

Session 11. Iatrogenesis: Exploring Ethical Obligations

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Overview

Iatrogenesis is defined as any adverse condition in a patient that is the result of a treatment error by a physician, health care professional, or member of the medical team. These events contribute significantly to patient morbidity and mortality.¹⁻³ Iatrogenic events are preventable. Harm can also come to patients 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. Many errors of omission or commission are institutional or system failures, such as insufficient enforcement of standards for hand washing resulting in inappropriately high rates of health care-associated infections.

This module will explore the individual and systems ethical responsibilities in the disclosure of iatrogenic events. Participants will discuss professional integrity, “duty to warn,” and transparency. They will examine the moral and legal implications of the response to iatrogenesis. Participants will also review their response to colleagues involved in iatrogenesis. Finally, they will examine the role of apology after iatrogenesis has been disclosed.

Participants may *confidentially* identify types/episodes of iatrogenesis and reflect on how they relate to their practice of medicine. Within this context other complementary ethical issues may arise: respect for people, professional integrity, fiduciary duties, truth telling, accountability, etc.

Instructors Guide:

- Case Summary
- Alternative Cases
- Learning Objectives
- Suggested Reading for Instructor
- Further Reading
- Case Discussion
- Conclusions and Suggestions

Case Summary

A 7-year-old African American 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 “last hope” research protocol with a new investigational drug for AML. A thorough process of informed consent and assent was followed.

Unfortunately, during the first 3 days of chemotherapy treatment, he had significant side effects, including high fever and neuropsychiatric symptoms. The mother became very alarmed and insisted that something was wrong. On day 4, the principal investigator was informed that the entire study drug had been administered, which did not match the protocol instructions. Subsequent investigation revealed that the pharmacy had received a *new* batch of the drug with the same appearance as the old *lower-dose* batch. A labeling error of the new medication occurred. The new batch was labeled as with the lower dose. The excessive dose resulted in severe neurotoxic and nephrotoxic administration. The end result was that all further experimental therapy had to be discontinued. Thus, the child lost his last-chance treatment. He died a few weeks later in another hospital.

Commentary: This young child and his distraught parents had negotiated their way through the vicissitudes of daunting AML treatments, including bone marrow transplant (BMT), only to see their last hope for recovery dashed by this iatrogenic event.

How can the treating clinician best deal with this painful situation?

- Is there an ethical duty to disclose?
- Is there a legal one?
- Do they differ?

Alternative Cases

1. A 14-year-old Hispanic girl was hospitalized because of headaches and fever. She had an unremarkable neurologic examination. A CT brain scan was read as compatible with cysticercosis, and her spinal tap showed a low blood glucose, mild pleocytosis, and negative cultures. Chest radiography was normal, and tuberculosis (TB) test result was negative. An infectious disease specialist and a neurologist were consulted. Treatment for cysticercosis was begun. A few days later, the patient’s headaches got worse and she developed nystagmus and high fever and was noticed to have third nerve palsy with diplopia. She subsequently had a seizure and was transferred to the critical care unit, where she became comatose and died. That same day, a CSF culture report came back positive for *Mycobacterium*, later identified as *Mycobacterium bovis*. Posthumously, it was discovered that she had consumed unpasteurized milk in Mexico.

Commentary: Although in the first case, death was attributable to an error of commission (overdose), in alternative case A, there was a diagnostic error and the patient died because of an omission—not having been provided drug therapy against TB meningitis.

- Is there an ethical duty to disclose?
- Is there a legal one?
- Do they differ?

2. It is New Year’s Eve. A 4-year-old child arrives in the emergency department with abdominal pain. A diagnosis of acute appendicitis is made. The on-call attending surgeon arrives. He confirms the diagnosis and indicates immediate surgery. As he is scrubbing and getting ready, the nurse on the case notices that the attending surgeon is agitated and has alcohol on his breath. She now has to decide whether (and how) she will stop the attending surgeon from operating.

Commentary: Alternative case B is the most urgent. In this scenario, the potential for harm is enormous, as the surgeon’s skill will most likely be blunted by his alcohol intoxication. Moreover, the situation is complicated by the power differential between the surgeon and the nurse. To complicate matters, there is a history of friendly relationships and camaraderie among the surgical team that will clearly be disrupted by addressing the surgeon’s drinking and placing a hold on surgery. Alternative case B illustrates yet another obligation, that of being our “brother’s keeper”; to protect the public from those we are concerned may harm them.

- Is there an ethical duty to warn?
- Is there a legal one?
- Do they differ?

**All the cases described have happened. Gender, age, and ethnicity of the patients have been altered to avoid identification.*

Learning Objectives

1. Identify the ethical issues involved in the disclosure of iatrogenesis, give examples.
2. Understand systemic and individual responsibilities for iatrogenesis.
3. Discuss fiduciary relationship, professional integrity, “duty to warn,” transparency.
4. Recognize the need for apology and repair.
5. Examine the relationship between ethical obligations and legal requirements.
6. Consider the need for assistance and solidarity with the professional involved in iatrogenesis.

Suggested Reading for Instructor

American Academy of Pediatrics, Committee on Bioethics. Policy statement: Professionalism in pediatrics: statement of principles. *Pediatrics*. 2007;120(4):895-897

Silber TJ, Hilliard MA. Iatrogenesis: ethical and legal aspects. *Adolesc Med State Art Rev.* 2011;22(2):289-300

Further Reading

Serwint J, Bostwick S, Burke A, et al. American Academy of Pediatrics- *Resilience in the Face of Grief and Loss: A Curriculum for Medical Students, Pediatric Residents, and Fellows.*

<https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/Section-on-Hospice-and-Palliative-Medicine/Pages/Resilience-Curriculum.aspx>

Case Discussion

As these cases indicate, physicians and other health care professionals work in settings where patients could be harmed. Below are questions about the clinician's ethical responsibility.

Is there a 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 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 (doctors, attorneys, police, financial advisors, etc.). Hence, the ethical concept of a *fiduciary relationship*, one in which the interest of the patient or client be considered above that of the professional. The fiduciary obligation of the medical professional is based-on the privilege of being granted permission to become intimately involved in the life of others as part of a curing and healing enterprise. Thus, from the perspective of professionalism, clinicians are expected to do their utmost to prevent errors, alert systems to actual or potential iatrogenesis, and disclose errors when they occur.

On the basis of truth telling, trust, and the special nature of the doctor-patient relationship, a patient's right to know about iatrogenic events trumps the doctor's self-interest and any desire for discretion and privacy. This position has its grounding in the basic principles of autonomy and respect for people. The application of these principles is essential: all people are entitled to be informed about important events that can directly affect them.

What can we learn from the cases described?

Iatrogenesis is often related to systemic issues—for example, in our main case, insufficient staffing of the research pharmacy led to lack of double checking of the medications prepared. In alternative case A, proper use of consultants, participation of the more senior attending physicians in the case conferences was noted; nevertheless, the dimension of personal responsibility cannot be overlooked, as is seen in alternative case B.

In alternative case B, the individual's professionalism is still the cornerstone of correct behavior, and health care systems are in place to ensure that professionalism is flourishing. Hence, there is a clear duty to warn when a member of the health care team is impaired (potential for iatrogenesis). Health care systems need to address this through a system of preceptors, supervisors and administrators with authority to intervene. In the unprofessional behavior described in alternative case B, it was good to know that the surgical nurse did her duty and the child was operated on by another surgeon. Prevention of iatrogenesis is an obligation that extends to everybody, from those in a supervisory role to those in subordinate roles.

What is the legal approach to iatrogenesis?

The legal/risk management approach to iatrogenesis exists in parallel to ethical considerations. It takes into account that such an event may lead to a malpractice suit. Indeed, in the mind of many professionals, it is best to “not make waves,” meaning not mentioning the event, not documenting or releasing the details, in short not “making it worse” by disclosing it to those affected. This approach is not advised.

Although this module does not pretend to give legal advice, it endorses the current state of the art in risk management, which favors clear documentation, transparency, and completion of incident reports. Although it is certainly important to avoid finger pointing, a description to the patient (and/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 error. Most malpractice cases have more to do with gaps in communication and adversarial relationships, with perceived secrecy and defensiveness, than with the actual medical events involved.

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

There is agreement between the ethical and the legal approach to iatrogenesis. Both need to address the professional's obligation toward the patient and to the institution in which the episode occurred. Both need to be considered in the search for a resolution. In the end, the old dictum should always prevail: good medicine makes good ethics and good ethics makes for the best possible legal outcome.

How can individual accountability and system responsibility be adequately addressed?

Even when there are individual errors, iatrogenesis is often related to systemic issues—for example, insufficient staffing of the research pharmacy (main case). Iatrogenesis may include lax supervision of professionals, especially when a history of intoxication or substance abuse is known or suspected (alternative case B). Constructive approaches to iatrogenic events must consider the possibility that training has been insufficient or that supervision and instructions have been neglected and/or not strictly enforced.

Nevertheless, the dimension of personal responsibility cannot be overlooked. Personal contributions to errors must be considered in the context of the systemic deficiencies that might facilitate them. This “no blame” paradigm has been questioned in a patient safety improvement article that proposes the adoption of explicit punitive approaches to poorly performing physicians.⁴ 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.⁵

What are the ethics of apology and repair after iatrogenesis?

Clinicians involved in iatrogenesis need to explain to the patient and family, in understandable language, what happened, or if not clear, what will be done to understand what happened. Moreover, physicians should also express their heartfelt regrets and apologize for the error incurred. Physicians, preferably senior members of the health care team, need to inform patients and families how the adverse event will be remedied, and specifically what can be done to help the patient, especially when permanent harm has occurred.

Patients that have been harmed deserve an apology.⁶⁻⁸ For such an apology to be ethically significant, it needs to:

1. Be clear about its content, recognizing what went wrong and how it happened.
2. Express the heartfelt sorrow that it caused in all involved and the regrets that followed
3. Include any amends or repair that can be offered, making sure the patient does not experience abandonment of care.

The main case of the adolescent with AML can illustrate 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 had caused the confusion, where it had occurred, when it was identified, and the corrective steps undertaken. The oncologist met with the parents, and she could not help but tearing up as she disclosed the event. Her tears spoke more eloquently than any words could 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 lecture devoted to the topic of “Safety and Prevention of Iatrogenesis.”

In alternative case A, the attending physician talked to the family, recognized and described the treatment team’s error in accepting the diagnosis of cysticercosis, which had not been sufficiently challenged. All were misled by the unusual characteristics of the case, such as the negative TB test result and normal chest radiograph. The family was subsequently met by the division director, who spent time with them listening to their tragedy. Everybody on the team expressed their sorrow, gave condolences, and continued seeing the family while they were awaiting the brain death criteria. Testing the family for TB was undertaken and another little girl (a cousin) received a diagnosis of bovine TB and was treated successfully. This never became a legal case.

Finally, one should remain in contact with the patients and their families. Frequently after the adverse event the doctor patient/family relationship is terminated. This is usually due to professional embarrassment, fear, sometimes even misguided legal advice. 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 that on top of experiencing the

consequences of an error they do not feel alone and abandoned. In many cases, the involved doctor's show of kindness to the unfortunate victim and the family may be of great help towards the emotional healing of the distraught professional himself. When the treating pediatrician can express a heartfelt regret, apologize and especially add what can be done to help, it makes a difference.

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

The events described in the main case and alternative case, in which the patients had a fatal outcome resulted in enormous emotional pain to the clinicians involved. This emotional pain may manifest in the form of torturing guilt, insomnia, anxiety, depression, and self-doubt. The remorse and regret a clinician feels may become overwhelming.⁶ On occasion, errors have led to a painful self-imposed end of a professional career. This is a time for support and solidarity with our afflicted colleagues, who have been rightly referred to as "the second victim." They should not be avoided; kind understanding and support can indeed accompany the necessary corrective measures.

Conclusions and Suggestions

If one accepts that iatrogenesis is often the result of deficiencies in the system, there is an ethical obligation to identify and correct those deficiencies that contribute to error. This can be accomplished through debriefing, morbidity and mortality conferences, and performance improvement reviews. Iatrogenesis affects each individual in the system, requiring personal reflection and commitment. Reviewing and documenting, communicating well with all those involved, and maintaining the integrity to disclose medical errors and the moral courage to prevent potential iatrogenesis (duty to warn) are all part of the medical professional's ethical obligations. Iatrogenesis must be openly addressed and the documentation must be transparent and followed by disclosure, apology, and amends.

References

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