The Society of Cardiovascular Anesthesiologists' FOCUS Initiative: Locating Errors Through Networked Surveillance (LENS) Project Vision

Elizabeth A. Martinez, MD, MHS*

Jill A. Marsteller, PhD, MPP†

David A. Thompson, DNSc, MS, RN*

Ayse P. Gurses, PhD*

Christine A. Goeschel, MPA, MPS, RN*

Lisa H. Lubomski, PhD*

George R. Kim, MD*

Laura Bauer, MPH*

Peter J. Pronovost, MD, PhD*

From the *Departments of Anesthesiology & Critical Care Medicine and Pediatrics, The Johns Hopkins University School of Medicine and the †Department of Health Policy & Management, Bloomberg School of Public Health, Baltimore, Maryland.

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Address correspondence and reprint requests to Peter J. Pronovost, MD, PhD, The Johns Hopkins University School of Medicine, 1909 Thames St., Second Floor, Baltimore, MD 21231. Address e-mail to ppronovo@jhmi.edu.

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BACKGROUND

Although the methods to measure preventable harm are imprecise and immature, preventable harm is one of the leading causes of death, disability, and increased costs of care.[1,2] The field of anesthesiology has been recognized for its efforts to improve patient safety, but much work remains to reduce harm to patients having cardiac surgery.[3,4]

Despite significant publicity regarding patient safety and efforts to improve it since the publication of *To Err Is Human*[3] 10 years ago, there is little empiric evidence that health care is safer. For example, reports of wrong-site surgery continue to increase year after year despite a national patient safety goal* and widespread efforts intended to reduce such events. Although the true increase in wrong-site surgery is debated and may represent reporting bias, we clearly have not eliminated this sentinel event or other events for which there are data. One logically asks why a country that spends more than 2 trillion dollars a year on health care, 17% of its gross domestic product, continues to produce significant preventable harm. Why do wrong-site surgeries and other adverse events continue despite substantial efforts by regulators, hospitals, and professional societies? The problem is complex and implementing solutions has been exceedingly difficult. However, the solution is conceptually simple: we must adequately develop and apply rigorous science to analyzing errors in the delivery of health care.[5,6] For example, despite there being a national policy to prevent wrong-site surgery, there are little to no data showing the effectiveness of this intervention. Few quick fixes will improve safety. Similar to biomedical science, safety improvements will require a robust and disciplined science that matures over time.

Perhaps the greatest barrier to measurable progress in patient safety is the inability to evaluate with scientific rigor whether patient safety interventions are effective. This is the result of insufficient research funding and, paradoxically, the interdisciplinary nature of patient safety. There is sparse research funding for "basic science" in patient safety, especially to develop measures and tools to improve it. As a result, measures are often of poor quality, and the interventions of limited effectiveness, if not harmful.[7] There are many disciplines that inform the science of patient safety, including organizational sociology and industrial psychology, clinical medicine, human factors engineering, health services research, economics, epidemiology, biostatistics, and informatics. Each discipline views the world through a unique "lens" and has a different frame of reference for viewing various aspects of patient safety risks and interventions as compared with others. Unfortunately, these lenses are

*National Patient Safety Goals for 2009—Universal Protocol. Available at: http://www.jcrinc.com/NPSG%2DUniversal%2DProtocal/. Accessed September 29, 2009.

rarely, if ever, joined together to focus on a comprehensive picture of patient safety. We will not create an effective and efficient approach to patient safety and demonstrate progress without integrating the wisdom of these various disciplines.

It is important to recognize that patient safety research is "applied research." Thus, it seeks to answer questions that are important to multiple decision makers, be they patients, clinicians, or policy makers. Traditional biomedical research generally progresses in a "feed forward" mechanism by progressing from basic science, to clinical testing, to practice. Patient safety research often uses a "feedback" mechanism in which researchers start with a goal (e.g., put a man on the moon in 10 years) and work backwards to figure out how to accomplish this goal.

The Society of Cardiovascular Anesthesiologists (SCA) Foundation used this feedback philosophy to set the laudable goal of attaining harm-free cardiac surgery through an initiative called Flawless Operative Cardiovascular Unified Systems (FOCUS). We describe a continuing collaboration between a research team at the Johns Hopkins University Quality and Safety Research Group (QSRG) and the SCA Foundation to achieve harm-free cardiac surgery.

SCA FOUNDATION LEADERSHIP: FOCUS INITIATIVE

The FOCUS Initiative has the potential to add important new knowledge to the field of patient safety and positions the SCA Foundation and anesthesiologists to be world leaders in this emerging science. The SCA Foundation solicited requests for proposals to create harm-free cardiac surgery. After a robust process to review applications, the Foundation selected our research team to develop and test research methods to achieve this goal.

LOCATING ERRORS THROUGH NETWORKED SURVEILLANCE

Our approach to the project was to integrate the wisdom of diverse disciplines. First, we planned to identify a diverse group of hazards in cardiac surgery by (a) conducting a literature review of published hazards, (b) reviewing error report data in cardiac surgery, and most importantly (c) prospectively identifying hazards through cardiac surgery case observations, surveys, and interviews in a sample of hospitals. Second, we will work with the SCA, the SCA Foundation, and participating hospitals to formulate a prioritized list of the hazards identified and develop specific risk-reduction interventions. Third, using our experiences with the prospective evaluation tools, we will develop a self-assessment tool that cardiac surgery programs can use to conduct peer-to-peer confidential learning-based evaluations.

To achieve these objectives, we assembled an interdisciplinary team of internationally recognized patient safety experts and β-tested our protocol at The Johns Hopkins Hospital. Prior efforts to improve patient safety have been independent rather than interdependent, competitive rather than cooperative, and focused on efforts rather than results. Few research projects have integrated diverse disciplines to develop a more comprehensive view and train a broader and richer set of lenses on patient safety. The Locating Errors Through Networked Surveillance (LENS) project sought to overcome that limitation.

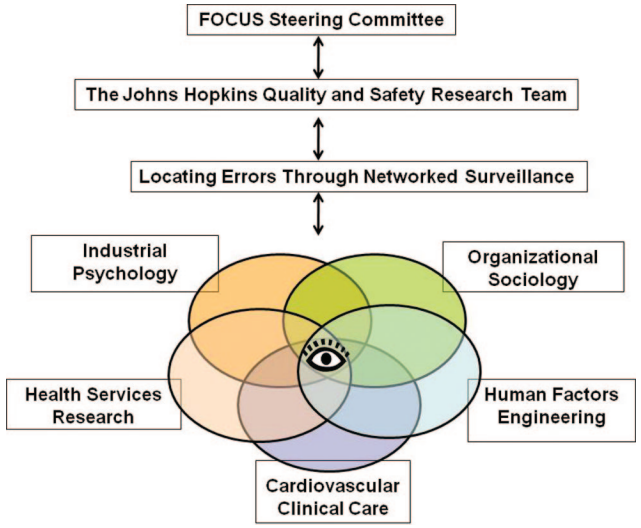

Figure 1. The overall structure of the project that was developed by the Johns Hopkins University Quality and Safety Research. The LENS (Locating Errors Through Networked Surveillance) (the eye graphic) approach was to integrate the wisdom of diverse disciplines (industrial psychology, organizational sociology, human factors engineering, and cardiovascular clinical care) to identify safety hazards.

Below, we describe the variety of disciplines participating in this effort and the project structure (Fig. 1). Although the boundaries of these disciplines overlap, they represent differing areas of expertise within health services research and use different lenses and tools to evaluate safety risks.

Disciplines

- *Organizational Sociology* examines the collective behaviors, beliefs, motives, and expectations of the people working within organizations.
- *Human Factors Engineering* studies human characteristics and humans interacting in and with the world around them and applies that knowledge to design safe, efficient, and comfortable systems.
- *Industrial Psychology* captures human behavior in the presence of other humans, against the backdrop of a technologically advanced and psychologically complex work environment or organizational setting.
- *Clinical Medicine* focuses on clinical practices in the operating room (OR) in the context of teamwork, communication, and a complex environment. The clinical arena of cardiac surgery is notable for complex team and clinical factors. Cardiac patients

are at high risk and often exposed to complex interventions. There are certain clinical practices accepted as the "best practices" or the "standards of care." However, we lack tools to evaluate the routine use of such practices.

PROJECT STRUCTURE

Identifying Hazards

To identify a broad range of hazards in cardiac surgery, we conducted a focused literature review, reviewed error reports, and directly observed cardiac operations. We elected to conduct a focused literature review rather than a systematic literature review because the quantity and quality of empiric evidence in our experience have been limited. Because a national error reporting system is not yet available in the United States, we reviewed cardiac surgery errors voluntarily reported to the National Reporting and Learning System, maintained by the National Patient Safety Agency in the United Kingdom, which collects all types of errors from hospitals in England and Wales. It is one of the oldest national error reporting systems in the world.

The prospective identification of hazards through direct observation is the richest and most labor-intensive component of the program. The SCA Foundation undertook the process of selecting sites to participate. They requested volunteers, and 42 centers applied. To participate, sites needed an anesthesiologist who was prepared to serve as the local coordinator and to recruit a local surgeon, a surgical nursing leader, and a perfusionist leader to actively participate and support the research work. The SCA Foundation selected 5 sites from the pool of applicants based on size, teaching status, and geography. They sought a convenience sample because this was a pilot to develop and validate the observation techniques for use in a larger study. The QSRG developed an evaluation tool for direct observations of cardiac procedures by integrating validated instruments from the disciplines represented on our team into a comprehensive interdisciplinary tool that accounts for 3 major areas: interactions among cardiac OR team members; clinical performance of known quality and safety processes; and ergonomics/safety of the human-machine interface in cardiac ORs. We conducted direct on-site observations using teams of specially trained observers with anesthesiology, human factors engineering, nursing, outcomes, and patient safety research backgrounds. A strength of observation over other data collection techniques is that one can assess what actually occurs, as opposed to what is "on the books" as an expectation.

Observing behaviors as a safety assessment tool has limitations. Providers know when they are being watched, which may alter their behavior. In addition, attitudes and perceptions of providers and management cannot be assessed through observation. To address this latter issue, we also administered surveys of safety and teamwork climate, motivation to implement patient safety policies, organizational culture and orientation toward quality improvement activities, and perceptions of use of patient safety-related processes in the cardiac ORs. Managers of nursing, cardiac surgery, perfusion, and anesthesiology were each interviewed about the policies, practices, and initiatives in place, as well as relationships with other hospital units.

Prioritize Hazards and Develop Risk-Reduction Interventions

To develop a prioritized list of hazards, our research team coded all the hazards into a qualitative analysis program called NVIVO (version 8). A taxonomy of cardiac surgical hazards was developed specifically for this project based on previous literature and the actual observation data.

The research team is in the beginning stages of prioritizing hazards based on their estimated frequency, severity of harm, likelihood of detectability, and preventability. The SCA Foundation will then convene clinicians in cardiac anesthesiology, surgery, nursing, and perfusion, and patient safety experts to prioritize this list further and select a set of hazards for which interventions to reduce risks will be developed and pilot tested. Hazards could occur in training, implementing evidence-based practices, culture and teamwork, devices, or management support, among others. Once the SCA Foundation selects hazards, they will support and help lead research to design, implement, and evaluate interventions to mitigate these hazards in SCA membership organizations. If interventions are effective, the SCA Foundation will broadly disseminate them. To accomplish global dissemination of an intervention, the SCA Foundation will leverage the existing relationship between the Johns Hopkins research team and the World Health Organization, and World Alliance for Patient Safety.

The research team will apply the robust safety science they used to identify hazards to design risk reduction interventions. The interventions to reduce risks will vary by the type of safety problem (e.g., translating evidence into practice and organizing risk), and a framework previously published will help us categorize these hazards.[9] We will also use a conceptual model to help classify interventions that will most likely (strong) or least likely (weak) mitigate hazards (Fig. 2). Types of interventions from strongest to weakest in this model include eliminating or preventing the mistake, making the mistake visible, mitigating the hazard should a mistake occur, and reeducating staff or creating a policy absent of any of the stronger features. Described below are examples of each intervention type applied in anesthesiology.

- *Eliminating or preventing mistakes*: Perhaps the most trumpeted improvement in patient safety

Action	Strength of Intervention	Example
Eliminate or prevent mistake	*Strongest*	- Change shape of connecting parts so that oxygen and nitrous oxide are not able to fit together
Make mistake visible		- Place an orange "epidural only" label at the hub of epidural tubing
Mitigate harm		- Remove concentrated electrolytes from patient care areas
Educate	*Weakest*	- Develop policy or educate staff about appropriate use of PCAs

Figure 2. The conceptual model describing the 4 types of interventions used after learning from a mistake. The intervention types are listed from strongest (designed to eliminate or prevent a similar future mistake) to weakest (educate staff). An example of an intervention in anesthesiology is provided to illustrate these intervention types. PCA = patient-controlled analgesia.

involved redesigning the shape of yokes to prevent the connection of an oxygen gas cylinder to a nitrous oxide yoke. This is the strongest level of intervention because it completely eliminated the possibility of that particular error.

- *Making mistakes visible*: Most drugs that anesthesiologists administer are drawn up in color-coded syringes (e.g., blue syringes are narcotics). This system makes potential mistakes visible and reduces the probability of inadvertently giving patients the wrong medication. This is the second strongest level of intervention because there is still the possibility of error, but it is greatly reduced.
- *Mitigating harm should it occur*: Many anesthesiology teams draw up different narcotics to be approximately equivalent in analgesic potency and side effects. For example, morphine is typically drawn up as 1 mg/cm^3, fentanyl as 50 μg/cm^3, and hydromorphone as 0.2 mg/cm^3—all approximately equivalent in analgesic potency and risk. If such standards are used, substituting one narcotic for another will most likely not result in harm. This represents the third strongest level of intervention because it reduces the likely consequences of error but not the likelihood of error.
- *Educating clinicians and/or creating policies*: These are the most common interventions implemented in response to adverse events at most organizations. Unfortunately, they are the least likely to prevent recurrent harm. Considering epidural catheters as an example, they are extremely similar to IV tubing and the 2 will easily connect together. However, the medication used in epidurals to block pain can kill if it is injected IV. Reeducating staff or creating a protocol about the proper use of epidural catheters may work for a while, but humans are fallible and this mistake will resurface.

The FOCUS project will likely use multiple types of interventions to improve cardiac operative care. The program's specific benefit will depend on local structures, processes, culture, and leadership. The SCA Foundation will play an important role in facilitating shared learning among multiple professional societies, health care organizations, and researchers as national and international cardiac surgery programs move toward implementation of strategies that we identify during the LENS project within the FOCUS initiative. For example, if a device hazard is identified, the foundation and QSRG team will work on a national level to replicate Commercial Aviation Safety Teams in health care to accomplish this work.[8]

Develop Peer-to-Peer Assessment

One of the most novel and beneficial aspects of the FOCUS initiative is the peer-to-peer assessment. Peer review in health care is generally conducted by an internal or an external regulatory agency. Health care is one among the high-risk fields that does not have an established external peer review by a nonregulatory agency to focus on learning and not judging. Frequently, peer review within a health care organization is often ineffective and focused more on maintaining the institution's reputation and protecting its physicians than on protecting patients. Moreover, external peer review is largely used to judge rather than learn and provides a minimal level of patient safety. Although some success has occurred in cardiac surgery with peer review and quality improvement,[10,11] none of these efforts have been broadly implemented.

An alternative peer review process used for nuclear safety involves a robust and confidential peer review process in nuclear plants. The World Association of Nuclear Operators (WANO), a voluntary organization that is widely acclaimed for improving nuclear safety, conducts these reviews. Staff members from plants that are WANO members serve as evaluators. When a WANO member nuclear organization requests a peer review, trained evaluators conduct site visits to assess local practices and compliance with safety protocols and produce a confidential report. This approach focuses more on learning than on judging and has produced substantial results.

In the final phase of the FOCUS initiative, we will try to create an external nonregulatory peer-to-peer assessment process. First, we will create tools to enable hospitals to conduct peer-to-peer assessment of cardiac anesthesiology and cardiac surgery programs. To accomplish this, we will simplify the tool used for the prospective observation evaluation and test this simplified tool. We will evaluate the feasibility of training clinicians, who lack formal training in patient safety, to use this tool. Ideally, we envision a self-assessment tool that clinicians with a minimal amount of training could implement.

CONCLUSION

Ten years after the Institute of Medicine *To Err Is Human* publication, there is still little, if any, empiric

evidence of improvements in patient safety. This likely is because the science to improve safety has been relatively superficial. This needs to change. The SCA Foundation sought to create harm-free cardiac surgery and assembled an interdisciplinary team to reach this goal. The strategies moving forward are to identify hazards, develop focused interventions to mitigate or eliminate the most important hazards, and develop tools to enable effective peer-to-peer assessments. The FOCUS LENS project will help ensure that the SCA Foundation, the SCA, and anesthesiologists are in the vanguard of safety leadership and science by building on anesthesiology's rich history and courageously embracing an innovative vision to answer the question: Are patients safer?

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