Five Systemic Barriers Keeping Health Care from Becoming Ultra safe

A Conceptual Framework for Organizational Safety

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Abstract : While debate continues over various estimates on the amount of preventable medical harm occurring in health care, there seems to be a general consensus that health care is not as safe and reliable as it might be. It is often assumed that copying and adapting the success stories of non-medical industries such as civil aviation and nuclear industry will make medicine as safe as these industries. It is not that simple. This paper explains why proposing a bench-marking approach to safety in high risk industries is needed to help translate lessons to health care. The most significant difference among industries is not so much in the relevant safety toolkit. These are similar for most industries but rather the difference lies in the industry's willingness and mindset to abandon historical and cultural attributes and beliefs linked to performance and autonomy in a constant drive towards a culture of safety. Five successive systemic barriers are identified that presently keep health care from becoming an ultra safe industrial system: (1) the need for placing limits on the discretion of workers, (2) the need to reduce worker autonomy, (3) the need to transition from a "craftsmanship" mindset toward achieving the principle of "equivalent actor", (4) the need for system-level (i.e., senior leadership) arbitration in the optimization of safety strategies, and (5) the need for simplification. Finally, health care must overcome three unique problems: a wide difference of risk among medical specialties, difficulty in defining medical error, and a series of structural constraints (public demand, teaching role, and chronic staff shortage). Without such a framework to guide development, ongoing efforts to improve safety by adopting these strategies may yield reduced dividends. Rapid progress is possible only if health care is willing to address these structural constraints in order to overcome the five barriers to "ultra-safe" performance.

Introduction

Five years ago, the US Institute of Medicine report, 'To Err is Human,' highlighted the need to make patient safety a major priority for health care authorities (1). From that date, the pressure on patient safety has continuously grown in western countries. The priority focus has been put on the identification and reduction of 'preventable events'. Significant changes have already occurred in the accident and incident reporting system, and the associated techniques of analysis (2-6). It remains unclear, however, what the upper limit of harm prevention is (7). Many have proposed that adapting success safety stories and tools of ultra-safe systems, such as aviation or nuclear industry, will lead to comparable successes and safety figures for health care (8, 9). The reality is probably more complex. Many complex industries, for example, the chemical industry or road safety, have followed the same strategy. They have copied safety tools from advanced systems, and made important gains in the past two decades. However, most of these efforts are hitting a ceiling in their safety results well before the level reached by civil aviation and the nuclear power industry (10). This limit does not seem to be due to either insufficient tools, or to the low competence among workers, nor to naïve safety strategies. For the most part, it seems to be the consequence of a conscious trade-off between safety goals, performance goals, and the organization of the specific profession. Becoming ultra-safe may require health care to abandon traditions and autonomy that make the work effective, profitable, and pleasant for professionals.

A comparative analysis of industry behaviour demonstrates that becoming an ultra- safe manufacturer requires accepting five generic types of constraints on activity). The analysis is based on the screening of professions in various socio-technical activities such as aviation industry, nuclear industry, chemical industry, food industry, driving, or health care. The benchmark analysis aims at associating specifics traits of these industries with their safety performance. The description focuses on five high level organizational dimensions derived from the general literature on risk and safety (11-13), each associated with a range of values: type of expected performance (from daily work or highly innovative, to standardized or repetitive), initiative to allow professionals on the sharp end (from full autonomy to full supervision), type of regulations (from few recommendations to full specification of regulations at international level), pressure from justice after accident (from little judicial scrutiny to people and system systematically sued), and supervision and visibility by media and people in the street of the activity (from little concern to high demand of national supervision).

We consider that a value of a given dimension becomes a barrier when it is present for all work situations of equal or lower safety level, and absent for all work situations of greater safety level. The barriers can be ranged along the safety axis considering the average safety level of work situations that have been unable to cross each of these barriers. Note, a barrier may partially be under control, and therefore overlapping other barriers also partially under control, then making the relative impact on each on observed final level of safety more complex to read.

We consider that one barrier is more constraining than another barrier, when the maximum safety performance associated with absolute no control is lower than for another barrier. The safety barriers in this paper are fundamental 'root-barriers'. Each of these root-barriers represents a significant change in practice with considerable economical, political and performance trade-offs. After a brief overview of risk mitigation in industrial activities, the paper presents the five barriers and potential approaches to help mitigate them.

Risk Assessment and Communication in Industrial Activities

It is usual to measure the overall safety profile of an industrial system by reporting on the number of adverse events over a period of time (i.e., an annual rate). The figures are generally weighted according to the volume of activity (i.e., number of miles travelled per year). The parameter best used to specify the volume of activity – the denominator in a safety calculation -- depends on what drives meaning in each industry, and therefore is poorly standardized across industries. For example, civil aviation uses one million departures as the relevant parameter for the volume of activity (the denominator), whereas, military aviation uses flight hours as the relevant denominator. Reliably measuring health care and patient safety outcomes are the first challenge for health care benchmarking (14-15). In health care, the numerator is preventable harm.

In many industries, the weighting process reflects the comfort level of the organization/industry with its risk exposure. For example, the risk of fatal accidents in road traffic, which is one of the top three causes of death in western countries, is often weighted by travel convenience and the mileage travelled (16). Using this denominator may lead to the perception that road transportation is a very safe domain when compared to other alternatives. The unwary consumer of such risk reports may therefore erroneously interpret road travel as much safer than modes of travel whose risk is calculated using a much larger denominator such as in aviation. In fact, aviation is far safer than road travel. In this paper, we will concentrate on the *rate of catastrophic events per exposure* among industrial and human endeavours as an anchor allowing comparison of accident rates across industries to health care (Figure 1). Viewed through this lens, accident rates presently range from 10^{-1} to 10^{7} events per exposure. This ratio is the most accessible and allows easier comparisons across industries.

Civil aviation, nuclear industry, and railway transport in Europe, have a better than $1*10-^{6}$ rate of catastrophic accidents per exposure, such as plane engines completely failing leading to loss of aircraft -- that is, a rate of death lower than one per million exposures. The rate of fatal adverse events among hospital patients is much greater, but also varies by domain (1). In the fields of obstetrics, anaesthesiology, or blood transfusion, the risk of fatal adverse events per exposure is less than 10^{-5} (17). Conversely, deaths from surgery have a total fatal adverse event nearing 10^{-4} (14). Numerous papers give this 10^{-4} risk of accident as an extrapolated average value in health care (18, 19). Of course, all of the statistics do not have the same validity given differences in definitions and comprehensiveness in monitoring methods (20). Some derive from large databases with objective assessment, while others derive from local estimates. This is particularly true for health care. One can consider that the results published on the rate of adverse events are reasonably convergent in the literature, but we also acknowledge the important discussions on the accuracy of the numerator and denominator in the calculation (21-22). However, for this paper, we consider that these variations do not deeply alter the proposed safety framework. We propose to reason more in terms of relative ranking than in terms of precise safety values. Moreover, our working hypothesis on the stability of the relative ranking is all the more reasonable since the industries we are inferring from have been chosen as they are clearly separated by many logs of amplitude.

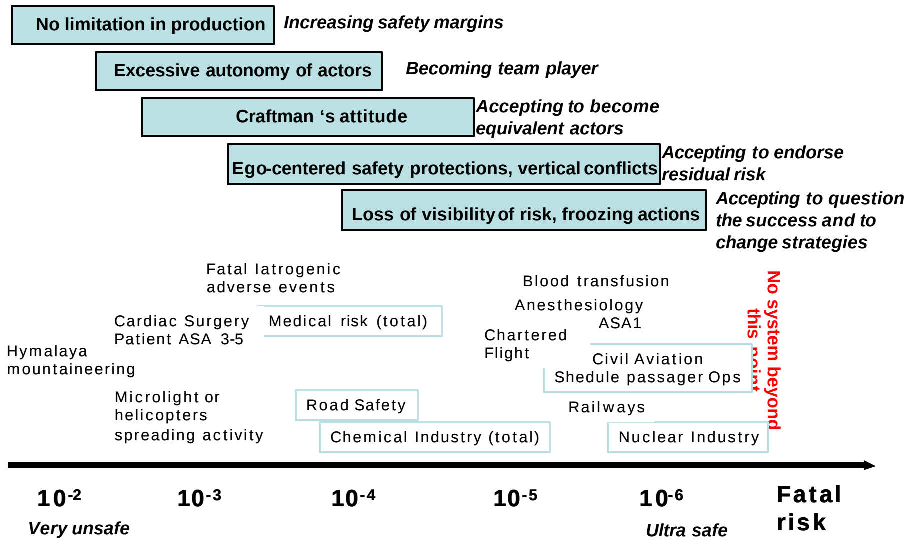

Figure 1*. Average rate per exposure of catastrophies and associated fatalities in various industries and human activities. The five barriers presented in the paper are represented. The size of the box represents the range of risk where the barrier is active. Reducing the risk beyond the maximum range of a barrier presupposes crossing this barrier.*

Medicine Bench-marking: What are the limits and barriers to achieving safety?

With the precautions mentioned in the previous section on the calculation of risk, it goes without saying that the risk of catastrophic events across industries demonstrates impressive differences. Some sectors are stuck at a low safety level (e.g., micro light or helicopter transport, emergency surgery), some are stuck at an average safety level (e.g., road safety, occupational accidents in trade industry or in fishing), some are at good levels (e.g., petrochemical, anaesthesiology), and the best are at safety levels beyond 10^{-6} (nuclear industry, civil aviation). Five systemic successive barriers seem to characterize limitations in safety improvement.

First Barrier: Accepting Limitations on Maximum Performance

The first barrier involves regulations that limit the level of risk allowed. This level is dictated in situations where high levels of production and performance are also sought. When these limits don't exist, as in-- "get this high level of production, no matter what it takes" -- characterizes very unsafe systems. When the maximum performance is not bridled, allowing individuals or systems autonomous decisions without regulation or constraints, the risk of fatal events nears $1*10^{-2}$ per exposure. For example, mountain climbers who summit more than three 8000 meter Himalayan peaks have a risk of death that exceeds one in thirty (23). This figure has been consistent over more than fifty years of mountain climbing. Similar figures are observed for a series of heroic surgical interventions in medicine such as repairing complex paediatric heart anomalies (24). This level of risk characterizes both amateur and pioneering systems. One has to note that professionals acting in these conditions are often extremely competent individuals. Low safety levels do not arise from incompetence. The greater risks in complex domains are incurred by experts who are challenging the boundaries of their own maximum performance. The more audacious the expert, the more risky the adopted strategies, and the more frequent the bad outcomes.

Fortunately, most industrial systems have passed beyond this phase of audacious pioneering and have bridled their maximum potential production and performance by comprehensive regulations, and self imposed guidelines. These systems deny even experts absolute discretion. There is a risk by over regulation. Flu vaccinations and blood transfusion are good examples of unintended consequences of over regulation. In the past two decades, an impressive series of safety restrictions on blood acquisition have successfully reduced the risks associated with the transmission of AIDS, hepatitis virus, by ten-fold (25). These safety reinforcements have led, however, to a severe reduction of accepted blood donors. This illustrates a classic trade-off between ultra-safety and productivity. On one hand, the improved limitations on blood gathering procedures avoid the rare dramatic transmissions of diseases. On the other hand, however, this practice mechanically results in the risk of not having blood readily available when needed for example, for traumatic shock. This affects the total population of patients until reliable synthetic blood alternatives become available.

Second Barrier: Abandoning Professional Autonomy

The second barrier involves restricting the autonomy of health care professionals. In road safety, road traffic is a collection of drivers, each of them pursuing their personal goals (destination, timing, etc). For each individual, all the other actors (drivers, pedestrians) are in some sense barriers to reach these personal goals. Road safety requires that drivers not act purely autonomously but they must each subordinate their own goals given others that share the road. In the highly charged political, and legal environment of the nuclear power industry we have seen gradual reduction in autonomy with improved safety. The Three Mile Island disaster led to the emergence of norms throughout the industry (26). The dread of even a single potential catastrophe and its implications for all industry members outweighed any objections to creating robust reporting systems for near misses and reduced autonomy of the plant operators. Backed by communal pressure, local proactive safety methods became institutionalized and effective across the industry. The intensified approach to process improvement through a focus on safety led to financial gains through more efficient power production (fewer outages, shutdowns, and reduction of capacity) (9). In aviation, comprehensive risk management programs over the past 30 years including crew resource management, have led to reduced pilot authority, making aviation extremely safe. The decades long aviation effort to improve safety through system monitoring and feedback holds many important lessons for health care (27).

A growing movement toward educating health care professionals in teamwork and strict regulations have reduced the autonomy of health care professionals, and thereby improved health care safety (28). But the barrier of too much autonomy is not totally overcome when teamwork must extend across departments or geographic areas, such as among hospital wards or departments. For example, it is not uncommon that, due to unforeseen personal or technical circumstances, a surgical case starts and ends well beyond schedule. The operating room may be organized in teams to face such a change in plan, but the patient's ward waiting for the patient to return is not be part of the team, and is unprepared. The surgeon and the anesthesiologist need to adopt a much broader representation of the system (e.g., anticipate problems for others, moderating goals, etc.). Thinking systemic and anticipating consequences of processes across departments remains a major challenge.

Third Barrier: Transitioning from a Craftsman's Mindset to one of an "Equivalent Actor"

The third barrier appears when systems have already accepted limitations on individual discretion (after successfully crossing first barrier), and have acquired the capacity to work well at team levels (crossed second barrier). We believe that to achieve the next increase in safety, health care professionals must face a very difficult transition: abandoning their status and self-image as craftsmen, and instead, adopting a position that values equivalence among their ranks. For example, a commercial airplane passenger usually neither knows nor cares who is the pilot or the co-pilot flying their plane; a last minute change of captain is not a concern to passengers, as people have grown accustomed to the notion that all pilots are, to an excellent approximation, equivalent to one another in their skills. Patients have a similar attitude toward anaesthesiologists when they face surgery. In both cases, the practice is highly standardized, and the professionals involved have, in essence, renounced their individuality in the service of a reliable standard of excellent care. They are selling "a service" instead of an individual identity. As a consequence, the risk of catastrophic death in healthy patients (American Society of Anaesthesia risk stratification type I-II) undergoing anaesthesia is likely very low – close to $1*10^{-6}$ per anaesthetic (29).

Conversely, most patients do request and can recall the name of their surgeon. Often, the patient has chosen the surgeon, and believes that the result of their surgery could vary according to that choice. This view is typical of a craftsman market. Safety figures for surgeons are much worse than for anaesthesiologists, nearer to $1*10^{-4}$ than to $1*10^{-6}$. (30) This is the case for many small industries, such as chemical companies, business companies in aviation, or farm-produce industries (in companies with fewer than 50 employees). In France the risk of catastrophe from such small companies is worse than $1*10^{-4}$, although larger chemical companies have an average risk closer to $1*10^{-5}$; large aviation companies or food manufacturer companies are even safer, with a risk near $1*10^{-6}$ (31). The difference between small companies and big companies is the production "à la carte" of products, such as cheese or fireworks. These products belong to protected commercial niches that have suffered over time from large variations in quality and product safety.

Ultra standardisation and the 'equivalent actor' principle require stable conditions for activity. These conditions are reached in some areas, for example: pharmacy, radiology, and non-emergent anaesthesiology. They are less common in intensive care units, emergent surgery, where unstable conditions, such as non-permanent staff, variation in patient acuity, and little control of planning are the norm.

Fourth Barrier: System-level Arbitration Required to Optimize Safety Strategies

This fourth barrier is created by the increase of medical malpractice liability pressure and media scrutiny. These are paradoxical consequences of systems reaching very safe levels of performance (32). The safer a system is, the more likely it is that society will seek to blame someone or seek legal recourse when injuries occur. In France, for example, the rate of litigation per 100 physicians has increased from 2.5% in 1988 to 4.5% in 2001 (33). The consequence of this paradox is that patient injuries that occur tend to be massively more expensive in terms of patient compensation, and thus they fuel the liability crisis. Accidents therefore become politically and financially intolerable because of their consequences and cost rather than because of their frequency and severity. The public and the media are capable of censuring companies or hospitals, leading to the sweeping new policies, firing of individuals, and sometimes even destroying industries. The recent passing in Florida of a constitutional amendment making all quality assurance data available to the public represents the public's will to better scrutinize health care providers (34). This is already leading to a decrease in reporting of adverse events in Florida. It is worth noting that the most recent safety problems can bias the objective risk assessment. They do this by assigning a lower value to individual deaths, even if numerous, while a higher value is assigned to a concentration of fatalities, even if rare. This biased view is seen, for example, with respect to aircraft accidents. In such conditions, health care professionals fear for their own position and behave accordingly. The liability crisis in Florida supports this barrier as a key to creating safer conditions when physicians feel vulnerable.

The fourth barrier is the result of a tendency of professionals and their unions to overprotect themselves in the face of legal pressures and threats of litigation. This occurs when insufficient consideration is given to the unintended consequences for the rest of the staff and system. This barrier echoes the second barrier, excessive autonomy, except that it is much more subtle and perverse. The actors are not ignoring the goals and constraints of their colleagues as they did with respect to the second barrier. Health care professionals and executives claim their willingness to improve safety by confronting the fourth barrier, and act by imposing additional constraints on other colleagues. However the perverse effect is that their safety decisions primarily absolve them of their responsibility, without clear recognition of the impact of their decisions. An additional perverse effect of top-down safety reinforcement is the existing potential difference in perception of patient safety at the various levels of the organization. Top management views safety in terms of mitigating the consequences of a crisis, so as to avoid jeopardizing the total organization (35). To them, patient safety is just another source of risk, among other sources which have similar consequences to the organization, such as troubled industrial relations or inadequate cash flow. Chairmen of clinical departments traditionally approach safety by confusing safety with quality and focusing on production line issues. Individual clinicians are more aware of patient safety issues given the risks that may damage their own self image or reputation. Society censures including being confronted personally or socially with one's own errors or failures is difficult for a proud clinician to accept (36, 37). The 1980's blood transfusion crises provided an example of the fourth barrier, with consequent over-regulation and conflicts among the three levels. Many patients were infected with the AIDS virus because of the absence of systematic AIDS testing during blood donation in France. It was commonly believed that the public health authorities delayed the introduction of HIV testing to avoid losing money and national reputation by refusing to use a US testing kit (38). The relevant medical authorities in fact, had recommended immediate action. As the crisis became public, blood donations become scarce due to the loss of donor confidence. Furthermore, the increased controls and paperwork made donation more demanding and time-consuming. The result was that many doctors voluntarily reduced the use of blood. Today, ten years after the crisis, and with dozens of additional controls implemented, the risk of transfusion-transmitted viral infection is intrinsically much safer (39). But an unintended consequence of these events in France has been severe anemia, a pathology which had essentially disappeared in Western countries is becoming common again (40).

Fifth Barrier: The need for simplification of the professional rules and regulations

This fifth and ultimate barrier typically derives from the perverse effect of excellence. The barrier is generated by the accumulation of safety layers which make the system very complex and ultra-protected. Accident reporting looses relevance and people forget to report. The visibility of risk becomes small, and decisions are taken without clear proof of their benefit, sometimes introducing a potential contradiction among regulations and policies (41). New safety solutions at this point have unintended effects. For example, the rate of production of new guidance materials and rules by the European Joint Aviation Regulators is significantly increasing, with over 200 new policies, guidance documents, and rules per year. All this despite global commercial aviation remaining for years at a safety plateau of $1*10^{-6}$. Since little is known which rules or new guidelines are really linked to the actual safety levels, the system is purely additive -- old rules or guidance material are never discarded or removed. Regulations become difficult to apply, and pilots engage in more rule violations in reaction to this increasing legal pressure. Some areas in medical safety follow this same pattern. For example, the protections against fire in hospitals have been subject to five successive revisions in France in the past eight years. All this, despite having little data about whether or not these regulations have actually improved fire safety, as opposed to simply making the system more unwieldy. In health care, arcane vocabulary, complexity and opaqueness of the process leads to risk becoming poorly visible to the practitioners.

The ultimate safety solutions for automated aircraft have consisted of developing electronic cocoons and flight envelopes to protect the aircraft against pilot errors, such as excessive input on commands, under-speed or over-speed, etc. Quite paradoxically, these protections have became a significant cause of several recent near misses and accidents in glass cockpits, due to the crew‘s misunderstanding of the software logic (42, 43). We can extrapolate from the unintended consequences of automation and complexity in aviation to health care, pointing to the comparable negative side effects of technical complexity in medicine. With actual patient risks less observable, the best move is to simplify the system, eliminate non-productive regulations, and give more latitude to the clinicians.

Designing a Healthcare Specific Framework

Health care faces many of the same barriers that other industries have faced in striving towards ultra-safe levels. Health care must accommodate in addition at least three other specific contextual factors. First, risks in health care are not homogeneous. A number of clinical domains, such as trauma surgery, experience serious complications in the order of $1*10^{-2}$ that are not all related to medical errors (44). The risks are inherent in the clinical circumstances. On the other hand, some health care sectors are inherently extremely safe, such as gastroenterology endoscopy, with the risk of incurring serious adverse events below $1*10^{-5}$ per exposure. Second, the magnitude and impact of human error is unclear in medicine. Fundamentally, three risks are combined in health care: the risk of the disease itself, the risk entailed by the medical decision, and the risk linked to implementing the selected therapy. These three risks generally do not move in the same direction. This complexity makes error prevention harder to predict and grasp. Terminally ill patients may have their fatal prognosis changed by an audacious surgical strategy. But, the most audacious strategies are less evenly distributed in the profession, are the most demanding technically, and are the most prone to errors. Third, the stress including personal harm factors such as getting infected with the AIDS virus weigh on the clinical staff in a unique way.

The unusual level of stress factors affecting health care workers derives from at least four contextual factors. First, health care is one of the few risk-prone areas where public demand considerably limits the application of common sense safety enhancing solutions, such as limiting the flow and choice of incoming patients. <u>This demand is a direct threat to overcoming Barrier One – bridling performance</u>. Second, health care is one of the few risk-prone areas for which the system is so extensively supported by novices, such as students, interns, and residents. There have been several attempts to evaluate the risks associated with beginners (45). One of the most interesting studies from the U.S. Department of Veterans' Affairs demonstrates that the risks in surgery remain higher in teaching hospitals, even after adjustment for case severity (46). Third, health care is one of the few risk-prone areas where there are so many obvious sources of human error in work design, and where so little has been done to reduce them. Among these are: excess fatigue on the job, systematic overtime and overloaded work schedules, and chronic staffing shortage (47-49). Fourth, an endemic source of errors in medicine is the shifting of more clinical care and technology to the ambulatory setting, such as the transfer of liposuction practices from hospital wards to doctors'office. A recent report suggested a ten-fold increased death risk of liposuction when combined with tummy tucks performed in clinics as opposed to hospitals (50).

Conclusions and Take Home Points

Health care is constantly improving. New therapies emerge and pertub the system while learn, results improve, new therapies emerge and so forth. However, health care has yet to traverse fully the five barriers presented in this paper. Quality improvement programs including a set of monitoring tools, such as reporting tools and standardized protocols, do not by themselves have the power to overcome these barriers. To paraphrase Reason, who said of the aviation community in the late eighties, today's patient safety efforts are akin to "presently fighting mosquitoes, but not draining the swamp [of error]" (12). Aviation made considerable efforts in the 1980's and 1990's to overcome the first three barriers, and are now focusing on the forth and fifth barriers. Health care has yet to master even the first barrier to safe performance. Consequently, efforts to emulate aviation are misplaced if the health care industry focuses on the same barriers that aviation is focusing on now. Mastering the five barriers will be a challenge.

These will require accepting limitations on performance by reducing professional discretion and reducing productivity pressures. The reduction of errors may require that health care constrain the professional latitude that health care providers have. This specialization would constrain performance rather than treating each professional as an expert of unlimited capability and decisions.

This tendency is clear in ultra-safe systems. For example, civil aviation imposes severe constraints on flights, such as restricting pilots on the type of plane they may fly, limits on operations due to traffic conditions and weather conditions, and a minimum list of equipment required before an aircraft can fly. Line pilots are not allowed to go beyond these limits even when they are trained and competent. Hence, the flight (product) offered to the client is safe, but it is also often delayed, rerouted, or cancelled. Would health care and patients be willing to follow this trend, and reject a surgical procedure under circumstances where risks are outside the safe boundaries? Physicians already accept individual limits on their maximum performance scope in privileging process; societal demand, workforce strategies and competing demands on leadership will undermine this goal. A hard line policy could conflict with the ethical guidelines recommending trying all that is possible to save individual patients. What about the patient's needs for a relationship with the physician? How is this accounted for in the equal actor model?

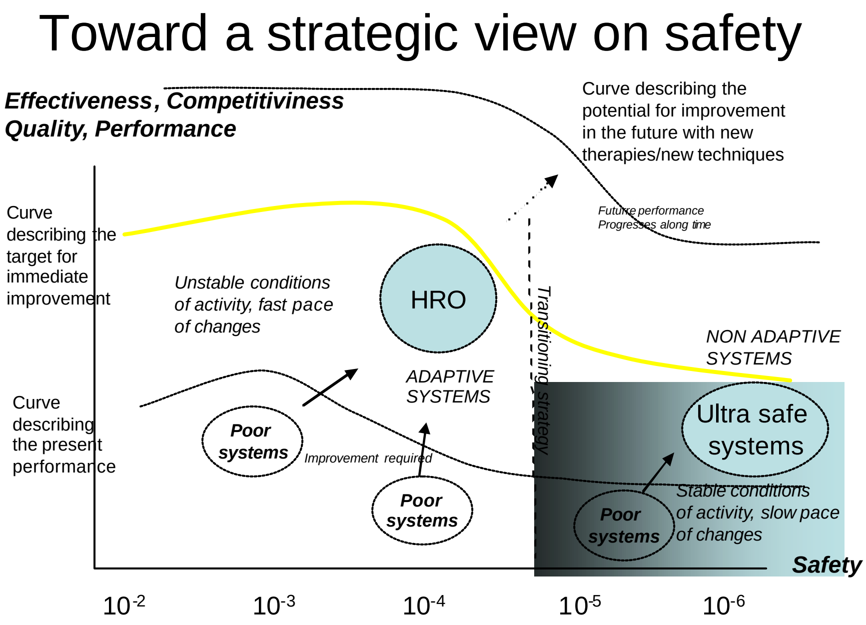

Figure 2 *Toward a strategic view on health care safety. A tentative conceptualization of 'two tier medicine' may result from the distinction between a 'first speed' ultra safe medicine in a limited number of clinical domains, and a 'second tier' medicine for sectors where a certain level of risk is inherent. (HRO-High reliability organization—see tex.)*

Another important lesson from other industries is moving from individual training, regulation and assessment to teams of health care providers. Given the interdisciplinary nature of health care and the necessity for cooperation among the workers who perform it, teamwork is critical to ensuring patient safety, error recovery and mitigation. Teams make fewer mistakes than do individuals, especially when each team member knows his or her responsibilities, as well as those of other team members. Teams elevate the importance of non-physician input and reduce physician autonomy. However, simply installing a team structure does not automatically ensure it will operate effectively. Teamwork is not an automatic consequence of co-locating people together and depends on a willingness to cooperate for a shared goal (51).

Table 1. Comparison between Two Tiers of Medicine

	Ultra-safe systems	**High Reliability Organization**
Examples	Nuclear Industry Commercial Aviation Blood transfusion Anaesthesiology ASA* 1-2, Radiotherapy	Military systems Chemical industry Intensive Care Units Surgery wards
Safety goal	Safety first Quality of work preserved against unacceptable pressure	Production first (imposed) Safety as high as possible for the imposed level of performance
Safety level (risk per exposure)	*Better than* $1*10^{-5}$*, possibly* $1*10^{-6}$	*Better than* $1*10^{-4}$
Stability of the process	Well codified and delineated area of expertise, Ultra dominant rule -based behavior Consistent recruitment of patients (flow and quality)	Broad area of expertise Frequent knowledge-based behaviour Unstable recruitment of patients (flow and quality)
Complexity of expertise required	Limited complexity. Actors are requested to stick to procedures. Equivalent actors	Potential complexity, severe and abnormal cases are the challenge Reluctance to simplify Deference to expertise of individual experts
Situational awareness	Good, at least for the managers	Good situational awareness of all actors, whatever their role and status
Supervision	Inside (team) and outside supervision and control (black boxes)	Inside supervision and mutual control (team supervision)
Teamwork	Effective team work and communication resulting in good task sharing, controls, and collective routines	Effective team work and communication, with special attention paid to provide safe adaptation to the range of individual experts

*ASA-American Society of Anesthesiology risk modification system (range 1-5).

An improved vision by health care leadership of the safety and danger properties of health care is needed to optimize the risk-benefit ratio. Such stratification could lead to a tentative differentiation between two different "speeds" or tiers of medical practice, each with its own type and level of safety goals. "Two tier medicine" could distinguish between medical sectors that are stable enough to reach criteria for ultra-safe medicine, whereas, those domains that chronically face unstable conditions, and are therefore inevitably less safe. For this last category of medical activity, the model of so-called "High Reliability Organizations" (HRO) could be a sound, alternative safety model (52). High reliability organizations have been defined as organizations that have been able to consistently reduce the number of expected or "normal" accidents (according to the Normal Accident Theory)—through culture change, technology, and other means—despite an inherently high-stress, high-tempo environment (53) (figure 2).

High reliability health care organizations will be unable to constrain their production – they must inherently be innovative, and require more flexible risk arbitration and adaptation rather than strict limits (54). Table 1 shows a detailed comparison of these two future tiers of health care. Physician training would have to accommodate this "two tiered" approach to health care. Patients would have to understand that aggressive treatment of high-risk disease may require accepting a higher risk and number of medical errors from clinical treatment.

Key Messages

1. Health care's premium on autonomy, the drive for productivity, and the economics of the health care system, may lead to severe safety constraints and adverse medical events.
2. Several key building blocks must be addressed before focusing on other solutions to the problem of unsafe medical care. Among these major building blocks are the need to control maximum production, the "principle of equivalent actor", and the need for standardization of practices.
3. Safety in health care depends more on the dynamic harmony among actors, than on reaching an optimum level of excellence at each separate organizational level.
4. Open dialogue and explicit team training among health care professionals is a key factor in establishing a shared safety culture in health care.
5. A tentative conceptualization of 'two tier medicine' -- i.e., differing acceptable levels of risk in separate areas of care -- may evolve logically from distinguishing between health care sectors where ultra safe characteristics are reachable, and other sectors, characterized by ambition, audacity, and aggressive efforts to rescue patients, where a level of acceptable risk is inherent in the goals.

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Tables and Figures

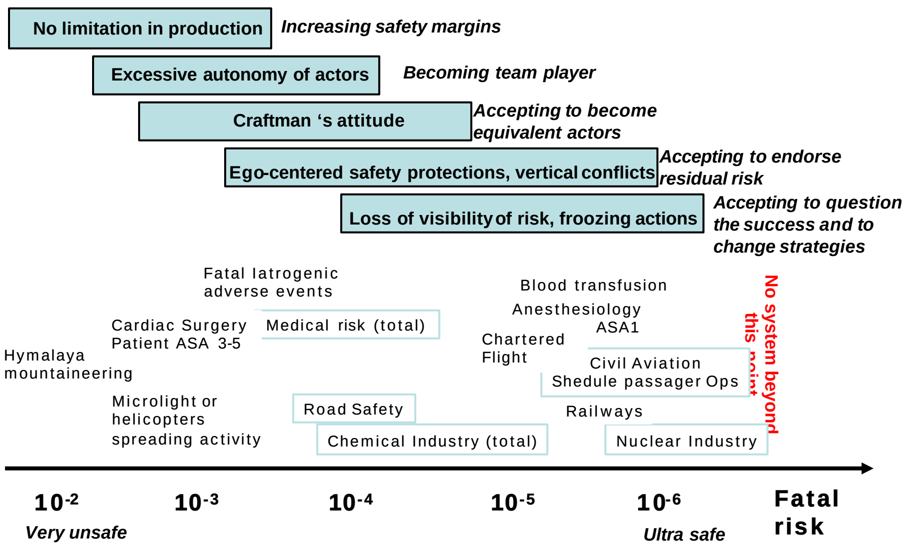

Figure 1*. Average rate per exposure of catastrophies and associated fatalities in various industries and human activities. The five barriers presented in the paper are represented. The size of the box represents the range of risk where the barrier is active. Reducing the risk beyond the maximum range of a barrier presupposes crossing this barrier.*

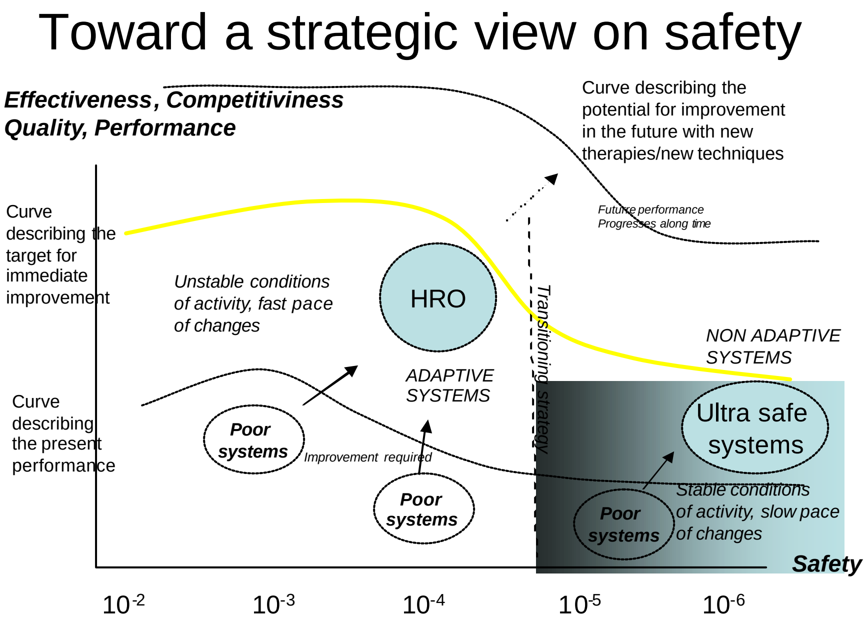

Figure 2*. Toward a strategic view on health care safety. A tentative conceptualization of 'two tier medicine' may result from the distinction between a 'first speed' ultra safe medicine in a limited number of clinical domains, and a 'second tier' medicine for sectors where a certain level of risk is inherent. (HRO-High reliability organization—see tex.)*

Table 1. Comparison between Two Tiers of Medicine

	Ultra-safe systems	High Reliability Organization
Examples	Nuclear Industry Commercial Aviation Blood transfusion Anaesthesiology ASA* 1-2, Radiotherapy	Military systems Chemical industry Intensive Care Units Surgery wards
Safety goal	Safety first Quality of work preserved against unacceptable pressure	Production first (imposed) Safety as high as possible for the imposed level of performance
Safety level (risk per exposure)	*Better than* $1*10^{-5}$*, possibly* $1*10^{-6}$	*Better than* $1* 10^{-4}$
Stability of the process	Well codified and delineated area of expertise, Ultra dominant rule -based behavior Consistent recruitment of patients (flow and quality)	Broad area of expertise Frequent knowledge-based behaviour Unstable recruitment of patients (flow and quality)
Complexity of expertise required	Limited complexity. Actors are requested to stick to procedures. Equivalent actors	Potential complexity, severe and abnormal cases are the challenge Reluctance to simplify Deference to expertise of individual experts
Situational awareness	Good, at least for the managers	Good situational awareness of all actors, whatever their role and status
Supervision	Inside (team) and outside supervision and control (black boxes)	Inside supervision and mutual control (team supervision)
Teamwork	Effective team work and communication resulting in good task sharing, controls, and collective routines	Effective team work and communication, with special attention paid to provide safe adaptation to the range of individual experts

*ASA-American Society of Anesthesiology risk modification system (range 1-5).

Improvement;