Patient Safety Science in Cardiothoracic Surgery: An Overview

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Introduction

Cardiothoracic surgeons have a rich history of quality improvement and a strong ethos of transparency and innovation allowing for the rapid diffusion of standards, techniques, and benchmarks. This approach has resulted in improvements in patient outcomes and in the recognition of our specialty as leading in quality and safety. The development of the Society of Thoracic Surgery's databases is pivotal in driving much of the incremental improvements and refinements in techniques and processes of care by capturing important risk factors and by reporting risk-adjusted outcomes using methods that serve as the gold standard for other registries and clinical databases worldwide [1].

Although morbidity and mortality have continued to decrease over time, errors and preventable events continue to yield suboptimal outcomes [2]. Contemporary cardiothoracic surgical care is a complex sociotechnical system involving sophisticated techniques and equipment, health care professionals with varying levels of skills, and high-risk patients. We work in safety-critical environments where the complexity of care and the patients' risk factors exponentially increase the potential for significant harm. Given this degree of complexity, optimal conditions are critical to successful outcomes. Because humans and poorly designed systems are vulnerable to error, a critical assessment of our systems of care and learning from other safety-critical industries are essential for improvement to continue. The traditional view that patient outcomes are related only to the surgeon's technical skill has given way to an evolving and broader framework wherein health care outcomes are affected by a multitude of factors in a highly integrated and complex environment.

Adverse Events in Cardiothoracic Surgery

We make two implicit individual and organizational promises when patients entrust themselves to our care: first, to do everything possible to provide excellent care, and second, to do no harm. In some instances, patients do not get the care that is expected and are inadvertently harmed [2]. Deviations from established protocols, lapses, and nonobvious ("latent") conditions are important elements contributing to harm. Not all errors result in adverse events, and not all such events are caused by error. As such, it is important to distinguish between preventable and nonpreventable events in understanding the nature of patient safety.

Two thirds of surgical adverse events occur in inpatients, and approximately half of these are preventable [3]. The incidence of adverse events among patients undergoing coronary artery bypass grafting or cardiac valve operations is 12.3% compared with 3% among all surgical admissions. Of the 4,828 reported incidents related to cardiac operations over a 4-year period in the United Kingdom's National Reporting and Learning System, a voluntary web-based incident reporting system, 21% occur in the operating room; of these, 32% resulted in some level of patient harm [4]. Other investigators have also identified an alarming rate of safety hazards during cardiac operations [5]. On the basis of studies using structured observation, contextual inquiry, and extensive data capture using a systems engineering and human factors framework, hazards in the cardiac operating room are widespread and numerous opportunities exist for improvement focusing on fostering a culture of safety, increasing compliance with evidence-based practices, improving communication and teamwork, and developing a partnership among stakeholders.

A public inquiry of clinical failures in pediatric cardiac operations at the Bristol Royal Infirmary concluded that systemic factors had contributed to that organization's inability to detect and correct problems [6]. The analysis highlighted the importance of strong and effective clinical governance, a strong quality improvement infrastructure, and a culture of transparency in mitigating patient harm. Ongoing surveillance for quality, routine audits, and an in-depth examination of adverse events, near misses, and other unsafe conditions are the hallmarks of a safety-focused organization.

Learning From Failure

One of the forerunners of modern industrial safety and accident investigation programs, Heinrich's classic safety pyramid of industrial accidents proposed that for each major injury there were 29 minor injuries and 300 precursor events [7]. Although the exact ratio is disputed, examining unsafe situations and "near misses" prove to

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be considerably more fertile than the more frequent practice of directing major improvement efforts based on the relatively few harmful events. At-risk behaviors and activities that are not consistent with safety protocols and training, such as bypassing preoperative checklists or lax patient verification practices, have a profound impact on a safety-oriented team culture.

Precursor events that contribute to harm appear to be ubiquitous in the cardiothoracic surgical environment. These events deviate from the expected and optimal course of a process, and they precede an adverse or catastrophic outcome. Examples include equipment failures, scheduling mixups, missing diagnostic test results, medication errors, and technical operative problems; these events are unrelated to patient characteristics.

A prospective study identified 1,627 precursor events in 464 cardiac operations [8]. Of these, 32% were considered major. Alarmingly, only 31% of these events were discussed by the team, whose members thereby missed opportunities for collective learning and team building. Furthermore, the number of precursor events had a strong association with the risk of death or near miss (Fig 1) [9] after adjustment for cardiopulmonary bypass time.

Efforts to prospectively identify conditions that pose potential or real risk to patients are not always standard practice in cardiac surgery [10]. Behaviors such as deviations from normal procedures and other seemingly minor events cause a cascade effect, resulting in distractions that lead to major events and poor outcomes.

Examining mortality rates in low-risk patients undergoing standard cardiac surgical procedures, investigators at Papworth Hospital concluded that preventable deaths were due to either inadequate myocardial protection or failures in communication [11]. After correction of the systemic factors identified initially, subsequent adverse events were isolated mainly to technical errors [12]. Thus, routine examination of deaths and "near misses" in low-risk groups may unmask pervasive systemic errors and weaknesses to be targeted for modification.

Learning from error can occur at both an individual and an organizational level through incident reporting and analysis. Incident Reporting Systems and Root-Cause Analyses are essential tools that enhance an organization's ability to learn from error. Incidents are traditionally underreported as a result of the pervasive focus on individual blame, compounded by "hindsight bias." Because the value of an Incident Reporting System is dependent on the culture of an organization, hospitals are able to learn from each event only when individuals feel psychologically safe to report problems without fear of reprimand. A properly conducted Root-Cause Analysis uses a structured, systematic approach to incident analysis, which takes into account the complex nature of the health care environment and recognizes that error is an inevitable component of social systems. The lessons learned through the use of these tools allow an organization to identify and eliminate unsafe conditions and help mitigate future patient harm.

The Science of Safety

Safety science is an interprofessional field, which has evolved from work conducted in a wide variety of industries that consider accident investigation, loss prevention, and risk management to be integral components of their mission. Many of the concepts emerging from this

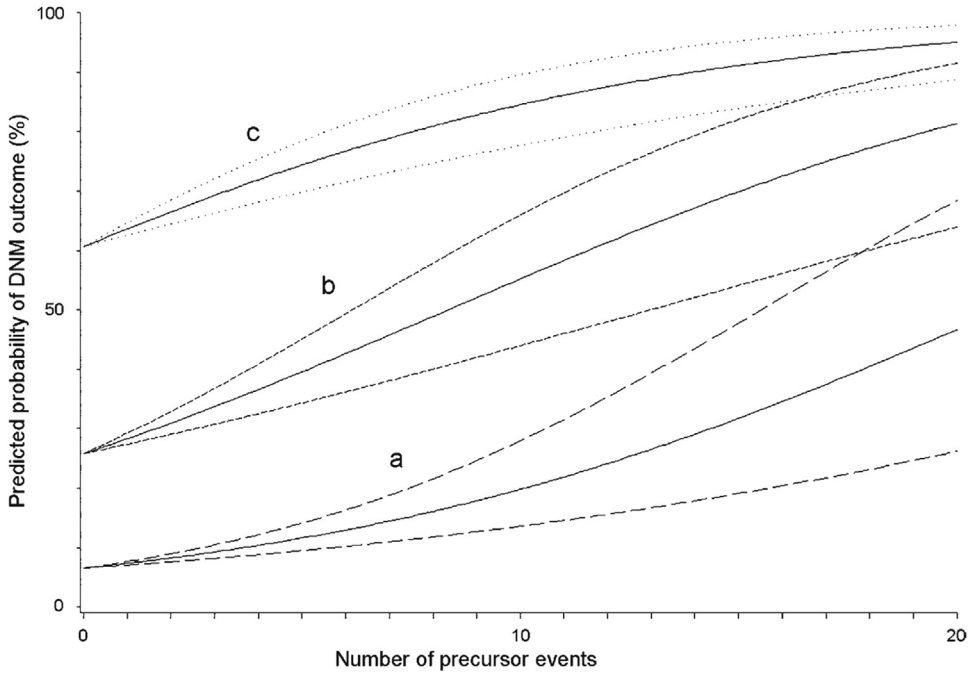

Fig 1. Predicted probability of death or near miss (DNM) versus the number of precursor events. (a) Low-risk patient (New York Heart Association [NYHA] class 1). (b) Medium-risk patient (NYHA class 2). (c) High-risk patient (NYHA class 4). (Dashed lines represent 70% confidence intervals.) (Reprinted from Surgery, 141, Wong DR, Torchiana DF, Vander Salm TJ, Agnihotri AK, Bohmer RM, Ali IS. Impact of cardiac intraoperative precursor events on adverse outcomes, 715-22, 2007, with permission from Elsevier.)