

# Human Error in Medicine: Change in Cardiac Operating Rooms through the FOCUS Initiative

Bruce D. Spiess, MD

Anesthesiology and Emergency Medicine, Virginia Commonwealth University Medical Center, Richmond, Virginia

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**Abstract:** Human error in medicine is a significant cause of patient mortality. While there has been increased attention to safety in medicine since the Institute of Medicine publication *To Err is Human*, the profession at large has not progressed to the same degree as other highly complex industries such as aviation and nuclear power. The Flawless Operative Cardiovascular Unified Systems initiative (FOCUS) is a multi-year study/intervention to learn about and to improve human error in cardiac surgery. FOCUS has developed into an ongoing re-focusing through prospective interventional research schemes designed to effect positive change for improved patient care in cardiac surgery. The program was developed in conjunction with the Johns Hopkins University Quality and Safety Research Group using an approach termed Locating Errors through Network Surveillance (LENS). The LENS process was undertaken at Johns Hopkins University and another five centers where three major areas were examined observationally: interactions (communication) between operating room cardiac team members, clinical performance of known

quality and safety dependent processes, and ergonomics/safety or human-machine interfaces. While collected data is currently being analyzed, preliminary results reveal over 800 human errors noted in the 40 cases observed. The errors observed are being categorized and taxonomy of errors is being created. Categories used in the FOCUS analysis include: teamwork and communication, compliance with existing protocols, knowledge or supervision, vigilance or situational awareness, equipment failure/design, poor operating room design/ergonomics, handoffs and transport problems, lack of professionalism, and ambiguity of responsibility. FOCUS is an initiative to change practice driven by science. Interventions based upon the observations already underway include efforts to decrease infection, adoption of the aviation concept of the “sterile cockpit”, briefing and debriefing, reduction of drug error, and peer-to-peer assessment. The first FOCUS data is sobering and shows tremendous possibility for improvement. **Keywords:** communication, teamwork, anesthesia, cardiac surgery. JECT. 2011;43:P33–P38

It is estimated that approximately 100,000 patients die each year in the United States due to human errors in medicine (1–4). How many others suffer some harm is not known. The Institute for Medicine published *To Err is Human* over 10 years ago (1). Since that time lay pressure has mounted and some studies have been done on the problems of human error. Many of these studies are isolated at single academic institutions and have no interventions. The Veteran’s Administration has taken a lead on communication and instituted changes (5,6). But, as a whole, medicine has not progressed to the level of safety seen in other high complexity, high reliability industries such as nuclear power or commercial aviation. There may be excuses and barriers why change is not coming faster. Techniques used in those industries may be not easily

transferable to medicine. However, the discipline of human factors in engineering has become an established academic science (7). Learning from accident investigations in the United States military and civilian aviation can be called upon to rigorously study how we do our business (8,9). The Flawless Operative Cardiovascular Unified Systems initiative (FOCUS) is a multi-year study/intervention to learn about and to improve human error in cardiac surgery.

## HUMAN ERROR—THE PROBLEM

The estimate of 48,000–98,000 lives lost to human error per year was in the mid 1990s in the United States (1). The World Health Organization (WHO) has embraced the problem as a universal one affecting surgery in both emerging and developed nations (10,11). In 2005 WHO has made safe surgery one of its foremost goals. In terms of a worldwide estimate of deaths in medicine due to errors the numbers are staggering, perhaps 500,000 people per year.

Address correspondence to: Bruce D. Spiess, Anaesthesiology and Emergency Medicine, Virginia Commonwealth University Medical Center, P.O. Box 980662, Richmond, VA 23298-0662. E-mail: bdspiess@vcu.edu

To put that into laymen's terms it would equal a fully loaded 747-400 crashing and killing all the passengers every other day for 1 year. Imagine the outcry if that were to happen. In the United States 2 trillion dollars per year is spent on healthcare, we do approximately 25,000,000 surgeries and have no idea how many deaths occur due to human error in surgery. In cardiac surgery there simply are no numbers with a denominator to even give us an estimate.

Anesthesiology has led the way around the world in developing patient safety with risks of death due to anesthesia predicted to be dramatically declined due to enhanced training and better monitoring. But perhaps it is also due to a culture of safety that has grown through this last generation of anesthesiologists as they were trained. Safety, begets more safety. The nuclear power industry makes safety its major concern. Even major construction projects promote safety ahead of all other concerns.

In 2007 at the annual meeting of the Society of Cardiovascular Anesthesiologists (SCA) the FOCUS initiative was announced to the membership and the public. Speaking at that meeting was John Nance, a commercial airline pilot for Alaska Airlines who said: "Although individuals may make mistakes, it is possible for teams to be flawless." That is how the airline industry has created cockpit resource management (CRM) techniques. Those CRM techniques are a buzzword for anesthesiology and often speakers regarding this topic think that all we need to do is to be like pilots. That is naïve, yet laudable.

## HUMAN FACTORS ENGINEERING

The discipline of human factors analysis is a complex and evolving social engineering study. It is developing a disciplined science that now formally approaches complex industries with proper ways to structure the human aspects of a production. Cardiac surgery is governed by the same principles as are other industrial events. The six-sigma training has been often focused upon as a goal for high reliable industries. Few realize that this effort to reduce human error arose out of the Minnesota Mining and Manufacturing Company (3M) as a method to reduce waste and bad products coming off its assembly lines. As an applied science, most of us in medicine are not comfortable or familiar with the observational nature of human factors engineering yet we can take the methodology and study cardiac surgery.

One way to understand human factors is to look at a traffic accident and to see perhaps how one driver ran a stop sign leading to a crash. That is important but human factors engineering might well look at that event and say: yes a stop sign was run and perhaps it could be more visible but what were the factors that caused either driver involved in the crash at that instant to not be as alert or as potentially

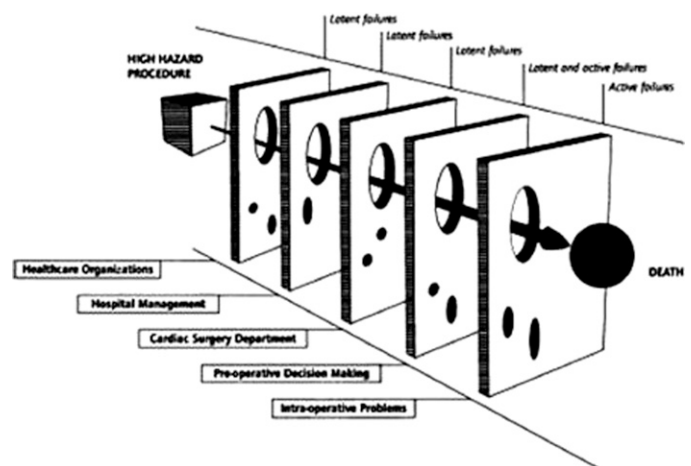
safe as they are otherwise. Indeed it may well be that such a driver could have been distracted by his mental or emotional events of the day, a fight with his spouse or a conflict at work. Perhaps there were design flaws in the road or the way landscaping had been done to the side of the road. Mental state and distractions are a major part of human factors work. One cannot outlaw driving while thinking but understanding what human distractions occur and what can be prevented is part of the science of human factors.

It has always been said that single events do not cause major human errors. A "Swiss cheese" model has been proposed showing that latent failures due to hospital organization, operating room set up, all the way to an individual's immediate situational awareness may be part of a particular series of events leading to a catastrophic mistake (Figure 1) (12). This "Swiss Cheese" model has been applied to cardiac surgery, but clearly more needs to be done (13).

The cardiac operating rooms are incredibly complex environments. They have evolved in medicine to be hierarchical structures with leaders (surgeons) driving many decisions. Some work in the culture of safety has been done in operating rooms (5,14-16). Those that have highly respected cultures of safety across all disciplines tend to really have better outcomes. In cardiac surgery in a single center an examination of breaks in concentration was undertaken. It showed that such breaks were common and influenced human error (14).

## THE FOCUS INITIATIVE

Academic medical societies serve their membership most often as education liaisons. Six years ago the SCA undertook a philanthropic mission and in so doing they changed



**Figure 1.** The latent series of events that lead to an adverse outcome/death. The holes must match up for the eventual sentinel event to occur. Any intervention can possibly avert disaster. Adapted from Carthey et al. (12). Reprinted with permission.

their mission. When FOCUS was presented to the SCA leadership it was explained as a long-term research project. But FOCUS is more than a research project to classify the human errors in heart surgery. It is a constant re-focusing through interventional schemes to take the basic research and to change the fabric of cardiac anesthesia, surgery, perfusion, and nursing such that patient care is improved. This fundamentally also changes the mission of the SCA as a research and teaching organization into an instrument of social and medical change.

In 2004–2005 the vision for FOCUS was endorsed. Human factors engineers were consulted to advice the SCA in writing a request for proposals. A large number of organizations responded to the request for proposals. Ultimately this led to the selection of the Johns Hopkins University-Quality and Safety Research Group (JHU-QSRG led by Peter Pronovost, MD) to be a collaborative partner in performing the initial research. JHU-QSRG had pioneered early interventional human factors research in infection control in intensive care units (13,17,18). Through the use of checklists, empowerment of teamwork, and improved safety culture, the infection rate for central line placements had dropped to zero when their human systems were used. They had developed and proposed methods for survey, interview, and direct observation of cardiac surgery that follow human factors engineering principals. The JHU-QSRG brought to bear experts from the science of patient safety, organizational sociology, industrial psychology, clinical medicine, human factors engineering, biostatistics, and informatics. Each of these experts has their own lens through which they view the problems. One can appreciate that by simply looking at the stakeholder groups who contribute to patient care in the setting of cardiac surgery. Clearly, an anesthesiologist, cardiac surgeon, perfusionist, and nurse all have different lenses through which they see tasks in the operating room.

The JHU-QSRG team created an integration of these specialists and through an approach they termed Locating Errors through Networked Surveillance (LENS), (Table 1) the study was carried out (Figure 2) (19). Tools for study were created at JHU-QSRG and beta tested within the JHU hospital system before being applied to other centers. While developing these tools for research, they conducted an extensive literature search and reviewed any worldwide error reporting systems within cardiac surgery. A British safety surveillance system had existed for years, and through query of that data, some further refinement of the LENS system was possible.

The SCA solicited centers within the United States for participation in the first FOCUS observational research project. A site selection committee developed criteria to get a balanced sample of cases and types of institutions within the constraints of budget. Five centers (plus JHU) were selected to undergo the LENS human error research

**Table 1.** Disciplines in LENS.

Disciplines in LENS	
Organizational Psychology	The collective behavior, beliefs, motives, and expectations of people working within organizations.
Human Factors Engineering	How we as humans interact with our environments and other humans to accomplish tasks of our jobs.
Industrial Psychology	The study of human behavior in the interaction with other humans working in technologically advanced or complex organizational environments.
Clinical Medicine	The sub-specialty personnel involved were specialists from anesthesia, nursing, cardiac surgery, and perfusion.

Adapted from Martinez et al. (19).

project. It was important that all members of each center’s team be amenable to observation. Therefore, consent (not of the patient) of the participating persons within each discipline was sought. Of note a cardiac anesthesiologist was the primary investigator at each site and he/she secured the cooperation of the lead cardiac surgeon, most importantly, as well as everyone else.

At each of the five centers a total of four cases were observed by two teams (40 observations). Observing human behavior as a safety tool has the limitation in that by doing so it may change the behavior of those being



**Figure 2.** The LENS schema of interaction between diverse disciplines all looking at cardiovascular operating room care. Reprinted with permission from Martinez et al. (19).

watched. However, the observing team blended, as best possible, into the environment of the host hospital. Cross-observational checking and multiple observer techniques tried to reduce the risk of one observer bias. Surveys on teamwork, climate, motivation, and implementation of patient safety policies were given before and after the observations to each member of a hospital team that was observed. Three major areas were examined in the observations: interactions (communication) between operating room cardiac team members, clinical performance of known quality and safety dependent processes (check lists, sterility, antibiotic usage, glucose management, etc.), and ergonomics/safety of human-machine interfaces. This also dealt with layout and architectural structure of an operating room to best conduct the tasks at hand.

The data has been collected and collated. Well over 1000 hours of human computer time has been expended to code the observations. It should be noted that data here was prospectively collected. Often safety data is collected from error reporting (voluntary) and critical incident analysis (similar to aviation accident investigation). At the time of writing this manuscript, analysis is on-going, therefore the results are preliminary leading to a large picture overview.

**PRELIMINARY RESULTS OF THE FOCUS/LENS DATA**

In the 40 cases observed there were over 800 human error events noted. From the site surveys there were large discrepancies in perception of the culture of safety within an institution. Generally, surgeons were more satisfied with the culture of safety and also felt communication was better than did other groups of practitioners. There was considerable variability in the response to questions about punitive versus nonpunitive responses to error. For example, the overall average of respondents said that 36% felt there was a culture of non-punitive response to error (or 64% felt they would be penalized), however at one institution greater than 50% felt a positive environment existed whereas at another institution less than 25% felt positive about how error was dealt with. Greater than 50% of all respondents felt that openness of communication existed but again large discrepancies existed between institutions. It is unclear at this point whether a culture of safety and openness of communication does correlate with observed levels of error.

The errors observed are being categorized and taxonomy of errors is being created. This is a difficult and time-consuming task. Aviation accident investigation has broken this down to just four main categories but that has not yet been done in these medical observations. Some categories presently being used in the FOCUS analysis include:

teamwork and communication, lack of compliance with existing protocols (hospital standards), lack of knowledge or supervision, lack of vigilance or situational awareness (distractions and flow interruptions), equipment failure/design, poor operating room design/ergonomics, handoffs and transport problems, lack of professionalism, and ambiguity of responsibility. Some illustrative examples will help the reader to understand the observed areas for improvement (Table 2).

In terms of observation of hospital policies or protocols, it was a universal event (all 40 cases) that there was an incomplete prep performed prior to draping and the start of surgery. In many cases there was incomplete or lack of full sterile precautions in the performance of central line placements. In terms of equipment the most often observed problem was in preparation, management, and rapid ability to change life sustaining drip rates on programmable intravenous pumps. Of interest, although often reported in the literature and noted in the British error reporting database, there were no observed human drug errors. The operating room design, and particularly the anesthesia work space, was not conducive to safe practice. Electric cords created a hazardous work environment with some personnel observed tripping over these cords and falling against key life support equipment. The anesthesia work space was cluttered, poorly organized, and not conducive to having stressed practitioners finding key life saving drugs easily.

These initial observations will be further analyzed and it is anticipated that many professional manuscripts will be published from the data.

**Table 2.** A partial list of human factors that contribute to the development of adverse events in the cardiac operating rooms.

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

Reprinted with permission from Spiess et al. (20).

## NEXT STEPS

FOCUS will be driven by science and data. FOCUS is also not an exercise to merely create more academic literature but it is an initiative to change practice. Interventions based upon the observations are already underway. This is not easy or intuitive but needs to be driven by the data.

One of the first initiatives will be effort to decrease infection through empowerment of the team to follow known effective measures of infection control. This would include proper and complete prep before surgery, as well as complete sterile technique, draping, scrub, gown, and glove for central line placement. JHU-QSRG has success with this through their project in Michigan, and now in the United Kingdom. Empowerment means that the team will communicate and find that patient safety, rather than productivity-revenue generation, is their number one concern.

Another task force will be formed to look at surgical briefing and debriefing with a sub-project being the establishment of a study/intervention to create a "sterile cockpit." "Sterile cockpit" is terminology borrowed from the CRM airline industry. For 10 minutes after rollout until reaching 10,000 ft/3000 m, the pilot and co-pilot cannot communicate on any other level than flying the aircraft. The same rule holds for approach and landing (10 minutes prior to touchdown). In cardiac surgery there must be an anesthesiologist during the crucial times of induction, intubation, and line placement. For the surgeon it may well be placement of lines for going on bypass. For the perfusionist, it clearly is commencement and weaning from bypass. How do we as professional teams create the "sterile cockpit" environment of complete focus during those times? Maybe they already exist in some "best practices," but would safety be improved if there were actual cultural rules created so that any member of the team could ask for "sterile cockpit" whenever needed?

Briefing and de-briefing is another technique borrowed from CRM. In the cockpit, interestingly, the teams least likely to make errors are ones that have not been familiar or are friends. That means that structure comes into play. It is through briefing and de-briefing that a pilot and co-pilot formally express their expectations of each other. In situations where surgeon and team briefing and de-briefing routinely take place not only does a culture of safety improve (we suspect) but so does equipment readiness, resulting in breaks in concentration/flow being reduced and patient safety improving. To prove such a "best practice" an established structured team briefing and de-briefing must be constructed and tested. There are several existing ones for surgery with the United States Veterans Administration hospitals now mandating such events. FOCUS will create, beta test this, and then measure its effectiveness.

Another task force is being formed to reduce drug error. This effort is being coordinated with the Anesthesia Patient

Safety Foundation. Human factors analysis will help to drive the interventions proposed.

FOCUS also plans to create peer-to-peer tools for cardiac teams to improve their patient safety. Peer-to-peer assessment is a major safety innovation of the nuclear power industry. In medicine, laboratory medicine uses peer-to-peer inspections to provide the highest standard of performance. Through FOCUS it is envisioned that well developed and tested tools could be used by visiting teams from an outside institution to do a yearly (perhaps semi-annual) review of a cardiac team's safety performance.

Near miss reporting is extremely important for the civil and military aviation safety records. Recently, it has been noted in the United States that near miss mid-air collisions have spiked in occurrence. Why is that? What can be done? All are under review. Without near miss reporting the only thing that would lead to analysis is the catastrophe. Take for example the massive oil spill in the Gulf of Mexico, a human error classic event. Had near miss analysis been consistently applied to that industry, perhaps this blow out may have been prevented. For cardiac surgery we have no such near miss analysis reporting. Critical incident analysis in hospitals and morbidity and mortality conferences are an effort at catastrophe analysis. What is needed is the establishment of local and national/international non-punitive, anonymous near miss databases. Eventually FOCUS will work towards establishment of such a database.

## SUMMARY

It is through research, data analysis, interventional tools, and FOCUS that we as an industry can make human error reduction our standard. The public expects excellence in cardiac surgery. Unfortunately, we have little data regarding the reality versus the perception. The first FOCUS data is sobering and shows tremendous possibility for improvement. One has to wonder just how many lives will be saved and morbid mistakes prevented by systematically applying the lessons learned from human factors engineering to cardiac surgery.

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