

Bring Your Life into FOCUS!

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All of us make mistakes. The nature of being human is to err. John Nance, speaking at the Society of Cardiovascular Anesthesiologists (SCA) 29th Annual Meeting (April 22, 2007, Montreal, Canada) during the Flawless Operative Cardiovascular Unified Systems (FOCUS) initiative opening address noted, “although individuals may make mistakes, it is possible for teams to be flawless.” Although this concept has been embraced by other high-risk industries, notably aviation and nuclear power, it has not yet been embraced by medicine. Cockpit (crew) resource management (CRM) is a key facet of the safety culture in aviation.¹⁻³ CRM represents a culture of safety within the entire team responsible for servicing, preparing, and flying the aircraft, and includes the concept that if anyone notes anything untoward, they are to speak up, be heard, and know that they will be taken seriously for the safety of all.¹⁻³ It recognizes that no one individual, no matter how high their rank, is infallible. Checklists, guidelines, and standardizations are all part of CRM. Above all, teamwork through communication for a common goal, safety, is paramount. Each team member creates crosschecks through briefings, debriefings, expectations, and supervision in the overall spirit of creating a flawless outcome. Therefore, CRM is a culture, or unified human system, by which teams can operate flawlessly!

FOCUS represents a progressive, revolutionary leadership initiative for the SCA. The anagram for this program was chosen carefully, because it is only through teamwork that we can be flawless. In this editorial, we summarize the vision and progress that is the FOCUS initiative.

The goal of the FOCUS initiative is to substantially decrease the incidence and severity of human error in the cardiac operating room through scientific analysis leading to culture change.

HUMAN ERROR

Let us frame the problem of human error in medicine. Since the late 1990s, human errors in medicine have gained the interest of the lay press.⁴⁻⁸ It has been estimated that 48,000 to 98,000 lives are lost every year in US hospitals because of medical mistakes.^{4,5} That is almost certainly a gross underestimate.⁶⁻⁸ Worldwide the number may exceed 500,000 lives! In aviation terms, that would mean the crash of a fully loaded Boeing 747 every other day for 1 year (to account for the known statistics in the United States alone). What would the public outcry be if such events actually occurred in commercial aviation?

By no means does America have a corner on the human error market. Recognizing the damage caused by human errors in surgery, the World Health Organization has made reduction of this specific problem one of its goals since 2005.^{9,10} However, despite lofty ideals, rarely a week goes by wherein print or broadcast media (e.g., *Newsweek*, *USA Today*, or CNN) do not report another story on human error in medicine.

The aviation and nuclear power industries are held up as examples in which human error has been dramatically reduced if not virtually eliminated. It was not always that way, however! The single largest airline casualty event was caused by 2 fully loaded 747s colliding because of a misinterpretation of a tower communication. The near meltdown at Three Mile Island and the catastrophic events at Chernobyl were caused by human errors. However, after those errors, these high-risk industries

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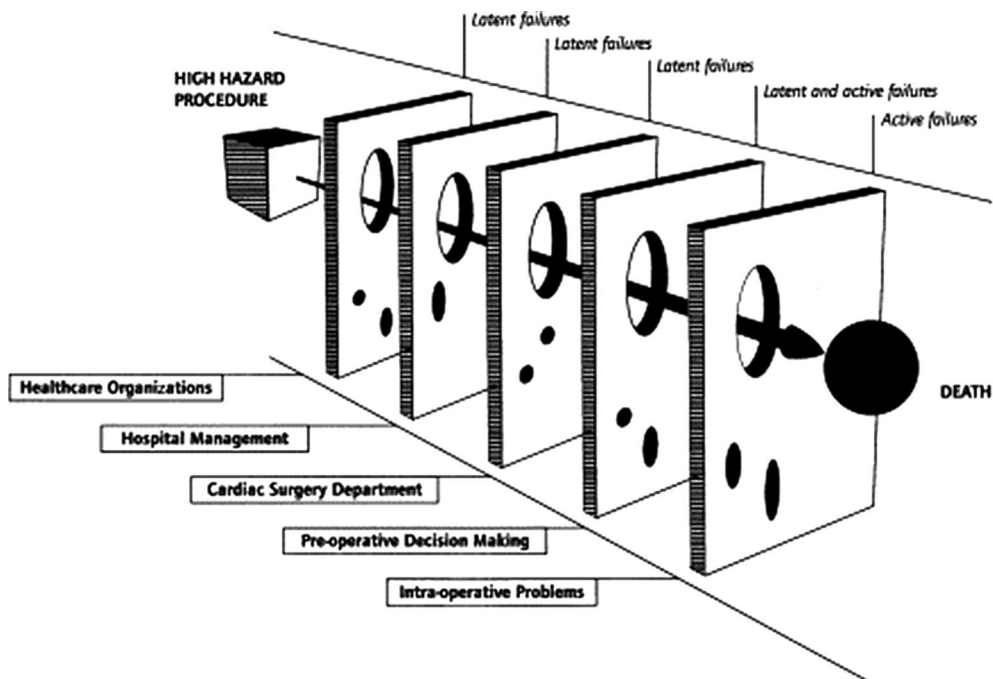


Figure 1. The “Swiss Cheese” model of human error adapted to health care/hospital organizations. Clearly, it is far more complex than this illustration, but a series of human events from organizational levels down must happen before a bad outcome is realized. Plugging of a hole at any level may well avoid serious adverse events. (Reprinted with permission from Carthey et al.¹⁷ © Elsevier 2001.)

undertook human error analysis to determine how human errors occur and to put policies and processes into place to prevent simple errors from becoming catastrophes.

HUMAN FACTORS ANALYSIS OR ENGINEERING

Human factors analysis is a complex and evolving science.¹ Investigators examine not just what error occurred, but why the events happened, exploring human-to-human interactions, human-to-machine interfaces, and what circumstances set up a well-meaning and well-trained individual to make an error. Human factors analysis focuses on the process that permitted the error, rather than on the individual who made the error. Human factors analysis also understands that an accident is caused by the culmination of a series of events, rather than a single, isolated error.

Every person reading this article can reflect on the last or most memorable of his or her personal errors. An example may be a drug error made in the administration of fentanyl, wherein another “blue syringe” containing neosynephrine is injected. A sudden blood pressure increase might be the result, and the patient might develop a small parietal intracerebral hemorrhage after surgery. No death occurred. Small strokes are not uncommon after heart surgery. What was the cause of this adverse outcome, the syringe swap error? Actually, perhaps 5 to 10 human errors led to that single event (a drug error).

Figure 1 depicts the “Swiss Cheese” analogy of the error process. Only when the holes, i.e., a series of human events or errors, line up in series does an

adverse outcome result. It is important to understand why a highly trained individual committed the error and how other events lined up to permit the error. If factors (human) failed the individual and allowed such an event, then a true culture of safety, using human factors analysis, would examine not just the error, but what circumstances set up the event, and could then build systems to overcome the deficiencies. In-depth understanding of the human factors that led to error can help us create systems to prevent it.

HUMAN ERROR ANALYSIS IN MEDICINE

Anesthesiology has led medicine in improving patient safety and has been rewarded in kind by a reduction in malpractice premiums.¹¹ Advances in technology, such as the pulse oximeter, have improved patient safety in our specialty, often by reducing human error. By warning of hypoxia, the pulse oximeter notifies the anesthesiologist of the error of esophageal intubation.

The Anesthesia Patient Safety Foundation has led medicine by providing research, education, simulation, establishment of practice guidelines, and other methods. The American Society of Anesthesiology Closed Claims study is a prime example of learning through retrospective analysis of adverse outcomes. Closed claims analysis helps us understand patient and practice risk factors that contribute to bad outcomes. Such work is laudable and important, but the complexity of human factors may not be evident from retrospective analysis. So, in addition to these national efforts, guidelines, scenario training and simulation, better equipment, and more rigorous training have

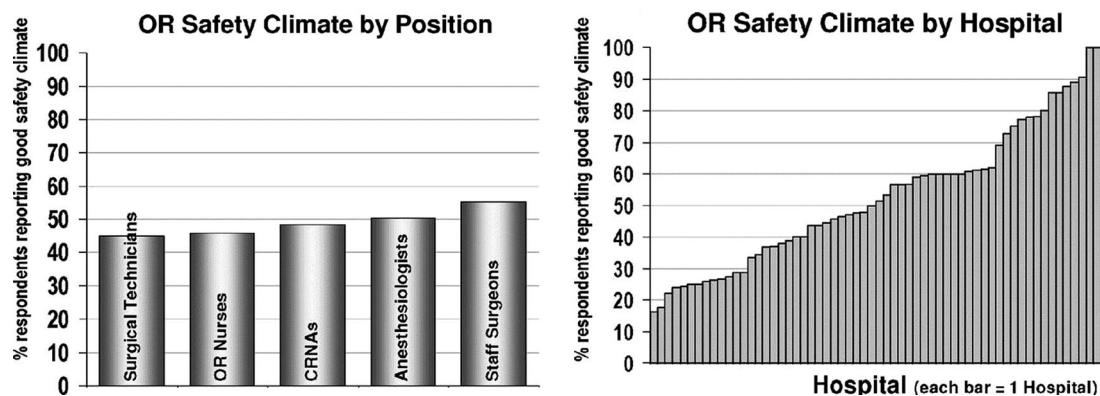


Figure 2. There is a highly variable safety climate in operating rooms. The level of safety climate has a correlation to safety adverse events and patient outcomes. (Reprinted with permission from Makary et al.²⁰)

been developed to improve patient safety. However, human errors persist.

Why, with such efforts, has medicine (and anesthesiology in particular) not been able to duplicate the successes seen in aviation? Perhaps most importantly, although human error has been studied in the operating rooms,¹²⁻¹⁸ human systems in medicine have rarely been systematically studied to the depth at which commercial aviation (or nuclear power, interstate transportation, construction crews, or even the assembly lines of automobile manufacturers) has been studied.¹⁹ Traditionally, patient safety research within hospitals is driven by quality assurance committees reviewing sentinel events. Themes of major, recurring sentinel events may drive change that is highly influenced by local politics. Human error may be dealt with by disciplinary action and/or the shunning and dismissal of highly trained individuals.

Although it has been shown that the rate of adverse outcomes is lower in operating rooms where patient safety is highly valued (Fig. 2), rather than seek to change the local culture to one of safety, the motivation for change may be to reduce malpractice payouts.²⁰ The cardiac operating rooms, in particular, are incredibly complex environments in which a number of highly trained professionals interact with each other and with a wide range of highly sophisticated electronic equipment to provide care of a single patient. Few systematic studies in cardiac anesthesiology or surgery have been performed regarding human error/factors across multiple institutions or internationally. The studies that have been done in cardiac and trauma surgery have been within a single institution having a unique culture.^{15,16}

All of us caring for cardiac patients have factors that affect our ability to be at peak performance: emotional stresses, fatigue, ability to concentrate, situational awareness, and so on. These normal stressors may result in a lack of concentration, leading to error. These factors are well described in aviation, transportation, and other high-risk industries but have not been systematically researched in the operating room.

Other high-risk industries have adopted national error and near-miss reporting systems that drive process improvement. The transfusion community makes use of an Eindhoven classification model, a near-miss taxonomy developed for the chemical industry. This analysis classifies near misses into 3 major subheadings: technical (equipment and software), organizational (oversight, regulations, and guideline), or human (violations or failure to follow established rules). The use of such a system would guide processes to improve patient safety. There are no such punitive-free, anonymous, national error reporting systems in surgery or anesthesiology.

Although it would be tempting to conclude that the operating rooms would be suddenly improved by adoption of the CRM process, the answer to decreased human error in the cardiac operating room is not so simple as to say that the anesthesiologists, surgeons, perfusionists, and nurses have to be better communicators. Communication may be one of the major areas of focus. However, should the efforts to improve patient safety be focused only on CRM or on other systems or processes? For example, we must also know whether there are inadequacies, latent and hidden, within any of the machine/human interfaces that could result in error. Acquisition of proper and modern equipment, labels for syringes that cannot be misinterpreted, or operating room design with proper ergonomic function might be extremely important. Other areas for improvement might well include administrative efforts to provide better equipment, changes in personnel numbers, shift and work structure, or call schedules that make work more efficient or safety oriented (Table 1). Clearly, improvements in safety must be driven by research and data.

THE FOCUS INITIATIVE

FOCUS is a progressive, revolutionary leadership initiative for the SCA. The SCA has functioned for its 30-year history as a research- and education-facilitating society. In a larger sense, through education

Table 1. Human Factors That Combined Contribute to Adverse Outcomes

Organizational factors
Policies
Procedures
Staffing
Call schedules
Safety climate
Resources—equipment
Supervisory factors
Training
Safety climate
Teamwork
Social factors
Communication
Familiarity
Response in emergencies
Mental status—situational awareness
Fatigue
Task saturation
Confidence to make correct judgment
Environmental factors
Operating room set up
Ergonomics design
Feedback
Computer crosschecks
Alarms
Organizational simplicity/complexity
Anesthesiologist/practitioner factors
Technical skill
Knowledge base
Experience
Confidence
Physical-mental preparedness/impairment (illness)
Situational awareness

Multiple levels of preconditions for unsafe acts interact to create the “Swiss Cheese” holes in human error. Key words and situations are found up and down the chain of factors. Indeed, in some small way, every adverse outcome has human error involved.

and by advancing knowledge, patient safety is continuously improved. This mission cannot be diminished, but, by embracing the FOCUS initiative, the SCA leadership and the SCA Foundation have charted a bold new course: one whereby, through research and implementation, they can improve patient safety. The SCA plans to lead the way in creating a culture of safety in the cardiovascular operating room, wherein Flawless (teams working together) Unified (we can all adopt the measures) Systems (human interactive programs) will result.

The FOCUS initiative has been in its formative stages for >5 years, with the intent to study surgeon/anesthesiologist communication, and how a whole team and its individual parts work (or don't work). The FOCUS Steering Committee articulated the goals of the initiative (Spring 2006) in a request for proposals. A number of responses were forthcoming, leading to 6 finalists who were interviewed. The Johns Hopkins Quality and Safety Research group under the direction of Peter Pronovost, MD, was contracted to conduct the research and collaborate on implementation of the findings. The Johns Hopkins group (an extensive multidisciplinary team) has an international reputation of scientific leadership, publication, and success in patient safety. An accompanying commentary by Martinez

et al.²¹ explains the “LENS” (Locating Errors through Networked Surveillance) processes to be used. Along the way, the SCA and the SCA Foundation have been joined by representatives from cardiothoracic surgery (the Society of Thoracic Surgeons and the American Association of Thoracic Surgeons), nursing (the Association of Operating Room Nurses), and perfusion (the American Society of Extracorporeal Technology). The process has had the valuable consulting services of Scott Shappell, PhD (Clemson University), who has a unique background in defense department (naval aviation) air accident investigation, civilian human factors accident investigation (TWA flight 800), and, most recently, in medical human factors work. FOCUS is lucky to have found such team members.

How then will FOCUS achieve the goal stated earlier, to substantially decrease the incidence and severity of human error in the cardiac operating room through scientific analysis leading to culture change? First and foremost is to study the current processes, cultures, and human factors at play in cardiac operating rooms. Research and data must drive this effort. As described in the accompanying article from the Johns Hopkins University Quality and Safety Research group,²¹ a thorough research of the literature and error databases was conducted to guide the observational research plan. Then, 5 initial cardiac surgical sites (plus Johns Hopkins University as a test site for the surveys) were selected, and observations and surveys were performed. Now, having concluded the first wave of observations, analysis of all of the accumulated data is being conducted. Through this analysis, preliminary recommendations for interventions will be created. The interventions will then be tested at newly selected cardiac surgical sites, using well-defined methods for measurement of human errors.

At this time, we cannot presume to know what the research will find, but interventions will not be based on supposition or armchair guessing. If an intervention cannot be tested, observed, and supported by data, it will not go forward. Parallel development of self-study programs or peer-to-peer assessment will allow all operative sites represented in the SCA to become familiar with the concepts and improvements identified by FOCUS. Any future successful reduction in human error will depend on the solid groundwork laid by careful and thorough research.

The task is immense. The SCA is committed to this goal over the long haul and has contributed significant financial support to perform the first phase of research. In addition to financial support, SCA members can participate by being on FOCUS committees and by participating in the next phase of research. Every SCA member can and should get involved with FOCUS. We owe this to our patients, who expect (and rightfully so) Flawless Operative Cardiovascular care. Individuals will always make errors, but teams who

develop a culture of safety through FOCUS can be flawless. The cause has charisma!²²

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