Executive Summary

FOCUS, a revolutionary collaborative of health care professionals, is championing a team-focused approach to reducing human error in the cardiac surgery operating room. Drawing from insights and approaches of other high-risk, high-stress industries and the results of a baseline study of human error in cardiac surgery, FOCUS challenges the medical status quo in an effort to improve patient safety. With this goal in mind, a dedicated group of cardiac surgery professionals convened in September 2011 with these objectives: strengthen this strategic alliance of surgeons, anesthesiologists, perfusionists and nurses, and share best team communication practices. With full involvement and shared representation and governance, the collaborative sees immense opportunity to meet and exceed standards of patient safety.
In 1999, the Institute for Medicine estimated 48,000 to 98,000 lives are lost each year in U.S. hospitals because of medical mistakes. This is comparable to a fully loaded Boeing 737 crashing every day for a year. And this estimate is likely quite low, especially given the fact that the Centers for Disease Control and Prevention noted that over 2 million hospital-acquired infections occur per year, leading to more than 90,000 deaths annually.

Of the roughly 357-500,000 patients who undergo cardiac surgery each year, 28,000 will have an adverse event, many due to human error.

Between a quarter to one half of surgery complications involve human error.

But it doesn’t have to be this way. The vast majority of these complications are preventable.

Seventy-four Veterans Affairs hospitals recently reported an 18% reduction in their annual mortality rate. They achieved this reduction by teaching teamwork and changing the basic culture of the operating rooms.

A recent study showed that certain surgical teamwork behaviors can save lives.

Using a model of operational excellence based on the Toyota production model, a cardiac surgery program in Pennsylvania was able to achieve an operative mortality rate 61% lower than that expected in their region. The same surgery program’s risk-adjusted rate of major complications was 57% lower.

How were such impressive life-saving results realized when so many patient injuries are reported? By taking a team-focused approach to reducing human error in the cardiac surgery operating room—an approach that is at the center of a revolutionary collaborative called FOCUS, which stands for Flawless Operative Cardiovascular Unified Systems.
Identifying and Addressing the Barriers to Reducing Human Error

As anyone who has ever spent time in cardiac surgery knows, operating rooms are incredibly complex environments in which a number of highly trained professionals interact with each other and sophisticated electronic equipment to provide care for a single patient. Every professional in that room—surgeon, anesthesiologist, perfusionist and nurse—is dedicated to providing the best care he or she can. National and local medical procedures and guidelines, professional society standards, rigorous training programs and technological advances all aim toward individual excellence.

But the truth that every dedicated healthcare professional, including those in cardiac care, must face is that we all make mistakes. That’s the nature of being human. It’s an unfortunate reality of our everyday lives—and it’s a critical fact of the high-risk, high-stress environment of an operating room. The inherent and inevitable pressures of the environment continually affect our ability to operate at peak performance, resulting in fatigue, emotional stress, miscommunication and inability to concentrate.

So it’s no surprise that the World Health Organization has made reducing surgical errors one of its primary goals since 2005. Yet errors persist. Why?

Because traditional approaches to reducing human error—typically driven by hospital or professional society quality assurance committees—have established precedents that make significant improvements in patient safety difficult.

PRECEDENT #1: The hierarchical medical culture has focused on individual human performance rather than human systems, on autonomy rather than teamwork.

Fatal airplane crashes in the U.S. declined 65% over 10 years, while wrong-site surgeries in the U.S. steadily increased from 1995-2005.

High-risk industries such as aviation and nuclear power have performed rigorous examinations and human systems analyses of the complex environments within which their professionals perform—and have achieved phenomenal success in reducing human error by focusing on teamwork. John Nance, aviation analyst and author of Why Hospitals Should Fly, states it simply: “Individuals can and will forever commit errors. Teams have the ability to be flawless.”

Crew Resource Management (CRM) is a key facet of aviation’s safety culture and it recognizes that no one individual, no matter how high his or her rank, is infallible. The entire team is responsible for servicing, preparing and flying the aircraft. 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, and effective communication in the overall spirit of creating a flawless outcome.

This team approach to safety is also based on Dr. James Reason’s model of organizational safety, in which human errors and latent system deficiencies are both required for an error to result in harm. Building a highly reliable organization requires all members of the team to be involved in designing, implementing, monitoring and refining the safety programs in their area. Communication is, clearly, most important. In the operating room, proper and modern equipment, syringe labels that cannot be misinterpreted and operating room design with ergonomic function are also important. Other areas for improvement might well include changes in personnel numbers, shift and work structure, or call schedules that make human decision-making resilient to error.

“The problem is not bad people; the problem is that the system needs to be made safer.”
— To Err is Human, U.S. Institute of Medicine

Although the team concept has become commonplace in other high-risk industries, it has not yet been fully embraced by medicine. The complex operating room environment has not been as systematically researched nor adequately confronted. And although human error in operating rooms has been studied, research in human systems in medicine is in its infancy.

PRECEDENT #2: Efforts to increase patient safety and outcomes have been independent rather than inter-dependent, competitive rather than collaborative, and focused on effort rather than results.

Surgeons, anesthesiologists, perfusionists and nurses are making important progress in increasing patient safety and outcomes. But we’re not doing it together. As a result, best practices and excellent work remain in silos—either within a specific team, or within one professional group.

The discourse around the topic of reducing human error in cardiac surgery is, in a sense, similar to the complex environment of a cardiac operating room: both require sharing knowledge and best practices, both require open and respectful communication and collaboration.

But few systematic studies of human error and factors in cardiac anesthesia or surgery have been performed across multiple institutions or internationally. Most studies that have been done in cardiac surgery have been performed within a single institution having a unique culture. While some cardiac surgery teams have discovered techniques and tools that deliver morbidity and mortality rates far below national norms, these teams’ best practices are not effectively disseminated. With no formal process for communicating their results, other teams often must “reinvent the wheel” at their own sites.
These are precisely the historical precedents that a group of determined cardiac surgeons, anesthesiologists, perfusionists and nurses gathered in Boston to discuss. Their goal: to identify a

“...times higher than that of any other major industry!” —surgeon

national collaboration to challenge these precedents, and develop a five-year strategic plan to realize significant, dramatic improvements in patient safety and outcomes by reducing human error.

The idea for FOCUS had its genesis in 2001, when Dr. Bruce Spiess, a Virginia Commonwealth University School of Medicine cardiac anesthesiologist with a passion for reducing errors, asked the Society of Cardiovascular Anesthesiologists (SCA) to underwrite the initial stages of a national effort to improve patient safety and reduce human error. The SCA established a separate foundation—the Society of Cardiovascular Anesthesiologists Foundation (SCAF)—to oversee and fund this work. To acquire baseline data, the SCAF, in collaboration with the Johns Hopkins University Quality and Safety Research Group (QSRG), conducted an observational research project—Locating Errors through Networked Surveillance, commonly referred to as LENS. Conducted from 2008 to 2010, LENS studied the causes of human error in cardiac surgery in order to identify how those causes could be reduced or eliminated.

“We need to document and analyze near misses.” —anesthesiologist

The study pointed repeatedly to the need to challenge Precedent #1 by focusing on teams rather than individuals. Why? Because most errors noted were “teamwork errors,” and the solutions to those errors are “teamwork solutions.”

For example, trained teams of observers sat in on 40 independent coronary artery bypass graft surgeries. The teams documented thousands of observations, including desirable behaviors, as well as those considered hazardous. Researchers then grouped these observations into 847 similar situations, which were then further grouped into the following 11 categories:

1. Care transition
2. Culture
3. Equipment
4. Infection prevention
5. Infusion pumps/drug errors
6. Knowledge/supervision
7. Operating room design
8. Preparation/planning
9. Situational awareness
10. Standardization
11. Teamwork communication

The study also made clear that overcoming Precedent #2 and affecting systemic change would require a national collaboration between the major societies whose members deliver patient care in the cardiac operating rooms.

With this goal in mind, a group of 17 cardiac surgeons, anesthesiologists, perfusionists and nurses gathered in Boston for a daylong symposium facilitated by Christine Cole, Kennedy School of Business, Harvard University.

Bruce Spiess began the day by thanking each person for attending: “Every healthcare professional in cardiac surgery is dedicated,” said Spiess. “And each is determined to provide the best possible care. That’s not in question. But despite our dedication and...”

“Each one of us believes that we are ‘better than average,’ but we all can’t be.” —anesthesiologist
determination, our human proclivity for error puts our patients at risk. To change this will require significant dedication and persistence over many years. It will require a cultural change. It will take the full engagement and enthusiasm of our representative societies. And the presence here of so many dedicated individuals indicates that this will be possible.”

Those in attendance agreed. Here are just a few of their comments:

“The patient perspective is important and we need patients involved or in the planning.”

“Frame the problems not as problems but as opportunities.”

“Respect is a behavior and through repetitive behavior you can develop trust.”

“How can we define and better share best practices?” —nurse

“Develop the metrics for safety in cardiac operating rooms and through that address business cases of how we will be successful.”

“FOCUS could/should address a fundamental lack of knowledge about patient safety among our colleagues. We should develop a patient safety manual, encourage societies to endorse it as a must-read for members.”

“It is hard to document the absence of something. It is easier to document when near misses happen.”

“Even the best athletes in the world have coaches. Shouldn’t we have them as well?” —surgeon

The following people gathered in Boston for a daylong Symposium facilitated by Christine Cole, Kennedy School of Business, Harvard University:

ATTENDEES

James Abernathy, MD, MPH, FASE, Anesthesiologist
Director, Cardiac Anesthesia, Medical University of South Carolina, Charleston, SC

Mary Frances Cedorchuck, Nurse Manager Cardiac Surgery
Beth Israel Deaconess Hospital, Boston, MA

Michael Culig, MD, FACS, Cardiac Surgeon
Forbes Regional Hospital, Monroeville, PA

Abe DeAnda Jr., MD, FACS, Cardiac Surgeon
Associate Professor, Cardiothoracic Surgery, NYU-Langone Medical Center, New York, NY

David Fitzgerald, CCP, Chair, AmSECT, Perfusionist
Inova Fairfax Hospital, Fairfax, VA

Chris Goeschel, ScD, MPA, MPS, RN
Armstrong Institute for Patient Safety, Johns Hopkins University, Baltimore, MD

Elizabeth Martinez, MD, MHS, Anesthesiologist
Mass General Hospital, Boston, MA

John Melleky, CFRE
SCAF staff, Richmond, VA

Nancy Nussmeier, MD, Anesthesiologist
Professor, Department of Anesthesiology, SUNY, Syracuse, NY

Bruce Searles, BS, CCP, Perfusionist
Dept. of Cardiovascular Perfusion, SUNY Upstate Medical University, Syracuse, NY

Scott Shappell, PhD, Human Factors Engineer
Professor, Clemson University, Clemson, SC

Stanton Keith Sherman, MD, Anesthesiologist
Brigham and Women’s Hospital, Boston MA

Linda Shore-Lesserson, MD, Anesthesiologist
Professor, Department of Anesthesiology, Albert Einstein College of Medicine, Bronx, NY

Bruce D. Spiess, MD, Chair, FOCUS Steering Committee
Professor of Anesthesiology, Senior Fellow VCU, Virginia Commonwealth University, Richmond, VA

Thoralf Sundt, MD, Cardiac Surgeon
Chair, Thoracic Surgery, Mass. General Hospital, Boston, MA

Paul Uhlig, MD, MPA, FACS, Cardiac Surgeon
Central Plains Cardiothoracic Surgery, Wichita, KS

Joyce Wahr, MD, Anesthesiologist
Chair, SCA Foundation, University of Michigan, Ann Arbor, MI

Three others also attended: Jan Headley, Director, Edwards Life Sciences and Jill Wroblewski, Clinical Program Manager, Nonin Medical, both strong supporters of FOCUS.
A Vision for Excellence

The group agreed that the goal of FOCUS is to save lives through collaboration. In a roundtable discussion, participants shared their vision for this collaboration and identified five key themes.

Theme 1: Excellence is erratic. While some cardiac teams work together incredibly well, others find the goal elusive.

How FOCUS will help: FOCUS will identify and disseminate best teamwork practices.

Theme 2: Excellence is transferable. Cardiac surgery teams are often the most cohesive of all teams in a hospital; there are many excellent models for other cardiac surgery teams to follow.

How FOCUS will help: FOCUS will communicate these best teamwork practices nationally and provide training to ensure that all members of all surgery teams understand and follow these best practices.

Theme 3: Excellence depends on evidence. Patient safety efforts are too often viewed as problems needing immediate fixes rather than opportunities for ongoing research and testing.

How FOCUS will help: FOCUS will provide a national platform for coordinating and measuring the impact of patient safety efforts.

Theme 4: Excellence requires collaboration. Strategic alliances among cardiac surgery professionals are essential to build upon successes.

How FOCUS will help: FOCUS will unite all cardiac surgery professionals around a nationwide strategic initiative, thereby reducing redundancy of safety efforts.

Theme 5: Excellence is built upon respect. The trust and respect among cardiac teams serve as a strong framework for this collaboration.

How FOCUS will help: FOCUS will advocate for an openness to the process of improvement needed for cultural change, building upon existing professional trust and respect.

Then, in subsequent breakout sessions, the group identified steps for moving FOCUS forward over the next five years. Key recommendations were made regarding structure, engagement and impact:

**STRUCTURE**

Recommendation 1: Identify and strengthen FOCUS as a collaborative, strategic alliance of all cardiac professional societies with shared representation and governance.

Recommendation 2: Establish a separate and independent foundation that is not within the auspices of any particular professional society to ensure equitable representation and financial stability.

**ENGAGEMENT**

Recommendation 3: Ensure full engagement, support and initial ownership by the four key professional societies:

- The Society of Thoracic Surgeons (STS) to represent surgeons
- The Association of peri-Operative Registered Nurses (AORN) to represent nurses
- The American Society of Extracorporeal Technology (AmSECT) to represent perfusionists
- The Society of Cardiovascular Anesthesiologists (SCA) to represent anesthesiologists.

Recommendation 4: Broaden involvement as appropriate to other groups committed to improving patient safety: physician assistants, critical care nurses, intensivists, pharmacists, patients, hospital executives, third-party payers and insurance companies.

**IMPACT**

Recommendation 5: Identify and prioritize projects that can have immediate impact on encouraging human systems-based improvements and collaborative sharing of best practices through quick wins.

Recommendation 6: Call together interdisciplinary educational meetings devoted to patient safety and teamwork development.
The Call for Leadership

It was clear among those in Boston that now is the time for cardiac surgery professionals to take bold leadership roles in reducing and eliminating the causes of human error. For the first time, there is a vehicle to make this happen, and that vehicle is FOCUS. This acronym, which stands for Flawless Operative Cardiovascular Unified Systems, was chosen carefully, for it is only through unified human systems that surgical teamwork can become flawless and only through collaboration that FOCUS can create that shared excellence.

Through FOCUS, we can improve patient safety and outcomes by reducing human error. Many advances in technology have brought us to more complex care for increasingly severely ill patients. Yet if 25 to 50% of adverse outcomes are contributed to by human error, our efforts to make cardiac surgery “flawless” stand as the single greatest potential advance in patient care to date.

The opportunity to fundamentally change the culture of cardiac surgery is an immense opportunity to demonstrate for all of medicine that this highly regarded, highly complex, highly interconnected human endeavor can meet and exceed the standards for patient safety. By embracing teamwork, valuing the efficient communication of “unified systems,” and creating a culture of safety, we can reduce death and suffering of heart patients—the focus of all cardiac surgery professionals.

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Increasing patient safety and improving patient outcomes by reducing human error in cardiac surgery

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