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Normal Accidents: Human Error and Medical Equipment Design

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ABSTRACT

High-risk systems, which are typical of our technologically complex era, include not just nuclear power plants but also hospitals, anesthesia systems, and the practice of medicine and perfusion. In high-risk systems, no matter how effective safety devices are, some types of accidents are inevitable because the system's complexity leads to multiple and unexpected interactions. It is important for healthcare providers to apply a risk assessment and management process to decisions involving new equipment and procedures or staffing matters in order to minimize the residual risks of latent errors, which are amenable to correction because of the large window of opportunity for their detection. This article provides an introduction to basic risk management and error theory principles and examines ways in which they can be applied to reduce and mitigate the inevitable human errors that accompany high-risk systems.

The article also discusses "human factor engineering" (HFE), the process which is used to design equipment/human interfaces in order to mitigate design errors. The HFE process involves interaction between designers and end-users to produce a series of continuous refinements that are incorporated into the final product. The article also examines common design problems encountered in the operating room that may predispose operators to commit errors resulting in harm to the patient.

While recognizing that errors and accidents are unavoidable, organizations that function within a high-risk system must adopt a "safety culture" that anticipates problems and acts aggressively through an anonymous, "blameless" reporting mechanism to resolve them. We must continuously examine and improve the design of equipment and procedures, personnel, supplies and materials, and the environment in which we work to reduce error and minimize its effects. Healthcare providers must take a leading role in the day-to-day management of the "Perioperative System" and be a role model in promoting a culture of safety in their organizations.

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BACKGROUND

High-Risk Systems

We live in an era of high-risk systems. These are systems that are characterized by "interactive complexity and tight coupling." Interactive complexity refers to systems, such as nuclear power plants, hospitals, anesthesia systems, and the practice of medicine and perfusion, that have numerous components and steps that need to be done in a specific order. Tightly coupled systems are those in which each step in a process is highly dependent on the results of other steps, which must be done in a timely manner in order to achieve the desired outcome.

In some high-risk systems, no matter how effective safety devices are, some types of accidents are inevitable. These accidents have been referred to by the seemingly contradictory term "normal accidents." Charles Perrow [Perrow 1984] has described "normal accidents" as those that occur inevitably in complex systems that are characterized by multiple and unexpected interactions. Such accidents will happen regardless of the number of safety devices, the quality of the care provided, or the vigilance of the operator. In other words, in complex systems, humans will make errors.

The following discussion provides an introduction to basic risk management and error theory principles and examines ways in which they can be applied to reduce and mitigate the inevitable human errors that accompany high-risk systems.

DISCUSSION

Errors

"Error" is a generic term that encompasses all occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome and the failure cannot be attributed to the intervention of chance. Error is either the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan of action (error of planning) to achieve a goal. It is also important to distinguish two other kinds of errors: active errors, whose effects are felt almost immediately, which Reason has further subdivided into slips, lapses, and mistakes (see Figure 1, ◉) [Reason

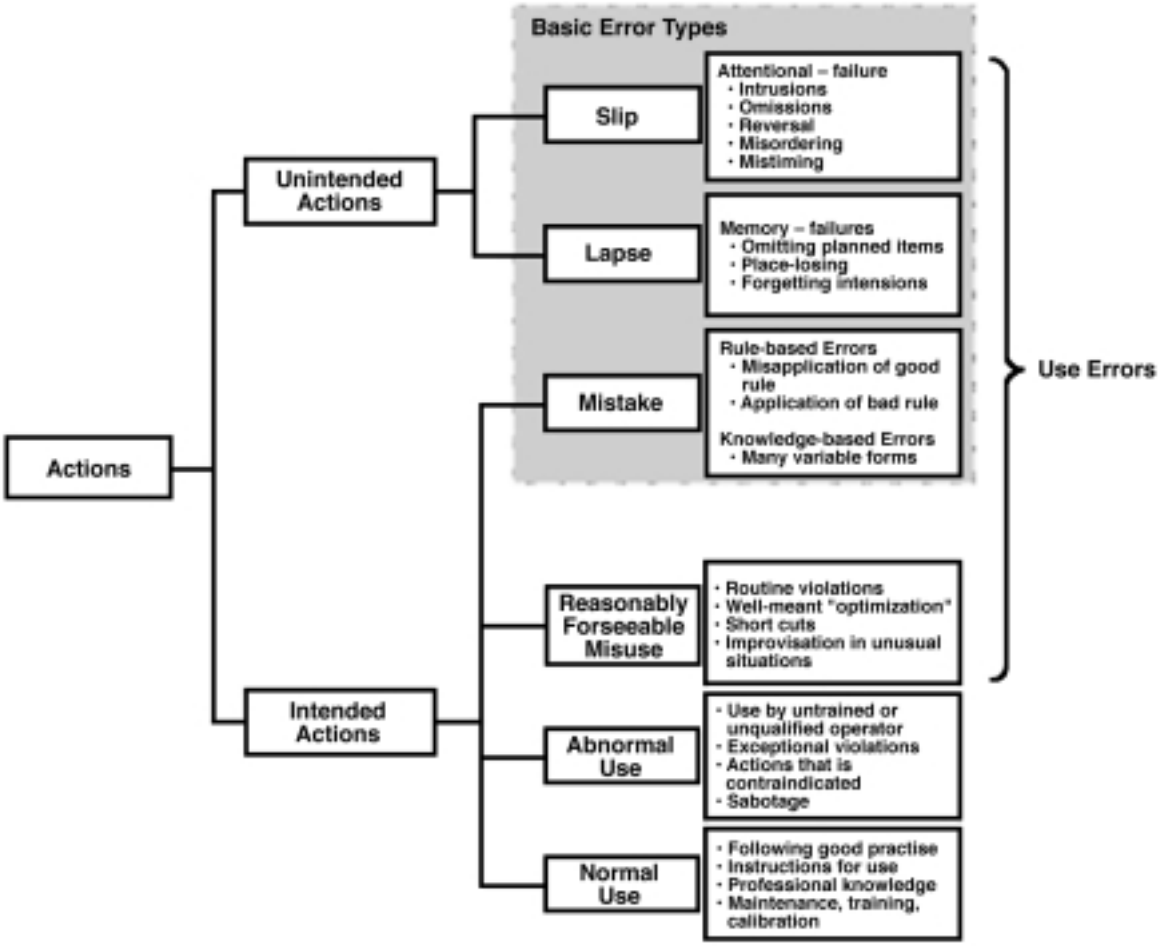

Figure 1. Classification of Operator Actions [Reason 1990, modified].

1999], and latent errors, whose adverse consequences may lie dormant within the system for a long time and become evident only when combined with other factors that breach the system's defenses.

Latent System Errors

Latent errors are most likely caused by the actions of such persons as equipment designers or architects, who inadvertently design equipment or rooms that are not suited for their intended purposes, or by hospital administrators who develop processes and procedures that do not take into account all readily foreseeable difficulties. Latent errors are often preventable because they may lie dormant in a system for a long time, providing a larger window of opportunity to identify and mitigate or prevent them before catastrophe strikes. When latent errors are identified, it is important to manage them in a timely manner according to their risk. These errors are often ignored on the assumption that "they will never happen" or that "all the wheels can't fall off the wagon at once." Workers often do not report latent errors because they are reluctant to be seen as "complainers" or as antagonistic to equipment or processes advocated by their "superiors."

Person Failure Model

The "person failure model" is, unfortunately, the dominant error model in the healthcare professions. It assumes that adverse events arise from unsafe acts or omissions that are the result of inattention, carelessness, laziness, lack of knowledge, or lack of motivation. For the person who purportedly caused the error, this attitude causes shame and embarrassment, remorse, and fear of liability. In cases of error that result in extreme consequences, such as the accidental death of a patient, these negative responses may lead to depression, alcoholism, drug abuse, and even suicide of the healthcare provider.

Because this error model is likely to result in errors not being admitted, it may lead to the same errors being repeated by others, resulting in further unnecessary patient or healthcare provider harm in the future.

Systems Failure Model

The "systems failure model," on the other hand, assumes that healthcare providers, no matter how well trained, conscientious, and motivated, will sometimes make errors because errors are inevitable in complex systems. The training of each

individual working within a high-risk system should include instruction in error avoidance and error mitigation skills. For example, flight simulator training and crew resource management training in aviation has been very successful in reducing and mitigating error in that industry.

Risk

Risk management, like most specialized branches of knowledge, has its own vocabulary. The Risk Management Standard for Medical Devices ISO 14971 defines the following terms:

- Harm: Physical injury and or damage to the health of people, or damage to property or the environment;
- Hazard: Potential source of harm;
- Risk: Combination of the probability of occurrence of harm and the severity of that hazard;
- Risk analysis: Use of available information to identify hazards and to estimate the risk; and
- Residual risk: Risk remaining after protective measures have been taken [ISO/IEC Guide 51, 1999].

It is generally accepted that risk involves three key concepts [ISO 14971, 2000]:

a) The probability of occurrence of harm;
b) The consequences of that loss; and
c) The perception of the loss; that is, how seriously the stakeholders view the loss and how it might affect them. (Stakeholders include manufacturers, distributors, purchasers, users, and patients.).

The risk assessment and management process is described in ISO Standard 14971. This schema may be applied to processes, devices, healthcare providers, and the environment in which they interact. It is important for healthcare providers to apply a risk assessment and management process to decisions involving new equipment and procedures or staffing matters in order to minimize residual risks.

Equipment Design

In his book, *The Design of Everyday Things*, Donald Norman lamented:

All these wonderful devices are supposed to save us time and produce faster, superior results. But wait a minute—if these new devices are so wonderful, why do we need special dedicated staff members to make them work—"power users" or "key operators"? Why do we need manuals or special instructions? . . . Why do so many features go unused? . . . Why do so many people have the flashing "12:00 a.m." on their VCRs? [Norman 1988].

Human Factors Engineering

As medical systems become more complex, "human factors engineering" (HFE), also know as "usability engineering," of equipment and equipment-human interfaces becomes increasingly important. HFE uses a team approach in the design and development of equipment. The HFE team consists of research and development engineers, cognitive psychologists, ergonomics specialists, and end users of the equipment.

HFE must start at the beginning of the design process. The HFE design approach adheres to the creed "form follows function." Therefore, the questions to be answered are: what is the equipment for, what is the expected environment of use for the equipment, who are the expected operators of the equipment, and what are their educational and cultural backgrounds? This information provides a basis for the design of the equipment/human interface. The HFE process then moves on to the production of mock-ups and prototypes, which are then evaluated by end users. Suggested changes are made, later prototypes are built incorporating the suggested changes, and the prototypes are tested. Several iterations of this process are undertaken to reach the final product. Many countries, including the United States, now require manufacturers to document their usability engineering process and present it as part of the medical device licensing application. The FDA website has some useful information for manufacturers on how to comply with these new regulations. The Association for the Advancement of Medical Instrumentation (AAMI) makes an HFE standard available [ANSI-AAMI 2001] and the International Electrotechnical Commission (IEC) has a standard that is in the process of development [IEC 60601-1-6].

Common Problems Contributing to Errors

Common problems that contribute to errors can be found everywhere. For example, in several of our operating rooms we have the gas drops on the wrong side of the patient's head, requiring that the anesthetic machines be placed on the wrong side of the patient. While this latent error rarely causes problems, it is easy to imagine that, in a critical incident, it might result in a cardiac arrest. If a morbidly obese smoker with obstructive sleep apnea and coronary artery disease develops laryngospasm after extubation, it may be very difficult to bag the patient adequately with the left hand while holding the mask with the right hand. If this unnecessarily poor configuration of equipment is not corrected, it is likely that a cardiac arrest will eventually result.

Equipment errors in anesthesia and critical care commonly involve infusion pumps, syringe pumps, or PCA pumps. Often this equipment is not intuitively easy to use, as it is difficult to press buttons with imprecise visual and tactile feedback. Other pumps may have factory configured default values that are dangerous. There have been numerous errors and some deaths associated with a particular PCA pump [Vicente 2000]. When the pump is turned on and one of the optional modes selected by the hospital is used, it offers a default drug concentration of 0.1 mg/ml. If the operator of the device fails to recognize this concentration and inserts a syringe with a drug concentration of 1 to 2 mg/ml, the patient may receive a 10 to 20 times overdose of narcotic when the pump is put into use.

Some syringe pumps on the market make error correction virtually impossible. For example, with one particular infusion pump, if an incorrect weight is entered, to correct the error the pump must be turned off, then turned on again and allowed to perform its power-up self-test, followed by a reiteration of the whole programming sequence. Such a delay is a safety hazard when an emergency drug must be started immediately.

Some new anesthetic machines offer two common gas outlets, which increases the risk of providing an anesthetic without a fresh gas flow if the wrong gas outlet is selected. One particular piece of equipment only has a very small, easily overlooked yellow LED light to indicate that the secondary common gas outlet is in use.

Likewise, the design of some blood warmers is potentially dangerous due to the risk of air embolus if the IV bag or blood bag is not de-aired prior to use. Rapid IV infusers and warmers should have air detectors and/or air traps to prevent massive air emboli. These and other common problems with design may predispose operators to commit errors that lead to patient harm.

Investigation of Errors

"Root cause analysis" is a process for identifying the basic or causal factors that underlie variations in performance. It focuses primarily on basic clinical and organizational systems and processes, not individual performance. This approach attempts to identify improvements in processes or systems that would decrease the likelihood of the same problem occurring in the future.

Charles Perrow has described a framework for the investigation of errors. A mnemonic device for describing this framework is the acronym DEPOSE: Design, Equipment, Procedures, Operators, Supplies and Materials, and Environment [Perrow 1984].

Flaws in one or more of the six factors that make up the acronym DEPOSE contribute to the making of errors: (1) design of equipment or of the environment in which the equipment resides, (2) equipment failure, (3) incorrect procedures or failure to follow standard procedures, (4) operator error or miscommunication, (5) lack of supplies and materials, and (6) a noisy, hot, or otherwise improper environment in which a operator must function.

Creating a "Safety Culture"

Reason describes the need for a "safety culture" [Reason 1997], one in which all participants within a system understand the factors that determine the safety of the system as a whole. The organization as a whole, from the CEO downward, must maintain a state of vigilance toward potential problems and act in a timely manner to resolve those problems before an accident that could have been prevented occurs. There should be an anonymous, blameless reporting mechanism available to the participants in the system, and the administration must be supportive of this "safety culture" [Helmreich 1998].

CONCLUSION

While recognizing that errors and accidents are unavoidable, we must continuously examine and improve the design of equipment and procedures, personnel, supplies and materials, and the environment in which we work to reduce error and mitigate its effects. We need a blame-free, litigation-free protective environment that allows and encourages anonymous reporting of near misses and serious adverse events. There must also be a partnership between patients, healthcare providers, engineers, researchers, manufacturers, and regulatory bodies to reduce and mitigate risks. Finally, healthcare providers must take a leading role in the day-to-day management of the "Perioperative System" and be a role model in promoting a culture of safety in their organizations.

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