

Return to Sender(s)

More Questions than Answers

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I am a physician and educator and have been engaged with the patient safety community at least since attending the NPSF meeting in December 1997 that led to *A Tale of Two Stories*² and I have been trying to adapt and apply what is being learned to work in the ICU and operating room. Like others, I have found Senders' questions provocative. I do not have answers for most of them although, in keeping with my understanding of the tradition established at past meetings on error, this is apparently a perfectly acceptable state of affairs. What follows are my efforts to craft a reply that does justice to the questions and also to what I have learned from others and have seen and continue to see in clinical practice. I hope that I may be forgiven for plain speaking. I understand that this, too, is a tradition for these meetings. -- MOC

Question 1: What evolutionary advantage, if any, exists for the persistence of erroneous behavior in Homo Sapiens?

The classification of human behavior as erroneous imposes value judgment where none may be appropriate. There is natural variation in human performance. Humans are also endowed with an intense curiosity about how our world actually works, and routinely engage in behaviors that allow them to test their own abilities, the abilities of others, and their understanding of how the world works. These behaviors, coupled with conflicted demands and priorities in complex situations are what produce the variable performance that is erroneously categorized as erroneous. As in every other field of safety research, investigation into 'human error' is a dead end avenue for research.

2. Thresholds for perception of well-defined stimuli have been experimentally defined. Can this knowledge inform understanding and amelioration of errors in complex work settings?

Absolutely. Indeed some of the greatest opportunities to make progress in safety in medicine and in other domains pertain to attention, its management,

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² Cook RI, Woods DD, Miller C (1998). *A Tale of Two Stories: Contrasting Views of Patient Safety. Report from a Workshop on Assembling the Scientific Basis for Progress on Patient Safety*. Chicago: NPSF.

and the design of improved displays and device interfaces. Careful study of work *as it is performed*, with a comprehensive understanding of *both* the work that is being done *and* practitioners' cognitive models of it, has been and will be the foundation for improving performance and reducing the incidence and severity of failures in a variety of domains.

A detailed understanding of what is being done and why it is being done should be the centerpiece of all efforts to enhance safety in complex systems. Careful attention to the way that data is presented to its end users, with appropriate presentation in a format consistent with their cognitive models, can be extraordinarily helpful in empowering practitioners, especially in situations of high tempo, high uncertainty, and high consequences. Poor design and poor human interface remain major unrecognized obstacles to both productivity and safety in a variety of domains and particularly in medicine. Making progress in this area will be hard, but it is likely to be a very fruitful avenue.

3. Is there a recognizable state of the central nervous system of the actor prior to the emission of an error?

No. The vast majority of medical failures and incidents are systems failures. The latent failure model arises from the observation that most disasters occur in a setting where the performance of those participating is at its usual high level. In fact, disasters seem to occur in settings where deteriorating conditions of work overwhelm the capabilities of workers to extract success when failure threatens. Although there may be minor variations in individual performance as well as variations in the performance of different individuals, these are not usually major causes of incidents. Indeed, the persistence of the notion of error in the literature and during consideration of these kinds of events is one of the major problems that frustrates deeper understanding and insight.

4. Is error proneness a truth or a myth?

There is variation in the performance of individuals within a system. Additionally, different systems operate with different resources, different priorities, and different constraints. As a consequence, different systems produce different kinds of failures at different rates. Incompetent practitioners may produce failure at a high rate - but do not account for a significant proportion of failure in the real world, few failures of complex systems by their actions alone, and almost no failures of well-designed systems.

The question is directed towards individuals but should be asked relative to groups and organizations. Organizations may be prone to failure - that is they

may have extraordinary production demands, diminishing resources, and deterioration in safety margins whose full magnitude have been unappreciated.

Investigation into error proneness is a dead avenue of investigation and waste of intellectual capital.

5. Does fatigue increase error probabilities? Or does it result in changes in the kind of error?

Fatigue clearly diminishes the ability of operators to make optimal decisions. Interestingly, all of medicine has recently been enjoined to reduce the number of hours that residents work to reduce the incidence of fatigue related sub-optimal decisions made by trainees. Hilariously, this regulation was created in a vacuum of safety data about the consequences of its implementation, which may prove to be substantial. Although there is no question that the ability of operators to make optimal decisions degrades with fatigue, there is a paucity of high quality data about how this plays out in health care and, consequently, little or no basis for recommendations on work hours. Mandating particular work hours without addressing other aspects of the work situation is the kind of well intentioned but potentially disastrous directive that may squander what political capital that the safety movement has.

Reducing the number of hours worked by housestaff (or any other healthcare professional) has several unintended consequences, whose magnitude is unknown (but knowable), and whose deleterious effects may surpass those produced by fatigued physicians. First, "Cross cover" is routinely identified as a source of sub-optimal decisions about patients. Mandated work hour reductions increase the amount of time that patients are cared for by physicians who are necessarily less familiar with them. Second, significantly reducing physician hours threatens to further transform the relationship between the physician and patient, from one of ownership to that of a shift worker. The importance of this change in relationship is unknown (and perhaps unknowable) and difficult for us to perceive at the beginning of an era of reduced work hours for physicians. I personally think that this consequence may prove, in the long run, to be more troubling than fatigue.

Efforts to reduce hours worked by trainees trades sub-optimal decisions made by fatigued operators for sub-optimal decisions made by cross-covering operators. It is likely that the quality of decisions made in healthcare has been degraded by this recent, well intentioned effort to reduce the rate of "error" from fatigue.

6. *Can people be trained to detect and control their own or others' errors?*

Yes and No. Individuals and groups develop habits to trap failures arising from variations in their own performance and the conditions of work. Cross checking the work of others is routine in environments with modes of failure amenable to this kind of detection, e.g. naval aviation. Of course, operators tend to ignore cross-check activity if it rarely or never detects important failures. Hence, routine guarding against rare events is likely to fail - because the operators involved will shift their attention to more productive tasks. It is remarkable that so many "safety" people do not understand that you cannot increase the attention of humans. You can only make better use of it. This is especially relevant for those already subjected to high workload, which includes a majority of those at the sharp end of healthcare. Outsiders frequently underestimate healthcare heterogeneity and uncertainty and are uncalibrated about the likely effect of attempts to externally manage attention, e.g. the consequences of adding computer based 'reminders'.

7. *How do we apply whatever science of error we have to the design and use of medical devices in order to reduce or better, eliminate, the potential for patient injury?*

There are several perhaps insuperable obstacles to making substantial progress on patient safety.

First, many of the resources that have been allocated to improve safety have been squandered on ill-conceived, poorly executed proposals. The principle reason for this is the poor understanding of the state of the art by both medical practitioners and the various institutions and organizations supporting investigation into safety. The vast majority of the projects undertaken are going to fail in ways that would have been predictable to those familiar with the history of safety in other domains. The payoff from the investment is going to be correctly perceived by sponsors as minimal or absent. It will be difficult for them to justify further investments in an area with such little early return.

Second, safety is poorly positioned to compete against other areas for resources, for either investigation or implementation. The large number of dead-end avenues of investigation in its early history will be used against it by those seeking to divert research money toward "hard" science. Safety as a field may be further impeached by the many initiatives launched by naïve but well intentioned practitioners that have consumed large amounts of resources and conspicuously failed.

During the past decade there have been no huge improvements in safety brought to national scale. The myth of low hanging fruit has been dispelled by experience. Research in safety will require both time and money, neither of which may be forthcoming. It is likely that implementing any meaningful

program on safety will be hugely expensive - far more so than has been discussed in any public forum.³

It may be that the greatest scientific contribution of the assembled group of experts on "error" is to help the administrative and regulatory parts of healthcare become recalibrated regarding the fruitfulness of currently "hot" initiatives in healthcare safety. Many of the proposals for improving safety are both unproven and enormously expensive. Both computer order entry and bar code administration have been offered as solutions to failures arising from the actions of humans. But the performance of most systems under development or in use is poorly understood and both their modes of failure and predilection for it remain unknown. Simulation has many proponents, but is clearly an expensive way to provide limited return on the safety dollar.⁴

There are promising areas of inquiry that should receive further attention. Common medical devices require study before we can make meaningful recommendations about how to improve their design and increase the safety of their use. Careful, detailed understanding of how these devices work and how they are actually used will clearly be useful (see Mark Nunnally's work). Similarly, technical work analysis is another potentially profitable way to investigate ways of understanding how work is done and safety is made and broken. See Emily Patterson's work at Ohio State and Matt Weinger's work at UCSD fit in this category.

Two of the most serious impediments to research on patient safety are the ignorance of physicians of the state of the art of safety science, and the ignorance of safety researchers about the complexities and constraints that shape healthcare. Substantial improvement in the state of the art will require a long-term, carefully planned sustained investment in developing a growing cadre of investigators and experts in patient safety, people who bridge the gap and have credibility on both sides. Improvements in patient safety will come from this

³ A Medicare drug prescription program could well consume all of the resources that health care might have allocated to research into safety and the implementation of well considered safety programs.

⁴ Full scale simulations of operating room activity, for example, might require 2 physicians and 5 other role players/directors/debriefers, only 1 of whom may benefit from the simulation. It is easy to imagine 24 scenarios that might be worth simulating, and that it might take 8 to 10 days to work through them all. If only one person benefits directly from the simulation run, then the direct costs could be \$30,000 per person per year or more, making this modality comparable to the yearly cost of attending medical school. Is this the most productive way to spend scarce dollars to improve patient safety?

cadre. It will produce new discoveries, perform evaluations, implement the new approaches, and also recognize and denounce ill-conceived ideas, wasteful proposals, and fraud. It is this cadre that will ultimately be the repository of the state of the art on patient safety.

Although it would be politically desirable to transition quickly from research to application to practice improvement, significant improvements in safety are likely some ways off in the future. If we were granted a billion dollars (or ten billion) to improve patient safety, we would not know how to spend it. If we were granted a hundred million dollars to conduct investigation into patient safety, we would run out of competent investigators and projects before we ran out of money. Rome wasn't built in a day. A well conceived, successful program to sustain improvements to patient safety won't be either.

A FEW GENERAL COMMENTS/QUESTIONS:

- 1) Some accidents may be less expensive to have than to prevent (for example, awareness during anesthesia⁵). Is there a methodology that might be used to guide the response to incidents of this nature? How do we explain these rational uses of resources to injured people and their advocates?
- 2) Medical incident reporting systems deal with a vastly complex world, and generally produce only hints about what went wrong or how those circumstances came to be. For example, comparing the reports to the FDA's database MAUDE with Dr Nunnally's results, it is clear that incident reporting systems do not speak for themselves. Making sense of incident reports requires substantial investment in complex research directed at the sources and evolution of incidents themselves. The phase 3 drug evaluation system has created near ideal circumstances for incident reporting and a massive network for disseminating incident results across the medical community, yet this system has failed to detect major problems with drugs under development.⁶ Looking forward, what can the group say about the likely yield of incident reporting? What might be done to improve the performance of medical incident reporting systems? Should this approach to making the world safe for patients be abandoned?
- 3) Unfunded mandates, e.g. reduction in work hours during training, are proliferating as a 'solution' to safety. Is there a rational response to this kind of activity? On the

⁵ O'Connor MF et al. (2001). BIS monitoring to prevent awareness during general anesthesia. *Anesthesiology* 94: 520-2

⁶ O'Connor M, et al. (2002). Upper Bound for Performance of Incident Reporting Systems Based on Experience with Phase III Adverse Event Reporting. *Anesthesiology* 96: A1089.

whole, do unfunded mandates increase safety or peril? Do they simply shift failures from one location to another?

4) Practical issues, of course, remain the most difficult to link to research results. For example, should the FDA compel drug manufacturers to change the labeling of their drugs to include information about off-label use? Off-label use is extremely common but a difficult regulatory issue. How would the group go about formulating advice on this issue?

5) There is no simple easy way to educate clinicians about the effects and side effects of new drugs as they come in to use.⁷ Is there any efficient or effective way to redress this problem? Computerized reminders are now all the rage but those with more experience with information technology urge caution. Is there any way to restrain the irrational exuberance over technology that appears when such questions like side-effect knowledge are raised?

6) It would be a great service if the conference generated some lists that would be extraordinarily helpful to the broader world of medicine such as:

- a) A list of ineffective measures to improve safety
- b) A list of futile avenues of research
- c) A list of research approaches that are likely to be fruitful
- d) A list of how previously safe organizations fall off the wagon

⁷ Foss JF, Daves S, O'Connor M (2000). Anesthesiologists Are Not Discontinuing the New MAO Inhibitor Selegiline Preoperatively. *Anesthesiology*; O'Connor M, Daves S, Foss J (2000) Anesthesiologists Are Not Discontinuing Metformin Preoperatively. *Anesthesiology*.