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A Medical or a Managerial approach for assessment of Quality and Safety

# Introduction

Why measure quality improvement and for whom?

For a better rating of health care organizations or for a better life of patients?

No man can serve two masters

At the moment of celebrating my 50 th anniversary as physician taking care of patients, and my 35 years as Professor of Medicine at the University of Paris, I have the great honor to be invited by the International Society for Quality in Health Care to deliver the ISQua Global Leader Lecture on a managerial or a medical approach for assessment of quality and safety. I am delighted to be able to do this at the historical and prestigious home of the Royal College of Surgeons in Ireland.It is an opportunity to stand back and consider what we have learnt from the past and to foresee new avenues on quality and safety of health care.

My own successive experiences as *physician* treating patients with leukemia, as *scientist* discovering how to transform and restore in vitro and in humans a malignant cell into a normal cell and as chairman of several *public health* agencies especially chairman of the board of the Haute Autorité de Santé, HAS, the French Authority for Health and Healthcare, looking for improvement of quality of health care, gave me the opportunity to recognize the binary and conflicting vision of the quality of health and health care.

On the one hand managers, espousing collective interests demand quality measurements based essentially on care processes that should be implemented in order to ensure lower liability insurance premiums, a high score in the assessment by the regulatory authorities and an optimal distribution of limited health care resources. On the other hand, patients desire the best care available and physicians baulk at collecting data on process indicators preferring to concentrate their efforts on the optimal medical care for individual patients and on clinical outcomes whatever the means and the cost.

The dispute on quality and safety between the two parties, medical and managerial, could be actually summarized as a conflict between individual and collective interests.

The individual interest is based on trust, dialogue and confidence between a physician and a patient in order to deliver the best care for each patient. Conversely, the collective interest focusing on organizational and economical aspects of health care delineates the limits of health care feasibility according to safety, finances and facilities at population level in view of fixed amount of national health expenditure.

This could be translated as more efficacy at individual level and more safety and sustainability at the collective level.

Furthermore, is questionable the utilization of the same tools such as indicators, certifications, accreditations to assess the quality and safety for two distinct purposes - improvement of medical practice and better management of health care organizations –. For instance quality indicators will be utilized for governmental decisions and planning, has said the Sate Secretary of Germany, Lutz Stroppe, which is not the first purpose of such measures. In fact, a better practice necessitates measures related to precise interventions while decisions and planification need integrated parameters.

For patients and physicians, increasing quality and safety, will often mean more patient centered facilities, more available health products and more approved procedures. On the other hand, managers compel the health professionals to follow rules, processes or controls and to limit the patients’ expectations. Both sides are referring to quality and safety. The binary approach considers as a primary objective either the health of the individual patient whatever the cost, or the optimization of common resources applying epidemiological, statistical and economical analyses.

How to combine these apparently conflicting medical and managerial approaches for quality and safety of health care? Both sides have to take a step forward, to understand each other, and neither to override the other nor to turn a deaf ear.

Each party should ask the same basic questions: why and for whom are we promoting quality and safety of Health and Health care?

I shall try to answer these questions considering various circumstances, firstly, by the recognition of the binary approach, secondly, by referring to values - values of health and social values - thirdly, by drawing insights and lessons, keeping in mind that we deliver health care for patients’ health.

My conclusive remarks will be to not make a choice between a medical OR managerial approach but to combine the medical AND managerial points of views for better patient care.

For this purpose, I propose to subdivide my talk in 2 major themes, quality and safety:

1. Quality assessment considering two aspects, health care products and health care organizations
2. Safety assessment of health care activities and the role of resilience engineering compared to prescriptive strategy.

And I shall conclude looking at quality assessment of health care systems and satisfaction of the population.

**Quality assessment**

1. **First topic: quality assessment of health care products**
2. Let us first look at the binary Individual and collective interests in Health Technology Assessment

After the market approval by specific agencies such as EMA, FDA, or PMDA for European, American and Japanese populations, health insurers assess the cost effectiveness of a drug, device or procedure, allowing decisions for price, reimbursement and volume of dissemination.

Why is a drug, after European market approval, often assessed differently in various countries although the same clinical data are analyzed by each national expert committee? For instance, three countries with a national health insurance, England, France and Germany, considering the expensive drug Sofosbuvir, a direct anti Hepatitis C virus agent, effective against all the known genotypes of the virus, delivered three different decisions. The drug today reimbursed for a very limited number of patients in England was first refused for reimbursement, is reimbursed according to the level of evidence restricted to results of clinical randomized trials in Germany, and is reimbursed for severe cases in France.

The economical assessment (collective interest) because of the high cost, probably interfered with the medical assessment (individual interest). Is the cost prevalent to the effectiveness of the drug or the reverse? Do we perform the assessments of the effectiveness and the cost simultaneously, mixing the medical and economical aspects or separately?

Looking first at the English and French opinions on Sofosbuvir, an example among many other expensive drugs, no or almost no reimbursement in England and reimbursement to specific cases in France. We can explain the discrepancy by the difference in national priorities:

In England the cost of opportunity and in France the loss of opportunity.

1. What are the underlying social values?

In England, decision makers apply an utilitarian policy - with this amount of money, one can spend better for other conditions-, while in France we apply an equalitarian policy, -each patient must have an even chance to be cured and thus should have a beneficial treatment at any price-. Utility or equality? Two social values leading to two different decisions.

Utility considers the collective interest first, using QALYs, based on citizen preferences, and defining the limits of cost per QALY, excluding de facto the reimbursement of very expensive drugs, or drugs providing short term improvement treating cancer or elderly patients, forgetting the patients' and physicians' expectations.

Equality considers the patient expectations. Conversely, this may put in danger the finances of the national health insurance and may leave out better opportunities.

Utility in England using cost per QALY, equality in France, equality of chance independently of the types of disease and treatment, reflect the binary vision of collective or individual interest, the economical or medical approach. The applied methodologies confirm the differences in their approaches. In England the economical and medical assessments are performed simultaneously while in France the economical assessment follows the medical assessment. Moreover, in order to avoid any loss of opportunity, the medical assessment is done one by one immediately after market approval, while in England the assessment is delayed and performed by class of drugs in order to have a better assessment of cost of opportunity.

The contrast between the two social values utility and equality, collective and individual interests was recently lowered, due to the pressure of patients and physicians in one side and to the economical constraints in the other side. In England, some new innovative drugs are considered separately and immediately after market approval and specific assessments are constructed for some diseases such as cancer or social conditions, such as the elderly. In France, economical considerations, are being progressively implemented since last year: both sides have made a step to combine medical and economical approaches.

In Germany the main social value is accountability. Anyone is accountable and takes responsibility for his actions. In the Sofosbuvir example, only the randomized trials presented by the pharmaceutical company and not the observational ones were considered. Those randomized trials concerned a subtype of the disease that was already being treated successfully by previous drugs while the innovation was the sensitivity to Sofosbuvir of “difficult to treat” genotypes, which in this case was demonstrated by observational trials. For the German regulatory bodies, pharmaceutical companies should only present randomized trials and are responsible of the refusal of the innovative efficacy if they do not apply the admitted statistical methodology. Therefore, the strange initial decision was to accept the treatment for those who were already well treated, excluding those who could have a major benefit. Accountability in Germany is also applied to find a “fair price for a medical product”. Accountability is also applied to any actor in health care. Providers, prescribers, are accountable for the incurred expenses.

1. Insights and lessons

The three social values, utility, accountability and equality lead to three approaches to decisions:

- Utility, in England, referring to the cost of opportunity induces a decision on reimbursement

-Accountability, in Germany, basing the willingness to pay on the comparison with the costs and the effectiveness of previous technologies for similar applications, leads to price negotiation and focuses the decision on pricing

-Equality, in France, referring to the loss of opportunity, leads to a definition of the exact indication in order to restrict the volume of dissemination.

The three social values utility, accountability and equality explains the three major positions of the decision makers of the three countries : reimbursement in England, pricing in Germany and volume (or package price x volume) in France.

Two major countries, China and USA have recently developed policies aiming at universal coverage for health care. In China, progressive coverage obliges to follow pragmatic and “harmonious” decisions accepting recently, for instance, reimbursement of insulin for type 1 diabetes or of dialysis for patients with kidney failure, while in USA, country of the “liberty”, fighting against monopolism and enhancing competitions, authorities preferred to move from the european model of national « health technology assessment» to the « comparative effectiveness research » model referring to 3 words, comparison, effectiveness and research. No word about the cost.

Subsequently, they instituted by the Affordable Care Act a new body, the « patient centered outcome research institute » insisting on the priority of medical findings and clinical outcomes, and refusing the QALY methodology by law.

‘*Sec 1182 ‘(e) The Secretary shall not utilize such an adjusted life year as a threshold to determine coverage, reimbursement, or incentive programs* ”.

In conclusion of this first part on quality assessment of health technologies, countries defer differently to the collective or individual interest, the economical or the medical approach for the assessments of products and procedures, mainly according to social values, utility, equality, accountability, harmony, liberty. All these values could be roughly categorized into two arguments, the cost of opportunity or the loss of opportunity, leading to two major social values, utility or equality reflecting the collective interest or the individual interest respectively.

1. **The second topic on quality assessment is the Assessment of quality of Health care organizations (HCOs)**
2. Let us look at the binary managerial and medical approaches

Health Care Organisations undertake accreditations and use quality indicators with the objective to respond, of course, to patients’ expectations,but also to respond to the expectations of payers and to avoid complaints and scandals, thus lowering insurance premiums and giving arguments to the lawyers. Responses to questions about quality in the perspective of helping lawyers, protecting reputations and convincing payers do not represent quality of health care itself.

In most cases, the accreditation procedure promotes, assesses and reports on requirements that leadership, organizations and protocols are effectively in place. This is an approach that is more managerial than medical. Everybody would be satisfied, if the compliance with the numerous processes and protocols was related to clinical outcomes of patients, mortality, complications and quality of life. However, several studies demonstrated the absence or the weak link between quality of the implementation of processes in Hospitals and clinical outcomes, in surgery, in cardiology and in many other topics. This becomes a crucial issue as administrators and regulatory agencies are looking at accreditation and quality indicators as a mean to adjust their financial and organizational policies and as a mechanism to support payment for performance. Moreover, several studies demonstrated that the payment for performance has pragmatically no influence on the clinical outcomes in Health care organizations and one could say that the payment for performance is not performing.

Thus the question on the managerial or the medical approaches is a central question in the assessment of quality of Hospitals.

Are the quality indicators designed and used in a legal, administrative, insurance and regulatory perspective or for a better -patient centered- outcome strategy? For a protection against threats and complaints or for an improvement of clinical outcomes?

1. What are the underlying values:

Why and for whom do we apply quality assessment? A better health or a better stay in hospitals? Do we value a perfect apparent organization, a well oiled machine, a beautiful monument, with a perfect respect of processes and protocols, or an organization combining efficacy, safety, and access to care, in order to increase the percentage of cured patients, to diminish the rate of mortality, the rate of complications and to give a better quality of life to the patients? While patients may ask for a clean building with numerous facilities and comfort, their first choice is to have a better clinical outcome when they stay in a hospital.

Could a common value of health care reconcile the controversy between the managerial and medical visions of quality?

“*In health care, said Michael Porter from Boston, stakeholders have a myriad of often conflicting goals, including access to services, professionalism, cost containment, safety, convenience, patient centeredness and satisfaction. The value is defined as the health outcomes achieved per dollar spent. Cost reduction without regard to the outcomes achieved is dangerous and self defeating, leading to false “saving””.*

The goal and thus the value of health care are related to the clinical outcomes, less mortality, less morbidity and a better quality of life.

The collection of clinical outcome indicators is not yet successfully implemented. The hospital mortality rate, in itself an apparently non ambiguous quality indicator whose application is restricted to Health care organizations, is often measured.

England was particularly sensitive to in-hospital mortality after the tragedy of the cardiac surgery in Bristol. A Safety Agency was created and Brian Jarman proposed a methodology to compare HCOs according to mortality of hospitalized patients.

“*However,* as said Nigel Hawkes journalist*, the public inquiry into the Mid Staffordshire NHS Foundation Trust, disclosed ingenious ways of modifying outcomes (in order to improve their rating) and of concealing deaths. For instance, changes in coding practice resulted in many deaths being excluded from the calculation of hospitals by classifying increasing numbers of patients as palliative care cases. …”.*

The purpose of data collection on clinical outcomes is a central question. The clinical outcomes indicators are mainly made to improve the medical practice and should not be perverted by the threats of dismissal or of administrative prescriptions. These perversions encourage deviations and gaming practices that are often due to economical constraints either directly (reducing the cost) or indirectly (having a better rank and consequently a higher income). Conversely, medical arguments could not be an excuse for refusing demands of measurements and data collection.

In the purpose of collecting clinical outcomes indicators, we organized in 2010, with Fiona Godlee, Chief Editor of the British Medical Journal a joint symposium HAS-BMJ. We envisaged the possible construction of indicators from clinical outcomes, called reverse indicators, similar to reverse genetics: starting from a difference of outcomes in the care of a disease and searching for an indicator related to this difference and easy to record. We obtained several hundred abstracts coming from clinicians demonstrating their involvement and enthusiasm when quality indicators corresponded to their expectations, that is to say, to find outcome indicators or process indicators related to a better clinical outcome.

Anyway the goal and thus the value of health care is the patient’s better life.

1. Insights and lessons:

If we admit together that clinical outcome is the key element determining the value of health care, we should revise our tools for quality assessments of quality of health care. Clinical outcomes are the result of efforts over the full cycle care from the first symptom to the discharge of the patient and not only of the well organized care given in hospitals.

The clinical outcomes of a perfect care in hospital could be erased by a bad care before or after hospitalization. Conversely, good primary care could be erased by difficulties of access to hospitals or by safety problems during hospitalization. The outcome is the addition of the quality of care before, during and after hospitalization. This chain of care is not adequately assessed at present time by accreditation nor by the process indicators reflecting Hospitals’ activities.

For instance, the optimal pathway of the treatment of Acute Myocardial Infarction (AMI) bypasses the general practioners and the hospital emergency unit. We started 10 years ago, at the Haute Autorite de Sante in France, programs on the whole pathway of patients with AMI and cerebrovascular accidents. We constructed the optimal pathway with all categories of professionals. “Time is heart” in case of AMI, “time is brain” in case of stroke and any procedure shortening the time before vessel desobtruction was preferred.

We plotted indicators of efficacy, safety, and access to care within the pathway. In the case of AMI, the patient calls directly the ambulatory care units through a specific phone number. This is available everywhere in France today, allowing the delivery of emergency procedures at home and a direct access to interventional cardiology units.

It has led to a 50% decrease of mortality and a 50% decrease of cost.

The optimal patients’ pathway combines the individual interests and the collective interests, a better life for the patient and an economical advantage.

In fact, what have we learned from the past? Where should we move?

We used an industrial approach of quality and safety looking at processes. We have constructed quality indicators applied in all Hospitals, in order to sort Hospitals in quality categories. Should we move to looking at clinical outcomes, mortality amenable to health care, avoidable complications, morbidity and quality of life?.. We have implemented “administrative” indicators with no actual commitment of the physicians who are the principal actors. We partitioned quality assessments to sectors of health care such as HCOs or GPs, forgetting the links between them and the final end point which is the clinical outcomes resulting on the whole pathway of the patient that is to say to improve the efficacy, safety and access to care at each step of the patient pathway from the first symptom to the discharge.

In this perspective, we should assess a full cycle care of a disease and compare year after year the improvement of clinical outcomes instead of making comparisons between Hospitals at a given time. The approach considering clinical outcomes for each type of disease and the full cycle care, modifies completely our view on the quality and safety assessment…and icing on the cake, both individual and collective interests are joined by the optimal patient pathway, as we demonstrated for AMI.

Furthermore, health care in hospitals is not stable. Several disruptive innovations are in development such as to day targeted oral treatments for cancer patients, ambulatory surgery, tumor ablation without surgeons, replacement of bacteriology laboratories by small boxes and cartridges at bed side, the use of connected numerical devices, and so forth.

The ability to adaptation, the transfer of competences and the well organized interfaces between hospitals and proximity care are probably the major challenges for the future.

Therefore the question today is not “do we have to move from accreditation and quality indicators of HCOs to outcomes indicators of the whole patient pathway?” but “how to do it”? Coordinated care and integrated care are considered differently in various countries**.** In England, the health care budget is given to the proximity care general practitioners (GPs) who decide the best pathway with the help of Clinical Commissioning Groups. In the USA, the coordination of the pathway is more centralized by one actor (usually hospitals) through the presence of -Accountable Care Organizations-. In France, the pathways are organized by the Regional Health Agencies using guidelines from the Haute Autorité de Santé.

**And now , we move on to the safety assessment**

Although quality is the addition of efficacy, safety and access to care, safety itself could replace all of them. If a patient receives a non efficacious procedure, he or she is in danger. If a patient has not access to a beneficial treatment or to a precise diagnostic tool, he or she is in danger. No efficacy or no access induces a safety issue. Thus, quality and safety are consubstantial. The discrimination between quality and safety in separate agencies or administrations should no longer survive.

Safety is the first priority of and for customers.

However, no or little progress in patient safety occurred during the last decades, except in some specific domains.

We have made improvements on targeted safety issues, such as the decrease of frequency of nosocomial infections by a common and concerted effort; meanwhile, no effect on the frequency of antibiotic resistant bacteria was observed. Another way of progress was to isolate one element from the whole health care system (also called fragmentation) and to use an industrial approach of safety on this element, obtaining an ultrasafe status, similar to civil aviation. These independent ultrasafe domains, such as for red blood cell transfusion, being totally fixed, evolve and adapt poorly. They are regulated separately by specific organizations (blood banks or agencies) minimizing the interfaces with the rest of the health care system. Systematic fragmentation is dangerous in an adaptative complex system, excluding some parts from the evolution and therefore fragilizing the whole system.

Apart from these examples, little improvement in patient safety was noted during last decades and almost 10% of hospitalized patients experienced a severe adverse effect everywhere in the world, some of them leading to death. Taking a comparison often quoted by journalists, and taking into account USA only, the number of events is equivalent to a crash of a jumbo air craft every day. Several voices have repeatedly reported this lack of improvement, although many quality and safety rules, guidelines and controls were promulgated and applied.

An article written by top leaders of health care safety, Lucian Leape, Donald Berwick, Carolyn Clancy and others, reported that« *While effort to improve patient safety have proliferated during the past decades, progress toward improvement has been frustratingly slow »*

The two French inquiries, ENEIS or Enquête Nationale des Evènement Indésirables Sévères, carried out at 5 years interval in 2004 and 2009 did not disclose any change in the rate of severe adverse events in HCOs and sometimes results were worse 5 years later.

The question is: how could we increase the safety in health care and notably in HCOs which are sources of severe adverse events for the patients? We shall focus our discussion on two topics of safety assessment: no blame or sanction policies, and prescriptive strategy or autonomy?

1. **Let us start with the Safety assessment of health care activity , and the question:“no blame or sanction”?**

Delivering health care is not like conducting a well-oiled machine, an aircraft or a car. The system is complex and evolutive adding innovations everyday, including tools and procedures, involving many categories of professionals. This creates myriads of unexpected events which could also be beneficial, due to accidental acts often called serendipity and we have to admit that several major medical discoveries were made through unexpected results.

1. Let us look at the binary behaviour: Guilty or not guilty? That is the question

Confronted to an adverse event, the spontaneous attitude is to find a guilty person and to apply sanctions. Managers feel that they have done their duty and the victims feel better compensated when they can put a name on the origin of the event and rebuke an individual. However, for better safety we should concentrate our efforts on the search of causes of an accident, in order to repair the defects. In case of adverse event, notably of a non preventable event, the harm is not the result of one deleterious action of a single individual. Usually, the damage is due to the addition of several defects along chains of activities involving various professionals together with the presence of environmental abnormalities.

Let’s take for example a deck of cards and build a house of cards. One after the other, the cards are gently put and connected to the others. Then one card destroys the house. It could have been the previous or the following one. Is the event due to this one card? To the king of heart or the queen of spades? Is the figure on the card responsible or guilty? No, it is due to all previous cards with their small defects fragilizing the whole house. They were well adapted in the configuration of a small house but not for a high one.

The health care system becomes progressively more complex. Similarly with the house of cards, adverse events are not due to the last actor but to the addition of several small defects and interfaces.

Errors are inherent to any adaptative and evolutive complex system such as health care; a fault is due to one person, done voluntarily, and usually he or she repeats it.

To err, to wander is not to commit a fault.

An error could be deleterious or beneficial. Any adaptative system intrinsically should have unexpected events. The absence of errors means that the system is definitively fixed and could not have any development. Errors represent the engine of evolution and adaptation of the system. For instance, evolution and the adaptation of the living world in the Nature are the result of genetic errors regulated by natural selection. No natural evolution is possible without errors and nobody is responsible for a genetic disease.

The error is not human, the error is the result of multiple causes inside the adaptative and evolutive complex system confronted to a specific environment

Thus we should modify our initial spontaneous attitude: (1) the last actor is not a guilty individual, and (2) it is our duty to recognize and repair all the successive defective elements.

1. “Guilty and sanctioned” or “no blame no shame” policy; “ all about me” or “search of all causes”, a conflict between individual and collective values

On the one hand, each patient wishes and has the right to know “all about me”, and, on the other hand, the objective of the collective interest aims to recognize all causes leading to the adverse event in order to repair the system. Ideally, these two values could be combined, informing everybody, patients, families, administrators on the results of the inquiry. In fact, nobody speaks when someone looks for a guilty person and aims to apply a sanction. Either we aim to have one or several guilty persons paying damages and being sanctioned which are for the victim a moral and possibly a financial “compensation”? This attitude obliges to a total transparency. Or we wish to look for the repair of a series of small defects which obliges each actor to participate in the inquiry of the root cause analysis, with no notion of blame or shame, in an effort to loosen tongues. The professional experienced the same surprise as the damaged person, never having wished such harm, and is deeply depressed by the catastrophic event and could be considered as a second victim. He could not speak but cries. Instead of helping to understand what happened, people, patient, hierarchy, managers, lawyers, judges, ask him to justify his attitude. He is asked to explain himself instead of being asked to participate in the analysis that aims to explain the adverse event. He should not be considered a guilty person but a victim of the adaptative system. Several countries implemented psychological help for them.

We are confronted here to a conflict between the individual interest based on the transparency value and the collective interest in the repair of the system based on the safety value. These two values, transparency and safety, both worthy of respect, are mutually exclusive.

Patients themselves have a similar binary feeling. Not only do they ask for a total transparency but they also wish to prevent the re-occurrence of such adverse event.

1. What are the Insights and lessons

Countries like USA (Patient safety and quality improvement act 2005) and Australia prioritize the collective value of safety, based on a voluntary reporting, establishing privilege and confidentiality protections for patient safety work product. Nobody should know of the debates between the actors of an event. Conversely, in other countries like Japan (article 21 of medical practitioners act, 1948), the obligation of health care professionals to declare any unnatural death to the police was extended since 1990 to medical errors. An independent agency will be created in 2015 for the search of the causes of deaths. The link between the agency and the police is not defined and article 21 has not been revised. Between the two attitudes (protection and declaration to the police), Denmark decided that, after a severe adverse event, two types of inquiries were possible, one totally protected for the search of causes, the second totally opened to help the patient. In France, we have implemented through a law (March 2002) firstly, the obligation for the professional who was present at the event to inform within 15 days the patient of a damage due to an adverse event and secondly the creation of a funds for no fault compensation: the no fault compensation for financial compensation and information by the professional to alleviate the legitimate concerns of the patient. The patient only receives the information about the immediate circumstances, since the time of two weeks is not enough for a root cause analysis. The professionals should then engage mortality and morbidity reviews which are a mandatory indicator for the accreditation of the HCOs.

In order to enhance reporting and repairs, we have implemented at the HAS a program of accreditation of physicians “at risk” (surgeons, anesthetists, gynecologists) based on the analysis of near misses. Any physician engaged in this program receives a financial incentive as part of his insurance premium that is paid by the National Health Insurance. In this context of near miss, the search of causes is easier since there is no damage of a victim. Furthermore, one barrier, that could be identified and reinforced, stopped the deleterious process. More than 10 000 physicians are now enrolled in this near miss program.

It appears that the examination of a limited number of cases per year leads to significant repair of the local system if an actual root cause analysis is performed decreasing the interest for a mandatory exhaustive reporting of all adverse events. In fact, defects in a chain, for instance the drug delivery chain from the prescription by the physician to the patient treatment, depends on the organization of health care, on the architecture of the building and on the circuits inside the HCO. The causes of these successive defects will differ in each hospital decreasing the interest of a national exhaustive reporting

Thus, when confronted to the adverse event, each country responds differently to the conflict of individual or collective interests: each country has to make a choice between the individual value of total transparency and the collective value of safety of the health organization, by repairing the series of even small defects.

1. **Second topic on safety assessment:**

**A choice between Prescriptive strategy or autonomy and resilience engineering?**

1. Two approaches originated by two tragedies explain the binary attitude

During the last World War, the US navy was in a great part destroyed in a short time. Reconstruction of the ships could be realized within a few months but not the training of performing crews. Education and training to obtain efficacious crew usually need several years. The innovative idea of prescribed processes applied at all levels of hierarchy allowed the Navy to have crews almost as performing as those obtained by the classical education. The magic effect of obtaining excellent actors with no efforts, and with the advantage of having interchangeable personnel through prescribed processes, explains the rapid and dominant dissemination of processes in any activity of the society. No more education for any device, even for domestic use. A series of multiple manuals are piled up on shelves everywhere. Health care procedures followed the same scheme. For any activity, prescribed processes and protocols were made with the belief that they increased the safety and allowed an easy replacement and movement of personnel.

On the other hand, a second tragedy occurred in USA when the shuttle Columbia exploded the 1st of February 2003 with 7 astronauts seven years later to another shuttle, Challenger, on January 26th 1986 with also 7 astronauts. All the prescribing procedures were followed. The NASA asked a group of scientists to find new rules for safety: David Woods, Eric Hofnagel, Nancy Leveson, Yushi Fujita, René Amalberti and others proposed the new concept of resilience engineering.

“*The definition of resilience,* said Eric Hofnagel*, can be the ability of a system or an organization to react and to recover from disturbances at any stage, with minimal effect on the dynamic stability”*

The personnel should not always follow the prescribed protocols but should adapt their decisions to the variability of the context. Sometimes, the professional is confronted to an unknown context, either not similar to the previous one, or by the addition of several minor disturbances. In these circumstances, no training could be organized and no rules could be promulgated. Errors, deleterious but also beneficial errors, could occur and the strategy is to prevent damage, while retaining the new advantageous conditions rather than prescribing strategies which erase any variability.

Civil aviation policy retains the basis of protocols and prescribed procedures. Aircrafts and travels are not so variable and a prescriptive strategy avoids any trouble in timetables. However, no improvement in the rate of accidents (1 per million of flights) was observed during the last 25 years. Conversely, US army safety moved towards more autonomy reducing mortality. Health care safety is still mainly governed by a managerial approach following a prescriptive strategy.

Two instructive stories enlighten the two approaches. During the take off from New York Kennedy Airport a flight was dangerously compromised by one bird stopping an engine and then another one stopping the other. The captain, Chesley Shullenberger, contacted the control tower. He did not follow the orders (going back, going to La Guardia or going to the private airport Teterporo) and put the aircraft A320 in the Hudson Bay saving all the passengers' lifes. He was a 67 years old man and previously a pilot from the army, the US Air Force, perhaps explaining his exploit of adapting the procedure to the context.

The second story is the study of unexpected mortality after common surgery of 85000 patients in 186 hospitals during 3 years reported by Ghaferi A.A. The centers were classified according to the mortality rates and the best and the worse were compared: no difference in the quality parameters (accreditations and indicators); no differences in the number and types of severe complications. The difference was due to the adaptation to variability, the rapid reaction of the actors whatever their position in the hierarchy when confronted with the beginning of a complication, not loosing time for reporting, not waiting for prescription and applications of protocols. The difference is due to the team spirit, the team reaction, anticipation and resilience.

1. What are the binary values underlying prescriptive strategy and autonomy policies?

The two approaches, either retrospective following protocols and prescribed procedures constructed according to previous accidents and events, or forward-looking adapting decisions according to variable and unexpected circumstances, represent two principles that can be compared to looking at the rear view mirror or looking ahead in a car.

On the one hand, following check lists, protocols, and other prescribed documents, segmenting the activity and allowing the interchangeability of the personnel could lead to an ultrasafe health-care sector such as blood transfusion. However, the prescriptive strategy diminishes accountability, protecting the actors against complaints. The success of the prescriptive strategy led to a proliferation of protocols, protocols for controls, controls of controls decreasing the responsibility of the personnel, who is more concerned by the documents than by the patients themselves. No variability is accepted and thus no minor adverse events, delays, or small defects could occur, while an unexpected rare event could induce a dramatic tragedy with no immediate nor adapted response.

Conversely, autonomy obliges to have a common view, an empowerment of the actors, a permanent vigilance, and a rapid reaction to any variability exercising talent and intelligence. If many small adverse events could occur due to the variability, a severe adverse event could be often prevented or stopped before consequent harm occurs.

These two attitudes consequently induce two feelings about the work life: to be in or out of the common objective exerting talent or transcribing protocols: two attitudes when confronted to an adverse event, anticipating and adjusting or reporting the event and waiting for orders.

If the error is not human, due to the complexity of the adaptative system, the anticipation is human, avoiding harms due to errors arising during unexpected events

1. Insights and lessons

The two policies are not mutually exclusive. One needs to have perfect techniques to be talented. An artist such as a violonist should first acquire the violin techniques and then add his personal touch transforming the music to a brilliant play. A surgeon should have excellent skill in surgical reasonings and techniques before exerting his talents in innovative procedures. Innovations could be implemented only on a solid organization.

Too many protocols kill protocols, too much autonomy induces anarchy. However, prescriptive procedures and autonomy cannot be applied simultaneously, but sequentially. Prescriptive strategy is mandatory in some circumstances, such as the check list in operating theatres, and resilience is preferred in case of emergency to adapt the procedure to complex conditions. The problem is to reduce the number of protocols to the minimum required and to not have a lot of documents, so numerous that nobody could follow them. Autonomy asks everybody to be permanently on alert, vigilant and attentive which is more a characteristic of a clinical behaviour.

. Hierarchy and managers should not be obsessed by protocols and processes. Resilience engineering certainly increases safety.

**In conclusion**

We could caricature

On the one hand, the managerial, economical, regulatory approach, vying to avoid complaints and mishaps by perfect processes, to minimize the load by the cost of opportunity principle, to categorize the best and the worse through accreditation and industrial quality indicators, paying for performance, looking for guilty people and sanctioning error, refraining any autonomy, aiming to have a perfect system with fixed procedures,

And

On the other hand, the patient centered clinical approach looking for better clinical outcomes, mortality, complications, quality of health through efficacy, safety and access to care, managing for the optimal full cycle care, before, during and after hospitalization, comparing year after year the patient pathway for a disease, paying for participation in a full cycle care, applying the no-blame no-shame principle to find causes and to repair the multiple defects, favoring autonomy anticipation, resilience adaptation and limiting protocols and prescribed procedures to those related to clinical outcomes in order “to react and recover from disturbance at an early stage, with a minimal effect on the dynamic stability”.

In fact, we need both approaches in order to have excellent and well organized HCOs, good links between the HCOs and their environment and to obtain the best outcomes for the patients. A cross talk between the two approaches feeds a cross fertilization. The difficulty is to find a balance between the two approaches and not to be too “managerial” as we could have been in the past, nor too “medical” avoiding the risk of anarchy.

For instance, health professionals make guidelines of good practice according to a strict methodology defined by regulatory bodies.

To combine managerial AND medical approaches, I tried to explain that quality and safety assessments should derived from value-based rationales and management, from evidence-based strategies inducing better clinical outcomes, and from the development of team work based on anticipation.

I could stop the lecture at this stage.

**However, we have to consider that politicians who make the decisions interfere with this approach.**

Frequently, politicians wish to assess the national health system before making decisions on the organization of health care. The choices of criterions are related to the health, the health expenses and to the satisfaction of the population. Looking at the results on health of the population, one can note that the ranks of the nations have nothing to do with the economical and medical concerns.

The macro approach of the quality assessing health systems and population outcomes seems to be independent from the micro or meso indicators of quality of health care**.**

In fact, the satisfaction of the population is the major concern of politicians.

Satisfaction is mainly related to access to care: financially, geographically, timely, as well as access to innovations and sophisticated procedures. Any constraint to access to care induces a decrease in the satisfaction of the population.

Access to care is the result of the cross talk between managerial and medical approaches of quality and safety in health care. It should not be decided by administrative orders nor by the medical forces. The balance between the constraints due to the environment and the availabilities of the professionals needs a permanent dialogue of managers and health professionals.

**At the end of the lecture**, four insight and lessons could be drawn

1. To make a choice between utility and equality: cost of opportunity or loss of opportunity
2. To move from processes indicators and accreditation of HCOs to full cycle care evaluation and patient outcomes indicators, mortality, morbidity and quality of life
3. To err is not human. Errors are due to the adaptative and evolutive complex system. It is preferable to apply a no blame no shame policy in order to find the multiple causes and to repair the health care organization than to apply individual sanctions
4. To anticipate is human. Resilience engineering is inherent to health care practice and vigilance and talents should be promoted.

We have probably to move for more medical and less managerial approach for assessment of quality of health care. More attention on efficacy, safety, and access to care applied at each step of the whole patient pathway, is the key issue for quality of health care.

Satisfaction of the population about the health system is usually related to access to care and bundled care that is geographically, economically, and timely accessible, a perfect example of medical and managerial combined effort.

My last words: managerial OR medical approaches should not stand alone in a binary relationship but must be complementary for assessment and improvement of quality and safety in health care. These two companions, managerial AND medical approaches must pull themselves together, hand in hand, in order to cope successfully with the same goal,…for what and for whom?..for a patient’s better health.