Most people will readily place their lives in the hands of a doctor or a hospital, yet they live with fear and trepidation in regard to commercial airplane flights or driving on major freeways. Based on statistical evidence, it appears that our trust is misplaced.

Even though medicine and the medical industry has been around longer than aircraft and automobiles, the medical industry has not kept pace with the safety record of these other industries. Is it because these industries receive considerable notoriety and government oversight when an airplane crashes, killing 400 people in one incident? When people die individually due to medical errors, however, the notoriety and attention is just not there — apparently because no one is tracking the totals. With less notoriety, there is less oversight and forceful attention or regulation applied to the process.

One would expect some undesirable outcomes in high-risk industries, such as medicine, nuclear power, bullet trains, weapon systems, commercial aircraft, etc. But it does not seem reasonable to go into a hospital and have the wrong leg amputated, to die from a chemo overdose or to die from the erroneous application of the wrong drug. A physician's prime directive is “first, do no harm,” yet this is not what's happening. Can, and should, the medical industry be forced to maintain safety statistics, with a government mandate to reduce and control these statistics as is done in other high-risk industries?

Medical Safety: Death by Medicine

by Clifton Ericson

Do you wake up at night in a cold sweat because you are dreaming about dying in a car wreck while on your way to work? Are you afraid to fly to Barbados for a vacation because you fear dying in a catastrophic commercial aircraft crash? Well, fear no more! Research shows that you are more likely to die from a medical error than an automobile accident or a commercial aircraft mishap. Although the problem is well known in the medical industry, it seems little is being done to seriously address and fix the root causes. Perhaps it is time that medicine makes a major paradigm shift, moving from an age-old arts-and-crafts mentality to a more modern engineering mentality and approach to resolve the many complex issues associated with modern medicine.

Current statistical data show that more people die each year in the U.S. from medical errors than die in traffic accidents. Studies have been performed on the root causes of this problem, with recommendations as to how to alleviate it. After 10 years, few of the recommendations have actually been implemented. Although sincerely concerned, it appears that the medical industry is not yet prepared to take the necessary steps to resolve its medical error problem. It is disconcerting that the public does not seem aware of the extensiveness of this problem. Some important issues need to be addressed, such as: are doctors part of the problem or the solution? Does the medical industry need to make a major paradigm shift?

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To err is human, but to allow errors to kill is preventable and unacceptable. In Death by Medicine, author Gary Null concludes that the leading cause of death in the United States is medical errors [Ref. 1]. The yearly death rate even exceeds that of automobile accidents. Medical error is not just a matter of lost wages, lost days of work or lost productivity — it is a matter of life and death. Null cites the following rather startling U.S. medical statistics:

- The number of people with in-hospital adverse reactions to prescribed drugs is approximately 2.2 million per year.
- The number of unnecessary or inappropriate antibiotics prescribed is approximately 45 million per year.
- The number of unnecessary medical and surgical procedures performed each year is approximately 7.5 million.
- The number of people unnecessarily hospitalized each year is 8.9 million.
- The number of deaths caused by medical errors is currently about 800,000 people per year.

In contrast to these stark figures, in 2010 in the United States, 32,788 people died in auto accidents, 652,091 people died from heart disease and 559,312 people died from cancer in 2005. It is, and should be disconcerting that the number of medical error deaths is so much higher than these figures.

In 1986, Alphonse Chapanis, the respected human factors engineer gave a presentation "To Err Is Human, To Forgive, Design" at the 25th annual American Society of Safety Engineers (ASSE) professional development conference and exposition in New Orleans [Ref. 2]. Dr. Chapanis issued a challenge to the engineering community by introducing his concept that the only true human errors are really design errors. He stated that engineers should design products that look into the future and guard against all the types of use and misuse that people might make of them. This concept includes all of the human conditions that can occur when using the product — fatigue, boredom, inattentiveness, misunderstandings and other factors. Equipment, systems and machines have to be made to accommodate how people are, not the other way around. His work dealt with human error in many different industries, including the medical industry.

Error is defined as the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim [Ref. 3]. According to noted expert James Reason [Ref. 4], errors depend upon two kinds of failures: Either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct (an error of planning).

Human error is the incorrect or wrong execution of a required human action; i.e., it is a human failure. Human error and mistakes typically result from the frailties of human nature. Human errors can easily cause hazards and place people, equipment and systems at risk. Human error is an act that through ignorance, deficiency or accident departs from, or fails to achieve, what should be done. Errors can be predictable, or they can be unpredictable and random. Errors can also be categorized as "primary" or "contributory." Primary errors are those committed by personnel immediately and directly involved with an accident. Contributory errors result from actions on the part of personnel whose duties preceded and affected the situation during which the results of the error became apparent.
In order to eliminate or reduce human error, the concept itself must be understood. There are several ways to categorize human error, such as:

- By fault type
  - Omission
  - Commission
  - Sequence error
  - Timing error
- By situation assessment versus response planning
  - Errors in problem detection
  - Errors in problem diagnosis
  - Errors in action planning and execution (for example: slips or errors of execution versus mistakes or errors of intention)
- By level of analysis
  - Perceptual (e.g., optical illusions)
  - Cognitive
  - Communication
  - Organizational
- By exogenous versus endogenous source (i.e., originating outside versus inside the individual)
  - By exogenous versus endogenous source (i.e., originating outside versus inside the individual)
- By physiology (burn-out, depression, addiction)

Medical errors committed in hospitals and other types of healthcare settings have been classified into the following categories:

- Human factors
  - Fatigue
  - Depression
  - Burn-out
  - Diverse patients
  - Time pressures
  - Variations in training and experience
  - Failure to accept the prevalence of errors
- Medical complexity
  - Complicated technologies
  - Powerful new drugs
  - Intensive care
  - Prolonged hospital stays
- System failures
  - Poor communication
  - Unclear lines of authority between physicians, nurses and other care providers
  - Complications as patient-to-nurse-staffing ratio increases
  - Disconnected reporting systems within a hospital
  - Fragmented systems in which numerous hand-offs of patients result in lack of coordination and errors
  - Drug names that look alike or sound alike
  - The impression that action is being taken by other groups within the institution
  - Reliance on automated systems to prevent error
  - Inadequate systems for sharing information about errors that hamper analysis of contributory causes and improvement strategies
<table>
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<th>Cost-cutting measures by hospitals in response to reimbursement cutbacks</th>
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<tr>
<td>Irrelevant or frequent warnings that interrupt work flow</td>
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<td>Environment and design factors — for example, in emergencies, patient care may be rendered in areas poorly suited for safe application or monitoring</td>
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One potential cause of medical errors stems from medical schools. The knowledge, skills and attitudes needed for safe practices are not normally taught in medical school. The methods and processes for system safety need to be taught in medical schools in order to start the paradigm shift in medical thinking.

Technology-induced errors are significant and increasingly more evident in healthcare systems. As a result, a new term has been coined: technological iatrogenesis. This term describes a new category of adverse events that are emerging from technological innovations that create disturbances and contribute to medical errors. Healthcare systems are complex and adaptive, meaning there are many networks and connections working simultaneously to produce certain outcomes. When these systems are under the increased stresses caused by the diffusion of new technology, unfamiliar and new errors often result. If not recognized, over time, these new errors can collectively lead to catastrophic system failures. For example, in a survey of more than 500 healthcare facilities, 84 percent of respondents identified automated drug dispensing as a cause of error. Technology may lead to a false sense of security in regard to healthcare safety.

Pay for performance (P4P) is being touted as a possible solution to medical system problems. P4P systems link compensation to measures of work quality or goals. The idea is to connect at least part of an employee’s pay to measures of performance. However, current methods of healthcare payment may actually reward less-safe care, since some insurance companies will not pay for new practices to reduce errors, while physicians and hospitals can bill for additional services that are needed when patients are injured by mistakes.

Evidence-based medicine is being suggested as a possible cure for medical errors. Evidence-based medicine is an approach that integrates an individual doctor’s exam and diagnostic skills for a specific patient, with the best available evidence from medical research and best practices available. The doctor’s expertise includes both diagnostic skills and consideration of an individual patient’s rights and preferences in making decisions about his or her care. The clinician uses pertinent clinical
research on the accuracy of diagnostic tests, and the efficacy and safety of therapy, rehabilitation and prevention to develop an individual plan of care.

An advantage of evidence-based medicine is that it may reduce adverse events, especially those involving incorrect diagnosis, outdated or risky tests or procedures, or medication overuse. Errors related to changing shifts or multiple specialists are reduced by a consistent plan of care. As medical advances become available, doctors and nurses can keep up with new tests and treatments as guidelines are improved. There are some negative aspects, however; for example, managed care plans may attempt to limit unnecessary services to cut the costs of health care, despite evidence that guidelines are not designed for general screening, but as decision-making tools for an individual practitioner to use to evaluate a specific patient. Implementing guidelines and educating the entire healthcare team within a facility costs time and resources. Clinicians may resist evidence-based medicine as a threat to traditional relationships between patients, doctors and other health professionals, since any participant can influence decisions.
Safety in healthcare seems to be where the aviation industry was about 40 years ago, when engineers and managers did not question the establishment. Engineers went to reviews — similar to the Morbidity and Mortality boards in hospitals — where active discussions are held, but there is practically no discussion of how to change the system to prevent more accidents. Very few participants challenge each other or hospital superiors to bring out what is best for patient safety.

A number of things can be done to address and correct many of the root causes of the medical-error death problem. For example, the system safety engineering discipline has been successfully applied to industries such as commercial aircraft, nuclear power, high-speed rail and weapon systems. The system safety process has helped to keep accident and mishap rates extremely low in these industries. Special engineering tools are applied, including hazard analysis and fault tree analysis to identify hazards and mitigate their root causes. These processes and tools could easily be applied to medical processes.

Tools from the reliability engineering process could also be applied to the medical industry. For example, Failure Mode and Effects Analysis (FMEA) is just now being introduced to the analysis of medical processes. The FMEA technique identifies potential failure modes in a design or a process, and then evaluates the overall effect of these failure modes should they occur. Once failure modes having high probability of occurrence are identified, they can be mitigated through the application of alternative steps or the application of special safety measures in the process.

Systems engineering and systems engineering tools would also be applicable in establishing and maintaining disciplined medical processes. For example, functional flow diagrams, events sequence diagrams, and configuration control processes would provide many benefits.

Another safety tool that is now beginning to gain ground in the medical industry is the checklist. It seems ludicrous that something as simple as a checklist has not been previously applied in medical procedures. The safety checklist is used in the airline industry to help pilots ensure that all of the necessary and critical steps in a process are performed. Prior to use of the checklist, many pilots were forgetting necessary steps, resulting in aircraft-related mishaps. The checklist became extremely important when pilots were under stress due to some emergency.

Atul Gawande, an associate professor at Harvard Medical School, has written a book titled *The Checklist Manifesto — How*...
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The noted management expert W. Edwards Deming taught that improving the process is the only way to improve quality. This philosophy seems to directly apply to the medical industry's problem of unnecessary medical errors. By changing its overall process to one that is well defined, measurable and disciplined — similar to those in engineering and manufacturing — the medical industry may be able to reduce and control its accident rate. It may require a major shift in thinking for the medical industry to change its practices. Perhaps the time of the individual doctor reigning free and uncontrolled is over. Perhaps, too, some major changes are also needed in the medical insurance industry, which forces many medical decisions that may not be appropriate. Death by medicine is an unfortunate and unacceptable problem that can only be solved through major paradigm shifts and the commitment of the entire medical profession and industry.

About the Author

Clifton A. Ericson II has 45 years of experience in the field of system safety, software safety, hazard analysis and fault tree analysis. He worked for the Boeing Company for 35 years and is currently a system safety consultant performing system safety analysis and training. Ericson was president of the International System Safety Society in 2001-2003 and won the Society's President's Achievement Award in 1998, 1999 and 2004 for outstanding work in the field of system safety. He has many published technical papers, he is presently editor of Journal of System Safety and he is author of the following books:

- Hazard Analysis Techniques for System Safety, Wiley, 2005
- System Safety Primer, printed by CreateSpace, 2011.
- Fault Tree Analysis Primer, printed by CreateSpace, 2011.

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