and treatment for cysticercosis was begun. The patient’s headaches worsened; she developed nystagmus and fever followed by seizures. She was transferred to the critical care unit, where she died. That same day a cerebrospinal fluid culture report came back positive for *Mycobacterium*, subsequently identified as *M. bovis*. Posthumously, it was discovered that she had consumed unpasteurized milk in Mexico.

2. A 3-week-old, recovering from pneumonia, is about to undergo surgery for a tumor that is partially obstructing the left main bronchus. The anesthesiologist reads the chart and examines the child. He then shakes his head and sighs. The frightened teenaged mother observes his unspoken actions in petrified silence.

3. It is New Year’s Eve. A 4-year-old arrives at the emergency department with abdominal pain. After a tentative diagnosis of acute appendicitis is made, the on-call attending surgeon arrives. He confirms the diagnosis and prepares for immediate surgery. As he is scrubbing, the nurse notices his agitation and alcoholic breath. She now must decide how she will respond.

Learning Objectives
1. Identify iatrogenic events and give examples resulting from individual errors and system malfunctions.
2. Describe individual and system responsibilities in the disclosure of iatrogenic events.
3. Discuss physician responsibility to demonstrate professional integrity, duty to warn, and transparency interface with disclosure.
4. Examine the role of apology and relationship repair in the setting of iatrogenesis.
5. Consider related legal and moral implications of iatrogenic events

**Suggested Reading for Instructor**
[http://aappolicy.aappublications.org/cgi/content/full/pediatrics;120/4/895](http://aappolicy.aappublications.org/cgi/content/full/pediatrics;120/4/895). Accessed May 12, 2011


**Further Reading**
Berlinger N. *After Harm: Medical Error and the Ethics of Forgiveness.* Baltimore, MD: The Johns Hopkins University Press; 2005


**Case Discussion**
*Is there a general duty to disclose iatrogenesis?*
The disclosure of a medical error is based on the principle of truth telling. This, in turn, is based on the human survival value provided by trust. Without such trust a civilization suffers and eventually anarchy and disillusionment prevail. This is made more salient in dangerous situations, when one’s life and well-being are placed in the hands of professionals (eg, doctors, attorneys, police, financial advisors). Hence the ethical concept of a fiduciary relationship, one in which the interest of the patient or client is to be considered above that of the professional.
How does a physician’s ethical responsibility to demonstrate professional integrity, a duty to warn, and transparency interface with disclosure?
The origin of a disclosure obligation is established by the privilege of being granted a license to get intimately involved in the lives of others as part of a curing and healing enterprise. Based on truth telling, trust, and the special nature of the physician-patient relationship, it is appropriate to consider that a patient’s right to know about iatrogenic events trumps the physician’s desire for privacy. From the perspective of professionalism, clinicians are therefore expected to do their utmost to prevent errors, alert systems to actual or potential iatrogenesis, and disclose errors when they occur.

What is the basis of the ethical obligation a physician has toward a patient when an iatrogenic event occurs?
These ethical obligations inherent to the physician-patient relationship are an extension of and grounded in the more basic principle of respect for persons. The implication of this principle is inescapable. Every person is entitled to be informed about the important things that can directly affect them.

The professionalism of the individual is still the cornerstone of the right behavior. Systems are in place to ensure its flourishing. There is a clear duty to warn when another member of a health care team is impaired (potential iatrogenesis). Health care systems need to address this potential through a system of preceptors, supervisors, and administrators who have authority to intervene. It is essential for all on the health care team to know their duty to the patient and promptly report incidents of unprofessional behavior including on-duty alcohol or drug use. Prevention of iatrogenesis is an obligation that extends to everybody, from the highest authority in a system to the humblest beginner.

Identify iatrogenic events and give examples that result from a single individual error as well as those related to system malfunctions.
Iatrogenesis is frequently related to systematic issues. Examples include insufficient staffing of the research pharmacy or a lack of double-checking of the medications prepared there. Iatrogenesis may include improper supervision of consultants, especially where a history of substance abuse is known. Nevertheless, the dimension of personal responsibility cannot be overlooked.

How are individual accountability and system responsibility addressed when iatrogenic events potentially include both aspects?
Constructive approaches to iatrogenic events must consider the possibility that training has been insufficient (eg, the body language in the alternate case 2) or that supervision has been lax (eg, alternate case 3). Personal contributions to errors need to always be considered in the context of the systematic issues that might facilitate them. The current no-blame paradigm has been questioned in a patient safety improvement article that suggests the adoption of explicit punitive approaches to poorly performing physicians (Wachter and Pronovost). An opposing view was expressed in a longitudinal study in a large facility, which found that penalties did not deter undesirable behavior. Instead, penalties drove underground the evidence of noncompliance and encouraged people to conceal their errors (Dekker and Laursen).
If one accepts thatiatrogenesis often occurs as a result of system failures, one needs to conclude that there is an ethical obligation to identify and correct those systems that contribute to error. Methods to address system errors include debriefing, morbidity and mortality conferences, and performance improvement reviews. Iatrogenesis also affects each individual in the system, requiring personal reflection and commitment to improvement as well as studying, documenting, and communicating well with all those involved. All health care personnel need to exhibit the professional integrity to disclose medical errors and the moral courage to interrupt potential iatrogenesis (duty to warn) and fulfill professional ethical obligations. When it occurs, an episode of iatrogenesis needs to be openly addressed, the documentation transparent, and the incident followed by disclosure, apology, and amends.

**What approaches can be identified to facilitate apology and relationship repair in iatrogenesis?**

Clinicians involved in iatrogenesis (and their team, if necessary) need to explain to the patient and family in understandable language what happened or, if necessary, what will be done to understand what happened. Physicians should express their heartfelt regrets and apologize for the error incurred. Physicians and senior members of the health care team need to inform patients and families how this type of problem will be remedied and specifically what can be done to help a patient when harm has occurred.

Patients who have been harmed deserve an apology. For such an apology to be ethically significant, it needs to be clear about its content, recognizing what went wrong and how it happened; express the heartfelt sorrow that it caused in all involved and the regrets that followed; and include any amends or repair that can be offered.

The case of the child with AML illustrates the value of approaches that combine full investigation, complete disclosure, apology, and repair. The parents were given a copy of the medical record and a report that explained exactly what had happened, outlining step-by-step what caused the confusion, where it occurred, when it was identified, and the corrective steps taken. The oncologist met with the parents and could not help but tear up as she disclosed the event. Her tears spoke more eloquently than any words about the sadness and suffering that was generated by this error, as she recognized that any hope of rescuing this child from AML had been extinguished. Involvement of the legal system was necessary. Lawyers for both sides collaborated toward a settlement, which included a central feature—an endowed grand rounds devoted to the topic of safety and prevention of iatrogenesis.

**Is there a legal approach to iatrogenesis?**

The legal risk management approach to iatrogenesis exists in parallel with ethical considerations. It takes into account that such an event may lead to a malpractice suit. In the mind of many professionals it is best to “not make waves,” meaning to not mention the event, not document or release details—in short, not “make it worse” by disclosing it to those affected. Nothing could be further from the truth.

While this teaching guide cannot serve the purpose of giving legal advice, it endorses the current state of the art in risk management, which favors clear documentation, transparency, and the completion of incident reports. While it is important to avoid finger-pointing, a description to the patient or family about the sequence of unfortunate events and its aftermath is mandatory. The
reality is that the public does understand malfunction of systems and human errors, even if they do not want to be at the end of such misfortune. Most malpractice cases have more to do with gaps in communication and adversarial relationships, with perceived secrecy and defensiveness, than with the medical events involved.

**Does the legal approach differ from the moral approach to iatrogenesis?**

There can certainly be congruence between the ethical and legal approaches to iatrogenesis. Both incur obligations toward the institution in which the episode occurred. Both need to be incorporated into the search for a resolution. In the end, the old dictum should prevail—good medicine makes good ethics. To this we can add, good ethics make for the best possible legal outcome.

**What are the harms and implications of more subtle forms of iatrogenesis?**

Iatrogenesis usually implies actual damage to health. However, it is valuable to stress that there is an area of more subtle iatrogenesis that deserves strong consideration. This form of iatrogenesis means that a physician’s ill-chosen words or body language can be a source of distress and have a great effect on the emotional state and well-being of those depending on his or her care. The alternate case of the teenaged mother who is frightened by the anesthetist’s nonverbal communication is but one example. Because physicians are often unaware of this form of iatrogenesis, the author’s personal experience may be instructive: “While on rounds I experienced excruciating back pain that radiated to my groin. In agony, I walked toward the emergency department of the hospital near my children’s hospital. There, I developed hematuria and fainted as I was completing my insurance check-in. Still in my white coat, I was placed on a gurney and rolled in to be seen by the urology resident. I couldn’t have been happier, thinking that I would receive rapid relief from the searing pain that the displacing kidney stone was causing me. I was greeted by the enthusiastic urologist who, recognizing me as a doctor, gleefully shared his thoughts with me: ‘We will get a CT scan right away to check if you have kidney cancer.’” Insensitivity, verbal and nonverbal, has the potential to harm.

**What is the appropriate way to support physicians and members of the health care team in cases of iatrogenesis?**

The events in the cases in which the patient had a fatal outcome resulted in enormous emotional pain to the clinicians involved. This emotional pain may manifest in the form of guilt, insomnia, anxiety, depression, or self-doubt. On occasion, errors lead to a painful self-imposed end of a professional career. The remorse and regret a clinician feels may become overwhelming (Hilfiker). This is a time for support and solidarity with our afflicted colleagues, who have been rightly referred to as “the second victim.”

On the other hand, the real victims often suddenly see very little of their physicians. This may be because of professional embarrassment, fear, or misguided legal advice. It needs to be remembered that the victims of iatrogenesis merit priority over anything else. The first thing to do is to maintain human contact with them, as hard as this will be, so they do not feel abandoned in addition to experiencing the consequences of an error.

**Conclusions and Suggestions**

Iatrogenesis is common and may range from known complications of treatment, to errors on the part of an individual physician, to problems within systems. The physician’s ethical and legal
obligations to the patient in the setting of iatrogenesis function in tandem. When an episode of iatrogenesis is identified it needs to be openly addressed and clearly documented, and followed by disclosure, apology, and amends to the extent possible.

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