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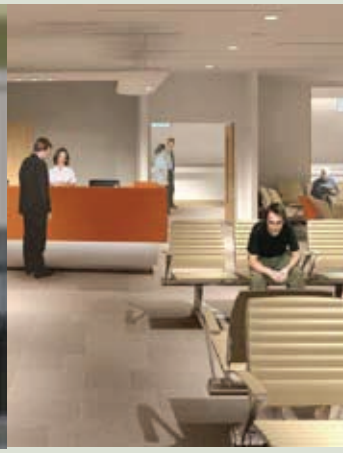

19.4 *Supplement*

Concepts for a Day Surgery Information Systems Policy in Europe

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This document is one of the outputs of the Day Surgery Data Project (DSDP) project [1]. Its general objective was to identify a set of Day Surgery (DS) indicators and to improve the Information Systems on DS in Europe. More specifically, DSDP intended to streamline and standardize existing data and health indicators on DS.

In particular, this document derives from DSDP's last WP, which aimed at providing practical guidance to MSs, local DS systems and facilities on how to formulate and implement policies concerning the health information system's component related to DS.

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VOLUME 19.4 ***Supplement***

Concepts for a Day Surgery Information Systems Policy in Europe

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Contents

Introduction

Health care systems face several challenges related to the organization and delivery of health services. An example is provision of services showing wide variability in terms of appropriateness, access and processes of care, contributing to waste, delays, unsafe outcomes, and dissatisfaction for both patients and providers. Although patients and providers frequently experience and complain about waits and cancellations, they also tend to accept waiting as an unavoidable feature of health care.

A key challenge for health care systems is the organization of traditional inpatient surgery services. This area offers a great opportunity, because today 80% of elective surgical procedures traditionally performed in a hospital setting with night stay should be appropriately transferred to Day Surgery (DS). During the last couple of decades, such great opportunity in the practice of surgery was made possible by a thorough understanding of the physiopathological basis of surgical stress and its management, by technological innovations (e.g. anaesthesiological drugs with less side effects, in particular less vomiting), less invasive surgical procedures (e.g. laparoscopic and arthroscopic surgery), and simpler anaesthesiological techniques (e.g. spinal and epidural anesthesia). All these advances allowed fast track surgery, i.e. procedures of shorter duration and of quicker recovery.

DS represents a major departure from current health services organization given that surgical activities represent about 40% of hospitals output. Despite their benefits, DS services are undersupplied and underused in the EU (European Observatory, 2007). A recent survey also shows a significant variation in the adoption of DS both among and within different EU Member States (MSs). At national level, the percentage of appropriate interventions carried out by DS services ranged from less than 10% to around 50% and the percentage of hernia repairs as day cases by MSs varied from between 6 and 73%; the corresponding figure in the US is almost 90%.

Presently DS represents a high quality and cost-effective approach, and will do even more so in the future as the prevalence of surgical needs of ageing societies, in particular hernias, varicose veins and cataracts, will continually increase. However, the DS model is not merely a new way of delivering surgical procedures but a system of care integrating different health micro-systems which include: patients and their families; general practitioners who select, inform and empower patients; DS surgical teams, ideally placed in a self-contained unit; community nurses, who assist patients at home; and hospital-based surgical teams serving as back-up in case of serious complications. DS places patients at centre stage, both designing care processes around their needs and expectations, and promoting new roles for patients and citizens, i.e. more active tasks in managing pre- and post-procedure phases. DS represents not only an appropriate response to the current segmentation of care delivery but, more generally and importantly, to demographic, epidemiological, social and economic pressures.

DS constitutes a missed opportunity for the improvement of surgical services, especially within the public sector component of many health systems, typifying the huge know-do gap between clinical and organizational evidence and service provision. In the future, European health systems will increasingly face an ethical and political dilemma regarding approaches that assure sustainable and equitable access to effective and safe procedures. DS adoption is part of the answer to such complexity. Optimizing the delivery of health care to European Citizens through the development of DS systems and services represents a considerable technical and managerial challenge, which requires the contribution of multiple disciplines, professionals and policy makers across different European countries and beyond.

DS is a system made of multiple processes and embedded in a larger system of surgical services delivery, which is also part of an even bigger health system, i.e. a macrosystem. Socio-technical systems, like DS, do not function smoothly without purposeful and well informed design and persistent change for the better. Therefore DS, like most organizational enterprises, should be conceived, designed and deployed using the lenses of system thinking, and monitored and enhanced adopting the tools of Continuous Quality Improvement (CQI). One of the most important instruments to monitor and improve DS performance is the information system (IS).

This document aims to provide practical guidance to MSs, local DS systems and facilities on how to design and implement policies concerning the health information system (HIS) component related to DS. The first part of the essay attempts to position DS IS in a broad perspective of services' management and continuous improvement. More specifically it clarifies why any organization, including DS, requires aims, strategies and systems; why organizational culture, specifically, the kind of culture which characterizes High Reliability Organizations is central to high performance in health care; why physician leadership is a fundamental prerequisite; why system and statistical thinking are necessary elements of planning and running DS; why CQI represents the essential approach to DS advancement; and how a DS IS should be a central part of such an effort. In the second part, the document illustrates principles for a DS IS policy. It identifies DS IS goals; the most important end users and their information needs; essential and ideal sets of indicators; the techniques of Statistical Process Control; and how information drawn from surveys, audits and, small, cyclical experiments should combine with routine indicators sharpening the picture with regard to DS performance. Finally, it clarifies how a DS IS should be devised and used as one of the main tools for both strategic and operational decision-making including CQI.

A solid IS can only release its potential when it is implanted in a managerial culture deeply knowledgeable of system and statistical thinking and inspired by the wish to constantly improve responsiveness to users' needs and create a productive work environment about which providers feel proud. The

quotes opening this document, expressions of two giants of management and sociology, i.e. W. Edwards Deming and Karl Lewin, remind us that goodwill is necessary but insufficient as a thrust behind good performance. Policy makers, managers and clinicians will be able to take full responsibility for the establishment and continuous improvement of DS systems, only when they grasp relevant theories, and are proficient in building local and relevant knowledge from empirical analysis.

Part I

Principles for a Day Surgery Information Systems policy

Organizational aims and strategies

The prerequisites of a functional organization are aims, strategies, and systems; these are the elements which can ensure organizational relevance and order, and avoid waste or even failure and chaos. Aims define what an organization intends to achieve. Strategies outline how the aims will be accomplished, i.e. with what instruments. Strategies are conceived, designed, and deployed with the aim to deal with the most important organizational issues. Strategies include structures such as policies, regulations, roles, boards, physical space, equipment, resources, and patterns. The latter dimension consists of practices, behaviors, power relationships, decision making and learning styles, and culture. Culture is the most important component, and therefore it is dealt separately in the following chapter.

Systems are logically arranged sets of processes, i.e. sequences of activities which reliably lead to predefined results contributing to the overall aim (Nolan, 1998). The main organizational systems include the production system, the human resources system, the financial resources system, and the IS. Organizational aims, strategies and systems must be purposefully designed, which means that they should be thoughtfully considered so as to achieve a coherence made of mutually reinforcing components.

Without clear and shared aims, an organization goes astray, individuals and units pursue whatever they find suitable, i.e. different tracks lacking a compass, possibly becoming paralyzed by power struggles. If an organization's building blocks have conflicting aims, its overall performance will suffer. For example, if finances are the only concern of a hospital administration, whereas medical staff pays attention exclusively to quality of care, a damaging tension will result. To attain a smooth functioning, the first step is to find common goals to build on. Aims need not be identical for every organizational actor, but there must be some higher and shared goals and collaboration among players.

Without strategies every unit and individual tries its best to achieve the agreed goals. Partially articulated plans, unclear mandates, improvised protocols, and permanently conflicting relationships are signs of useless strategies. Without systems every sequence of steps is undependable, and personnel is unable to consistently describe the processes. Low reliability implies that individuals and teams act on the basis of traditionalism, where the rationale behind the rules is simply "this is how we have always done things here". No standardization leads to defects, inefficiencies and confusion (Nolan, 1998). Significant progress requires integrated changes in structures, patterns and systems. Quality and safety, like patient centeredness and efficiency, don't just occur; they derive from systems purposefully designed that must be constantly reinforced (Kohn, 1999).

The glue which keeps together aims, strategies and systems, allowing outstanding performance, is a credible leadership which fosters a culture turning around responsibility for constant improvement, cooperation among stakeholders, and accountability for results. Without an alert, bold and fair leadership capable to steer the whole and manage its interdependencies, a system' performance becomes jammed, progressively drifting toward irrelevance and failure. Hence management must play a critical role in ensuring that

- organizational aims and strategies are clear, communicated, understood and accepted by all stakeholders,
- essential activities and tasks congruent with aims and strategies are broken down and assigned to units, teams and individuals and,
- the whole is brought back together through integration mechanisms, such as vision,
- leadership, systems, structures, practices, procedures, and culture.

In high-performing complex systems, leaders run professionals, units and whole organizations by example, keenly asking for inputs from frontline workers, and creating a culture in which continuous improvement becomes a widely accepted norm. Without a determined and knowledgeable leadership, human systems will not put into practice effective routines by themselves. If system members have divergent aims, someone must take responsibility for identifying common goals and build consensus around them. If organizational learning and improvement are deficient, someone must take charge of setting up the tools, creating the proper habit, and determining whether progress follows.

Like any other organization, health care requires aims, strategies and systems. The most important aim is to respond to the health needs, preferences and expectations of patients, their families and whole communities, through the delivery of appropriate, effective, safe, efficient and fairly distributed and funded services (Institute of Medicine, 2001). Health strategies define how the delivery of patient centeredness, high quality, efficient and equitable services is attained through the deployment of a mix of human, financial and technological resources. According to Bloom (2009), "Since the Institute Of Medicine's reports, advancing quality will mean more than business as usual".

In health care, the main systems include the clinical decision making system, the delivery system, the human resources system, the technology and logistical system, and the IS. Key processes of the clinical decision making and the delivery systems comprise: guidelines, procedures, protocols and pathways, which govern flows of information, staff, supplies, patients, and can be captured on a flow diagram. Without a functional health IS, every policy maker, manager or professional can state whatever is convenient, perhaps indulging in empty self celebrations, and pretending there is accountability.

The next chapter describes the role of culture and leadership within a health care organization, and suggests that High Reliability Organizations (HROs) exhibit key cultural foundation of a successful performance, in particular superior patient safety.

Organizational Culture, High Reliability Organizations and Leadership

The most important elements of an organizational culture are values and beliefs, i.e. espoused views about what is good and bad; and basic assumptions, i.e. the most fundamental truths about people and the world (Schein, 2004). Implicit assumptions, together with values in use, act as the fundamental drivers of organizational behavior. Being unspoken, they can only be inferred from patterns of behavior. As Peter Drucker (probably) remarked "Culture eats strategy for breakfast", meaning that fundamental assumptions and values trump official, espoused approaches.

Within health care, excellent performance requires a culture which turns around passion for the medical profession; compassion for the individuals who need our help; responsibility for constant improvement; cooperation to reach a common aim among clinicians, staff and managers; and accountability together with transparency toward patients and their families, the whole society, its representatives, i.e. politicians, and also managers and professionals (O'Leary, 1995).

The Institute of Medicine (2001) has defined transparency as "making available to the public, in a reliable and understandable manner, information on the health care system's quality, efficiency and consumer experience with care, which includes price and quality data, so as to influence the behavior of patients, providers, payers and others to achieve better outcomes (quality and cost of care)". The American College of Physicians (ACP 2010) has summarized the multiple healthcare domains to which transparency applies, in particular clinical quality and safety, efficiency, resource use, patients experience of care, professionalism, health facilities accreditation. For example, transparency of clinical quality entails "measures of the extent to which services provided meet recognized consensus or evidence-based structural, clinical process or positive health outcomes benchmarks or guidelines."

The ACP Ethics Manual (2005) endorses the notion of transparency within the patient-physician relationship. Clinicians should disclose any information relevant to the patient's understanding of his or her situation, including the experience of the clinician, the nature of the illness and options for treatments, and errors and/or mistakes made during care delivery. It is also expected that this information is provided in a way that the patient can grasp. Physicians are duty-bound "to interact honestly, openly and fairly, not only with patients, but also with other clinicians, insurers, purchasers, government, health care institutions, and health care industries." Today, accountability and transparency are core elements of a medical culture striving to offer its best.

Another cultural feature of excellence in health care is reliability. High Reliability Organizations are capable to deal with unexpected events under demanding circumstances. In order to do so, HROs use two fundamental strategies, anticipation and containment (Weick & Sutcliffe 2007). These strategies are enacted through a frame of mind, i.e. foundations for reasoning and guiding behavior, based on the following two clusters, respectively: first, a preoccupation with failure, reluctance to simplify and sensitivity to operations; and, second, a commitment to resilience and deference to expertise.

Preoccupation with failure entails that professionals are capable and willing to pay attention to weak or minor danger signals and act forcefully in response to those signals. Too frequently, in health care delivery, weak signals and near misses are ignored; even worse, sometimes loud signals are overlooked. Blaming can become a kneejerk response, which closes the investigation about the undesired occurrence and its causes, and leaves the signal unaddressed, as if it never happened. In an HRO no event investigation is considered closed until the results are communicated to the reporter, and remedial plans devised and implemented.

Conversely, a trouble sign for a safety culture is when managers and supervisors are not in the workspace personally looking at problems, and decisions appear to be made without command of the facts and without staff input. Another concern for a safety culture is when managers and workers stop making suggestions that cost money because they perceive this will not be heard by those with formal authority. Likewise, a warning signal exists when top management appears to only recognize and reward actions that keep production going.

Reluctance to simplify is another concept that HROs embrace in order to understand the complexity of processes within the organization. The idea is that every step in a process should be considered, no matter how insignificant or small, with the understanding that errors can occur at any point in the process. Sensitivity to operations ensures that all team members are aware of the big picture, through the team's ability to exchange clear and brief information, to acknowledge receipt of that information, and to confirm its accurate understanding. To this aim, teams adopt tools such as briefings and de-briefings; assertion; structured communication (SBAR: **S**ituation, **B**ackground. **A**ssessment, **R**ecommendations), and critical language (CUS: I am **C**oncerned, **U**ncomfortable, **S**cared).

Commitment to resilience means that leaders and staff are prepared to know how to respond once system failures do occur. Members serve as redundant systems to avoid, contain, and mitigate the consequences of errors. In order to prevent

errors and ensure workplace safety, team members solicit and obtain help when overloaded, monitor each others' performance to notice any deterioration, and take an active role in assisting other team members who need assistance, in other words adopt "good citizens behaviors" (Leape et.al., 2009).

HROs also utilize the concept of "deference to expertise", which, simply put, means deferring to the person who has the most expertise as it relates to the problem at hand. Furthermore, "deference to expertise" is a collaborative approach that assists in breaking down silos in the working environment. The high volume, standardized procedures distinctive of DS units would greatly benefit from HROs characteristics.

Mindfulness is the capability to perform consistently in complex settings, and is more likely when people are alert, unhurried, and not overloaded. HROs maintain a state of mindful interdependence among its members, who are better able to anticipate and respond to failure (La Porte et.al. 1991). This implies awareness and understanding that the complexity inherent in clinical and organizational problems, can be dealt with only by knowledgeable and motivated actors interacting collaboratively, and supported by reliable processes continuously improved. it is unfortunate that many medical schools still put utmost emphasis on individual proficiency, which is indispensable, but tend to ignore teaching how to cope with the interdependencies inherent in clinical work, i.e. how to communicate, collaborate, and cooperate.

The converse of a HRO is a mindless business, characterized by high levels of risk and harm, that appear acceptable to providers, managers, and even patients/families. In these contexts, harm, such as nosocomial infections or forgotten foreign objects in abdominal cavity, are deemed inevitable events. Professionals are unaware of the hazards; tend to be overoptimistic; consider clinical work as a routine with little surprises; frequently fail to rescue patients developing complications or preventable adverse events, such as gastro-intestinal tract hemorrhage or kidney failure; miss early signs of medications' reactions; celebrate near misses as another lucky occurrence; and hide preventable adverse events to themselves, colleagues and administrators.

Self-contentment with real or supposed success, and an emphasis on efficiency, go together with disregard of possible failure. Providers are unable to respectfully communicate one's own ideas, wants and needs in a professional environment, and authority is never challenged. A mindless approach covers up problems that are getting worse. Latent, i.e. built-in, defects are not identified, not even conceived, and therefore providers are condemned to repeatedly fall into existing traps, and blame the providers who find themselves at the wrong place in the wrong moment.

A blame culture manifests itself especially when facing preventable adverse events. It considers errors and harm as the results of individual blunders caused by providers who are not enough dedicated, thoughtful, or capable (Runciman & Merry, 2003). Such unsophisticated interpretation calls for a simplistic answer, i.e. naming, blaming, and retraining or firing. Investigations of errors and adverse events are superficial, and stop early, just after a culprit has been identified. A blame culture ignores crucial cognitive (e.g. memory and attention), emotional (e.g. motivation and stress), and physical (e.g. sleep deprivation and fatigue) determinants of performance of individuals. A blame culture also disregards the influence of teamwork, e.g. the degree of trust, mutual support, collaboration and cooperation among members. It also overlooks faulty processes, policies and prevalent culture.

HROs leadership is engaged with the frontline providers to understand and use their insight in making operational decisions. The presumption is that those on the sharp end are often aware of problems and must feel free to bring these to the attention of leadership, where they will be heard and addressed. HRO leaders successfully orchestrate open communication with the clinical leaders, department chiefs, quality and patient safety officers, to review the data from quality, and incident reports (Aspden, Corrigan, Wolcott, Erickson eds., 2004).

Leaders in HROs demand "minority opinions and healthy pessimism", and place equal value on reliable production and operational quality and safety. Leadership in HROs ensures that, weak signals are acknowledged as evidence of a system in need of improvement. Rather than viewing near-misses as proof that the system has effective safeguards, a leader regards them as symptomatic of areas that require additional attention. Leaders are wary of simplistic explanations for why things work or fail, and look for deeper patterns and webs of causation. Without a heedful leader willing to listen and respond to the insights of staff, and who know how processes work and what risks patients face, an organization disregards the possibility of failure and a culture of high reliability becomes impossible.

Mindless leaders perceive small signals, such as near miss, as irrelevant, normal ingredients of a messy work place, instead of patent warning signs of unsafe performance. Strong signals, such as obvious errors and severe adverse events, trigger a harsh reprimand by the person in charge, who whacks a front line employee in a weak position. After simplifying the chain of events and snubbing latent factors, the case is closed.

A blame culture, the opposite of a safe and just culture, entails that adverse events are not thoroughly nor fairly investigated, nor followed-up by corrective actions. According to Runciman et al. (2003) "Blaming and punishing for the inevitable errors that will be made by well-intentioned people working in health care drives the problem of iatrogenic harm underground and alienates those who are best placed to prevent such problems from recurring."

A mindless organization has no clear vision, nor mission statement, nor overall strategy on patient quality and safety. There is no benchmarking, and managers and providers do not know that other systems and health care organizations are moving fast toward better and safer performance. Learning from adverse events is minimal, anyway limited to an individual or a small group, which are unable and/or without authority to redesign systems. Analysis of incidents to identify types, trends, and their root causes, is absent or haphazard; it is essentially determined by the mood of the moment and, above all, by the political goal of staying away from powerful actors. Slow recovering from failures, even worse accidents, result in distressed and divided groups, fully alert about the need to watch one's own back. This is the opposite of what HROs do

as they try to take advantage of learning from poor quality, accidents, incidents, and near misses.

Mindless organizations do not align incentives behind unmistakable priorities, in particular quality and safety. The mood of the staff is characterized by fear and discouragement, inducing some of the best professionals to move to other organizations. Training and education around quality and patient safety is fragmented and occasional. A mindless organization is led by a mindless leadership characterized by indifference to systemic problems; refusal to hear bad news; detachment from front line staff; sometimes disrespectful attitudes, possibly disruptive behavior. Leaders show, at best, marginal commitment toward patient quality and safety, offering lip services when it is politically expedient. Mindless organizations slowly and unwarily move into unsafe territories, oblivious of their dangerous drifting, a phenomenon known as "normalization of deviance."

HROs concepts applied to health care present considerable challenges, because, above all, a culture rooted in exaggerated autonomy of professionals, steep hierarchical structures, and poor flows of information and patients. On the other hand, understanding how culture, leadership, and practices of HROs can contribute to quality and safety, concepts still in their infancy in health care, can inspire health care leaders to adopt them with intelligence, prudence and persistency.

Organizational cultures are deeply influenced by leaders, who, through their choices and deeds, unmistakably and constantly make clear core assumptions and values. Since physicians make many of the vital decisions concerning health care systems, their involvement as skilled and courageous leaders is an indispensable element of a productive and rewarding workplace (Berwick & Nolan 1998). A leader must make clear that success in terms of patient quality and safety involves mindful management of interdependences within and among teams, units and organizations. All organizations have a hierarchal structure. Historically, the upper tier is responsible for making decisions and providing directives, while the lower levels are responsible for implementing. This often represents a fundamental constraint for many sectors and organizations, and health care is no exception. According to Lucian Leape (2009), "Many physicians do not know how to be team players and regard other health workers as assistants. Outmoded hierarchal structures inhibit collaboration and learning".

Leaders contribute to establish a quality and safety culture in different ways: they communicate clear and high expectations so that members have an unmistakable understanding of what they are to do; and they support members on how to practice new and required behavior. Leadership reinforces desired behaviors, making sure they become deeply-rooted habits, and promotes a just culture, and congruence among core values, assumptions and strategies. Leaders of HROs provide training and education, including core competencies of human factors, system complexity, high reliability and effective communication. Health care leaders of HROs may celebrate their successes, but they are also aware that failure can strike at any moment. They maintain calm mindfulness of this risk in their subordinates, without creating distress.

Leaders play crucial roles not only making sense of what happens, both within and outside an organization, but also conceiving and communicating a compelling vision, which clarifies where the organization is heading and how to get nearer to the aim. Leaders are role models, what they do is much more important of what they say. Above all, leaders must be effective in dealing with moments of truth, i.e. challenging situations which evolve rapidly and opaquely. A genuine leadership always listens to and provides feedback to the source that reported quality or safety concerns. When a leader is under stress, facing unclear problems, feeling embarrassed and threatened, a tension can surface between espoused and deep values. For example, the head of a DS unit might espouse the importance of every professional, even junior, being assertive and contributing to the identification of hazards and glitches, still yell at a resident if he/she dares to respectfully offer some reasonable thoughts about a procedure. An episode like this can seriously undermine the credibility of a leader and the culture of a team.

Leaders play a fundamental role in shaping the culture of an organization, preventing and solving ambiguities and incongruence among cultural layers. Regardless of the attitudes and beliefs that health professionals are imparted during training and education, dominant assumptions in a hospital or unit, typically reflect the values of senior leaders. Organizational leadership establishes strategic direction, aligns members, motivates and inspires staff, and promotes learning. Experts in organizational change theory believe that for an organization to embrace change, and implement new strategies promoting quality and safety, a sense of urgency must be permeated into the entire work force (Kotter, 2008).

Without strong, charismatic, engaged leadership at the highest levels, changes to improve quality and safety, and establish HRO principles in health care will be unsuccessful. Visible leadership by the trustees, CEOs, and physician leaders is the single most important success factor overcoming the crucial barriers of diminished awareness, deficient accountability, mediocre capabilities, and ineffective actions.

In summary, organizations with ambiguous aims, dull strategies, poorly designed systems, weak leaders, and destructive cultures are ineffective, inefficient and disfunctional; similarly to patients whose prognosis becomes clear only after a diagnosis is made, organizations' troubles should be detected and treated. Signs of problematic performance in health care organizations are high variation of clinical processes, more specifically underuse of effective care, like in patients with high blood pressure left untreated; overuse of supply-sensitive care, like use of traditional surgery when DS is appropriate, or surgical procedures in patients with back-pain; and misuse, meaning failures to execute procedures properly, and their consequences, i.e. errors, adverse event and near misses. Important root causes of these drawbacks are both conceptual, i.e. lack of system and statistical thinking, and strategic, i.e. lack of methods of quality and safety measurement and improvement. The next chapter first spells out basic principles concerning systems thinking applied to management and, second, elucidates what statistical thinking is.

System thinking and statistical thinking

System thinking

According to Peter Senge (1990), a scholar who contributed to combine management and systems thinking, system thinking: is the "discipline for seeing wholes, recognizing patterns and interrelationships, and learning how to structure those interrelationships in more effective and efficient ways". Further he describes this approach as "a way of thinking about, and a language for describing and understanding, the forces and interrelationships that shape the behavior of systems." System thinking moves understanding of how a system functions from a simplistic view made of isolated events, each with a single cause which must be identified and fixed, toward an appreciation of webs of causation. Mental models missing this perspective can only have a shallow grasp of systems' dynamics.

The holistic view of systems thinking radically diverges from Descartes's scientific reductionism, which studies systems by breaking them down into their separate elements and has dominated western philosophy until recently. Systems thinking is relevant to any area of basic and applied research and has been useful not only to the study of health care and clinical work, but also to the environmental, political, and economic systems, among many others.

Systems Thinking is a structured approach to problem solving, which looks at accomplishments and failures as originating from the whole system, rather than from isolated components and offers a deep understanding of the underlying structure. System thinking's most central concept is that all systems are composed of inter-connected parts so that a change to any element or connection among components affects the entire system. This implies that approaching each isolated part one at the time, without seeing, in a structured way, how each component affects the whole through feedback, is deeply flawed and does not help understanding nor problem solving. The idea that an improvement in one unit can adversely affect another unit or the whole system, constitutes a crucial and counterintuitive truth.

Each system is structured to produce the effects that it gets: sensible and reliable structures bring about organizational success; faulty structures generate substandard results. Systems behavior depends much more on relationships and coordination among parts than the individual components, because that governs how the elements work together. In other words, the structure of a system, i.e. how the system is organized in terms of connections patterns and feedback loops, determines its behavior. Feedback loops are connections causing output from one component to influence input to that same part. Some feedback loops are nonlinear, which explains damping and accelerating effects, where small catalytic events can cause extensive changes. Every element is influenced by one or more feedback loops and therefore systems have more feedback loops than parts, which creates extraordinary complexity and unexpected effects even from small changes. This phenomena, known as emergent behavior, is counterintuitive and accounts for why parts and structure are constantly changing and complex systems are self-organizing and adaptive. Systems thinking also warns us that causes and effects are frequently separated by distance and time, which explain delays. Delays make the linkage of cause and effect more difficult to grasp. For example, the sequence of low compliance with hand hygiene protocols and the subsequent hospital infections are separated by time.

An important observation of systems science is that appropriate change may have positive impact out of proportion to the size of the change. Pareto conceived the 80/20 rule, which refers to the fact that, in general, 80% of problems originate from 20% of causes. For example, 80% of patients complains might derive from 20% of staff behaviors. Pareto's diagrams are a useful tool to highlight the most influential root causes of performance, where efforts should be focused. Senge (1990) also characterizes system thinking as "a discipline for seeing the structures that underlie complex situations, and for discerning high from low leverage points". Leverage points or triggers are carefully chosen changes on the structure of a system which are directed toward an important barrier of performance, and therefore able to yield substantial improvements.

When applied to management, systems thinking teaches us that an organization is made up of different functions, units, equipment, infrastructures, human resources, and processes, and high performance can only derive from the integration of its diverse components so that each contributes to accomplish the designated and shared aim. System thinking goes beyond organizational charts and job descriptions to a more sophisticated and relevant picture of people and technologies interacting through reliable or, at the other extreme, undependable processes.

Interdependencies entail communication, collaboration and cooperation among systems' actors, preventing a silo effect, where components of an organization ignore each other, or an even more detrimental atmosphere where somebody's defeat is somebody's else's win. Another key managerial implication of interdependency is that organizations need purposefully designed, simple, standardized, well integrated and reliable processes.

Managers and clinicians who do not have sufficient understanding of the processes they carry out, are incapable to manage them effectively. Michael Hammer (2001), co-author of Reengineering the Corporation, argued that "People who are aligned around a common goal but lack the discipline of a well-designed process will go nowhere … likewise the best-designed process has no chance of survival when people aren't aligned around the process and its goals." "No matter how hard individuals work, they cannot overcome a flawed process design, much less the burden of no design at all."

Five general structural and cultural approaches to design effective systems include:

- the standardization of processes to reduce detrimental variation;
- the setup of feedback loops to ensure fine-tuning of the system;
- shortening cycle times;
- accepting that human error is ubiquitous; and

- adopting the norm of mutual respect with no exception.

Standardization should be adopted for recurring processes and be introduced taking into accurate account inputs from front-line professionals. For instance, physicians within the same unit too frequently demand different preoperative laboratory exams or different sets of surgical instruments or devices for the same procedure. Such inconsistent approaches do not add any value, on the opposite they create avoidable waste, confusion and errors. The Park Nicollet Medical Center in Minneapolis, for example, standardized surgical case cart content; this initiative reduced instrument counts by 60% and the number of instruments' sterilization by 40,000 per month, saving thousands of dollars for the hospital. Nevertheless, in view of the fact that diseases are widely diverse and physiopathology and therapies are extremely complex, physicians will always require a high degree of autonomy. Consequently standardization is not appropriate for unexpected situations and rare processes. Moreover, given that health care should be patient centered, the portion of variation relevant to the specific needs and preferences of an individual patient, is desirable and should not be removed.

A second approach to effective system design are feedback loops ensuring that specific and constructive information regarding positive and negative events is promptly delivered to relevant stakeholders, who can swiftly search for causes and respond to improve performance. For example, charts like VLAD and CUSUM adopted in operating theatres, represent useful tools for fast feedback on performance (Grigg et.al. 2003). A third answer consists of shortening cycle time of a process, which will often improve performance beyond expectations. For example, defects will be reduced and productivity will rise if lab exams are available without delay; discharge letters are completed sooner; and communication among clinicians flows promptly.

A fourth key toward effective organizational design is to create a culture that regard individual errors as likely; admit errors; learn systematically from them and lessen their consequences. At the same time, high-performing systems have zero tolerance for irresponsible and voluntary violation of norms and protocols. Human beings overrate their capability to operate without generating mistakes. Even though human errors are inevitable, reliability, i.e. error free performance during a time period, can be improved by some form of built-in redundancy, such as decision aids and reminders, desired actions as defaults, use of scheduling, and taking advantage of established habits (Resar, 2004). More in general, high reliability processes require standardization of basic procedures, multiple procedural checks, solid training, shared discipline, a commitment to team-work, a strong collaboration between professionals and mutual accountability. Sectors like the civil aviation and the armed forces have confronted all these issues more systematically, at an earlier time and with more success than health care. Reliability principles provide a proficient way to examine complex systems and their processes, calculate their overall reliability, and develop mechanisms to increase the likelihood that the systems will perform its intended functions consistently.

Among professionals, physicians, more than pilots, have an unrealistic perception of their abilities under stressful conditions; for example, one study revealed that one-third of ICU staff denied ever making errors. Such assessment is not only far from reality but also regrettable, because denial of fallibility inexorably hides failures and near misses, and is also incapable to mitigate errors after they materialize.

The fifth element of a high-performing system is to ensure respect for staff, including junior members, whose contributions are regularly solicited and valued. Such attitude furthers motivation and brings out the most of everybody's potential. A system which ignores or, worse, looks down at inexperienced personnel, or rigidly operates on the basis of formal hierarchies, is doomed to second-rate performance.

Purposeful design is necessary but not sufficient. A systems perspective recognizes that unintended consequences are an almost unavoidable product of change in a system's structures and processes. Managers and professionals, who are determined to improve systems, are on the alert for unanticipated effects and do not act as if those are exceptional events; on the contrary they search for and consider them as a reason for watchfulness toward intelligent transformation.

When the effort to improve a system encompasses its broader boundaries, instead of considering a more limited dimension, the opportunities for improvement become larger as well. In other words there is a positive correlation between the scope of change and the potential for success. Such potential is counterbalanced by the challenge to manage a wide transformation of the system. This fact derives from the most central of the systems concept, i.e. that interacting elements influence each other in complex ways and confronting isolated elements or a restricted number of parts is bound to be partially effectual, at best. Expanding the scope of change requires augmented skills to manage and work in the larger system, accepting some loss of control for the opportunity to influence it and increasing cooperation with other professionals.

Some systems are simple, where following a simple recipe produces the results. Other systems are complicated, i.e. machine-like, where we can rely on installation of technically correct solutions designed by experts. A third type of systems are complex, i.e. organic; in this case appreciation of uniqueness, adaptability, and staying tuned in to what is happening are key. Health care systems are complex and dealing with them as if they were simple or machine-like is a prescription for disappointment. As Einstein reminded us "You cannot solve a problem using the thinking that got you there".

Modern health care organizations are highly complex workplaces involving many individuals with different skills and responsibilities performing a broad variety of tasks. When organizations first analyze how work is done, they are usually surprised by its complexity. A health care process frequently involves different clinical disciplines and several departments and may encompass 50 or 100 steps, engaging people from several units. Such processes are rarely deliberately designed; rather, they tend to evolve from customs. Because nobody knows the entire process, there are often redundant and unnecessary steps, i.e. substantial waste. Changing processes is a constant challenge that requires negotiation and coordination between managers and their respective staffs across all departments involved.

Leaders and managers unaware of systems principles will be hesitant both about organization's design and management, acting rigidly and naively. Even though they do not understand how structures and processes affects a system's performance might show self-confidence and throw buzzwords, but in reality they act in the darkness. Therefore their improvement attempts will often be futile, typically investing more resources similar to those used in the past and enforcing more rules and stricter control (Berwick 1998b). Such changes rarely result in progress, which in any case are costly and short-lived; in most occasions, improvised changes further compromise performance, producing unnecessarily complex, fuzzy, inefficient and conflict prone organizations

When decisions are based on one-off outcomes or events, instead of a thorough understanding of patterns, this results in useless interferences. The alternative to an understanding of processes, i.e. their performance and capability, is tampering. This means overreacting in front of common causes, i.e. thinking that change has occurred and decisions are necessary when in fact there is no change. For example, staff are reprimanded because the last survey shows a (statistically insignificant) worsening of patients' satisfaction. Lack of process knowledge can also persuade managers and professionals to do nothing in front of real change, i.e. a special cause. For example, a surge of surgical wound infections following the integration of recently educated staff in a unit is ignored because it is judged a non event. An understanding of common and special cause entails the concepts of statistical thinking which are concisely explored in the following pages.

Statistical thinking

Interpreting organizational reality and acting upon it without any quantitative anchor contributes to waste, de-motivation and paralysis. Management of a system and its processes should also be based on a somewhat sophisticated set of principles and methods known as statistical thinking. Statistical thinking is a philosophy that integrates systems thinking and statistical methods. It is an overall approach to improvement more broadly applicable than statistical methods, a way of reasoning, taking action and interacting with colleagues, subordinates and supervisors. Such approach, which significantly improves the usefulness of data analyses, consists of the following three essential principles:

1. Organizations should be thought of as systems and processes; this means that all work occurs in a system of inter-related processes, i.e. sets of sequential activities that turn inputs into outputs and outcomes affecting customers;
2. Variation is in every process and gives rise to uncertainty;
3. Variability must be understood and managed; reducing variation, i.e. decreasing the dispersion around central values and moving the whole processes toward better performance are key steps toward success.

The first point was investigated in the previous section, whereas the following pages will cover basic ideas around variation.

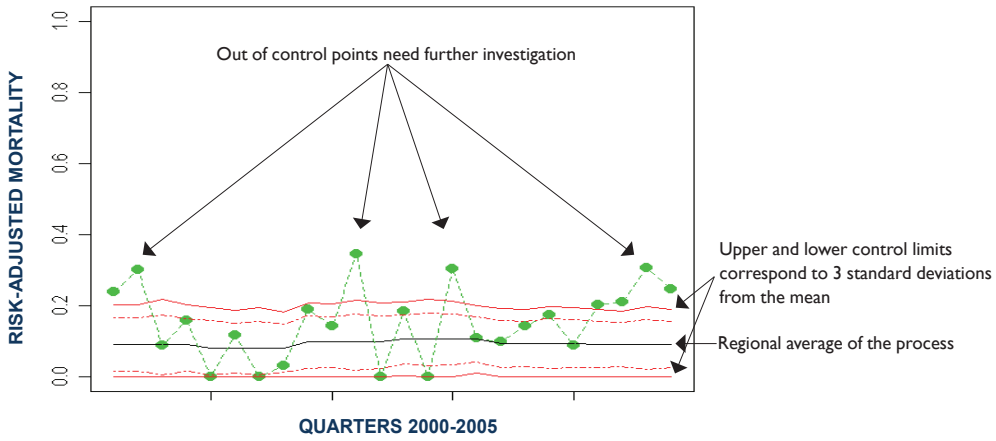
Statistical Process Control (SPC) is the method of choice to understand variability and interpret indicators when attempting to improve systems and processes (Mohammed et. al. 2001). SPC central tenet asserts that all processes show variation, which should be distinguished between: 1) Common-cause or random variation, i.e. intrinsic to the process and 2) Special-cause or systematic variation, i.e. a result of factors extrinsic to the process that disrupt it, make it unstable and therefore not improvable until is brought back to stability. Examples of sources of special-cause variation are lack of standardization and work carried out by a dysfunctional group.

Control charts are the main graph tool used by SPC and their rationale, principles and techniques are briefly exposed in the following paragraphs (Woodall, 2006). Control charts reveal if the observed variation can be expected based on the assumptions defining the process itself. In other words, control charts establish, graphically, if a process is in statistical control. The control chart is composed by three lines: the central line (CL), the upper (UCL) and lower (LCL) lines (see the following graph, page 12). The central line represents the process' mean; the last two are called control limits, and identify the confines of common-cause variation, corresponding to three standard deviations from the mean. Any point outside the control limits suggests the presence of a special cause, and should be analyzed. The following example, illustrating risk adjusted intrahospital mortality, shows eight observations above the upper control limit, which should be further investigated for special causes. Studying causes of random variation or, even worse, acting on observations contained within control limits, would represent a waste of time. On the other hand, if the process' mean around the risk adjusted intrahospital mortality is judged unacceptably high, the proper approach would be to examine the current processes of care and re-design them on the basis of benchmarking and short cyclical experiments as described further on.

Control charts are useful in CQI efforts applied to health care as tools for monitoring and improving services' performance. The use of control charts in the context of health care differs from that for industrial practice. Differences are due to a larger presence of attribute data, i.e. counts, discrete as opposed to continuous data, in health-related applications than in industrial settings. Furthermore, there is no clear distinction between the analysis of historical data and the monitoring stage. Other differences are due to the necessity to risk adjust outcome data before constructing control charts, because patients mix varies across time and space, whereas inputs to and design of production processes can be strictly kept under control. Accordingly, control charts in a health care context are constructed taking into account the risk-adjusted probability estimates in contrast with the hypothesis of constant probability of failure under industrial applications.

A process which shows excessive variability across time is unreliable. Organizations' performance is heavily influenced by the reliability of their processes (Resar, 2004). Reliability is the measurable ability of a process, procedure, or service to perform its intended function in the required time under commonly occurring conditions. Reliability equals the number of actions that conform to standards divided by the total number of actions taken. Reliability is measured as the inverse of the system's failure rate. Thus, a system that has a defect rate of one in ten, or 10 percent, performs at a level of 10-1.

Hip fracture: control chart of risk adjusted intrahospital mortality in Hospital V, Veneto Region, Italy, 200–2005.



From: Gnesotto R., Gennaro N., Turra R., et al. (2007) Rapporto su misure di efficacia, accesso, sicurezza, ed equità del Servizio Sanitario Regionale del Veneto, Agenzia Regionale Socio-sanitaria, Venezia

For example, if 90% of surgery patients get their prophylactic antibiotic within an hour of surgical incision, the reliability of that process as measured by defect rate is 10-1.

Without purposeful system design, systems' and operators' performance is unreliable. Unconstrained human performance, i.e. guided only by intent, vigilance and hard work, like for most health professionals, will usually have reliability worse than 95%, whereas constrained human performance can reach 95% reliability or better. Some researchers have calculated that most people under work and time pressures make errors at the rate of 10-2 even when doing their best effort. The key lesson for management is that high reliability systems must be designed to compensate for the limits of human ability. Without a proper design of processes and their relationships, monitored and continuously improved, the inevitable result is a mediocre performance. Higher degrees of reliability can only be reached through the adoption of human factors and principles of reliability science.

System and statistical thinking applied to health care

Modern medical care, even in its simplest form of ambulatory and home care, is delivered by several interacting systems, each consisting of diverse professionals, managers and technologies. Several sociologists and scholars of organizations have stated that health care is the most extraordinarily man-made complex system, composed of a vast number of interacting human and nonhuman elements. There is a lot of complexity in care systems and also in clinical work on individual patients because many variables interact in unpredictable and non-linear ways behind a thick screen of uncertainty and opacity. Non-linearity implies that, on occasions, an apparently insignificant thrust might be enough to tilt for good an unstable system or patient, even at distant times and places.

Medical education is based primarily on training conceived at a time when medical encounters essentially consisted of one doctor meeting one patient and opting for a clinical course with little or no support from other clinicians. Medical training still focuses on learning how to work on our own to diagnose and treat sick individuals. Most health professionals tend to develop a strong identity with their individual craft and the unit they belong to; professional societies, research interests and organizational arrangements contribute to the fragmentation of health care organizations. Such situation, combined with a lack of training around systems concepts, conceals complex interdependencies and induce health professionals to adopt workarounds in the attempt to overcome perceived weaknesses of other units. This contributes to the intricacy of the processes, further narrows the system view, and disguise structures and processes behind an increasing confusion.

High performance systems can only be constructed of outstanding elements. Within health care, this means that professionals must cultivate their clinical acumen and humanity. Technical incompetence, i.e. lacking full command of a specific clinical area, and interpersonal ineptitude, i.e. inability to communicate effectively and compassionately, result in substandard care. Adequate knowledge and skills are essential to medical practice, still that is not enough; a professional with no understanding of systems looks at events as isolated episodes, unable to see patterns. As a provider caring for a patient, she carries out discrete tasks, but misses the overall clinical picture. As a member of a team, she is unable to see her contribution to the whole unit and organization, i.e. how others depend on her and she depends on others. When faced with problems, she tends to accept defects as inevitable or, more frequently, to blame, complain and reinvent the wheel, of different sizes, shapes and functionality, which leads to extensive variation.

A mindful professional, proficient in system thinking, is able to analyze and improve her interactions with other system elements and collaboratively create a whole that is greater than

the sum of its parts. Instead of an apparently straightforward search for a wrongdoer, which only brings about frustrations, withdrawals and conflicts, she looks at defects of internal processes, and learns from benchmarks.

Medicine has been slow to incorporate science of complex systems. Physicians are not trained to design work, too often attempt to solve systems problems with skills that are appropriate for interactions with patients, and tend to simplify the reason for defects assigning blame and shame. Today's health care complexity compels the adoption of system thinking both for clinicians and managers. Only a purposeful design of systems, through collaboration crossing artificial professional and managerial fences, and their continuous improvement through small experiments can bring lasting progress to health organizations (Batalden & Mohr, 1996).

One of the most important problems affecting health care systems is low reliability of processes. The Institute for Health Improvement (IHI) has classified reliability into the following categories:

- Failure in greater than 20% of opportunities; this class reflects a chaotic process;
- Failure in 80 to 90% of cases, i.e. one or two failures out of ten opportunities; it means that no articulated process exists, and thus front line users lack a consistent and clear understanding of the process, providing different descriptions;
- Failures in 95% of cases or better, i.e. five or less failures out of one hundred opportunities; even if variation is still too wide, front line users can easily convey the sequence of steps in the process.

These categories are not simple practical groups based on mathematical criteria; more importantly, they reflect systems design characteristics and therefore have diagnostic value and suggest certain solutions.

Multiple studies in OECD countries show widespread inconsistencies in the delivery of high-quality care. Clinicians successfully apply proven medical evidence in common acute, chronic, or preventive care processes less than 80 percent of the time, which means they work with chaotic processes. The low level of reliability for health care basic processes compares poorly with most other industries, for example car production, banking or luggage handling by airports.

According to Resar (2006), the four following reasons partially explain why health care performance is so unreliable. First, an unrealistic idea of health professionals as infallible human beings who can basically rely on hard work, paper tools, memory and personal vigilance instead of standardized processes. Such mind-set is reflected by the reproach most commonly used when a professional is caught in error: "Next time, pay more attention". Such call is unreasonable because it ignores established scientific evidence concerning the emotional, motivational and cognitive attributes of the human mind.

Our psyche tends to wander, is unable to keep a high level of concentration for prolonged periods of time, is easily distracted by interruptions, suffers much from fatigue, hypoglycemia and dehydration, is significantly compromised by sleep deprivation, and struggles when trying to perform several tasks at the same time. Many adverse events result from errors made by a person who is capable of performing that specific task safely, had done so countless times in the past, and faced significant personal consequences for the error. Although brittle features of human cognition cannot be modified, what we can and should focus on is the re-design of systems and settings taking into account human factors, i.e. how people interact with technologies and processes.

A second reason behind poor reliability in health care is an ample tolerance toward clinical autonomy. This translates into wide variability in how even basic processes should be carried out. When processes are not standardized, everybody has a different idea on how they should be executed; such situation is confusing also because it compels the organization to supply different mix of resources and diverse training and supervision modes for processes sharing the same objectives. Expectations about and ownership of processes remain vague; assignment of clear responsibility for performance and its analysis, including frequency and causes of failures, are impossible given the messy arrangements, and this precludes improvement. Such degree of professional autonomy and disorganization would be unthinkable in aviation, nuclear power stations or the military.

A third explanation of inadequate consistency in health care is that reliability goals are not explicitly stated, even when systems are purposefully designed. The concept of reliable processes and its relevance for effectiveness and safety is widely disregarded by health care professionals and managers. A fourth motive of insufficient reliability derives from the fact that performance is usually judged against mediocre averages of outcomes rather than benchmarks of processes. Even if comparisons are with top performing processes, feedback is not always intended for improvement or is ignored, because the data, the source or the messenger are perceived as scarcely credible.

Medical care is delivered by complex systems that do not respond in simple ways to interventions. Clinicians who understand basic systems science will be less frustrated when they become aware of such reality. Then they will be able to analyze systems' problems and take actions likely to bring about real and lasting improvement. The Institute for Healthcare Improvement (IHI), among other organizations, promotes the adoption of reliability principles in health care with the view to increase the consistency with which appropriate care is delivered, reduce defects of care processes, and therefore improve patient outcomes. The emphasis needs primarily to be placed on processes rather than outcomes. The first steps for health care leaders are to understand the importance of variability and reliability in care processes, to select a set of essential clinical processes, to measure their reliability and to devise strategies to move from chaotic processes to a level of reliability above 95%, before taking more demanding challenges.

Thoughtful design and attention to surprises are essential managerial capabilities, however human mind's limitation in understanding and controlling complexity also requires constant improvement through small tests of change. Experiments gradually deepen understanding of relationships among elements and bring processes nearer to a smooth

functioning. The illusion to design the "perfect" system from scratch inevitably produces setbacks and frustration. The core concepts of system and statistical thinking have been integrated in general models of organizational improvement. The most influential among such models is the one conceived by Edward Deming (Walton 1989). This topic is concisely exposed in the following section.

Continuous quality improvement

New knowledge, technologies and therapies, and changing demographic, epidemiological, social, political and economic forces affect health care systems. Setting goals for systems of care is necessary but not sufficient; goals must be tied to a specific strategy relevant to a particular organizational, professional and cultural context. This means a strategy that builds not only on existing assets but also "creates strength through the coherence of its design" directing its energy and resources on pivot points (Rumelt, 2011). To survive and succeed, i.e. to fulfill a consistent purpose of obtaining the best outcomes for patients, health care systems need persistent improvement in both their structures and processes. Leaders need to overcome the inertia dragging down their system and supply the will and driving force for change. For example, primary care physicians and specialists will not come together spontaneously to design a new referral system which is a necessary component of DS.

Some health care systems and processes drift into inappropriate and risky modes, which sometimes lead to depression, paralysis and even death of the unit itself and, more importantly and sadly, of various patients. Organizational pathologies should be diagnosed and treated strategically, i.e. using structured approaches such as observing and being inspired by benchmarks, i.e. learning about best practices and conducting small experiments. A strategic approach employs a set of established methods in a lucid and flexible way.

Until the early '90s, quality assurance through accreditation has dominated efforts to improve in health care quality. Quality assurance is based on inspection where services are compared with standards for structures, processes and outcomes; it therefore represents a judgmental approach to quality. Once standards are attained, possibly in the course of a tour de force immediately preceding the visits by the inspectors, the job is done and it is time to sit back until the next call. Such approach has several negative effects. Personnel may become so observant of the standards that they neglect other important aspects of their responsibilities, and innovative approaches to problem solving may be inhibited. Compliance with a standard may also imply mediocrity if the services concerned are capable of much better performance. Even worse, excessive reliance on standards may encourage gaming, i.e. dishonest behavior as the rule of the contest is merely to appear compliant with them. In summary, achievement of basic standards, even if indispensable, is not enough to guarantee genuine efforts to gradually improve quality.

The philosophy and practice of CQI is based on a set of principles and techniques developed last century between the '20s and 50s' by brilliant thinkers in particular Shewhart, Deming and Juran, first applied to the manufacturing industry and much more recently, late 80's, to health services especially in north America. During the last century, Quality Improvements techniques have been used by industries to improve process performance striving for production processes "on target with minimum variance". Until recently, health settings have seen a negligible application of such methods.

Traditional management approaches to improving structures and processes are largely based on trial and error selecting solutions without sufficient study of the underlying causes. Habitual approaches to problem solving suffer from several shortcoming, in particular:

- No space for individual members and teams to express their potential within the context of shared goals,
- Decisions without involving staff who have crucial knowledge about why problems exist,
- Staff reluctant to reveal difficulties and why things go wrong, lest they be blamed for not working effectively,
- Changes blocked because of resistance from staff or managers.

CQI is an especially valuable strategy for improvement consisting of several steps, carried out in recurring sequences reinforcing each other. It begins with listening to the voice of the customers, then to the voice of the process and finally integrates professional standards into streamlined processes and structures. A precondition of adopting and using CQI is managers and professionals acknowledging that performance can always be improved and, most probably, somebody somewhere else is doing better. The key aim of CQI is a greatly narrowed variation around high levels of performance.

Measurement and improvement are inextricably linked in any model for improvement. Capable improvers identify plausible alternatives to the status quo. They draw ideas from many sources, i.e. customers, relevant theories, learning from direct observation of experts through benchmarking, communication with other professionals and scrutiny of their own advances and failures. The table on page 15 summarizes and contrasts the traditional with the modern approach to quality.

First of all, CQI requires listening to the customers, both external and internal, with the aim to understand their expectations; this can be achieved through questionnaires, sets of individual interviews and focus groups. Comprehension of customers' expectations represents a prerequisite for being both responsive and accountable. Being responsive involves the capacity and willingness to act positively and proactively in response to patients' reasonable and valid wishes. Being accountable entails answering for the use of resources entrusted to somebody; the adoption of fundamental choices; the operations carried out; and the results achieved.

Expectations cannot be guessed; even professionals who spend their entire career in close contact with patients might have a different view from that held by users. For example, DS patients might deem especially important understandability of communication concerning their progress from the first phone contact for booking an appointment with a surgeon to the visit at home by a nurse after the procedure. Another expectation of DS users might concern courtesy of providers and staff and protection of privacy. DS users might also attach

Topic	Traditional Style	CQI Style
Rationale for quality	Conforming to standards	Continuously improving
Focus of quality	Organization defines quality	Customer defines quality
Timing	Reactive inspection/firefighting	Proactive planning/prevention
The role of leaders/ managers	Disciplining	Collaborating
Responsibility for quality	Quality expert unit	Everyone
Beliefs about problems roots	Problems come from employees	Problems come from design and processes
Beliefs about employees	People must be forced to improve quality	People want to improve quality
Beliefs about customers	They are problems	They are partners
Beliefs about processes	Management by opinion/authority Improve within departments using command and control	Management by fact Improve across departments using networks
Beliefs about quality	Quality costs more Attention on financial costs Not enough time to do it Conformance to standards	Quality directs resources Focus on tangible and intangible costs Not enough time to ignore it Conformance to customers' expectations
Methods about quality	Wait for power games or crises to force change	Continuously test small scale changes based on sound theory and evidence

(Modified from Berwick D. Health care quality: a new way of thinking).

special importance to prompt attention by providers when needs and questions arise especially in case of complications or complaints. Some of these aspects might appear trivial to professionals.

Patients are the best source of information regarding interactions and adequacy of communication with service providers; however, health care organizations are not hotels just responding to visitors' wishes. Patients have little technical expertise in assessing the appropriateness and adequacy with which clinical procedures are performed. They do not know what it means to do the right thing to the right patient at the right time in the right way, achieving the best possible results. This implies that awareness of customers' realistic, reasonable desires is only a first step toward improvement and, hopefully, excellence; next, it is indispensable to understand the processes through which services are generated, especially the steps which are most significant in creating value and incorporate relevant professional standards.

Benchmarking is an important source of better ideas to guide continuous improvement. It allows detection and transfer of best practices which account for superior performance. Benchmarking shows that there are better structures, patterns and processes, stimulates curiosity and motivates change. By learning from the best performers and setting improvement goals based on actual processes, organizations become better able to accelerate improvement. Benchmarking value derives from the fact that it not only uncovers precious information, but, more significantly, it transforms staff's viewpoint and behavior. Often great ideas come from studying how other sectors tackle similar processes. A well known example concerns the bar code, first adopted by supermarkets to speed payment operations and aid logistics. Often organizations start benchmarking when they find themselves in a strategic, political or financial crisis, but it would be more productive if they anticipated the pressures from emergencies, and adopted such approach when they are still doing well and have spare time and energies to invest. Benchmarking works best when is an integral element of a CQI strategy.

From a psychological and cultural viewpoint, a precondition of learning is the ability to listen to and the right disposition, we can call it humbleness, to accept that somebody somewhere is doing better, and a constructive attitude originating from not being too defensive about one's own practices. A leader's modesty to gather ideas from others, i.e. employees, partners, and customers, contrasts with a narcissistic personality in a top position, snubbing any advice to improve and hindering any step forward, because she takes for granted that her unit's accomplishments are top-quality and does not need measures to confirm what she already knows. Benchmarking

can interrupt the tunnel vision which affects managers and staff who are not used to looking outside beyond self-imposed limits. To go out and find others who are doing things in ways that are considerably different from what we do, maybe more efficiently, more advanced technically or more responsive to customers' expectations, is a wonderful opportunity for those who enjoy learning new ideas and have a solid professional identity. On the contrary finding out that somebody does better represents a humiliating defeat for individuals with inflated egos.

According to Camp (1993), benchmarking consists of the following sequence of activities:

1. determining what to benchmark,
2. determining who to benchmark against,
3. collecting information from all relevant sources,
4. analyze the gap between what our organization does and what others do,
5. revise our internal performance measurements and goals.

Health care presents just as much opportunity for benchmarking gains as either manufacturing or services. In health care, the key to benchmarking rests with understanding and improving the underlying processes and practices that drive quality and cost.

Another tenet of CQI is management by facts, not only about customers' expectations but also processes. Management based on factual evidence stands out against command and control by opinion and formal authority. Whereas the former model attempts to look at and improve broader processes incorporating multiple departments and creating collaborative networks, the latter deals tentatively and paternalistically with small portions of care delivery within a limited organizational space.

Improvement results from new structures and new processes that are purposefully designed. Intelligent change does not just happen because somebody, even a leader, wishes so; it must be prompted by solid theory and hard data and experimented on a small scale by using a plausible set of measures. As stated before, leveraged, i.e. smart and well-focused, changes can sometimes produce substantial, enduring results.

Initial focus of improvement work should be on the selection of important processes, i.e. frequent and significant because of a known link to an outcome, and on getting the process right. This means taking processes to an established level of reliability within a specific timeline, using reliability design principles instead of hard work and pleas to vigilance.

Although it is human nature to blame others for things that go wrong, Edwards Deming notes that, in most cases, the source of problems lies not with individuals who are incompetent or willfully negligent. Rather, the source is often the futile complexity of work processes, producing a lot of waste, and the lack of understanding how to improve them. Making improvements to processes requires better understanding of how work is done and frontline staff must be involved in this effort.

Leaders cannot simply empower people to discover better ways to work. In reality, the workforce rarely comes up with a bolder challenge to the status quo than leaders, who necessarily play a critical role in promoting change. Capable improvers move promptly to test promising changes on a small scale, then adjust their actions according to what they learn from these tests. At the other extreme, fake leaders do not see better alternatives or are timid in endorsing them; as a result their organizations are bogged down in unproductive routines.

Deming's management theory, that he called a system of profound knowledge, represents the best known and successful method to promote improvement (Deming 1986). Profound knowledge requires an understanding of systems, variation, psychology, together with a theory of knowledge. As already discussed, appreciation of systems consent us to see how their behavior depends greatly on relationships and coordination among parts more than the individual components. Comprehension of variation implies a statistical approach using the principles and techniques of statistical process control. Additionally, in a system where external and internal customers, i.e. patients and providers, are the most important component, knowledge of psychology is also vital, i.e. an understanding of and genuine concern toward patients and professionals. Deming believed that almost every act of management requires not only explanation, i.e. comprehension of current and past performance, but also prediction, i.e. plausible anticipation of the effects of changes on future performance. This brings to the fore the importance of a theory of knowledge, i.e. how we learn about organizational realities. As Deming (2000) explains: "Knowledge is theory. We should be thankful if action of management is based on theory. Knowledge has temporal spread. Information is not knowledge. The world is drowning in information but is slow in acquisition of knowledge. There is no substitute for knowledge."

An organization seriously engaged in continually making changes that lead to progress from the viewpoint of the customer, needs to adopt a system of improvement. The renowned fourteen Deming's principles for management shed light on the main values and beliefs that constitute the bedrock of CQI. Seven of such principles, especially relevant to the subject matter of this document, are the following ones:

- Maintain constancy of purpose;
- Adopt the new philosophy of CQI;
- Improve constantly and forever the system of production and service;
- Institute training and retraining;
- Institute leadership;
- Drive out fear;
- Break down barriers between units.

Achieving constancy of purpose requires setting clear objectives for DS and its information system and devising a lucid strategy to meet them. Consequently, staff carrying out the work become confident they have defined roles designed to meet specific organizational aims, rather than jobs that vary according to shifting priorities arbitrarily and erratically chosen by an incompetent management.

Adopting the new CQI philosophy and improving constantly and forever the system of production and service reflects the need for all staff to embrace the thinking behind continuous improvement and never stop making evidence based efforts to services design and delivery. For example, in order to involve all DS personnel, a task force should be established including representatives of managers and staff that will be affected by the new approach to quality improvement: GPs, nursing, anaesthesia, lab, pharmacy, booking, admitting, medical records, patient accounting, materials management, and finance. Such effort requires expert guidance possibly by external facilitators.

Institute training and retraining underlines that ongoing education and training is crucial for high-quality performance throughout an organization and that changing values, knowledge, attitudes, practices and behaviors is not something that can be achieved effortlessly and swiftly. *Institute leadership* and *drive out fear* imply that an organization cannot sustain high-quality performance without credible leadership, which welcome constructive criticism and suggestions from subordinates. Traditional management style assumes that threat of punishment encourages employees to perform well. On the contrary, a modern, CQI inspired leadership encourages innovation on the part of human resources, rather than stifling them with threats and a paralyzing fear. *Break down barriers between staff areas* stems from the awareness that walls restraining communication and collaboration between departments have a detrimental effect on quality because of the cross-departmental nature of most work processes.

The above mentioned philosophy and principles have been translated into quality improvement practices. Building on Deming's principles and system of profound knowledge, a clear-cut and efficient model for achieving improvements in health care is FOCUS-PDSA developed by the Hospital Corporation of America (Merritt & Morrison, 1988). It involves the following steps:

F Find a process to improve.
O Organize a team that knows the process.
C Clarify current knowledge of the process.
U Understand sources of variation.
S Select improvement strategies.

P Plan the improvement and data collection.
D Do the improvement, data collection and data analysis.
S Study the results.
A Act to hold the gains and continue improving.

The first steps in this process (FOCUS) involve the selection of a problem that is coupled with a work process. Staff, who have familiarity with the process and therefore understand it, are selected to form a quality improvement team and search for information to deepen their knowledge of the process. Based on its comprehension, the team generates ideas about possible root causes of problems. After selecting the most promising theories, the team collects data to test them. Once the root causes of the problem are identified, the team works to select possible improvements, brainstorm to identify solutions and select for testing those with the highest potential.

Plan-Do-Study-Act (PDSA) represents the cyclical part of the improvement process. The proposed solutions are employed in small-scale experiments, and data are again collected to examine the degree of achievement. If successful, the team implements changes accordingly, institutionalize them and adopts an ongoing data collection to make certain that the improvements are sustained. PDSA is a sequential method, introducing science into the act of reflection and allowing reliable learning from what one does (Berwick, 1998a). In essence it consists of inductive learning, i.e. accumulation of knowledge through thoughtful changes, when evidence suggests they are necessary and useful, followed by measurement and thinking about the intended and unintended consequences of those changes. Such formal cycles of reflection, action and again reflection are unusual in daily work which is normally guided by tradition: things are done in certain ways because they have always been done so. Powerful socialization processes teach new professionals the basic rules; too frequently one of the most important lesson is not to question the way things are done. On the contrary, the PDSA model recommends testing change in informative cycles to become part of daily activities throughout organizations.

Primarily, the model attempts to answer the three following questions:

- ***What are we trying to accomplish?*** Improvement must be intended, not just happen as an accident; in other words specific aims are indispensable.
- ***How will we know if a change leads to an improvement?*** Improvement can only proceed from measurement for the purpose of learning and acting logically. Knowing whether a change is an improvement implies the collection of relevant data on baseline performance, plotting the data over time, starting a test of change, and checking whether the charts show an improvement after the activation of change. Answering this question requires developing and operating an IS. Typically, PDSA cycles do not collect data permanently, but only during the experiments.
- ***What changes could we make that we think will result in improvement as defined by aim and measurement?*** This question addresses the central law of improvement, i.e. new aims require changes of systems. It is essential to identify promising changes, test them, to institutionalize those which have shown evidence of success and abandon those which represent useless alterations.

Improving health services delivery requires changing structures, patterns and processes of care. Changes should be based on the results and learning obtained from small tests carried out within a whole system, a single unit and even individual patients. As Don Berwick stated "learning from PDSA cycles has much in common with learning from prudent clinical work, in which therapies are initiated under close observation and adjustments are made as data and experience accumulate". One fundamental notion of CQI applied to health care is that quality improvement deals with effectiveness, safety and responsiveness instead of efficacy.

The appropriate knowledge building tools used for quality improvement are considerably different from those applied to determine efficacy. In the latter case, the gold standard is the double-blind randomized clinical trial, whereas quality improvement involves a sequence of small experiments through PDSA. Such small scale tests are the ideal approach for busy managers and clinicians who need quick answers to current challenges and do not have the resources to carry out major initiatives, which might fail anyway to clarify and solve the real issues. Most clinicians are familiar with clinical trials and much less with PDSA. This state of affairs should be supplanted by a new generations of physicians aware of the scientific basis of both methods and proficient in the interpretation of results and their use.

When the aim is to improve health systems, PDSA cycles are more appropriate and informative than either studies based on experimental design such as randomized trials or the mere implementation of change without quantitative assessment. PDSA cycles are much faster and less expensive than large studies, and can be carried out simultaneously on different processes and units. The resulting improvements can substantially advance an entire system generating surprising breakthrough by means of reinforcing loops of positive influence. The large space "neither of certainty nor of scientific ignorance" between the two extremes of "ideal" science and shallow hands-on management is ripe with opportunities, yet too frequently remains an uncharted territory.

Evidence Based Medicine (EBM) and CQI are complementary to the purpose of providing high-quality health care. EBM establishes the validity and applicability of the evidence to a specific clinical problem by means of the following stages:

- formulate an answerable question concerning a clinical problem,
- design and carry out a set of studies capable to determine the best evidence,
- critically review the evidence regarding benefits and harms and their balance.

Once we know what should be done to patients with a certain condition, the important concern becomes how to guarantee that such evidence is appropriately applied on every individual patient tended by whole care systems. In other words the problem turns out to be a knowing-doing gap, where we know what to do, for example, to patients with an acute myocardial infarction, but highly variable and unreliable processes fail our patients. This is a managerial problem, with which physicians are less familiar than with clinical epidemiology research. CQI is the preferred approach, using techniques like reminders, re-designing of processes with the aim to remove waste and ensure the right action is carried out by default and testing solutions through PDSA to determine what works in a particular setting. It is irrelevant to make an effort and spread a clinical practice supported by an inadequate scientific basis. Likewise it is pointless to stop once the evidence is established, we need to ensure that every individual who could benefit from the technology do obtain it.

EBM therefore strives to establish what are the right things that should be done to patients, i.e. clinical decisions informed by the best available evidence, whereas CQI intends to ensure that evidence-based clinical practices are carried out scrupulously, reliably and without waste by professionals and whole systems of care. These two approaches complete each other and together show clinicians and managers how to do the right things right.

PDSA is a scientifically bright, managerially pragmatic, economically efficient, and politically clever method. It requires psychologically mature users open to change their minds on the basis of new evidence. At the base of a system's purpose and the efforts at improving it are value judgments, and PDSA is also a moral obligation toward the people who entrust life and death decisions on us. A redesigned system may be an improvement overall, but it could also flip the balance of benefits for both internal and external customers. The inescapable political dimension of change requires both the ability to grasp who gains and who loses and skilled negotiation in overcoming resistance to change.

In summary CQI offers an alternative model for addressing work problems. The kernel of CQI is frontline employees that use a variety of analytical tools to gain an understanding of the processes of work, identify the root causes of problems, then design and carry out small-scale experiments to improve work, and finally ensure that gains are maintained.

Translating the above mentioned general improvement principles and models into steps specific to DS services in a certain geographical area should include the following steps:

- A common aim of reducing the burden of surgical diseases,
- An understanding of current DS system of care,
- An awareness of the traditions, values, policies and power balance, which promote or hinder the adoption of DS,
- The design of a locally sensible and actionable alternative to the status quo; the skills and knowledge necessary to implement the change; and the social and political support required for sustaining such effort, including a strong enough and mobilized coalition,
- A comprehension of a clinical improvement model in particular the PDSA cycle, for thinking about current outcomes and the underlying processes, re-designing processes, testing and institutionalizing the effects of change.

Day Surgery as a system

DS represents a major shift in organizing and delivering surgical services and, as a result, a challenging professional, managerial and political endeavor. It represents a breakthrough in surgical services' organization, delivery, safety, patients' satisfaction and cost. DS provides high volume of standardized surgical procedures stratifying patients on the basis of surgical needs, specialty, intervention and age. Such characteristics entail strict control over flows of patients, optimization of inputs' use, and strong coordination across specialties and professionals both within and outside DS units, i.e. General Practitioners and nurses delivering home care. Therefore DS requires tools for standardization such as clinical pathways,

protocols and checklists and a capable and dedicated leadership, knowledgeable and experienced in the use of CQI tools.

DS attributes give rise to an effective, safe and efficient service. They also make DS completely different from traditional surgical wards, which serve complex clinical cases affected by unclear health problems and/or unstable conditions, and necessitate elaborated diagnostic, procedural and therapeutic services, sometimes involving severe complications and adverse events.

Even if a DS system and its components, such as an operating room team, are called "micro-systems" to emphasize their small size, they are extremely complex. An operating room team may include several surgeons and assistants, anesthesiologists, and nursing and support staff, and multiple mechanical and electronic devices. Each component interacts again and again with many of the other elements, in particular each professional's background, role and character; the social and psychological circumstances of the patient and her clinical problem, the degree of cooperation among DS unit personnel, general practitioners and nurses delivering homecare.

A metaphor for DS is a clock, where mechanisms must work smoothly, without surprises or obstacles, supplying the right services in the right ways every time to a large number of patients. Given that DS represents the approach of choice for around 80% of surgical activity, the strengthening of its IS is an important endeavor for quality improvement and also for managerial, economic, ethical and political reasons.

Even if its design is well informed and lucid, DS, like any other complex system, does not function efficiently without purposeful and persistent change for the better. Important issues within an organization should not be identified, diagnosed and tackled only after crises burst open, possibly threatening its survival. Devising and implementing changes should be continuous, coordinated, and anchored in the organization's fundamental purpose. To accomplish this, an organization needs, first of all, to recognize itself as a system and operate as a system. In order to approach DS as a system, it is essential to have an understanding of systems and their variations, i.e. an appreciation of system and statistical thinking.

DS improvement can only start from an overall view of elements within and outside the DS unit, where procedures are carried out, and their interaction. One repercussion is that some professionals, especially surgeons, necessarily loose the illusory control over the whole system. This is not something that professionals, used to operate within the narrow and familiar boundaries of a traditional surgery ward, can accept lightly. Another ramification is the necessity to work collaboratively with other health professionals and staff with administrative responsibilities, for example for booking first appointments and follow up visits or managing the parking area dedicated to DS. Just as any other system, DS must be led and managed. An educated and fair-minded leadership using wisely an IS are two essential elements of success.

In conclusion, system thinking suggests that the design and strengthening of a IS for DS should be part of an overall effort to set up and improve DS. Focusing only on the IS as an isolated element, separated from an endeavor to design and constantly improve DS, will have little effect on DS performance. A perfectly designed IS might be a sort of a foreign body in a DS service managed by second-rate bureaucrats. At last, after a somewhat lengthy discussion around the theories and management principles that should guide DS undertaking, we turn to a policy for DS information system. A policy elucidates, by way of a document, the principles that must guide the development and management of an important issue.

Part 2

A Day Surgery Information Systems Policy

The first part of this document stressed that organizations are systems, heavily influenced by connections among their parts, more than by the isolated performance of its elements, frequently lack system and statistical thinking; and too frequently suffer from pathologies, whose main symptoms are high variation and low reliability of processes. DS is also a system, whose aim is to deliver appropriate, accessible, effective, safe, equitable, and socially satisfactory surgical care without night stay to individuals and communities.

A far-reaching transformation, such as DS, requires a radical change of structures, processes, and patterns away from traditional surgical services. Structures include policies, regulations, roles for organizations, boards, teams and individuals, physical space, and equipment; and patterns consist of practices, behaviors, power relationships, learning and decision making styles. Once again, a key concept is integration of purposefully designed structures, processes, and patterns, in order to achieve an overall coherence made of mutually reinforcing components. A common fault when promoting a strategic change is a piecemeal approach, which consider structural, process and pattern changes disjointedly. For example, process changes imply structural supports and both require congruent patterns of behavior, practices and organizational values.

DS functioning depends, among other factors, on the availability of reliable and valid data and their transformation into knowledge. An IS, and its policy, are crucial structures, a key element in the whole set necessary to ensure that DS design, implementation and continuous improvement is successful. Tim Ferris, co-chair of US based National Quality Forum's Consensus Standards Approval Committee, asserted that "Measures are the only way we can really know if care is safe, efficient, effective, and patient-centered. Performance measures also help us improve faster. We can make corrections earlier in providing care." Accordingly measures maintain everyone's focus on what matters most to patients. The aim of an information system is not only to learn how an organization is performing, but, above all, to set a foundation for a better performance (Eddy, 1998). Just observing is not enough; splitting the responsibility for analysis from the authority to act is an example of bad management.

Without measures it is impossible to build a picture beyond intuition. Heuristics, i.e. intuition based on experience, is critical in guiding our understanding of reality, but quantitative analysis sharpens our insights reducing the risk of biased interpretations. Health services performance is too important to be left to intuition alone. Understanding of surgical services' and DS' delivery performance by different organizational actors, i.e. policy-makers, managers and providers, aided by quantitative analysis represents a precondition of design, management and improvement. The alternative to analysis based also on quantitative and qualitative knowledge is to decide on the basis of impressions and hunches, or worse to decide on the basis of politicking, i.e. exchanging favors for personal and group gains.

A HIS is an essential source of quantitative analysis. ISs are composed of data, indicators, information, presentation and interpretation with the aim to support decision-making (Llloyd 2004). Data are basic elements which cannot be interpreted without being transformed and applied to a specific context. Vast quantities of data are relatively easy to access; however, rather than simply using the currently available data and letting those shape the questions which can be asked, it is important first to set priorities identifying the most important health care objectives and strategies and then find answers to the two following vital questions: who needs the information and for what purpose?

Information is data processed and analyzed in a formal and intelligent way. An indicator is a type of information, i.e. a measurement tool that is used as a guide to monitor and evaluate one dimension of health care, for example quality, safety or efficiency. A measure should be valid, i.e. able to reflect what purports to measure and capture its key dimensions; and reliable, i.e. objective, not subject to dispute because it provides the same answer if measured by different people in similar circumstances. Indicators should also be comprehensible, i.e. easily communicated by analysts and understood by users; reasonably cheap; and timely, i.e. not too remote from when events have happened. Furthermore, they should be capable to measure change, i.e. have enough sensitivity, and should reflect changes only in the situation under analysis.

Indicators are neutral, their sole purpose being to provide information. When they meet the essential statistical tests of validity and reliability, indicators allow comparisons to be made between health care facilities across local, regional and national boundaries (Llloyd 2004). Validity and reliability of data can sometimes be demolished by manipulation; where this happens the managerial and professional performance is so impaired that attempts at improvement only represent the facade of a propaganda operation. In reality, even valid and reliable indicators sensitive to change are indirect and partial measures of a single aspect of a complex situation continuously evolving. For that reason a more detailed data collection and analysis by the team of users is essential to determine what the indicator means.

Each indicator should be linked not only to a health care

element but also to a standard so that it will be easy to determine whether an organization's performance is satisfactory; still organizations successful in achieving established standards should continuously search for improvement opportunities. When based on ordinary accomplishments, such as a system's average, standards are an impediment to great performance. Therefore standards should be based on benchmarks, i.e. real superior performance, which contributes to creating a positive tension between current reality and possible results. Still, it is important to emphasize that best organizations do not consider benchmarks as limits to what is possible; instead they continuously aspire to discover and implement original ways on the road to excellence.

A proficient use of a IS is a complex task, very far-off from a banal reading of tables confirming what we already pretend to know. Information must be transformed into knowledge and sense-making; this means being able to see and interpret reality coherently. Still, recognizing that some aspect of performance is below acceptable levels is different from being proficient in understanding the reasons behind the problems and designing appropriate responses. Furthermore, knowledge is not decision-making; in order to formulate and act upon a congruent set of decisions, authority, responsibility and accountability must be assigned to capable, willing and motivated individuals placed in coordinated, aligned and collaborating units in a organizational context guided by clear goals and strategies.

IS purposes, primary and secondary users, sources and quality of information, and availability of expertise to support data collection, analysis and interpretation differ very much across MSs. Consequently there is no single magic formula for developing a DS IS in Europe. Although it is important to put forward a set of principles for IS development and recommendations to implement it, national and local peculiarities, both opportunities and obstacles, must be taken into thorough account and substantial and intelligent adjustments are necessary.

This second part of the document covers the following central aspects to a DS IS policy:

- IS goals,
- Sources of data,
- Dimensions of performance,
- Secondary users,
- Analysis and presentation of indicators,
- Promotion of measures' use.

Several matrixes help to clarify relationships among the above mentioned dimensions.

IS goals

The starting points for designing and improving a health care IS are the decisions the system is to support, and the ways the system's results will be used. In general, a HIS should serve multiple purposes, i.e. to design a health care system, facilitate its implementation, and improve and account for its performance, i.e. quality, efficiency and equity. More precisely, main goals of a DS IS include (McGlynn et. al. 1998):

- Support to authorization, accreditation and certification,
- Evaluation of performance,
- Quality improvement,
- Accountability,
- Transparency, and
- Research.

As already explained, achievement of basic standards through authorization, accreditation and certification, even if indispensable, is not enough to guarantee successful efforts to quality improvement. Therefore, it is crucial to adopt methods that support a learning environment promoting accumulation of pertinent knowledge and skills with the aim to improve performance. Such approaches are at the heart of CQI efforts. The primary aim of management and its tools, including the HIS, is improvement (Solberg 1997). Another valuable goal of a IS is evaluation, i.e. the systematic assessment of a system performance, in order to establish the degree of accomplishment of its aims and decide useful adjustments, wider transformation, or even its termination. Other important aims of HIS are research, accountability, and transparency.

Without valid and understandable information, accountability and transparency become at best impossible, at worst an exercise in manipulation of reality. The measures selected for accountability are generally measures that matter to external parties, in particular outcome data such as risk of death and also use of resources, such as costs of care. Since

Source / Feature	Completeness	Correctness	Timeliness	Complexity	Cost
Administrative	+	+	+	-	-
Enrolment	++	++	+	-	-
Medical records	+++	++	+++	--	---
Survey	++	++	++	---	---
Audit	+	+++	+	--	--
PDSA	+++	+++	+++	--	--

outcome data are difficult to measure, also because some of them deal with rare events, proxy measures such as returns to operating room within 24 hours and hospital re-admission, or surrogate measures such as patient satisfaction with the service or treatment, are often used. Data for accountability do not usually provide information about how the outcomes were achieved, or how processes might be changed to improve them. Accountability measurements are usually presented in evaluation reports and distributed to a wide audience, because they are meant to be accessible and non-confidential, and be used for judgment, not for improvement.

An important point that professionals designing and using IS must consider is the fact that a combination of measurement for accountability or research with measurement for improvement can sometimes be counterproductive. Measurement for research is typically too slow, too expensive and too elaborate to be useful for improving health care processes.

Further goals of HIS include (McGlynn et. al. 1998):

- Ensuring patients are better informed so that they can choose providers on the basis of performance;
- Defining payment arrangements and establish incentives promoting care's improvements e.g. pay for performance (P4P), pay for reporting (P4R), and performance-based contracting;
- Helping clinicians to make diagnostic and treatment decisions, i.e. ensuring the most appropriate sequence of tasks; promptly adapting the clinical path to unexpected departures from clinical progress, e.g. a complication or an adverse event; following-up patients; but also avoiding waste from repeated exams or duplication of drugs.

A functional IS is required not only for performance measurement, but also to support the modern practice of medicine. Several recent efforts to measure performance have recognized its feasibility and contribution to the modernization of clinical practice. The use of quality of health care measures to promote improvement, to shape reimbursement of services and to enhance transparency is now widespread, not only for hospitals, but also ambulatory and other community based care settings,

Sources of data

Main sources of data about DS performance include (McGlynn et. al. 1998):

- Administrative,
- Enrolment,
- Medical records,
- Surveys,
- Audits,
- PDSA cycles.

Most organizations employ several sources of information for multiple purposes. Given their easy access and prompt availability in electronic format, administrative data are the most frequently used data source to build measures, followed by patient surveys, and medical records. Many computerized systems are intended to serve administrative objectives and, as a consequence, some performance measurements based on them are approximate. Health care delivery rely mostly on paper medical records, and the only means to collect process data is by a burdensome and expensive manual review of medical records. However data on care processes are extremely valuable because they represent one of the main precondition of improvement. Surveys allow us to investigate important topics through the inquiry of a representative sample, drawing inferences on the whole population of interest with a known degree of uncertainty. Audits and PDSA cycles are sources of information rather limited in scope compared to other categories, but represent in depth inquiries, and indispensable prerequisites of local improvement efforts.

Secondary end users need to understand which questions can be answered by each data source, its limitations and how new information and merging of multiple sources can facilitate decision making. Integration of information should occur at two levels, i.e. combination of different sources of information, e.g. ad hoc surveys and administrative data; and integration of diverse elements of performance in an overall framework capable to clarify the relationships among them.

A critical concern in planning, building, and maintaining an IS is whether the information it contains is accurate enough to be used in a decision making process. Another critical characteristic of a routine IS is timeliness. In many occasions it is unable to provide the right data fast enough, i.e. producing information for decision makers within the time frame required by the decision making process. What is needed is a prompt, even if temporary, data collection able to provide answers to important and urgent questions. Managers responsible for planning health care IS should define timeliness standards with which data are made available to different users. Standards should be reviewed and possibly revised over time on the basis of their adequacy and the evolving needs of the system's users. The table on page 23 shows key data quality features for each source of data, i.e. ompleteness, correctness, timeliness, complexity and cost.

Predictably, there are trade-offs among attributes. At one extreme, analysis of administrative and enrollment data is relatively simple, quick and inexpensive, but presents limits of completeness, correctness and timeliness. At the other extreme, survey data tend to have satisfactory completeness, correctness and timeliness, but are difficult to design and carry out, and are expensive. Data collection from clinical records has compelling advantages in terms of completeness, and timeliness, but it is slow and expensive. Survey data collection and analysis has clear-cut pluses in terms of completeness, correctness and timeliness, but it is rather slow and expensive and requires expertise not easily found among clinicians nor managers. PDSA combines advantages in terms of high completeness, correctness and timeliness with relatively limited cost and technical complexity, once the nuts and bolts of this approach are learned.

The available sources of health care data are usually too incomplete and/or of insufficient quality to meet diverse information needs. A familiar limitation of data is a lack of distinctive identifiers for patients and facilities, rendering it

Dimension Source	Resource	Output / Access	Quality (processes / outcomes)	Safety (failures)	Satisfaction / Response	Cost / Efficiency
Administrative	Y	Y				Y
Enrollment		Y				Y
Medical records			Y	Y		
Survey	Y	Y	Y	Y	Y	
Audit	Y		Y	Y		Y
PDSA		Y	Y	Y	Y	Y

impossible to track the course of patients' care over time and to compare patients and providers across systems. Another shortcoming of data originate from variation in the quality of the same type of data over time and space, limiting the capacity to draw reliable inferences.

Dimensions of performance

A critical step toward building an IS is to conceive a relevant classification of indicators. According to Boxwala et al. (2004), a taxonomy, i.e. an approach combining accepted terminology and principles of the science of classification, can contribute to multiple goals at the organization, team, and individual provider level, in particular:

1. Improvement of quality and safety, i.e. identifying opportunities for better and safer care;
2. Benchmarking, i.e. determining the dimension and nature of over- and underuse of services, and frequency of errors, with the aim to carry out comparisons among organizations and identifying best performers;
3. Causal Modeling, i.e. ascertaining or inferring the causes of poor quality and safety, and conceiving/implementing interventions capable to diminish their frequency;
4. Compliance with government, accreditation and licensing bodies, i.e. mandatory and voluntary reporting to regulatory agencies.

Taxonomies are useful tools, which facilitate the detection and measurement of flawed quality and safety, and the evaluation of the impact of improvement initiatives. Their potential can best be exploited as clinicians and managers not only make sense of each category as isolated fragments, but consider them as a whole. Looking at indicators in isolation from an understanding of the network of feedback loops influencing providers' and organizational performance does not help much. For example, in the field of public health, only when we look "upstream" at the distal determinants of ill health, we will be able to formulate policies capable to intervene deeply in the web of causation. Similarly, in the area of quality and safety, it is indispensable to examine and act on the root causes, i.e. latent failures. Otherwise, we will only scratch the surface of the problem.

System thinking suggests that DS should be analyzed through an approach distinguishing between customers, inputs, processes, outputs and the relationship between inputs and outputs. Customers are both DS beneficiaries, i.e. patients whose needs are identified and alleviated; and professionals and operators whose knowledge, skills, motivation and coordination ensure that appropriate, quality and safe services are delivered. Inputs refer to the resources necessary to deliver the services, e.g. staff, Euros, consumables, infrastructures, technologies and policies. Processes are means which transform inputs into outputs, which satisfy users' needs and demands. Outputs are products or services delivered. Finally it is important to clarify the average cost of inputs as a whole and per procedure, and the relationship between outputs and inputs, i.e. productivity and efficiency.

Further, being DS a surgical service, it is important to gain insight on aspects peculiar to health care, specifically access, safety and outcomes. Access concerns the availability of DS units in a specific geographical area and population; more significantly, access involves the waiting time between a diagnosis and the relevant procedure. Safety involves the delivery of services without preventable adverse events, i.e. a key element of health care since the assertion "first, do no harm" of the Hippocratic oath. Outcomes have to do with the degree of improvement or, on the opposite, deterioration of patients' health status as a consequence of encounters with health care.

Such frame guided Day Surgery Data Project (DSDP)[2] approach to the selection of sets of essential and ideal DS indicators. DSDP also built a consensus process around sets of indicators, by means of a Delphi study, engaging a group of policy makers, managers and clinicians; nevertheless it did not involve patients and their families. Having a single core measurement set for a MS is the only way to identify regional differences, set national benchmarks, compare local health authorities, and public and private hospitals. For comparison purposes, each health organization should report a single essential indicators set. This would also considerably diminish the burden on health organizations, and the confusion among policy-makers, managers, clinicians, and citizens.

A HIS supporting DS should elucidate each of the above mentioned components. In general, current assessment and improvement efforts put greater accent on the broad spectrum

2 DSDP was funded by the European Commission - DG SANCO based in Luxembourg.

of health services and continuity of care. Ideally, a DS IS should also devise measures able to capture performance of GPs and home nurses, coordination of care, longitudinal change in outcomes, and costs of episode-of-care.

From the perspective of DS improvement goals, the most important measures are, first of all, process, and, secondly, outcome indicators. Health outcomes measures suffer from several drawbacks: probability factor, rarity, delay, weak control, confounding and comprehensibility. All these features together represent an important limit of these measures, which primary and secondary end users should be aware of. The probability factor means that most health outcomes are (sometimes highly) probabilistic. Good outcomes can happen when delivered services were inappropriate or of low quality. The opposite can also occur, i.e. bad outcomes can come about when every appropriate process was conscientiously and skillfully carried out in the right sequence for the right patient at the right time. The rarity factor points at the fact that some events, like death, are rare for most conditions and procedures. Still more so in a service such as DS which selects patients on the basis of good general health status and relatively simple procedures. The most relevant implications of the probability and the rarity factors is that these measures require large number of observations.

A third limitation of outcome indicators is that the time elapsing between procedures and result can hide their relationship. A fourth weak point is uncertain control over outcomes, i.e. how far results are attributable to health services opposed to other factors. Another shortcoming of outcome measures are confounding factors which have to be adjusted by way of multivariate models. A final weakness is that outcome indicators, such as a risk adjusted mortality ratio, are not easily understood by professionals and even less so by lay people; this obviously represents an obstacle towards the acceptance of measures.

If the health outcomes for a disease are infrequent, delayed, weakly controllable, and/or heavily confounded, corresponding indicators will produce inaccurate results, which, in the context of clinical and managerial decisions and patients' choices, are not just an academic puzzle, but a distorted representation of reality. This either sends secondary end users off track or make them conclude that the best alternative is to ignore irrelevant and doubtful information. Overstated reliance on statistical adjustments may produce measures that are misleading also for patients and their families who need to make routine choices about facilities and physicians.

Given that outcome indicators present several weak spots and improvements essentially derive from sound changes to processes, the proper approach is to use more process measures. Evidence based processes tend to tell the truth in a more straightforward way compared to outcome indicators: we either cleaned our hands before touching a patient or not, and there is no confounding which blur my degree of compliance or that of my colleagues. Most processes are common, their effects close to their delivery and controllable, and rarely confounded by other factors. An example is the administration of an antibiotic one hour before surgical incision. The percentage of surgical patients receiving such prophylactic drug in time and the percentage of the same group of patients who discontinued the antibiotic within 24 hours after completion of the surgical procedure are easily comprehensible by all stakeholders and, more importantly, can in a straightforward way, indicate who needs to do what. This is so for all other evidence based processes.

In order to shed light on the above stated dimensions, IS designers should select a set of essential indicators. Thus a principle informing IS is parsimony, i.e. collection of a limited group of highly valuable indicators. The heavy responsibility of proof should be on measurers proposing new indicators to conduct a formal assessment and document that the measure they want to add is evidence based, and cost-effective. Indicators should be selected on the basis of the following prioritization criteria:

- importance of conditions or procedures (e.g. prevalence/ incidence of conditions, frequency of hospital admissions);
- importance of adverse events associated with conditions or procedures (e.g. severity, disability, reduced productivity, direct costs);
- scientifically acceptable measure properties, i.e. when computed produce reliable and valid results;
- usable, i.e. comprehensible and relevant to anticipated secondary end users;
- feasible to collect with data retrievable within reasonable burden;
- assumed variability of processes, outcomes and risk of adverse events;
- potential improvement of quality and safety of care.

The weight assigned to a measure should signal the degree of importance of a related condition or procedure. Consistently, administrators should ensure their commitment to the improvement of data collection, collation, manipulation, analysis, interpretation and use. If the assessment of a certain dimension of performance is crucial, it follows that appropriate conditions must be produced, so that measures are credible and consistent.

An IS should also avoid too many measurers, where health organizations are overwhelmed by multiple requests made by different and inadequately coordinated institutions. Sometimes measures for accreditation purposes contain slight differences in definitions, time periods, or sampling methods, to measures requested for accountability reasons. Such situation imposes a heavy, useless and frustrating burden on health organizations, jeopardizing the credibility of requesting institutions and damaging the collaboration between them.

The following table shows which sources of data help exploring which dimensions of performance. For example, administrative data allow us to examine features of resources, outputs and access, whereas medical records provide insights on quality and safety.

Dimension Source	Resource	Output / Access	Quality (processes / outcomes)	Safety (failures)	Satisfaction / Response	Cost / Efficiency
Administrative	Y	Y				Y
Enrollment		Y				Y
Medical records			Y	Y		
Survey	Y	Y	Y	Y	Y	
Audit	Y		Y	Y		Y
PDSA		Y	Y	Y	Y	Y

Secondary users

The primary end user is any organization that is directly engaged in assembling health care performance measures and make them available to secondary end users with the anticipation, that these organizations and individuals, provided with the responsibility and authority to manage organizations and systems at various level, act consequently (McGlynn et. al. 1998). The primary end users play one or more of the following roles:

- gathering data;
- using data to construct measures;
- computing performance scores of providers.

Secondary end users will use the performance measures to guide strategic and operational decisions and also to answer research questions. They include clinicians, DS unit managers, DS Regional/National managers, policy-makers, citizens and researchers.

Secondary end users also comprise purchasers of health plans, e.g. insurance companies, and international actors such as the European Commission and the OECD. The latter ones only need a few comparable measures.

Each actor has different perspectives and need information for different reasons. Distinct users may have a common interest in a general issue but intend to ask very diverse questions about it; the ways in which those questions differ will have important implications for the data required.

Clinicians need to monitor their team and organizational performance, constantly improve quality, safety and patients' satisfaction and be accountable to their managers and colleagues. In addition to similar uses employed by clinicians, DS unit managers should also ensure the conditions which make authorization/accreditation/certification possible; improve flow of patients, information, supplies and clinical decisions; as well as enhance efficiency and responsiveness; and be accountable to their supervisors at local and Regional level. Regional and National DS managers have also to design and manage the authorization/accreditation/certification system, evaluate the system of DS services delivery ensuring its appropriate use, easy access and high coverage and propose significant and articulated changes in policies, strategies and systems.

Policy-makers must identify the values, aims and principles of the authorization/accreditation/certification and evaluation systems; revise them so that their relevance in a constantly evolving context is maintained; make allocation decisions; and be accountable to citizens and their representatives by means of appropriate channels. Citizens need to choose facilities, units and health professionals able to meet their health needs and to respond to their expectations. Finally, researchers should contribute to the evaluation of DS systems by more sophisticated analysis, as well as conceive and carry out both original investigations on several aspects of DS performance and improvement effort. These perspectives are substantially different spanning from an insider looking at detailed steps behind achievements and failures, to an outsider looking at the overall performance of a subsystem like DS.

The use of different types of measures depends by the end user, the setting of care, the mandate, and the legislative and cultural context in which measures are being applied. The table on page 26 summarizes HIS main goals and most important secondary end users, identifying on which goals each one tends to focus its attention. For example, clinicians are mostly interested in quality improvement and research. They are also very receptive to accountability data when published. Policy makers, being rather distant from care delivery and having responsibility for the overall performance of health care systems, pay special attention to authorization/accreditation/certification, evaluation and accountability goals

The next matrix, page 26, intersects IS goals with dimensions of performance. At one extreme, accreditation and certification goal essentially looks at structures, whereas accountability deals with every component. DS quality improvement should mainly emphasize process indicators, also because deaths are extremely rare. This fortunate fact is, from a statistical viewpoint, an example of the tyranny of small numbers.

When appropriate, measures should explicitly link processes using the "all or none" rule. This means that when bundles of care are tied by very strong evidence, and by time and space, measurements should be of the kind "all or nothing". For example, if one activity is not carried out of five composing a bundle of care, the corresponding measure will be as if no task has been completed.

Dennis O'Leary (1995), former president of the Joint Commission on Accreditation of Healthcare Organizations, was well aware of the dilemma arising from the essential role that quantitative analysis plays in health care improvement and the perils deriving from a superficial approach, when he

Goals	Accred / Certif	Eval	Improvem	Accountab	Research
Users					
Clinicians			Y	Y	Y
DS Units managers	Y		Y	Y	
Reg/Nat managers	Y	Y	Y	Y	
Policy-makers	Y	Y		Y	
Citizens		Y		Y	
Researchers		Y			Y

Dimension Goals	Struct	Output / Access	Quality (processes / outcomes)	Safety (failures)	Satisfact / Respons	Cost / Efficiency
Accredit / Certific	Y					
Evaluation	Y	Y	Y	Y	Y	Y
Quality improvem			Y	Y	Y	Y
Accountability	Y	Y	Y	Y	Y	Y
Research	Y	Y	Y	Y	Y	Y

stated that "the problem with measurement is that it can be a loaded gun, dangerous if misused and at least threatening if pointed in the wrong direction." By training, physicians are quite familiar with information resulting from biomedical and clinical research; conversely they are less accustomed to data for improvement and even less so to statistics for accountability. If purposes of information are confused or mixed up, results can be detrimental. Different purposes and recipients of communication require distinct data, analytical methods, graphical presentations and channels. In other words there must be clarity not only about aims and audiences, but also coherence with analytical and communication tools. Confusion about such issue can cause counterproductive effects such as resentment, resistance and strained collaboration, for example between secondary end users and providers.

When the aim is accreditation or certifica¬tion, structural measures are the most frequently used. As we already emphasized, processes are the main focus of every improvement effort. Only better systems and processes can deliver better results. Coherently, today process measures are the most frequently used by modern health systems. When the goal is improvement, information is assembled with the intent to better comprehend the extent and nature of the problematic process from the viewpoints of patients and providers, identifying current roles, tasks, sources of variation, waste and frustration.

Information is also put together in order to motivate change by showing the scope of the challenge and to allow comparisons with measurements repeated after changes are introduced and institutionalized. These data must be kept confidential. Public access is not only a waste of time, but a bad mistake because it probably creates distress from reciprocal accusations in search of somebody to blame, diverting attention and energy away from the real objective, i.e. a structured process improvement, such as PDSA cycles. Measures are limited in number, mostly process indicators, simple to collect through repeated small samples, not highly reliable, with no risk adjustment, and specific to a unit or a team. Improvement initiatives are completed within short periods of time by heavily involved owners of the process.

When the goal is accountability, data are presented with the intention to transparently compare performance of different hospitals, units and providers, reassure primarily the public and policy makers, and next managers and clinicians, prompt necessary change and substantiate decisions concerning the organization of health services. In this case, public disclosure is essential, samples are wide and might even involve whole populations, data are collected retrospectively and their elaboration requires external expertise; involvement of providers is limited or absent. Accountability measures are few, both process and outcome indicators characterized by high validity and reliability, together with patient-satisfaction and cost. Contrary to improvement efforts where reliability is not so important, this dimension, alongside validity, become essential for accountability. In a recent article in the NEJM, Chassin et al. (2010) have identified the following strict four criteria for accountability measures that address processes of care:

1. A strong evidence base showing that the care process leads to improved outcomes;
2. The measure accurately captures whether the evidence-based care process has been provided complying with definite standards;
3. The measure addresses a process that has few intervening care processes that must occur before the improved outcome is realized;
4. Implementing the measure has little or no chance of inducing unintended adverse consequences.

The authors propose that only measures meeting all four criteria be used for purposes of accountability, whereas other indicators meeting less strict criteria should be used for quality improvement initiatives. Outcome measures for accountability purposes necessarily are risk adjusted in order to control for confounders due to case-mix.

In general the evidence shows that public reporting of performance measures have minor effects on consumer choices, and a much stronger influence on providers behavior. Hence although the intention and the rhetoric underline the importance of free, and therefore informed choice, by consumers of health care, coherently with democratic values, in reality citizens select hospitals and providers on the basis of other criteria, such as easy access, previous experience and words of mouth. Nevertheless given that clinicians pay serious attention to public reporting and presumably take initiatives to improve their performance, the end result is, by and large, positive.

When the goal is research, the meaning of gathering information is to predict and explain cause-effect relationships and inform the scientific community and hopefully policy makers, managers and providers about the new findings and their implications for planning and practice. Circulation of information usually remains within the boundaries of limited groups and the language is for professionals and experts. Confidentiality about subjects is strict. Data collection is very complex, lengthy and involves numerous measures, frequently repeated, and samples are large in order to reduce uncertainty.

Analysis and Presentation: Statistical Process Control applied to Day Surgery indicators

The approach to presentation of data for improvement should be that of a dashboard, like in a cockpit where pilots check the instruments which give them clear signals or at least clues about what is going on, what will probably happen next and which decisions are required to complete a safe flight.

Indicators are useful, though partial, measures of a segment of reality; their interpretation is greatly facilitated by graphical presentations. Prior to presentation, a simple and very effective technique to organize data and indicators is stratification, which separates data gathered from groups that are deemed different so that patterns can emerge instead of being buried in averages. Common tools to present and then analyze indicators include:

- Histograms: the most frequently used graph for showing frequency distributions, i.e. how often each different value in a set of data occurs;
- Scatter diagram graphs plotting pairs of numerical data, one variable on each axis, to look for correlations;
- Box and whisker plot: a tool used to display multiple measures of variation, such as median and quartiles, on a single graph;

From a CQI perspective, where understanding of variation is a foundation of improvement, and beyond the traditional graphical presentations mentioned above, the most important graphs are control charts, which study how a process changes over time and space. Adding the time dimension to analysis, i.e. obtaining time series and not just single points in time, is invaluable to improvement efforts. Comparing current data to historical statistical limits leads to conclusions about whether the process variation is consistent, i.e. statistically in control, or is unpredictable, i.e. statistically out of control, affected by special causes of variation.

Reports on performance either with the aim to improve or to judge, should avoid a league table approach where organizations are compared and supposedly ranked in order of achievement. Ranking charts or ladders show units or whole systems arranging them from the "top" to the "bottom" of performance. Such use of information, especially by actors not directly involved in a process, initiate emotional responses; delight of the few coming out at the top and indifference, disappointment or cynicism, even fierce opposition, by most. Ranking can, as a result, more easily cause manipulation of data collection, collation, manipulation, presentation and interpretation. Moreover, standings are habitually not based on statistical methods, which implies that many differences are not worth mentioning. SPC not only overcomes the scientific problem concerning chance and enhancing accuracy, but also represents a constructive and useful approach both to systems improvement and judgment, skillfully surmounting the difficulties about ranking. Transcripts are for students judged by teachers, not for peers trying to learn from their own and others' performance, and to continuously improve services.

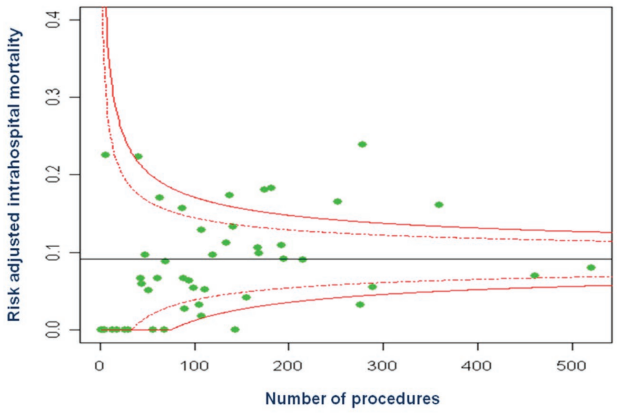
Control charts are therefore the main graph tool used to understand variability and interpret indicators when our aim is to improve systems and processes. There are several types of control charts, depending on the nature of the outcome in study. Main categories include:

1. Attribute control charts used for discrete data and
2. Variable control chart used for continue data.

Regarding discrete data, NP and P chart are based on the binomial distribution, whereas C and U chart are found on the Poisson distribution (Farrokh et. al. 2001). G and H chart are used to count the number of events among rarely-occurring errors, for example foreign object left in the abdomen. Furthermore, CUSUM (CUMulative SUM) chart is an efficient addition to the above tools and is widely used in health care settings to monitor outcomes in real time where services are delivered. Most of CUSUM charts used in the context of health care are Poisson-based CUSUM charts for count data. Another method of using risk-adjusted data to monitor the

ongoing performance of a single unit is the VLAD (Variable Life Adjusted Display) chart. Finally, funnel plots are used as a graphical aid for institutional comparisons, where an estimate of underlying quantity is plotted against an interpretable measure of its precision (Spiegelhalter 2005). Funnel charts are used for the comparisons of mortality risk of patients admitted in different hospitals or followed by specific physicians. An example from the Veneto Region Health Service - Italy is included below.

Hip fracture: funnel plot of risk adjusted intrahospital mortality, Veneto Region, Italy, 2005.



From: Gnesotto R., Gennaro N., Turra R., et al. (2007) Rapporto su misure di efficacia, accesso, sicurezza, ed equità del Servizio Sanitario Regionale del Veneto, Agenzia Regionale Socio-sanitaria, Venezia

Promotion of measures' use

HIS usefulness derives from the capability of primary and secondary users to fully use its potential which also means understanding its limitations and using deeper analysis when appropriate. Current utilization of performance measures by secondary end users vary widely. The design and implementation of a HIS should also carefully consider how to promote its effective use. Without this step, a compelling effort by designers and primary end users can produce no effect. A first point to bear in mind is that most primary and secondary end users are very busy in other important tasks and can dedicate little time and attention to measurement; therefore those who design a IS should clearly focus on high reliability measures, whose potential for important improvements of care is firmly established. Among national public institutions, Ministries of Health and National Health Agencies should put pressures on governments and parliaments in order to pass legislation mandating public reporting of a small set of validated structural, process and outcome measures by all public and private hospitals. Hospitals which are unable or refuse to report should face severe disincentives and be on a list made public. Ministries and Agencies should also (McGlynn et. al. 1998):

- endorse a set of essential, high-value and high-leverage measures built on a broad process of consensus building involving managers, citizens, and providers;
- provide full measure specifications;
- spell out where and how measures are being used;
- align mea¬sures to make reporting lean;
- make explicit the link between each measure and its end use;
- ensure a strong and integrated data infrastructure necessary to assemble the indicators;
- define standards (e.g. data fields and not free text) for electronic health records (EHRs) and devise strategies for their diffusion;
- prepare guidelines and train staff on data collection and analysis;
- design a user friendly web-site;
- establish a solid structure responsible for the overall management of the initiative able to monitor and support primary and secondary end users and guarantee validity and reliability of measures;
- be transparent in divulging the scientific evidence base of the measures in order to promote its accept¬ability among clinicians;
- disclose measures at regular intervals;
- make known improvements of performance following measures' publication; and
- build trust in the measurement process.

Health Ministries and Agencies should also establish a national program promoting continuous improvement; create a longer list of structure, process and outcome measures adaptable to local use, for example taking into account size of denominators; identify priority criteria; provide estimates of cost of measures; grant assistance and ensure high visibility to best examples and practices. This program should also explicitly integrate different indicators, sources of data, and methods such as surveys, audits and PDSA cycles. Measures developers and endorsers, including scientific associations such as the International Association of Ambulatory Surgery (IAAS), foundations and government agencies, should support the use of performance measures. Private hospitals should adopt mission and vision statements which explicitly attach key importance to continuous improvement and accountability and are committed to build a solid IS.

Without strategies bolstering IS utilization and supported by a constructive culture, a IS turns into a bureaucratic tool, only apparently a prerequisite of improvement and an instrument of accountability, in fact hiding, by design and/or by data manipulation, key facts about performance. The former Soviet Union is a perfect example of a manipulative use of ISs fabricated to celebrate many false achievements of an extremely rigid political system. A well designed HIS, capable to provide valid, reliable, relevant and timely information, and supported by the most modern information technology, becomes a useless instrument in the hands of policy makers, managers and professionals moved more by a desire to please someone in power or sing their own praises, than by the aspiration to

provide the best care to those who need it.

Beyond inherent technical difficulties, the resistance to build an IS capable to measure quality and safety of care derive from the assumption that such dimensions are, by and large, good, and the implied disrespect of medical professionals and distress to the public. As Keynes lucidly affirmed some policy makers prefer not to know; behind a fog of uncertainty and ambiguity any decision can be morally, technically, economically and politically justified, and the room for maneuvering becomes almost limitless. Politics as corridors' management is an important barrier to a streamlined HIS as well as a lucid formulation of DS policies. Policy makers should be aware of the importance of measurement, and allocate sufficient resources to this component.

Conclusion

Often there is a gap between the effects of therapies achieved under controlled circumstances and the reality of individual services delivery. Similarly, too often there is a gap between what a health care system achieves in terms of quality, safety, efficiency and equity and what it could and should deliver. Some of these differences represent chasms and must be reduced; this is so important that even the Universal Declaration of Human Rights, more than sixty years ago, recognized the right of every human being to enjoy the benefits of scientific and technological progress. Gaps and even chasms are invisible to health care systems which do not use sound IS. Here there are no problematic patterns, only fragmented episodes, each one with its explanation and a designated victim to blame and shame at the sharp end, where services are delivered. Given the importance of health services for the destiny of individuals and populations, it is hard to believe that too often we lack ways of appraising how well we are doing.

Medicine has been rightly called the greatest benefit to humanity; it cannot afford to let down its potential beneficiaries because of mediocre information, lack of knowledge of improvement methods, and fear of change. Currently the strength of the movement behind quality measurement and improvement is incontrovertible; even if it is still a teen ager in terms of biological age, quality improvement is taking place at an accelerating pace and countries which have fully embraced such approach have achieved remarkable success. For example, the powerful results of a valid HIS coupled with a national strategy of CQI is revealed by the successes achieved by several thousand US hospitals during the last decade (Chassin et. al. 2010). Health organizations and systems which resist or ignore it are already at the margins of what has become mainstream thinking and action. More importantly, whole societies will pay greatly if they underestimate the significance of health services quality and safety.

System thinking maintains that processes are interrelated, and optimizing each one independently can result in an even poorer performance. System thinking also affirms that processes should be studied systematically visualizing them through flowcharts and measuring their important steps. Processes vary as a result of both special or systematic causes, and common or random causes, which should be identified, examined and understood. Statistical analysis is essential in order to turn data into useful knowledge. Statistical Process Control is the modern approach to characterize variability, discriminating between its special and common attributes. Misinterpretation of variation may cause tampering with basically sound systems and processes, which might itself increase variation.

Comparisons are an important source of understanding and benchmarking, however contrasting does not equal ranking. Ranking has two major disadvantages: first it is emotionally and politically destructive for many, indifferent for most and only advantageous for the few who, provisionally, appear to lead. Its second serious shortcoming derives from the fact that differences, possibly expressed as percentiles and presented by histograms, have no statistical basis and represent mere subdivision into arbitrary categories.

The astonishing scientific progress of medicine has no effect until it is delivered appropriately, and measuring performance is one of the most powerful tools for promoting evidence based improvements. A HIS constitutes a strategic component of a health system. Its design and management must be based on principles of system and statistical thinking. A IS is a system itself, made of processes, activities and tasks. Its logic and structure must be in order, different components must be aware of their role as suppliers and customers, and how they are supposed to contribute to the overall aim of providing relevant, reliable, complete and timely information to different users.

An IS is a pillar to each phase of DS management, from policy design to implementation, monitoring, improvement and evaluation. Information supporting DS should shed light on its key components, in particular users, resources, access, processes, outputs, outcomes and productivity. Collecting valid and reliable data, transforming them into relevant indicators and presenting them graphically in ways which help focus attention on fundamental factors are essential activities of a functional IS.

Yet, by itself, building and running a HIS is not enough to ensure its competent and productive utilization. This tool can deliver its potential only if it is embedded in a comprehensive CQI effort bringing together system theory and statistical methods. Otherwise the risk is that data are piled, maybe indicators assembled and graphs displayed, but interpretation remains inadequate, key customers' expectations and clinical processes are not understood, and those with the responsibility to improve them exaggerate their reactions to normal variability and ignore special causes. A bureaucratic approach to HIS, detached from the reality of health care delivery, not explicitly supporting resources allocation and use, lacking the understanding of the role of and interaction between structures, processes, patterns and results, with no involvement of key stakeholders, is destined to turn into a dull instrument incapable to enlighten and prompt transformation.

As everyone knows it is easier to defend the status quo than to change it. Many deeply held assumptions, based on tradition more than evidence and about which we are often oblivious, guide our actions; this is true also for surgical services delivery. The unmistakable ethical obligation to continuously improve the quality and safety of DS care and meet patients' expectations requires physicians to address such topics as

systematically and professionally as clinical work. Availability of valid and useful indicators and their quantitative analysis using SPC might contribute to lessen divergence of opinions and also conflict of personalities and power. As the American Quality Society (AMQ) bluntly stated "Without data, everyone is an expert; team discussions tend to produce more heat (anger) than light (insight and learning)."

The bottom line is that the goal of quality and safety improvement, together with accountability, has become an integral component of health care. Improvement of performance and transparency imply information on performance. Only constructive organizational cultures, like those which characterize High Reliability Organizations can build a context where an IS becomes an instrument for improvement and accountability. A toxic culture will stunt growth and creativity, and transform data into a tool manipulated for power struggles.

A context of limited economic growth, broader needs, greater demand for accountability from civil society, payers, and policy-makers, and higher expectations concerning both services' responsiveness and participation to decisions about one's own health, implies accurate and reliable information on performance geared to better quality, safety, equity, and efficiency. Organizations and their leaders must be apt to such high roles and goals.

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