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The Antidote

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A Newsletter about Truth and Integrity in Medicine and Medical Malpractice

How the Civil Law Can Make a Difference by Compelling the Safety Engineering of Healthcare

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Why should hospitals be compelled to safety engineer healthcare? The answer is because that is the only practical way for hospitals to effectively comply with their legal corporate duties. It is a proven method to avoid liability from the foreseeable and avoidable harm now being inflicted in the delivery of healthcare. Because hospitals are required to assure the health and welfare of patients, compelling the hospital to adopt and follow principles of safety engineering can only be accomplished by using the civil law tort system. Until the rule of law compels hospitals to provide safe care to its patients, the patients will continue to suffer the harm which results from the failure of adopting the principles of safety engineering.

Understanding the principles of safety engineering and why society, through its civil courts, should require the enforcement of safety engineering in healthcare must begin with an understanding of safety engineering principles.

To the safety engineer, any risk of serious injury or death in any activity, including healthcare, is unacceptable if reasonable accident prevention methods could eliminate that risk. Before the risk of serious injury or death can be eliminated (i.e., from healthcare) it must be recognized as "unacceptable." Knowing how to perform surgery is not enough. Knowing how to perform surgery safely must be an essential component of both training and practice.

Many healthcare procedures are inherently dangerous to the safety and welfare of the patient. Frequently healthcare providers do not perceive the full extent of the danger and at critical times the patients are unconscious or helpless to protect themselves from the risk of injury.

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Historically medicine has been viewed as an “art” that requires balancing the risk of inherently dangerous treatment with the perceived higher risks of non-treatment. Reliance on the skill and training of the doctors and surgeons has often been a matter of blind trust.

The trust and faith of the patient in his physician has been recognized as vital to the healing process. The physician or surgeon has been expected to protect the patient from injury inflicted by the physician; however, the concept of a “known risk” of the procedure has been accepted as consent by the patient and excuse for the physician if the “known risk” harms the patient. The patient’s safety from avoidable harm has not been established as an essential component of the activity. No concerted effort has been made to identify those risks that are foreseeable and avoidable. The known risk regardless of its cause, has been used as a valid excuse for any harm, even harm that is avoidable by being careful.

An airline pilot has a personal reason to adhere to rules of safe operation. The pilot is always the first person at the scene of a crash. Healthcare is different. Because the surgeon or attending staff are not the potential target of the danger presented in a surgical procedure and because it poses no personal threat, the danger is easily minimized, sometimes ignored, and frequently is simply accepted as a “known risk.” For example, there are many gallbladder surgeries each year. One devastating injury that can ruin a person’s life is an injury that severs the patient’s common bile duct. Eliminating the risk with simulated training and the use of intra-operative imaging studies is not done. The result is that throughout the United States gallbladder patients remain “at risk” for common bile duct injury because it is accepted as a “known risk.”

A belief that bolsters the acceptance of the “known risk” is the “rareness” of the occurrence. This concept is especially important because it helps explain why the needless injuries continue. Experts suggest that only 0.4-0.6% of patients suffer common bile duct injuries. However, when it is realized that more than 750,000 gallbladder operations are performed each year with up to 4,500 patients suffering common bile duct injuries, “rareness” seems to pale as an excuse for accepting this complication as an acceptable “known risk.”

Safety engineering is based upon the premise that “any” risk of such injuries is unacceptable if reasonable methods could eliminate them.

So how would a safety engineer approach the problem of designing reasonable methods to eliminate common bile duct injuries? (It should be noted that the same approach would be used whether the injury is caused by PICC line infections, bed sores, major blood vessel injuries, or any complication of any healthcare activity that causes serious injury or death to the patient.)

Safety engineering begins with a formal safety assessment which identifies the hazards. A hazard is a condition or changing set of circumstances which presents injury potential. After the completion of a hazard assessment, the safety engineer turns to the concept of risk. Risk is simply the probability of injury in percentages. It is affected by many factors such as proximity, exposure, attention arrestors, noise, lights, the experience and intelligence of the actor, etc.

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Next, the engineer considers the concept of danger. Danger is defined as the unreasonable and unacceptable combination of hazardous risks. As noted above, any risk of serious injury or death is unreasonable and unacceptable if reasonable accident prevention methods could eliminate it.

In performing a formal safety assessment, the safety engineer asks several important questions. First, what might go wrong? A careful investigation will result in a list of potential causes of a mishap or accident and the probable outcome. Frequently in performing a safety assessment an engineer will look for failures that have occurred with an ongoing activity and analyze the failures to find out what did go wrong.

Another question that is important to the analysis is how bad and how likely is it that serious injury or death will occur? Answering the above questions leads to the final important question and it is, "Can methods or rules be designed to eliminate, reduce or control the risk of serious injury or death?"

One important question also invariably considered deals with what it would cost and how much better the activity would be with the elimination of the risks of injury or death. Finally, the safety engineer determines what action should be taken. What safety rules, methods, procedures, or designs will eliminate the risk of serious injury or death?

If serious injury or death cannot be reasonably eliminated, what reasonable steps can be made to control the risk of injury or death? An awareness of danger or safety consciousness is essential to the proper evaluation of any activity by a safety engineer. In the delivery of healthcare we have noticed that many of the activities and procedures are properly described as "inherently dangerous." An activity which is inherently dangerous can only be safely performed using special care and skill.

One function of a safety engineering evaluation of surgical procedures by necessity would deal with answering the question of whether or not the surgeon and the surgical team have the training and skill that is necessary to avoid injuring the patient. In the area of evaluating skill it is clear that some form of testing or evaluation is necessary if supervision of the activity is required.

In aviation, for example, pilots are not only evaluated for their physical and mental abilities but are required to continually train for the unexpected through the use of flight simulators. The use of simulated training in medicine is only in its infancy but provides an effective method of improving the outcomes of operative procedures that present unexpected and rare complications to the operating team.

The safety engineer who is performing a formal safety assessment for the first time in a hospital setting may find some difficulty in readily identifying all of the hazards that are present in the delivery of healthcare. Medical textbooks and medical teaching of the procedures may not routinely include specific safety instructions. Hospital policies and procedures may also fall short of incorporating safety instructions.

To the safety engineer, safety education cannot be separated from skill education. Yet this seems to be done all the time in medicine by accepting known risks and complications as inevitable and an acceptable result of healthcare.

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Safety engineering! This is the answer! This is the better way!

Next Antidote publication: “Safety Engineering, a Laparoscopic Cholecystectomy and How the Proper Application of the Rules of Law can Provide a Solution to the Problem of Severe, Often Fatal, Unintended Harm to the Patient Population.”