Structures, processes and outcomes for better or worse: Personal responsibility in patient safe care

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For healthcare institutions to provide highest quality healthcare services, elements of institutional structures and processes must align to achieve optimal clinical outcomes. Optimal clinical outcomes may include maintenance of health and wellbeing, improvements in health resulting from treatments for illnesses, and high patient satisfaction with the services provided. The provision of healthcare services thus requires that appropriate examinations, investigations and clinical interventions be provided and performed in a timely fashion as determined, where possible, based upon sound evidence of benefit to patients. In addition, healthcare services should be provided in a cost-effective fashion so as to avoid inappropriate use of resources that drive up costs but do nothing to improve clinical outcomes. So, providing necessary and appropriate healthcare services to achieve highest quality outcomes cost-effectively should serve to define the goals of an optimised healthcare system.

A critical point in this discussion is that providing care safely, and avoiding safety incidents resulting in harm and increased costs for healthcare services, is quintessential to achieving success in healthcare. Safety is quality and quality healthcare is patient safe healthcare.

The Donabedian Model

Over 50 years ago, Professor Avedis Donabedian at the University of Michigan established a framework for measurement of healthcare quality that has served as the benchmark for comparisons between healthcare institutions and systems.[1] Donabedian posited that the achievement of optimal healthcare quality outcomes would be dependent on the presence of appropriate and efficient structures and processes of care. Essentially:

Structures + Processes >>> Outcomes

Donabedian did not posit that having appropriate structures and processes would necessarily result in optimal outcomes, but rather that the adequacy in structures and processes was a necessary foundation for providing highest quality healthcare. The proof would depend on implementation and utilisation of the structures and processes, not merely the presence of appropriate and robust structures and processes.

   a. *The structures*

The structures supporting the provision of highest quality healthcare services necessary to achieve optimal outcomes include both physical and organisational elements. So, it's not just the physical environment in which services are provided but the administrative underpinnings of the institutions: leadership, accreditation and standards compliance; institutional culture; qualifications and competency of professional staff; education and training programmes; research and academic affiliations; policies and institutional instructions or guidelines; staffing, funding and any other foundational elements that one might want to include for particular institutions or integrated multi-functional systems providing healthcare.

Healthcare systems and institutions must have a framework of structural excellence so as to be positioned to provide the highest quality healthcare. Institutions lacking in any of these elements are, thus, not as well designed to provide highest quality healthcare or achieve optimal clinical outcomes for patients. Structures are the foundation upon which everything else either stands or falls. Insufficiencies in any of the subordinate elements mentioned above can impair performance, degrade the quality of healthcare services provided and adversely affect clinical outcomes.

b. The processes of healthcare

The processes of healthcare include the ways that healthcare services are provided in the actual work centres. These might include elements of standardisation to reduce variability in care, incorporating efficiencies in the performance of procedures in a cost-effective way, and processes that specifically consider ergonomic factors so as to enhance utility and utilisation. Though Donabedian did not refer to this specifically, a collateral perspective would be that the processes for providing healthcare services should be designed by those on the frontlines of healthcare – those who are most intimately involved and aware of the challenges that must be considered. These processes would, of course, be appropriate to distinctive settings, including general and specialist wards, clinics, operating theatres, pharmacies, laboratories, etc.

Where the Donabedian Model may not suffice

The Donabedian construct: Structures + Processes >>> Outcomes is thus a simplified framework for examining healthcare quality. But it may not go far enough for two reasons.

Firstly, the construct may not go far enough because Donabedian did not specifically discuss the human performance dimensions affecting both the structures and, more importantly, the processes necessary to provide healthcare services. The functional aspects of a healthcare system working well (and these include elements that reside within both the structures and processes components of his model) must rely most pragmatically and intimately on human performance and, thus, must address the factors that can adversely affect human performance. Individuals and groups or teams of individuals are responsible for design and implementation of elements and subordinate elements that reside within the structures and processes model Donabedian described. In my view, this is where the crux of the challenges resides. If we don't

fully understand and address human performance factors, then the structures and processes model will be insufficient to achieve the goals of highest quality healthcare performance, optimal clinical outcomes, improved cost-efficiency and enhanced patient satisfaction.

Where this gets even stickier is on the processes side of Donabedian's Model where individuals and teams are responsible for actually caring for patients, for utilising and implementing the processes of care patients depend on, and where the actual mistakes occur that can result in patient harm, i.e., the frontlines of healthcare. The processes may fail because of weaknesses in structures or because of limitations in the design of the processes. But assuming the structures and processes are robust and succinct, mistakes occur because of insufficiencies in individual performance; i.e., human factors. Investigating and analysing the reasons for individual insufficiencies or failures, the human factors that may result in mistakes, should reveal fertile ground for safety improvements.

Addressing the human factors aspects has the potential to have the greatest impact on improving patient safety. This is likely to be most relevant when investigating the considerable challenges of improving diagnostic accuracy and the prevention of diagnostic errors and delays – major confounders affecting quality outcomes, malpractice liability and healthcare costs.

Secondly, Donabedian did not specifically refer to patient safety as a quality performance measure. In fact, when Donabedian wrote his paper in 1966, there was little or no discussion regarding patient safety and little understanding regarding the magnitude of the problems with safety in healthcare. These would not come to light until the publication in the USA of the report by the National Academy of Sciences Institute of Medicine, *To Err is Human*, in 2000[2] and in the UK the publication of the report by Sir Liam Donaldson, *An Organisation with a Memory,* in 2000.[3] Why Donabedian did not specifically address safety as a component of healthcare quality is anyone's guess, but I presume that the general unawareness of the problems with healthcare safety, and the enormous magnitude of the safety problem specifically, were the reasons this was specifically not discussed. Donabedian was not a clinician and, to some extent, possibly unaware of how often human factors liabilities affect performance in healthcare settings, how commonly mistakes occur and, thus, the very substantial magnitude of the problem of safety in healthcare.

Since the publication of these two seminal reports there has been a plethora of literature and discussion regarding the factors that adversely affect the provision of safe healthcare. Journals, conferences and organisations specifically devoted to improving patient safety have appeared and the media has fully engaged on this aspect of healthcare. Patient safety incident reporting and investigations have become the norm. Major government-led investigations regarding serious patient safety incidents have taken place, and institutional reporting and analysis of harmful incidents has become commonplace. The major investigations have revealed that every element of the healthcare system calculus is accountable and should be held responsible for shortcomings in assuring safe patient care. Weaknesses in institutional leadership and culture have been paramount in the broader discussions of causal and contributing factors for safety

incidents and harm, whereas at the local level, unfortunately, a blame and shame culture has been commonly manifest in many settings — far too many settings.

The lack of candour, the unwillingness to discuss mistakes and to apologise to patients and family members, has resulted both from severe restrictions imposed by leaders and administrators on the kinds of information that can and will be shared with patients and family members (despite that the sharing of information by is a unique obligation of clinicians under the principles of medical ethics) specifically and most notably the principles of respect for autonomy, beneficence and of nonmaleficence.[4] Mistakes do and will happen despite the best intentions of individuals and teams of individuals, even as clinicians strive to do no harm.

Providing healthcare services is complicated stuff, and only by appreciating just how complicated this can be will strategies arise that can modulate this. It is on the frontlines of healthcare that this matters most, and where solutions will be found, all of which brings me to the 'personal accountability and responsibility' part of this article. Mistakes, errors, failures, or whatever one chooses to call safety incidents, occur on the frontlines and that is where our attention should most deservedly reside. Why these occur are the locks on the doors and how to prevent them is the set of keys. Only the keys can open the locks on the frontlines of healthcare.

Learning from 'other' industries

In the middle of the 20th century, the engineer F. Edwards Deming was studying the relationships between processes and human performance in Japan, in the automotive industry. What Demming understood was that insufficiencies and inadequacies in the design of structures and processes interfered with production and quality in manufacturing.[5] Demming believed that once these insufficiencies and inadequacies were identified and studied, then efficiencies could be designed into the structures and processes that would result in reductions in variability and improvements in the quality of products and. Out of this systematic approach, the total quality management approach to continuous improvements was born.

Weick and Sutcliffe in their 'High-Reliability' performance model[6] further expanded on Deming's principle because they also understood that individuals working on the frontlines of industry were likely to be the best resources for understanding the challenges inherent in the production processes and, thus, the best resources to help identify and navigate improvement opportunities. The frontline workers were the best ones to consult on whether a particular wrench was ideal for a particular function, and managers and executive leaders needed to pay attention to what the frontline 'experts' identified as opportunities and strategies for necessary improvements. Engagement with frontline staff also should work to improve morale because engagement means collaboration and collaboration imparts value. Valued workers are more efficient and productive on assembly lines and also in healthcare settings.

I'd like to think, though I don't know this for a fact, that Deming understood that although one could improve designs to enhance performance in many ways, one could not account for every

aspect of variability or, in this case, human liabilities that might affect performance on the frontlines. The factors that could be identified, and that he no doubt was aware of, were workplace-related factors that could impair performance, such as disruptive or disturbing environmental factors, workload volume and time challenges, task saturation, distractions, management issues and staff interpersonal factors, ergonomic human factors, etc. Less obvious or apparent were factors that are not specifically workplace unique, such as outside family, social and economic pressures, physical illnesses, psychological factors, that can degrade human performance but may not be apparent at a superficial level of examination, or that managers or colleagues may not be aware of at all. All this background 'stuff' is still percolating in our minds, often to our performance decrement. Though we may think we leave these things at home or outside work, the fact is that this is harder to do than many imagine or admit.

What the aviation Industry has taught us and where it falls down

Earlier in my career I spent some time working with aviators, especially with military fighter jet pilots who, when flying, often see themselves as becoming 'as one' with their airplanes. Often, I was told that these highly trained pilots left all the outside world behind them when they climbed into the cockpits of their fast jets. Well, maybe. These pilots were certainly very good at compartmentalisation, but in several mission debriefings, when I asked pointed questions, I learned that this compartmentalisation was not so smooth and streamlined as one might think or wish. Pilots don't simply package their personal lives and leave them behind when they come to work, and these 'hidden' human factors may adversely affect performance. Fortunately, the aviation environment is failsafe designed and that helps, but does not eliminate all factors that may affect performance. Whether healthcare workers, professionals and paraprofessionals can compartmentalise these 'hidden' human factors is uncertain, and the environment in which healthcare is provided is not nearly as failsafe designed as the aviation environment. The magnitude of this problem is anyone's guess and may be reason to worry.

One reason that fighter pilots may be able to compartmentalise outside pressures more effectively than clinicians is that the pilots' own lives are in danger when they fly, especially if they are distracted or inattentive; that is, they have skin in the game, as their own lives are at risk, whereas in healthcare our own lives are not at risk, only those of our patients. Perhaps this is a visceral difference, and perhaps I am overstating the magnitude of this, but the fact is that these aspects affecting human performance have not been studied as rigorously as more easily identified and acknowledged human factors, such as fatigue and hunger and ergonomics – the study of human factors concerned with the relationship between humans and elements of their environment so as to enhance utility and efficiency, most commonly in regards to human technology interactions.

The aviation industry is an excellent example of where structure and process design focusing on human performance in a defined environment have blended nicely to improve safety, specifically the relationship between air crew and the environment in which they work. Not only are our pilots, co-pilots and flight engineers superbly trained but they are superbly trained to work closely with each other, within settings that are uniquely designed to support their

efforts with an array of active and passive strategies and technologies at hand to assist them. Furthermore, they spend significant amounts of time in simulator training where malfunction scenarios are programmed to occur, creating controlled 'emergency' situations that test response times and enhance situational awareness under varying stressors.

However, the aviation industry is not a mirror image of the healthcare industry. The reason that the aviation industry lessons are not so concisely transferrable to the healthcare setting is because providing healthcare is a much more complicated undertaking than flying an airplane. There are far more independent variables to contend with, and the calculus is far more complex in my view. Thus, the likelihood that a mistake will occur in healthcare settings is much more common and, despite the efforts to design systems and processes to modulate human vulnerabilities, mistakes still occur and will continue to occur as long as humans take care of humans. The conundrum is that I question whether many well-meaning clinicians are aware of this or, if they are aware, then are willing to admit to the magnitude of this problem; i.e., to their own complacency.

To begin with, a typical commercial airliner has two or three members of crew working in a highly controlled and ergonomically designed workspace. The crew is continually interacting with active and passive technologies and communicating with ground and satellite resources that are assisting with a variety of aspects of flight control. The language they use for communication is standardised and they are pretty much undisturbed and, therefore, less distracted while they are working. Pilots and co-pilots have had identical training so there is an element of redundancy in professional competency that serves as another element to assure safety. Furthermore, these individuals work within a structure that supports teaming and coordination and encourages reporting of mistakes, errors, technical problems, etc., with a goal of continuous learning and improvements. Shared learning is the norm and individuals are respected for their efforts to report and improve.

Contrast this with a busy internal medicine ward in a typical NHS hospital where the patient workload is often at capacity or bulging beyond capacity, the environment is under pressures to discharge patients to make room for admissions waiting on gurneys in A&E units, patients are exhibiting a varying range of symptoms and illnesses compatible with a range of confounding complex diagnoses, staffing is inconsistent with agency nurses commonly filling in for full time staff. Physicians and surgeons, pharmacists, dieticians, housekeeping staff, trainees at all levels and of all professions abound, are continually coming and going and changing shifts. Furthermore, communication between members of staff, and between staff and patients, may be complicated by a range of environmental distractors, such as background noise, smells and interruptions, and social factors such as language and cultural nuances, varying levels of education, cognitive deficiencies, etc. One can easily see how the much more controlled environment of an airplane flight control deck simply does not translate so smoothly to the realities of working in a clinical environment. In fact, except for perhaps an operating theatre, there are few other examples where the healthcare environment and aviation environment seem similar at all.

Finally, there is a major cultural difference between air crew and clinical staff. Air crew are fully trained and understand that their lives, and those of their passengers, are at stake every time they fly, and safety is always the highest priority for them, every day. They think, eat and drink safety and redundancy and mutual crew member dependency and resource sharing. This is the cultural mindset.

In healthcare, this is not the case. To begin with one's own life is not in danger when we enter our wards and clinics. We are not likely to be harmed except by some occupational hazard, but these are rarely life threatening. Our patients may be harmed, but we are unlikely to be harmed. We are not as focused on safety, as our human nature doesn't dictate us to be so and our autonomic nervous system is not activated to do so.

Though we talk a lot about patient safety we do not necessarily think about this all the time because it is not our personal safety, and the concern about safety doesn't grab us in a visceral sense the same way it must for air crew. In an airplane, both the crew and passengers are in inherent life-threatening danger. On a hospital ward it is primarily the patients who are in danger of being harmed, and perhaps this is the key driver contributing to professional complacency. In fact, it is the lack of this visceral vulnerability that can feed a kind of professional complacency about the environment in which we work, about the risks that our patients face in this environment and about the risks that we, with our relative complacency, bring to the quality of care conundrum. We represent sources of benefits and also sources of risks to our patients, and yet many healthcare professionals do not see this or feel this or acknowledge this.

Examining personal responsibility

Because clinicians are generally kind, caring and compassionate professionals, and though or perhaps because we are benevolent in our intentions, we do not view ourselves as sources of harm. Because we do not think about the possibility that we will make mistakes, we may be more prone to making mistakes. The fact is, that although we may work within institutions with weak leadership, a punitive blame and shame culture, insufficient staffing and funding, weak guidance, and insufficient processes that lack standardisation and ease of implementation, we cannot, and should not, simply blame these institutional shortcomings for our mistakes. We are humans and we can, do and will make mistakes, and in contrast again with the aviation industry, our environments and work centres often lack elements of structure and process redundancy in safety that can prevent or modulate these. We have a responsibility to acknowledge this and to address subtle, yet pernicious, professional complacency as a contributing factor for patient safety incidents and harm.

So, how do we begin to address our individual responsibilities? How can each of us reduce the personal risks we pose for our patients? How do we begin to address the moral imperative to recognise and then overcome any professional complacency that may interfere with our performance? Well, it probably begins with our commitments under the principles of medical ethics, this time the foundational principle of beneficence. Clinicians are morally obliged to act

in the best interests of their patients and we generally do, but sometimes we can do better and an enhanced personal focus on our unique roles in providing patient safe care is a good place to start.

First, we must be willing to recognise and give a name to our inherent complacency and vulnerability for making mistakes for what they are. We then need to focus our efforts toward professional performance improvement in a sustained fashion, most notably by avoiding placing the responsibility for mistakes solely on the insufficiencies in structures and processes or other staff members that surround us. Though inadequacies and insufficiencies in structures and processes certainly abound, they do not necessarily explain all of the mistakes that occur in healthcare settings. We must recognise and admit our singular roles and, thus, our singular obligations to improve our own performance. A good place to begin would be if every day each of us would simply repeat the following mantra:

"I am a kind and caring professional about to enter a complex healthcare environment where patients may be harmed every day. I admit to myself that although I always intend to serve my patients as best I can, I also inherently represent a source of risk for them, and I may make mistakes that can result in harm. Though I may wish to deflect responsibility onto insufficiencies in structures, processes, leadership, culture, managers and even other colleagues, the fact is that I am also a unique risk to my patients. I will be very careful, every day, in every way, with every patient under my care, all the time; and I will strive to be even better tomorrow."

Next steps

This brings me back to Avedis Donabedian's Model for laying the foundation for quality healthcare. If Donabedian is correct, that solid structures and optimised and efficient processes are necessary for optimal healthcare services to be provided and best clinical outcomes to be achieved, then it is equally correct in assuming that enhancing human performance within healthcare settings will serve as the ultimate key to improving quality and safety. Recognition by clinicians of their own tendencies toward complacency and their own vulnerabilities toward making mistakes is to encompass a mandate for personal professional commitment and improvement.

If patients are harmed on the frontlines in healthcare settings, then it is on the frontlines that many of the solutions can be found and safety improvements nurtured. Leaders must recognise the expertise that exists on the frontlines and must value the contributions that frontline staff can make towards improvements in safety and optimisation of clinical outcomes. First recognising, and then modulating, the human factors liabilities that exist on the frontlines and overcoming the challenges of professional complacency will be necessary steppingstones towards sustained improvements in providing patient safe care.

Personal responsibility is a professional moral imperative for providing patient safe care!

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