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Managing risk in the operating room: From theory to practice

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Introduction (M. Le Bourg)

In the 1970s, the organization of industrial production showed its limits in its ability to react to new challenges. Industry responded by initiating an in-depth transformation of its organization and its practices, setting off a cultural transformation.

During this time, surgery and anesthetics underwent tremendous technical progress, contrasting with the slight reduction in the rates of incidents and accidents related to medical error, in particular in surgery. It therefore seems pertinent to raise the question of how we function in this domain.

Recognizing the problem

In 1991, Brennan and Leape published in the *New England Journal of Medicine* the results of a study based on a randomized review of more than 30,000 charts of patients hospitalized in the state of New York reporting iatrogenic incidents and accidents. This publication had an important impact within the medical community but also elsewhere: medical error had arrived at the forefront of the media stage.

In 1994, Leape attempted to explain the causes of medical errors: he adopted the ideas promoted by Reason, an English psychologist who had worked in industry. Reason emphasized that error is individual and inherent to the human condition and distinguished the active errors from latent deficiencies: he viewed errors more as deficiencies of the system than as individual faults. ''Although we cannot

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change the human condition, we can change the conditions in which humans work,'' said Reason. This is the conceptual hypothesis around which all risk management and patient safety improvement processes would later be organized.

It took several years for risk management programs to be implemented. This reluctance to accept the very possibility of medical error when things went wrong is largely due to our education and culture — in particular our surgical culture — that relates failure to personal fault.

Setting up concrete measures aiming to improve patient safety encountered obstacles that seemed even greater. Our surgical learning is centered on acquiring its technical aspects and leaves no or very little room for teaching communication methods or training physicians to work within a group. Our organization remains compartmentalized, each specific task is often carried out with great technical skill, but absent and imprecise communication between team members or with other units (sterilization, stock management, postsurgical recovery room, etc.) is frequent, without a common goal being defined, which leads to incidents such as operative site errors, the necessary material being unavailable, etc.

Risk management programs have taken a variety of forms, accreditation processes have been imposed on healthcare institutions, and more recently we have been encouraged to gain personal accreditation from the French National Authority for Health (*Haute Authorité de santé* [HAS]) and to adhere to dedicated structures such as Orthorisq, which federates the practitioners involved in this process.

These measures have often been perceived as additional administrative restrictions, whose meaning and relation to patient care sometimes seem ambiguous, with apparently few concrete responses to the specific risks involved in operating room activity. Similarly, the tools necessary to take action such as declaration of seminal events, checklists, and morbidity—mortality reports are no clearer than pieces of a puzzle whose overall image is unknown to us or at best nebulous.

Change is possible

Faced with accidents and their media coverage, beginning in 1995 American civil aviation set up a very ambitious and resolute program to control risks and improve passenger safety. Known as the Commercial Aviation Safety Team, this program attempted to meet the goal of reducing the number of accidents by 80% in 10 years and thereby succeeded in meeting this objective.Four broad lessons can be retained from this program:

- standardization of procedures;
- use of the checklist to ensure that validated procedures are applied consistently;
- improvement of team work and communication to reduce errors (Crew Resource Management Training Program);
- use of scientific methods, emphasizing the collaboration of all participants, to identify and reduce risks.

This program aimed to instigate permanent safety improvement.

There are important differences between our practice and civil aviation. The multiplicity of the types of incidents in surgery makes both their collection and statistical use difficult. Like industry, civil aviation is a clearly hierarchical structure. The leadership has the power, including the financial power, to institute quality control processes. The surgeons' place is at the side of the hospital hierarchy, our sphere of activity is limited when concrete measures involve several departments that depend on the hospital leadership, for example sterilization, stock and implant management, and infectious risk management policy, particularly if these measures have a financial impact. However, the common points between the cockpit and the operating room have been mentioned by many authors, suggesting that some of these methods can be applied in our field.

A number of individual and collective processes have been instituted over the past few years. Few results in terms of improved rates of incidents and accidents have been reported, however. Pronovost's work at John Hopkins Hospital in Baltimore on reducing the risk of infection when setting up a central venous line should be mentioned or, closer to our practices, the work led by Moorman at Beth Israel Deaconess Medical Center in Boston on building safer operating room teams (Harvard research program).

These experiences have one point in common: they have demonstrated the importance of communication problems and the role played by the team as the driver of change. They revisited the lessons of civil aviation, which were themselves directly inspired by the profound changes in the organization of industrial production beginning in the 1970s.

To assist us in understanding and taking inspiration from this mutation, Pierre-Marie Gallois, a renowned international specialist in industrial excellence, honored us by presenting the history, concepts, and methods that have proved themselves in the amelioration of industrial performance.

The experience of industry (P.M. Gallois)

A major transformation showing the limits of traditional organizations

If the first industrial revolution turned the 19th century upside-down, the second, illustrated by Charlie Chaplin's ''Modern Times,'' was just as upsetting and shook up the 20th century. Ford and Taylor, to mention but two protagonists, scientifically organized work and industrialized production. The resulting organizational principles prevailed until the first oil crisis in 1973, which tolled the end of the 30-year boom after World War II and opened the way to a third industrial revolution that would leave a considerable mark on deep-seated practices and organizations.

As early as the 1980s, the established order changed profoundly. Saturation of markets has stimulated competition and allowed demand, and therefore the client, to take power. Simultaneously, by broadening the scope of possible activities, progress in electronics, robotics, and computer sciences opened extraordinary perspectives of development. Finally, in industrialized countries, with the educational level in constant growth, labor was increasingly qualified and the gap between skills and roles widened.

Beyond price, it was quality, time, and customization, and then innovation and speed that became the true factors of competitiveness; thus, creativity, adaptability, cooperation, and robustness were the essential characteristics of organizations.

Taylor, who had separated those who think from those who do, had confined each person to a given place, with production efficiency resulting in the strict application of standardized operational methods. The know-how of a few who thought was thus encapsulated and made available to all the others who were expected to provide no more than knowledge of their work station, the necessary precise movements within this station, and adherence to the imposed rhythm. This conception of the organization that had in its time proved its efficacy was not the appropriate response to these new challenges.

Toyota's approach, initiated in Japan in the 1960s, by placing the client and quality at the center of its activity and considering that progress was a permanent and collective activity because it returns the place of intelligence to each and every employee, was the obvious true alternative to dying Taylorism.

A weighty heritage

Changing the rules of the competitive game led industry to view their organizations from a different perspective. Considering them through the lens of the client and speed, they appeared in a different light.

Activity consuming resources
Most activities that consumed resources and generated a time lapse actually have no added value, i.e., they have no true utility for the client. For example, in no particular order one can cite transferring, recopying, verifying, displacing and being displaced, searching for, ''doing and undoing,'' ''packaging, unpackaging, and repackaging,'' putting away and taking out, repairing, redoing, etc. Eliminating or at least reducing part of these activities requires profoundly revising processes and operating modes.

Complexity and division of work
The combination of a growing complexity and continued division of work leads to a multiplication of interactions. The quality of the productive act is conditioned by the proper execution of many other surrounding activities, upstream and downstream, of preparation, support, administrative processing, etc. Even with a high service rate in each of these contributing activities, the probability of proper execution of the basic operation remains low and can only be increasingly low if the organization of work is not deeply modified.

With this diagnosis in place, the endogenous causes could be identified, bringing into view three deep-rooted levels.

- Technical weaknesses such as lack of flexibility in certain production modes, the low level of robustness of primary processes, the low reliability of complex equipment, the inadequacy of implementations, insufficient dissemination of methodological and managerial know-how, etc.
- Deficiencies caused by the organization's unwieldiness, the insufficient cooperation between different departments and with service providers, the complexity and slowness of decision making, the poor use of skills, etc.
- Inappropriate behaviors in the highest ranks, including the lack of confidence toward collaborators, both internal and external suppliers, followed by lust for power, then by the lack of recognition, preoccupation with the short term, etc.

The challenge of global performance is therefore technical, organizational, but also and most particularly, behavioral. In other words, the search for efficiency is becoming as much an affair of rationality as of culture.

The fatal quality

More concretely, this transformation has come about through the mastery of quality and risks, quality in the broad sense, the ability to respond to the explicit and implicit requirements of demand.

Quality is not only the product or service conforming to specifications, but it also means simplification, fluidity, and therefore speed because by getting it right the first time it eliminates revision and correction activities as well as inspection and verification activities; quality is also creativity and progress in the development of an offer that responds proactively to latent needs; quality is above all a federating dimension through the cooperation of all the company's actors at all levels of client—supplier relations that provides meaning in channeling energies toward client services, both internal and external. Quality is a culture dedicated to service.

Seen from this perspective, one can no longer consider that quality is obtained by simply sorting before delivering to separate what complies with a standard and what does not; this vision is an operational and economic absurdity, which, even if it limits risk for clients does not serve them and removes a sense of responsibility from the entire organization. Indeed, there is great temporal and spatial distance between the observation of errors, defects, daily problems and their root causes in the choices of investments, organizations, the definition of operational modes, etc. Would it not be better to dedicate ''a little'' intelligence and energy in preventing and improving the upstream processes rather than wasting ''a lot'' of time and resources downstream to correct and sort?

So-called total quality can only be the result of an operational mode that encapsulates within processes (beginning with product design, resources, and organizations), that prohibits the generation of non-quality (by controlling processes, incorporating error anticipation, etc.), or at least that prevents the propagation of such (by developing self-verification, etc.), which constantly identifies and analyzes any discrepancies arising to feed a permanent progress procedure so as to continually advance toward greater robustness. This is what I call ''fatal'' quality.

Foundations of organizations that control quality and risks

When organizations capable of fatal quality are analyzed — entities that developed first in an industrial world and then progressively in the services — one can only observe that, beyond the techniques and methods implemented, they are all based on three fundamental pillars.

The reality principle

In the field, in the nitty-gritty of the situation, this is the only place a business can exist, where it is confronted with the obligation for quality, service to the client. It is also the place where the impact of good or bad decisions, choices or non-choices from the rest of the organization, are materialized. Yet, although the actors in the field are those who possess the best knowledge of the real world, its problems, and possible leads for improvement, paradoxically they have neither the means nor the authority to act.

The reality principle consists in reversing the traditional hierarchical pyramid to install this ''floor'' at the center, to give it the power to improve and put the line of command as well as the support functions at its service. In so doing, the organization principle is formulated as follows: the field serving the client and the rest of the business serving the field. This is made possible by management that makes itself available, is attuned to the client's needs, giving meaning to its activities, and kindling the desire to push limits by developing relations of the master—student type, if not father—son relations, paternalism in the best sense of the term, which gives rise to growth.

Application of this principle naturally leads to encouraging the visual, both for operational management and for driving progress. Accepting to see and understand reality, accepting that it be the reflection of the rest of the organization and most particularly of the business's mode of management, accepting to give it power, that is the first pillar of efficient organizations.

The progress principle

Controlling quality and risks and improving efficiency are not simply implementation of a change consisting of modifying current operation to come up to standard and regain a new stable state engraved in stone. Evolving becomes a continual and fundamental activity requiring permanently and radically reinventing the company while reinforcing the incremental fight against all forms of non-quality in daily management. Progression through rupture or by leaps assumes a clear ambition sustained by a descending approach managed by dedicated teams, associating anticipation and imagination with knowledge of the realities of the real world. Daily progress, on the other hand, means a strategy for actions distributed and entrusted to each of the business's individual members; their capacity for detection and action will have been reinforced to accomplish this task.

Accepting the progress principle means giving a new place to the human element, to all the individuals in the company by transforming them from simple spectators into actors or even authors of their organization. To illustrate this point, I always remember the words of two executives that I had the opportunity to work alongside in Japan, the first asserting that ''we are no longer paid to produce parts but to improve the processes that produce them,'' and the second convinced ''that a factory without personnel is condemned because it is incapable of progress.'' I completed these statements with the following: ''the role of management is to allow its teams to produce ideas and to implement them.''

Once the phase of remediation and updating of the major performance disparities has been accomplished, a well-conducted approach to progress gives this impression of ''serenity,'' in any event a well-organized fundamental movement, a movement of calm efficacy. This is the type of sign that identifies the highest-performance businesses.

Progression of the business and progression of men and women cannot be dissociated and are mutually energizing. The dynamics of progression combine two characteristics: rigor and high standards. Rigor is materialized by a logical sequence connecting the observation of a problem or a divergence with regards a required level of quality, the identification of causes, focus on the important cause, the search for control levers, action on the main control lever, observation of the result, with this process gradually continued while accepting the principle of trial and error, until the problem is eradicated or the objective met. At the same time, high standards are expressed as the will to continually extend the limits of quality, ensure that the process and the rise toward an ever higher level of efficiency is permanent.

Accepting the principle of permanent improvement means, finally, accepting the paradoxical idea that the problem is the source of progress. Consequently, this does not mean searching for any particular culpability and punishing an eventual fault, but rather seizing the opportunity to go back to the root causes in an attempt to eliminate them. There is no sustainable progress without this managerial attitude.

Permanent progress with its twin — continual learning — a group quest for perfection, set up as one of the business's major processes, is the second pillar of organizations that control quality issues.

The teamwork principle

It is not possible to improve what one cannot see, according to the reality principle, but it is also impossible to improve what is not in one's possession. The sentiment, or rather the need for belonging is another condition of progress. The progress principle also reminds us that the dynamics of improvement only becomes sustainable if all assume this improvement at their individual level, if each one is its author. Finally, opportunities for increasing efficiency have gradually been displaced; they are no longer at the level of each elementary activity, but more particularly in how they are combined: productivity of operations has little by little given place to the productivity of

interoperations. Yet the interoperations are curiously the domain of both nobody and everyone. Only with a multidisciplinary eye and with an interest in detail, where the devil is always hiding, will it be possible to understand them and optimize them. Intelligence yes, but group intelligence.

Three reasons naturally lead to considering the team and more specifically the empowered team as the basic element, the core of high-performance organizations. These teams allow greater quality, reactivity, and agility; they assume and organize their physical and cognitive environment, in which the visual plays an essential role; they are multidisciplinary and multitasking; the members are versatile and multiskilled, they distribute roles, the necessary game tactics, according to the situation. Finally, at the peak of their maturity, they are learning-oriented, they capitalize and disseminate their know-how, they initiate, organize, and lead in individual and collective skills acquisition.

An empowered team is a group of collocated individuals, connected through a shared ambition, who cooperate, learn, and evolve together. The team is characterized by a mission, a territory, a human size, multidisciplinary skills, roles to play, a simple managerial structure, stability over time, and an animation system. The visible part of team operation is this animation system based on perfectly punctuated rituals (daily, weekly, monthly, etc.), visual tools such as management boards displaying indicators, objectives, results, action plans, etc.

More profoundly, this results from leaving room for initiatives, creativity, for each person to breathe, providing meaning to action, allowing each and every member to be more than simple stonecutters but true cathedral builders, which these organizations lead at an exceptional level of performance.

In the background, the team principle induces very different management modes than those that remain the habit today, based on the development of horizontal cooperations (within or between operational teams, between field teams and support teams, etc.) and vertical cooperations, those set up along the chain of command.

Driving and leading an organization in teams for allowing them to reach the summits means breathing a dual energy into it; a ''top-down'' energy which, by giving perspectives and authorizations (spaces for autonomy and creativity) provides momentum and a ''bottom-up'' energy the one of initiatives, actions leading to progress, taking processes in hand, ...

This is a management style guided by the obsession for simplicity (in organizations and systems but also in human relations) and by the concern for the group result, which is characterized by the exemplarity, commitment, and charisma of its managers, who recognize and enhance the results, who make one proud.

Solidarity and complicity within the team, cooperation between teams, and subordination to the whole of the business, these are the qualities of this form of organization, the third pillar of enduring quality.

Summary

Because they aim to recenter and concentrate the energy and skills of the entire business's actors on value added tasks by progressively eliminating all others, because they shed light on the future by giving meaning and perspectives, these three principles produce true growth dynamics in the business and assist its members in their growth, making them proud notably in developing their sense of utility as well as their own capital: their employability. They contribute to making the company an adventure with its successes and difficulties and to returning people to a place they never should have lost.

Future perspectives

The new demands induced by the deep changes in the socioeconomic order have first of all led to revising practices, how things are done. This first level of modification very quickly collided with the organizations already in place, their complexity, their compartmentalization, the dilution of decision making, the loss of a sense of responsibility. Changing or making organizations evolve has proved to be more than a simple technical exercise. Every organization is the reflection of the business culture to which it belongs. We therefore cannot be content to play the role of simple mechanics of processes and systems of organizations to lead our businesses along the post-Taylorism road of fatal quality and agility. This is a profound change in culture; it is then by diffusion that this new culture will be transformed into organizations and their daily operations.

It is indeed the Executive Teams and the Managers, at all levels, who incarnate and pass on culture. They must therefore rethink their attitude. It can be described in four words: belief, commitment, boldness and trust. Belief in these principles that have been detailed above, encouraging one to defend and promote them in both word and deed; boldness to think and to dare to do otherwise, shaking the certainties and the preconceived ideas; commitment in action by giving up that part of power that allows teams to progress, but also by showing solidarity and being available in the field like true trainers; trust (which is bestowed) and credibility (the trust one gains) first by taking an interest in the working conditions and in removing ''the pebbles from the shoes'', so to speak, then in providing the means to progress, and finally in showing recognition.

High-performance organizations are like an iceberg: the emerged part represents the company's practices and as we proceed deeper and deeper, we found the culture, then the spirit of a team in movement, and finally the collective ambition.

An efficient and long-lasting business is therefore a place of creation and learning: performance is first and foremost a human affair, not a system.

Conclusion (M. Le Bourg)

In light of this presentation, we should be able to fit the puzzle pieces together. Managing risks in the operating room, a

particular form of a quality approach, should no longer be perceived as a succession of sporadic measures but rather a reflection and commitment at every moment aiming for permanent improvement. We are invited to a true cultural revolution.

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