Technological iatrogenesis: New risks force heightened management awareness

By: Patrick A. Palmieri, Ed.S., MBA, MSN, ACNP, RN, CPHQ, CPHRM, FACHE, Lori T. Peterson, Ph.D.(c), MBA, and Eric W. Ford, Ph.D., MPH

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Abstract:
Iatrogenesis is a term typically reserved to express the state of ill health or the adverse outcome resulting from a medical intervention, or lack thereof. Three types of iatrogenesis are described in the literature: clinical, social and cultural. This paper introduces a fourth type, technological iatrogenesis, or emerging errors stimulated by the infusion of technological innovations into complex healthcare systems. While health information technologies (HIT) have helped to make healthcare safer, this has also produced contemporary varieties of iatrogenic errors and events. The potential pitfalls of technological innovations and risk management solutions to address these concerns are discussed. Specifically, failure mode effect analysis and root cause analysis are discussed as opportunities for risk managers to prevent problems and avert errors from becoming sentinel events.

Article:

INTRODUCTION

Millennia ago, Hippocrates recognized the potential for injuries that arise despite the well intended actions of healers. The directive *primum non nocere* ("first, do no harm") is a central tenet in medicine. Derived from Greek, iatrogenesis literally means "brought forth by the healer" (*iatros* means "healer" and *genesis* means "brought forth by"). Although the word can refer to good or bad effects, typically iatrogenesis is used to describe a state of ill health or the adverse outcome resulting from a medical intervention or lack thereof. In many civilizations, iatrogenic sickness or death caused purposefully, by preventable error, or through negligence on the healer's part is a punishable offense.

Three types of iatrogenesis are described in the literature: clinical iatrogenesis, social iatrogenesis and cultural iatrogenesis.(Illich, 1) While iatrogenesis is a term generally reserved to describe the harmful consequences physician action, it can also result from the actions by other healthcare professionals, including those working in the area of information systems and technologies. As healthcare evolves, iatrogenic issues related to new technologies are described, but have yet to be organized into usable classification framework. Introduction of innovative technologies designed to improve human performance and reduce the likelihood of error in complex adaptive systems have not yet lived up to their promises.

Frequently, innovative technology is viewed by healthcare professionals and patients as necessary to improve imperfections commonly found in the care delivery system. Since the Institute of Medicine's(2) seminal report in 2000 and subsequent publications detailing medical errors, improved information technology systems have been held out as a necessity in making healthcare safer. Despite the imperative to adopt new information systems, innovation is inherently double-edged sword. The introduction of new health information technologies (HITs) has created new types of iatrogenic events.(Battles and Keyes, 3) New technologies are credited with reducing the complexity of the human-system interface; however, the opposite may occur if users are not proficient. Further, the lack of technical proficiency is likely to exist during the implementation phase of such a system. Therefore, it is critical to effectively manage the training and implementation phases of a new

information technology's adoption in order to mitigate the risk of iatrogenesis. The purpose of this article is to outline the potential pitfalls of information technology innovations and offer risk management solutions to address them.

Iatrogenic framework

Healthcare management and clinical publications frequently speak to the term iatrogenesis without specific reference to a model, conceptual framework or philosophical underpinning. Risk managers are routinely involved in dealing with the consequences of iatrogenic events that have information systems as part of their root cause. Given the increased incidence and recognition of iatrogenic events related to health information technology, risk managers need to develop strategies and tactics for preventing and responding to events – respectively.

In 1976, Ivan Illich published *Medical Nemesis* and outlined a typology of iatrogenesis (cultural, social and clinical). However, in the decades since Illich's monograph was published, information technology has evolved rapidly from a few clerks accessing mainframes to file claims for large hospitals to everyone involved in the system using computers. The constant introduction of new devices and their concomitant impact on work processes create discreet types of challenges for risk managers. Identifying these challenges allows for the development of countermeasures.

Technology as an embedded feature of health systems

Under the general umbrella of healthcare information technology (HIT; e.g., bar coding technology,(Poon et al., 4) electronic medical records,(Sidrov, 5) computerized physician order entry,(Bates, 6) and decision support systems (Kawamoto, Caitlin, Balas and Lobach, 7) promises to make healthcare operations both safer and improve clinical outcomes. However, neither promise has yet to be fully realized. (Ash et al., 8) The complexity of implementing HIT can generate new and unanticipated error varieties and/or actually exacerbate existing problems in medication order and delivery systems.

The Institute of Medicine's(9) 2001 call for the use of electronic prescribing systems in all healthcare organizations by 2010 heightened the urgency to accelerate U.S. hospitals' adoption of CPOE systems. However, many system implementations have experienced costly failures.(Ammenwerth et al., 10) Furthermore, there is evidence that CPOE may actually contribute to some types of adverse events and other medical errors. (Campbell et al., 11) For example, the period immediately following CPOE implementation resulted in significant increases in reported adverse drug events in at least one study (Bradley, Steltenkamp and Hite, 12) and evidence of other errors have been reported. (Bates, 2005a; Bates, Leape, Cullen and Laird, 13;14) Collectively, these reported adverse events describe phenomena related to the disruption of the complex adaptive system resulting from poorly implemented or inadequately planned technological innovation.

Complex adaptive systems characteristically demonstrate self-organization as diverse agents interacting spontaneously in nonlinear relationships (Anderson, Issel and McDaniel; Cilliers, 15; 16) where professionals act as information processors(Cilliers; McDaniel and Driebe, 16; 17) and co-evolve with the environment. (Casti, 18) Healthcare professionals function as diverse actors within the complex environment utilizing different methods to process information(Coleman, 19) and solve systemic problems within and across organizational layers. (McDaniel et al., 17) This robust problem-solving endeavor works to expose the presence of iatrogenic system properties. Risk managers can learn more from these systems by first observing the interactions of agents at various levels and places with the organization prior to implementing new policies and procedures.

Many organizations implement innovations addressing the symptoms of systemic dysfunction(Loewe and Domininquini, 20) while leaving the underlying causes unaddressed. In fact, McDaniel and Driebe(17) argue that neglecting underlying system relationships is the main cause of technology implementation failure.
The idiosyncratic and potentially severe nature of problems associated with CPOE implementation has given rise to the term "e-iatrogenesis" with the "e" referring to electronic sources of errors. (Campbell, Sittig, Ash,

Guappone and Dykstra; Weiner, Kfuri, Chan and Fowles, 11; 21) E-iatrogenesis is created by superimposing HIT innovation over existing areas of the complex adaptive system to unintentionally create added complexity. We recognize the broader impact of all technological innovations on the complex adaptive system. Hence, we describe the category of technological iatrogenesis as an emerging system property resulting from all technological innovation.

Technological iatrogenesis causation and prevention

There are important considerations for risk managers to make in determining the adoption of an innovation into a healthcare organization. First, they must consider relative advantage and the impact of the technology vis-à-vis the status quo. Compatibility is the degree to which the technological innovation is compatible with the collective experiential knowledge of the members of the organization. (Rogers, 22)

In the same vein, complexity is regarded as the degree to which the technological innovation is perceived as difficult or easy to implement and use. Rogers(22) explains that the more complex an innovation is, the less likely it is that the innovation will be adopted. One way to mitigate the risk of failure due to complexity overload is to allow end users to test it prior to implementation. These "trials" help to decrease uncertainty and increase implementation of the innovation.

Rogers(22) defines consequences to an individual or organization as the resulting changes after or as a result of the adoption or rejection of an innovation. There are three types of post-implementation consequences:

1) Desirable or undesirable (related to function or dysfunctional);

2) Direct or indirect (immediate response or second order response); and

3) Anticipated or unanticipated consequences (recognized and intended consequences).

Change agents frequently function without considering the iatrogenic consequences of an innovation. Therefore, it is important to recognize that by adjusting the innovative change process, change agents will be able to minimize the potential manifestation of harmful situations in the healthcare environment.

CPOE and electronic medical records have been federally mandated, therefore, adoption will occur. It is unlikely that the adoption will occur on the schedule suggested by the Bush Administration, where all prescriptions are entered electronically by 2014. (Ford, McAlearney, Phillips and Menachemi, 23)

Reducing e-iatrogenic issues

There are actions that risk managers advocate as solutions toward reducing the probability that technological iatrogenic processes will appear in their organization's technological innovations. In this section, we briefly address the contribution of root cause analysis (RCA) and failure mode and effect analysis (FMEA) tools as valid constructs for dissecting organizational processes and hierarchies in order to identify iatrogenic and adverse properties that might be fashioned by technical innovations.

The Joint Commission mandates the use of improvement tools such as RCA and FMEA for quality improvement processes. FMEA is used as a prospective accident prevention technique, while RCA is used as a retrospective accident analysis. These tools are quite helpful in identifying possible issues with existing systems or proposed system changes and investigating iatrogenic events *ex post facto* to identify the contributing factors.

FMEA is a risk assessment technique that systematically allows planners to identify potential iatrogenic processes in proposed systems innovations prior to the actual implementation.(Stamatis, 24) Because it offers proactive knowledge about potential iatrogenic system properties created through newly innovated processes, FMEA should be started early in the conceptual design process as a prospective review technique. As such, this method represents a proactive approach to minimize the probability of adverse effects arising from the

iatrogenic system properties. (Cohen, Davis and Senders; Senders and Senders, 25; 26) “Failure mode” describes the manner in which the system may not perform as expected, or fails. Referring to the examination and assessment of the failures, the “effect analysis” considers the consequences that might result from the identified failures.(DeRosier, Stalhandske, Bagian and Nudell, 27)

When analyzing the failures, the seriousness of consequence, the probability for failure, and the likelihood system defenses are carefully considered. The questions asked are:

1) What can fail?

2) How can it fail?

3) What is the cost of failure?(DeRosier et al., 27)

System or process implementation adjustments are considered and changes implemented to minimize the probability of iatrogenic results. With system maturation, new signs and or symptoms about the actual state of system reliability might surface. Potential iatrogenic properties signaling the probability of future failure require scrutiny. Over time as more intelligence is gathered, the FMEA can be used to review an aging innovation to determine the system and innovation compatibility. (DeRosier et al., 27) The more complex the healthcare process, the more essential the expert understanding of a system’s potential failure modes can be to minimize iatrogenesis and ensure the system’s proper operation. Diligent FMEA use is especially important when layers of process innovations are constructed into a specific system resulting in increased complexity. (Stamatis, 24)

Alternatively, RCA is a comprehensive adverse event review described by the Joint Commission as defining “the process that allowed an error to occur and identifies factors that underlie variability in erformance.” (Torpy, 28) As errors are the visible end-products of iatrogenesis, RCA is an appropriate tool to identify the iatrogenic etiology. The system approach to accident investigation is preferred. Accredited hospitals are required to conduct thorough investigations of every sentinel event – the most serious iatrogenic event that causes harm to a patient – using a process that identifies basic or casual factors underlying performance variation. (Joint Commission Resources, 29) By using a prescribed process for identifying the causal factors that trigger deviation in performance, the RCA permits a cautious survey of the healthcare environment (Joint Commission Resources, 29) to determine the technological implications.

An RCA helps to determine the interactive processes that permit system exposure to hazardous iatrogenesis. Through evaluating defensive breeches, an investigatory team can systematically unearth cascaded iatrogenesis and identify factors underling variability in performance (Torpy, 28) to uncover the origin of an accident and the most fundamental reason for factors contributing to the failure or inefficiency that created harm.(Joint Commission Resources, 29) With the introduction of well-intended technological innovation, systems are especially vulnerable to the creation of unknown hazardous properties (otherwise known as latent conditions).

Both FMEA and RCA activities involve human recovery efforts described by Van der Schaff and colleagues(30, 31, 32) as an important verification feature where usability, especially technical factors, is evaluated from the user perspective in order to identify emerging iatrogenic properties.

CONCLUSION

Since publication of the seminal Institute of Medicine report in 2000,(2) healthcare leaders have been examining the human factors and organizational accident sciences to learn how to grow into a high risk but low accident industry.

Balancing the function of risk management with the role of leadership in developing a safety-oriented organizational culture creates continual tensions. (Reason, 33) Designing an optimal patient safety culture, while

concurrently managing the financial status of a healthcare organization, presents additional challenges for management. (Joyce, Boaden and Esmail, 34) Healthcare leaders have even greater pressures when they must consider the penalties soon to be imposed by payers for not maintaining a patient safety culture (i.e., with limited iatrogenic properties).

Through "problemistic search,"(Cyert and March, 35) managers and leaders scan the healthcare environment for quick solutions to immediate problems regardless of complexity. Reason(33) states, "most managers ... attribute human unreliability to unwanted variability and strive to eliminate it." In addition, the majority of incident reporting systems used by healthcare organizations to remove iatrogenic system properties describe only what happened and pay little attention to the underlying iatrogenic sources. (Battles, Kaplan, van der Schaaf and Shea, 36) The concurrent pressures culminating from the current state of care delivery systems coupled with technological iatrogenic attributes create unsafe healthcare delivery systems.

Within the discipline of risk management, the value of learning and applying human factors principles(Leape et al., 37) and organizational theory to the complex healthcare system is inestimable. Understanding technological iatrogenesis and embracing the systems philosophy to error prevention is vitally important for risk managers desiring to achieve low risk, highly reliable organizations. According to Bennis(38) organizational cultures are created, supported, and sustained through leadership role modeling of acceptable organizational conduct. Specifically, risk managers can help leaders create and sustain organizational safety by understanding the iatrogenic attributes of healthcare organizations and embracing the system approach to preventing critical organizational incidents.

With the increasing regularity innovation that enters the organizational environment, risk managers must not only be aware of the obstacles to innovation, but also strive to help the entire healthcare team overcome them. Common obstacles include:

1) Short-term focus by upper management;

2) Insufficient time, resources, or staff;

3) Expectations to meet unrealistic payoff timeframes;

4) Management rewards are not structured to incentivize the adoption and implementation of innovation;

5) No systematic innovation process in place; and

6) The belief that the innovation is an inherently risky endeavor.(Loewe et al., 20)

While the primary object of many organizations in the healthcare arena is focused on the needs of the patient, the financial success of the organization is non-trivial and will be continuously recognized by Wall Street and others. Competition is fierce, government payments for Medicare and Medicaid services are minimal and under increasing regulatory pressures for increased patient safety, administrators and healthcare leaders must continue to be vigilant and using technology is one way to achieve success. Combating technological iatrogenesis will be vitally important for risk managers in their quest to reduce patient harm. Activities purposed at addressing the iatrogenic potential of technological innovation might culminate to achieve safer healthcare.

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