TOWARDS A THEORY OF PATIENT SAFETY – LESSONS FROM THE FIRST DECADE

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In the past decade, widely publicized medical accidents led to increased pressure on healthcare institutions to improve patient safety. Wrong leg amputation, lethal chemotherapy overdose, mistaken diagnosis of cancer leading to unnecessary surgery, anesthetic death, lethal drug-drug interaction were announced in the press as evidence that healthcare had become as dangerous as disease itself. Extrapolation of chart reviews led some experts to claim that between fifty- and one hundred-thousand U.S. patients die each year as a result of mistakes during their medical care. Beginning in 1994 with a conference held at the Annenberg Center in California, efforts to raise concern about patient safety culminated in an Institute of Medicine (IOM) report on patient safety, *To Err is Human* (Corrigan et al., 1999). Release of this report in late 1999 was a watershed for patient safety in the U.S. The report garnered political attention at the highest levels of the government and spawned a variety of governmental and private activities intended to improve patient safety and to do so quickly. The goal, announced by President Clinton in December of 1999, was to "reduce medical error by 50% in five years." (Cook, in press)

The targeting of error was particularly significant because it institutionalized the notion that the primary threat to patient safety was error by individual practitioners. The close linkage between practitioner error and safety seemed to be obvious in the wake of the press reports of accidents and the studies cited in the IOM report and medical, industrial, and political leaders quickly embraced the call for error eradication as a means to achieve safety. Government and private institutions began programs directed towards error: classifying error, counting error, and correlating error with factors believed to influence performance (e.g. fatigue) were undertaken in the next few years. Based on these error studies, countermeasures (mainly information technology such as electronic order entry) were developed and tested. In addition to the direct attack on error, efforts were made to identify the critical characteristics of organizations that might lead to better (i.e. "error free") performance. Prominent among these efforts were attempts to define and characterize a "safety culture" wherein error would be minimized.

By 2003 it became clear that the efforts to eradicate error were not producing the kinds of effects that had been expected. The wide variety of approaches that once seemed promising had been both difficult to put in place and far less effective than their proponents had promised. Error reporting systems that were put in place to measure the progress on error reduction provided conflicting data about the incidence and nature of error. Instead of a prompt reduction in the overall rate of iatrogenic injury, the patient safety movement seemed to be producing little tangible improvement and in some settings the situation may have become even worse. Instead of being a scientific and stable category of analysis, error now seemed to be malleable and ill-defined and the implications of researches into error and its prevention now became suspect. The relationship between error and accidents, once the primary tenet of the patient safety movement, began to fray.

In the later part of 2003 and throughout 2004 a retrenchment began. As it became clear that error was only tangentially related to safety, patient safety leaders began to recast the problem as one of avoiding harm rather than avoiding error. As error became devalued, incident reporting and error counting projects lost much of their attraction. The devaluation of these approaches created a new crisis as the various programs intended to forestall error produced results phrased in terms of error reduction. Following another IOM report (Aspden, et al., 2004) emphasizing information technology as a force to rationalize healthcare, attention turned to the need for immediate computerization of the clinical aspects of care. In the wake of this new report, the new President sought to encourage healthcare systems to invest in computer hardware and software in order to streamline and enhance healthcare while reducing errors. Within the plans for a new healthcare information infrastructure were plans to gather immense amounts of quantitative performance data from practitioners and healthcare facilities as a means of gaining control over soaring healthcare costs. The costs of this momentous shift to a universal clinical computing environment are already enormous and promise to remain so for the next decade. The pursuit of safety for the foreseeable future relies almost entirely on the development of clinical information systems.

The failure of error to provide an adequate basis for safety should not be surprising. People from several domains have sought to eradicate error as part of their pursuit of safety and none has been able to create any strong linkage between error and safety. Instead, these groups have found themselves searching for factors that influence systemic and individual performance more broadly. Although the search pathways are somewhat varied, in the end they all lead to development of a more nuanced and sophisticated view of the roles of human workers in the production of safety. In most cases, close examination of the technical work that takes place within the system reveals that workers are constantly making tradeoffs across multiple dimensions in order to generate acceptable results. These tradeoffs are essential to making the system work. Workers are variably skilled at anticipating the kinds of good and bad outcomes that can occur. They are under unremitting pressure to produce more and faced with irreducible uncertainty about the future. After accidents, observers conclude that worker error was a proximate cause of failure. But this isolated view of the world is too bias-laden and accident centered to be a sound basis for evaluation. Although it is difficult to appreciate in the aftermath of a catastrophe, workers are not the source of accidents but a primary defense against them. The occurrence of an accident does not come from localized error on the part of workers but from the dynamics of the larger system as the operating point of the system moves in relation to what Rasmussen calls the "boundary of acceptable performance" in order to remain in balance with the various influences.

The Rasmussen model of system dynamics (Rasmussen, 1997) provides an explanation of why efforts to improve safety have generated only equivocal indications of success. The key feature of Rasmussen's model is its dynamic character. According to the model, systems under economic and workload stress will be migrate towards high production and towards the boundary of unacceptable performance, i.e. the place in operational space where accidents occur. Migration towards the boundary can be offset by counter pressures, e.g. encouragements to "be safe", but economic and workload pressures are usually unremitting in real world systems so that preventing migration requires constant counter pressure and a willingness to tolerate the inefficiency that remaining distant from the boundary entails. (Figure 1)

Direct experience with accidents provides unambiguous information about the location of the boundary and offer opportunities to devise programs to keep operations away from the boundary. Because the boundary location is itself changing with time, however, long accident-free periods are the exception rather than the rule.

Rasmussen's model offers an explanation for the apparently marginal performance of safety programs in healthcare and other domains (Cook, Rasmussen, in press). Long accident free periods will result in migration towards the unacceptable performance boundary as the system seeks higher efficiency in operation. Workers will be encouraged

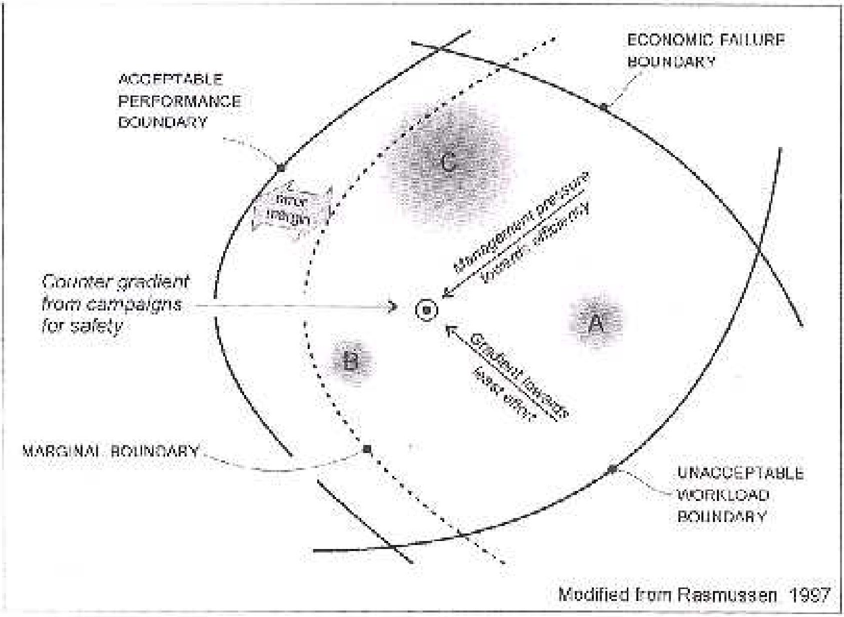

Figure 1

to "cut corners" to achieve production goals and the workplace will be regarded as too "rich" when accidents are rare. As the system operating point migrates towards the accident boundary under these pressures accidents occur. These provide indications that the system operating point has now become too "lean" and the economic and workload pressures will be overcome by the strong need to "be safe", moving the operating point away from the accident boundary. Significantly, the actual shape and location of the accident boundary can only be inferred. It is for this reason that high-reliability organizations are inherently conservative about applications of new technology or changes in operational procedure; their close proximity to the boundary of unacceptable performance requires that they constrain the movement of the operating point in order to avoid accidents.

In this formulation, safety is a dynamic rather than static feature of systems. An understanding of safety necessarily includes a detailed understanding of the dynamics of the system's location relative to the unacceptable performance boundary.

We can hypothesize, then, that experience with patient safety has played out along two lines. First, the popular emphasis on safety has acted as a counter gradient, moving the operating point of the system away from the unacceptable performance boundary but only so long as the that emphasis is sustained. Second, efforts to delivery of care, e.g. through use of information technology, result in a shift in the location of the acceptable performance boundary. But this shift does not alter the pressures that lead to migration towards the boundary and the system operating point gradually moves outwards.

What are the implications for patient safety? First, we have the history of the patient safety movement. Early in the patient safety movement, the notion that rampant error was the primary threat to safety led many to believe that rapid progress ("low hanging fruit") was possible. The loss of error as the central, organizing principle of safety makes it clear that progress is likely to take longer and be more expensive than was previously thought. Second, current emphasis on information technology is likely to shift the boundary of unacceptable performance outwards. Although this represents real progress, it is also likely that expense and effort required to achieve these gains will lead to their being consumed as production. The result is likely to be a healthcare system that is not accident free but instead has different *kinds* of accidents. Third, the loss of error as an organizing principle opens an opportunity for the development of a more powerful and useful theory of safety. Rasmussen's dynamic system model is the leading candidate for that theory.

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