Human error in medicine: Change in cardiac operating rooms through the FOCUS initiative

Bruce D. Spiess

Virginia Commonwealth University Medical Center, Richmond, Virginia, USA

Introduction

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 ten 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 with 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 excuse and barriers why change is not coming faster. Techniques employed in those industries may be not easily transferable to medicine. However, the discipline of human factors engineering has become an established academic science [7]. Learning from accident investigation in the United States military and civilian aviation can be called upon to rigorously study how we do our business [8,9]. The **F**lawless **O**perative **C**ardiovascular **U**nified **S**ystems 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 1990's in the United States [1]. The World Health Organization has embraced the problem as a universal one affecting surgery in both emerging and developed nations [10,11]. In 2005 the 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. 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 one year. Imagine the outcry if that were to happen. In the United States we spend 2 trillion dollars per year on healthcare, 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.

Anaesthesiology has led the way around the world in developing patient safety. Risks of death due to anaesthesia have dramatically declined due to enhanced training and better monitoring (we think). But perhaps it is also due to a culture of safety that has grown through this last generation of anaesthesiologists 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 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 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 buzz word for anaesthesiology 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 Minnesota Mining and Manufacturing (3M) as a method to reduce waste and bad product coming off its assembly lines. As an applied science, most of us in medicine are not comfortable/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/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 [12]. This "Swiss Cheese" model has been applied to cardiac surgery, but clearly more needs to be done [17].

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 culture of safety has been done in operating rooms [5,13,14,15]. Those that have highly respected cultures of safety across all disciplines tend to really have better outcomes. In cardiac surgery in a single centre an examination of breaks in concentration was undertaken. It showed that such breaks were common and influenced human error.

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 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-FOCUSSING through interventional schemes to take the basic research and to change the fabric of cardiac anaesthesia, 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 2004-5 the vision for **FOCUS** was endorsed. Human factors engineers were consulted to advice the SCA in writing a request for proposals (RFP). A large number of organizations responded to the RFP. Ultimately this lead 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 [16-18]. Through the use of checklists, empowerment of team work and improved safety culture the infection rate for central line placements had dropped to zero when their human systems were employed. They had developed and proposed methods for survey, interview and direct observation of cardiac surgery that follow human factors engineering principals. 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 anaesthesiologist, 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) the study was carried out (Figure 1) [19]. Tools for study were created at JHU-QSRG, and beta tested within the JHU hospital system before being applied to other centres. 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 centres 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 centres (plus JHU) were selected to undergo the LENS human error research project. It was important that all members of each cen-

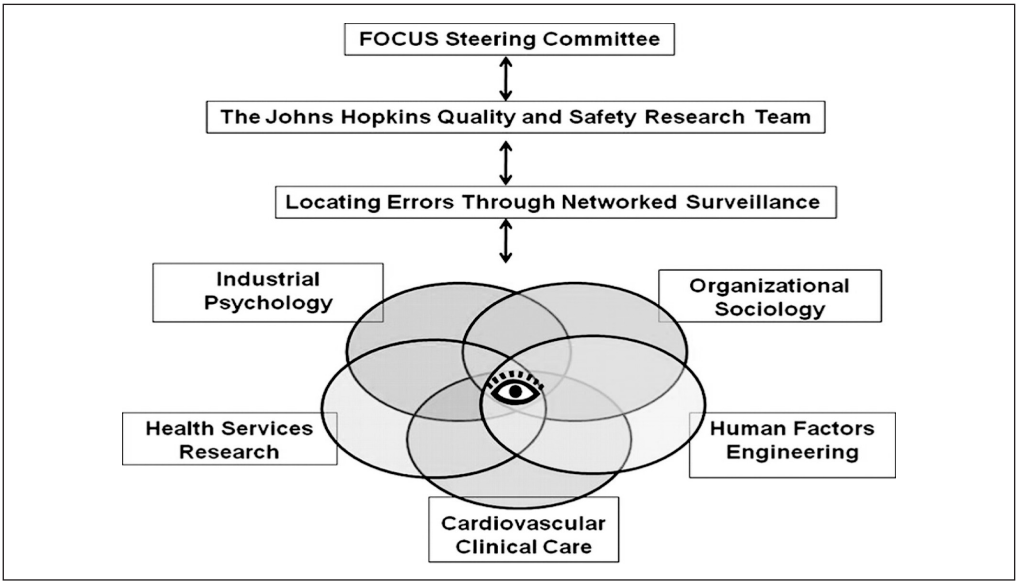

Figure 1: The LENS schema of interaction between diverse disciplines all looking at cardiovascular operating room care. Reprinted with permission from Martinez EA, et al. Reference # 19.

Table 1: Disciplines in LENS. Adapted from Martinez EA, et al. Reference #19.

Organizational Psychology: looks at the collective behaviour, 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 behaviour in the interaction with other humans working in technologically advanced or complex organizational environments.

Clinical Medicine: This sub-specialty personnel involved were specialists from anaesthesia, nursing, cardiac surgery and perfusion.

Table 2: A partial list of human factors that contribute to the development of adverse events in the cardiac operating rooms. Reprinted with permission from Spiess BD, Reference # 20.

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 stauts – situational awareness
– Fatigue
– Task saturation
– Confidence to make correct judgment

Environmental factors
– Operating room set up
– Ergonomics design
– Feedback
– Computer crosscheks
– Alarms
– Organizational simplicity/complexity

Anesthesiologist/practitioner factors
– Technical skill
– Knowledge base
– Experience
– Confidence
– Physical-mental preparedness/impairment (illness)
– Situational awareness

tre'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 anaesthesiologist was the primary investigator at each site and he/she secured the cooperation of the lead cardiac surgeon, importantly, as well as everyone else.

At each of the 5 centres a total of 4 cases were observed by 2 teams (40 observations). Observing human behaviour as a safety tool has the limitation in that by doing so it may change the behaviour of those being 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, 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 OR cardiac team members, clinical performance of known quality and safety dependent processes (check lists, sterility, antibiotic usage, glucose management etc.) and ergonomics/safety or human-machine interfaces. This also dealt with layout and architectural structure of an operating room to best conduct the tasks at hand.

The data have been collected and collated. Well over 1000 hours of human computer time have been put in 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 v. non-punitive responses to error. For example the overall average said that 36% of respondents felt there was a culture of non-punitive response to error (or 64% felt they would be penalized) and 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, 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 4 main categories but that has not yet been done in these medical observations. Some categories presently being utilized 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, ambiguity of responsibility, etc.

Some illustrative examples will help the reader to understand the observed areas for improvement. In terms of observation of hospital policies/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 IV pumps. Of interest, although often reported in the literature and noted in the British error reporting data base there were no observed human drug errors. The operating room design and particularly the anaesthesia work space were 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 anaesthesia 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 analysed and it is anticipated that many professional manuscripts will be published form the data.

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 efforts 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 10,000ft/3000m 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, for anaesthesiologist the crucial time is 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 equipment readiness, breaks in concentration/flow are reduced and patient safety improves. 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 utilized by visiting teams from an outside institution to do a yearly (perhaps semi-annual) review of a cardiac teams 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 would 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 data bases. Eventually **FOCUS** will work towards establishment of such a data base.

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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